August 2025

URGENT MEDICAL DEVICE CORRECTION
Heartstring III Proximal Seal System
Reference Number: 1336551

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August 2025

URGENT MEDICAL DEVICE CORRECTION
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails

to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
     - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis

because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)

- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.
        i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.

   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service at 1-888-880-2874, Monday through Friday between the hours of 8AM and 5PM (Pacific Time Zone).

Sincerely,

Electronically signed by:
Francisco Vicenty

Reason: I approve this document.

Francisco Vicenty Date: Feb 19, 2026 11:27:22 EST

Francisco Vicenty
Director Quality & Regulatory Compliance
Getinge, Cardiovascular Surgery

Albania (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

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2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
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   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy

(procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

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        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.
ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
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   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device <u>prior</u> to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution <u>prior</u> to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
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Additional Information

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We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Armenia (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
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Root cause investigation is ongoing at this time.

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   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy

(procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.
ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device <u>prior</u> to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution <u>prior</u> to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial

occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Australia (en)

5th February 2026

Urgent Product Alert

SUBJECT	**Heartstring III Proximal Seal System – Version 2**
LETTER ADDRESSED TO	Users of the medical device listed above
DEVICES CONCERNED	HS-3045, HSK-3038, and HSK-3043 All Unexpired Lots Manufacturing Dates: March 7, 2024 - Present
ARTG Identifier	158121
TGA Ref#	RC-2025-RN-00710-1

GETINGE, in consultation with the Therapeutic Goods Administration (TGA), is commencing a Product Alert for the Heartstring III Proximal Seal System (HS III Seal) due to 3 failure modes.

Problem Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical

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1/160 Lytton Road
Morningside, QLD 4170
Australia
Phone: 1800 438 464
sales.au@getinge.com
www.getinge.com/anz

procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp tocomplete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS IIISeal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
     - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
   - **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal

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1/160 Lytton Road
Morningside, QLD 4170
Australia
Phone: 1800 438 464
sales.au@getinge.com
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deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convertto use of an aortic clamp to complete the aortotomy.

- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
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- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimise the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirmingsuccessful loading prior to creating the aortotomy minimizes risk to patients becausethe aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimise occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used ona routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has beenloaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device mayfail during HS III Seal Deployment and cause patient harm. (see information relating toFailure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.
        i. Discard the failed HS III Seal.
        ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. **Failure of the Heartstring III Seal to Deploy into the aortotomy**
    a. Important reminders:
        i. Ensure the HS III Seal has been properly loaded into the Delivery Device as describedin the section above.
        ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

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1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

a. How to avoid/minimise the occurrence of this failure:
   iii. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   iv. If the HS III Seal fails to deploy as intended, the device should be replaced.

b. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   v. Occlude the aortotomy to control bleeding using an index finger.
   vi. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   vii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimise occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.

If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this alert is forwarded to any individuals that need notification within your organisation or any organisation where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

The root cause and corrective actions to address these 3 failure modes are still under investigation. Customers will be notified once any corrective actions have been identified via a subsequent market action.

Adverse reactions or quality problems experienced with the use of this product may be reported to your local

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1/160 Lytton Road
Morningside, QLD 4170
Australia
Phone: 1800 438 464
sales.au@getinge.com
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Getinge Australia representative or Customer Service on 1800 438 464 or emailed to Quality.AUNZ@getinge.com. We apologise for any inconvenience this may cause. Should you have any questions or need additional information, please contact your local Getinge Australia representative or Customer Service on 1800 438 464.

Yours Sincerely,

Nicole Ditrich
QRC Manager
Australia & New Zealand

Getinge Australia Pty Ltd
1/160 Lytton Road
Morningside, QLD 4170
Australia
Phone: 1800 438 464
sales.au@getinge.com
www.getinge.com/anz

Austria

German (de)

August 2025

Sicherheitshinweis

Proximales Versiegelungssystem Heartstring III

Referenznummer: 1336551

Modellnummer	UDI	Modellbezeichnung	Serien-/Losnummern
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proximales Versiegelungssystem Heartstring III	Alle nicht abgelaufenen Chargen
Distributionszeitraum:		1. Juli 2024 – Heute	
Herstellungsdaten:		7. März 2024 – Heute	

Sehr geehrte/r Anwender/in,

Mit diesem Schreiben möchten wir Sie darüber informieren, dass Maquet Cardiovascular, eine Tochtergesellschaft von Getinge, eine dringende Korrekturmaßnahme für das Proximale Versiegelungssystem Heartstring III (HS III Seal) vornimmt. Aus unseren Unterlagen geht hervor, dass Sie mindestens eines der von dieser Mitteilung betroffenen Geräte erhalten haben.

Beschreibung des Problems

Es wurden drei primäre Fehlermodi ermittelt.

1. **Ladeausfall der Heartstring-Versiegelung**: Dieser Fehler betrifft alle Fehlfunktionen des Geräts, die während des vierstufigen Ladevorgangs mit der Heartstring-Beladungsvorrichtung, der Sichtkontrolle einer erfolgreichen Beladung des HS III Seal und der Entriegelung der Einführvorrichtung nach erfolgreicher Beladung des HS III Seal auftreten.
2. **Ausfall der Heartstring-Versiegelung bei der Einführung in die Aortotomie**: Dieser Fehler betrifft alle Fehlfunktionen der HS III Seal und/oder der Einführvorrichtung ab dem Zeitpunkt, zu dem die Einführvorrichtung erfolgreich entriegelt wurde, bis zur vollständigen Einführung der HS III Seal in die Aortotomie und dem Austritt des gesamten Inhalts der proximalen Versiegelung (Anbindung, Zugfeder, Versiegelungsschaft, Verankerungslasche) aus der Einführvorrichtung.
3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Dieser Fehler betrifft jede Fehlfunktion eines erfolgreich eingeführten HS III Seal, welches die Blutung an der Anastomose nicht ausreichend kontrolliert, um dem chirurgischen Personal das Vernähen der Anastomose zu ermöglichen, trotz behutsamer Anpassung der Zugfeder nach der Einbringung der

Versiegelung und/oder Verwendung eines Blower Mister, einer Absaugung oder einer Kochsalzlösungsspritze zum Reinigen der Anastomosestelle. Dieser Fehler umfasst die Feststellung eines defekten oder beschädigten HS III Seal durch den Kunden nach erfolgreicher Einbringung des HS III Seals in die Aorta, die zu einer unzureichenden Hämostase führt oder führen kann, sodass das chirurgische Personal die Anastomose nicht abschließen kann, ohne das defekte HS III Seal zu entfernen.

Die Ermittlung der Grundursache ist derzeit noch im Gange.

Gesundheitsrisiken

1. **Fehler bei der Beladung:** Bei Verwendung gemäß der Gebrauchsanweisung des Geräts stellt ein HS III Seal ohne Beladung kein direktes Risiko für Patienten dar. Dieser Fehler kann jedoch zu einer Verzögerung des chirurgischen Eingriffs führen. Diese Verzögerung kann von wenigen Minuten zur Entnahme und Beladung einer neuen Versiegelung bis hin zu einer möglichen Umstellung von der Verwendung des HS III Seal zur Durchführung der proximalen Anastomose auf die Verwendung einer Aortaklemme zum Abschluss des Vorgangs reichen.
2. **Fehlgeschlagene Einbringung:** Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden die folgenden Verfahrensschritte bereits durchgeführt, was zu einem potenziellen Risiko einer Patientenschädigung führen kann. Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden bereits mehrere Verfahrensschritte durchgeführt, was das potenzielle Risiko einer Patientenschädigung erhöhen kann.
    - Die Aortotomie wurde angelegt.
    - Das distale Ende des Schlauchs der Einführvorrichtung wurde durch die Aortotomie eingeführt.
    - Der Kolben der Einführvorrichtung wurde gedrückt oder es wurde versucht, ihn zu drücken.
    - Die geladene HS III Seal konnte nicht erfolgreich vom distalen Ende des Schlauchs der Einführvorrichtung eingesetzt werden.
    - Wenn die Einführvorrichtung aus der Aortotomie entfernt wird, wird das HS III Seal nicht platziert. Blutungen aus der Aortotomie müssen durch Auflegen eines Fingers auf die Aortotomie gestillt werden.

    Die folgenden potenziellen Patientenschäden können auftreten:

    - **Verzögerung des chirurgischen Eingriffs**: Entfernen des nicht platzierten HS III Seal, Öffnen einer neuen HS III-Proximalversiegelung, Einlegen der Versiegelung in die Einführvorrichtung und Einbringung des beladenen HS III Seal in die angelegte Aortotomie (Verzögerung ohne zusätzlichen Eingriff) vs. Entscheidung für die Verwendung einer Aortenklemme, um die Anastomose abzuschließen, da die Einbringung der Versiegelung fehlgeschlagen ist (Verzögerung mit zusätzlichem Eingriff)
    - **Gewebeschädigung**: Kann durch das Platzieren eines geladenen HS III Seal mit zu weit geöffneter Spitze entstehen. Eine aufgeweitete Spitze hat einen größeren Durchmesser als der distale Schlauch der Einführvorrichtung. Das Einsetzen einer beladenen Versiegelung mit aufgeweiteter Spitze kann zu einer Schädigung des Aortotomiegewebes führen. Wird beim Einsetzen der betroffenen Versiegelung mehr Kraft aufgewendet, besteht die Gefahr einer Rückwandbildung in der Aorta während des Einführens. Gewebeschäden können auch beim

Entfernen der Einführvorrichtung aus der Aortotomie, beim Einsetzen eines zweiten HS III Seal mit Beladung in dieselbe Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortaklemme zur Durchführung der Aortotomie auftreten.

- **Blutung:** Es kann zu einem minimalen Blutverlust kommen, wenn die Einführvorrichtung aus der Aortotomie entfernt, die Blutung aus der Aortotomie manuell kontrolliert und ein Ersatz-HS III Seal eingeführt wird. Bei einer Gewebeschädigung kann ein größerer Blutverlust auftreten, der einen zusätzlichen Eingriff erfordert.
- **Embolisches Ereignis** infolge zusätzlicher Manipulation der Aorta zur Behebung der fehlgeschlagenen Beladung des HS III Seal.

3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Wenn ein eingesetztes HS III Seal keine ausreichende Hämostase für chirurgisches Personal zur Fertigstellung der proximalen Anastomose bietet, sind mehrere Schritte der Verwendung des HS III Seal Systems bereits abgeschlossen und können das potenzielle Risiko einer Schädigung von Patienten erhöhen. Die folgenden Verfahrensschritte werden bereits erfolgt sein.
   - Die Aortotomie wurde angelegt.
   - Das HS III Seal mit Beladung wurde in die Aorta eingesetzt.
   - Die Blutung aus der Aorta wird vom chirurgischen Personal als zu groß für die Durchführung der Anastomose erachtet.

   Die folgenden potenziellen Patientenschäden können auftreten:

   - **Verzögerung des chirurgischen Eingriffs**: kann wie folgt eintreten:
     - Zusätzliche operative Zeit, die für den Versuch aufgewendet wird, Anpassungen der Versiegelung vorzunehmen, um die Hämostase durch das eingesetzte HS III Seal zu verbessern, das defekte HS III Seal zu entfernen, ein neues HS III Seal zu öffnen, das Ersatz-HS III Seal zu laden und das geladene HS III Seal in die erstellte Aortotomie einzuführen (Verzögerung des Vorgangs ohne zusätzlichen Eingriff)
     - Das chirurgische Personal hält es für angebracht, für den Abschluss der Anastomose eine Aortenklemme zu verwenden, da das eingesetzte HS III Seal für keine ausreichende Hämostase für den erfolgreichen Abschluss der Anastomose gesorgt hat und entweder kein Ersatz-HS III Seal verfügbar ist oder das chirurgische Personal entscheidet, dass die Verwendung eines Ersatz-HS III Seal in der jeweiligen Situation nicht angebracht ist und eine Aortenklemme für den Abschluss der proximalen Anastomose gemäß der herkömmlichen chirurgischen Technik verwendet wird. (Verzögerung des Vorgangs mit einem zusätzlichen Eingriff)
   - **Gewebeschädigung**: Gewebeschäden können bei der Manipulation des betroffenen HS III Seal, bei der Platzierung eines zweiten HS III Seal mit Beladung in derselben Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortenklemme zur Fertigstellung der Aortotomie auftreten.
   - **Blutung:** Ein geringfügiger Blutverlust um das eingesetzte HS III Seal herum ist normal und bei der Durchführung der proximalen Anastomose mit einem HS III Seal zu erwarten. Ein größerer Blutverlust, der einen zusätzlichen Eingriff erfordert, kann auftreten, wenn eine Schädigung des Aortengewebes auftritt, unabhängig von der Ursache.

- **Embolische(s) Ereignis(se):** infolge einer zusätzlichen Manipulation der Aorta sekundär zur Behebung des Ausfalls des HS III Seal, um eine angemessene Hämostase zu gewährleisten.

Zwischen dem 1. Juni 2023 und dem 22. Juli 2025 erhielt Getinge die folgenden Beschwerden:

- 274 Meldungen im Zusammenhang mit einer fehlgeschlagenen Beladung, was einer Reklamationsrate von 0,386 % entspricht
- 96 Meldungen im Zusammenhang mit der fehlgeschlagenen Einführung, was einer Reklamationsrate von 0,135 % entspricht
- 30 Meldungen im Zusammenhang mit unzureichender Hämostase, was einer Reklamationsrate von 0,042 % entspricht

Empfohlene Abhilfemaßnahmen

Getinge stellt die folgenden Anweisungen zur Verfügung, um die vorstehend erwähnten Fehler zu vermeiden/minimieren.

1. **Ladeausfall der Heartstring-Versiegelung**
    a. Wichtige Hinweise:
        i. Gemäß der Gebrauchsanweisung des Produkts ist das HS III Seal für das Beladen und Entnehmen aus der Ladevorrichtung vorgesehen. Anschließend wird es überprüft und ggf. angepasst, um die erfolgreiche Beladung zu bestätigen, und schließlich entriegelt, bevor jegliche Adventitia aus dem geplanten Anastomosebereich entfernt und die Aortotomie angelegt wird. Die Beladung des HS III Seal und die Bestätigung der erfolgreichen Beladung vor dem Anlegen der Aortotomie minimieren das Risiko für Patienten, da die Aorta bis zur Bestätigung der erfolgreichen Beladung des HS III Seals unberührt bleibt.
        ii. Wenn die Beladung des HS III Seal nicht wie vorgesehen erfolgt, sollte das Gerät ausgetauscht werden.
    b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers
        i. Lesen Sie die Gebrauchsanweisung des Heartstring-Geräts vor der Verwendung durch, insbesondere wenn Heartstring nicht routinemäßig verwendet wird.
        ii. Beladen Sie das HS III Seal, indem Sie die Schritt-für-Schritt-Gebrauchsanweisung des Geräts sorgfältig befolgen.
        iii. Überprüfen Sie gemäß Abschnitt 4.3-4.5 der Gebrauchsanweisung die ordnungsgemäße Beladung des HS III Seal in die Einführvorrichtung durch Inspektion des beladenen HS III Seal nach dessen Beladung in die Einführvorrichtung und Entnahme aus der Ladevorrichtung.
        iv. Ein HS III Seal, das nach der Entnahme aus der Ladevorrichtung nicht ordnungsgemäß überprüft wird, kann während der Einführung des HS III Seal versagen und zu Verletzungen von Patienten führen. (siehe Informationen zu einer fehlgeschlagenen Einführung).
        v. Die erfolgreiche Beladung des HS III Seal vor der Reinigung der Aortenadventitia und dem Anlegen der Aortotomie fertigstellen.
    c. Zu ergreifende Maßnahmen bei ausbleibender Beladung des HS III Seal.

i. Entsorgen Sie das defekte HS III Seal.
ii. Halten Sie immer ein zweites HS III Seal bereit, um ein defektes Gerät zu ersetzen. Beachten Sie die Gebrauchsanweisung des Geräts, um eine erfolgreiche Beladung sicherzustellen.

2. Ausfall der Heartstring III-Versiegelung bei der Einführung in die Aortotomie

a. Wichtige Hinweise:
   i. Stellen Sie sicher, dass das HS III Seal wie vorstehend dargelegt ordnungsgemäß in die Einführvorrichtung eingelegt wurde.
   ii. Nachdem Sie das geladene HS III Seal aus der Ladevorrichtung entnommen haben, überprüfen Sie das geladene HS III Seal gemäß den Abschnitten 4.3–4.5 der Gebrauchsanweisung, um Folgendes sicherzustellen:
      1. Das geladene HS III Seal ist nicht gerissen.
      2. Der Teil des HS III Seal, der nicht in den Schlauch der Einführvorrichtung gelegt wird, ist nicht breiter als der Durchmesser des Schlauchs der Einführvorrichtung.
      3. Die Enden der Zugfeder sind so ausgerichtet, dass sie beide proximalen Ränder des beladenen HS III Seal berühren, während die Versiegelung in die Aortotomie eingeführt wird.

b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers:
   i. Nach Bestätigung der erfolgreichen Beladung des HS III Seal und Anlegen der Aortotomie das geladene HS III Seal in die Aortotomie einsetzen, indem die in der Gebrauchsanweisung des Geräts dokumentierten Schritte zur Einführung des HS III Seal sorgfältig befolgt werden.
   ii. Kann das HS III Seal nicht wie vorgesehen eingeführt werden, sollte das Gerät ausgetauscht werden.

c. Zu ergreifende Maßnahmen, wenn das HS III Seal nicht erfolgreich in die Aorta eingeführt werden kann.
   i. Die Aortotomie mit dem Zeigefinger verschließen, um die Blutung zu kontrollieren.
   ii. Ein zweites HS III Seal öffnen. Das HS III Seal gemäß Gebrauchsanweisung des Geräts laden. Das HS III Seal mit Beladung in die Aortotomie einführen und die Anastomose gemäß Gebrauchsanweisung abschließen.
   iii. Wenn das Einsetzen des zweiten HS III Seal in die Aortotomie nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

3. Keine ausreichende Hämostase durch die eingeführte Heartstring III-Versiegelung:

a. So vermeiden/minimieren Sie das Auftreten dieses Fehlermodus:
   i. Das geladene HS III Seal immer sorgfältig laden und prüfen, um sicherzustellen, dass es erfolgreich in die Einführvorrichtung geladen wurde, <u>bevor</u> Sie die Adventitia freilegen und die Aortotomie anlegen. (Siehe die direkt vorstehend aufgeführten wichtigen Hinweise.)

   ii. Die Heartstring Proximalversiegelung nicht bei Patienten mit einer dünnwandigen Aorta verwenden.
   iii. Bei Durchführung einer Mehrfachanastomose sicherstellen, dass alle Anastomosenstellen mindestens 1,5 cm voneinander entfernt sind, um eine Hämostase zu gewährleisten.
   iv. Das HS III Seal nicht vor dem Einsetzen in Lösung einweichen.
b. Zu ergreifende Maßnahmen, wenn sich das HS III Seal nach der Einführung nicht öffnet bzw. keine ausreichende Hämostase gewährleistet.
   i. Decken Sie die Aortotomie mit einem Zeigefinger ab und stellen Sie die Zugfeder vorsichtig ein, um sicherzustellen, dass das HS III Seal vollständig eingeführt wurde.
   ii. Bei anhaltend mangelhafter Hämostase:
      1. Entfernen Sie das eingesetzte HS III Seal gemäß der Gebrauchsanweisung des Geräts aus der Aortotomie.
      2. Beladen Sie ein zweites HS III Seal und setzen Sie die beladene Versiegelung gemäß der Gebrauchsanweisung des Geräts in die Aortotomie ein, um die Anastomose abzuschließen.
      3. Wenn das zweite HS III Seal nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

Von Kund-/innen zu ergreifende Maßnahmen

Getinge bittet Sie, die folgenden Maßnahmen zu ergreifen:

1. Bitte leiten Sie diese Mitteilung an alle Personen in Ihrer Organisation weiter, die darüber informiert werden müssen, oder an alle Organisationen, an die betroffene Produkte weitergegeben wurden.

Weitere Informationen

Getinge leitet diese Informationen an die zuständigen Aufsichtsbehörden weiter.

Wir bedauern etwaige Unannehmlichkeiten, die Ihnen hierdurch entstehen. Wir setzen uns für die Patientensicherheit ein und danken Ihnen, dass Sie sich dieser Angelegenheit umgehend angenommen haben. Wenn Sie Fragen zu dieser Mitteilung haben, wenden Sie sich bitte an Ihre Getinge-Vertretung oder den Getinge-Kundendienst.

Mit freundlichen Grüßen

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

English (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis

without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
     - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
   - **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
   - **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:
- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

<u>Recommended Mitigations and Actions</u>

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
   a. Important reminders:

      i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any

adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.

ii. If the HS III Seal fails to load as intended, the device should be replaced.

b. How to avoid/minimize occurrence of this failure

i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

GETINGE

Bahrain (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

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3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
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   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the

proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

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- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
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    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
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1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating

the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.

ii. If the HS III Seal fails to load as intended, the device should be replaced.

b. How to avoid/minimize occurrence of this failure

i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

d. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the

loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. **Failure of the deployed Heartstring III Seal to provide adequate hemostasis:**
   a. How to avoid/minimize occurrence of this failure mode:
      i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
      ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
      iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
      iv. Do not soak the HS III Seal in solution prior to deployment.
   b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
      i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
      ii. If lack of adequate hemostasis persists:
         1. Remove the deployed HS III Seal from the aortotomy per device IFU.
         2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
         3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Belgium

Deutch (nl)

Augustus 2025

Veiligheidsbericht in het veld

Heartstring III Proximaal Sealsysteem

Referentienummer: 1336551

Modelnummer	UDI	Modelnaam	Serie-/lotnummers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximaal Sealsysteem	Alle niet-verlopen kavels
Distributiedata:		1 juli 2024 - heden	
Productiedata:		7 maart 2024 - heden	

Geachte risicomanager,

Met deze brief willen we u informeren dat Maquet Cardiovascular, een dochteronderneming van Getinge, een dringende medische correctie uitvaardigt voor het Heartstring III Proximal Seal System (HS III Seal).Volgens onze gegevens hebt u een of meer van de apparaten ontvangen waarop deze melding betrekking heeft.

Probleembeschrijving

Er zijn drie primaire faalwijzen geïdentificeerd.

1. **Falen van de Heartstring Seal om te laden**: Deze fout is van toepassing op elke storing van het apparaat die optreedt tijdens het vierstappen-laadproces met behulp van het Heartstring-laadapparaat, de visuele inspectie van een succesvol geladen HS III-zegel en het ontgrendelen van het afgifteapparaat na succesvolle voltooiing van hetStappen voor het laden van HS III-afdichtingen.
2. **Het mislukken van de Heartstring Seal**in de aortotomie: Deze storing is van toepassing op elke storing van de HS III-afdichting en/of het afgiftehulpmiddel vanaf het moment dat het afgiftehulpmiddel succesvol is ontgrendeld tot het moment dat de HS III-afdichting volledig in de aortotomie is geplaatst en alle inhoud van de proximale afdichting (de riem, de spanveer, de afdichtingssteel en het ankerlipje) uit het afgiftehulpmiddel zijn gekomen.
3. **Het falen van de geplaatste Heartstring Seal om voor voldoende hemostase te zorgen:**Tzijn falen geldt voor iedereenEen storing van een succesvol geplaatste HS III-afdichting die de bloeding bij de anastomose niet voldoende onder controle houdt, waardoor de chirurg de anastomose niet kan hechten, ondanks een voorzichtige aanpassing van de spanveer na plaatsing van de afdichting

en/of het gebruik van een blaasvernevelaar, zuigpomp of zoutoplossingspuit om de anastomose vrij te maken. Deze storing omvat de identificatie door de klant van een defecte of beschadigde HS III-afdichting na succesvolle plaatsing van de afdichting.HS IIIAfsluiting van de aorta die resulteert/kan resulteren in onvoldoende hemostase waardoor de chirurg de anastomose niet kan voltooien zonder de defecte HS III-afdichting te verwijderen.

Momenteel wordt er onderzoek gedaan naar de oorzaak.

Risico's voor de gezondheid

1. **Laden mislukt:**Bij gebruik volgens de gebruiksaanwijzing (IFU) van het apparaat vormt een HS III Seal die niet goed laadt geen direct risico voor de patiënt. Een dergelijke storing kan echter wel leiden tot vertraging van de chirurgische ingreep. Deze vertraging kan variëren van enkele minuten voor het ophalen en laden van een nieuwe Seal tot een mogelijke overstap van de HS III Seal voor het aanbrengen van de proximale anastomose naar het gebruik van een aortaklem om de ingreep te voltooien.
2. **Mislukte implementatie:**Wanneer de geladen HS III Seal niet uit het plaatsingshulpmiddel kan worden geplaatst, zijn de volgende procedurestappen al uitgevoerd en kunnen deze bijdragen aan het potentiële risico op letsel bij de patiënt. Als de geladen HS III Seal niet uit het plaatsingshulpmiddel kan worden geplaatst, zijn er al verschillende procedurestappen uitgevoerd, wat het potentiële risico op letsel bij de patiënt kan vergroten.
    - De aortotomie is aangelegd.
    - Het distale uiteinde van de toedieningsbuis is via de aortotomie ingebracht.
    - De zuiger van het toedieningshulpmiddel is ingedrukt, of er is een poging gedaan om deze in te drukken.
    - De geladen HS III-afdichting is niet succesvol geplaatst vanaf het distale uiteinde van de toedieningsbuis.
    - Wanneer het toedieningshulpmiddel uit de aortotomie wordt verwijderd, wordt de HS III-afdichting niet geplaatst en moet bloeding uit de aortotomie worden gestopt door een vinger op de aortotomie te plaatsen.

    De volgende mogelijke schade kan voor de patiënt optreden:

    - **Vertraging van de chirurgische ingreep**: om de niet-geplaatste HS III-afdichting te verwijderen, een nieuwe HS III-proximale afdichting te openen, de afdichting in het plaatsingsapparaat te laden en de geladen HS III-afdichting in de gecreëerde aortotomie te plaatsen (vertraging zonder aanvullende interventie) versus de beslissing om een aortaklem te gebruiken om de anastomose te voltooien omdat de geladen afdichting niet kon worden geplaatst (vertraging met een aanvullende interventie)
    - **Weefselschade**: kan optreden als gevolg van het plaatsen van een geladen HS III-afdichting met een uitlopende punt. Een uitlopende punt heeft een diameter die groter is dan de distale buis van het toedieningshulpmiddel. Het plaatsen van een geladen afdichting met een uitlopende punt kan schade aan het aortotomieweefsel veroorzaken en als er meer kracht wordt gebruikt om de aangetaste afdichting te plaatsen, bestaat er een potentieel risico op terugslag in de aorta tijdens het inbrengen. Weefselschade kan ook optreden tijdens het verwijderen van het toedieningshulpmiddel uit de aortotomie, het plaatsen van een tweede

geladen HS III-afdichting in dezelfde aortotomie en/of de noodzaak om over te stappen op het gebruik van een aortaklem om de aortotomie te voltooien.

- **Bloeden:** Er kan minimaal bloedverlies optreden bij het verwijderen van het toedieningshulpmiddel uit de aortotomie, het handmatig onder controle houden van de bloeding uit de aortotomie en het plaatsen van een vervangende HS III-afdichting. Er kan meer bloedverlies optreden, waarvoor aanvullende interventie nodig is, indien er weefselschade optreedt.
- **Embolische gebeurtenis**als gevolg van extra manipulatie van de aorta om het falen van de HS III-afdichtingslading aan te pakken.

3. **Het falen van de geplaatste Heartstring Seal om voor voldoende hemostase te zorgen:**Wanneer een geplaatste HS III Seal niet voldoende hemostase biedt voor de chirurg om de proximale anastomose te voltooien, zijn verschillende stappen van het HS III Seal-systeem al uitgevoerd en kan dit het potentiële risico op letsel voor de patiënt vergroten. De volgende procedurestappen hebben plaatsgevonden.

   - De aortotomie is aangelegd.
   - De geladen HS III Seal is in de aorta geplaatst.
   - De chirurg is van mening dat de bloeding uit de aorta te ernstig is om een anastomose aan te brengen.

   De volgende mogelijke schade kan voor de patiënt optreden:

   - **Vertraging van de chirurgische ingreep**: kan als volgt optreden:
     - AExtra operatietijd die nodig is om de afdichting aan te passen om de hemostase te verbeteren door de geplaatste HS III-afdichting, de defecte HS III-afdichting te verwijderen, een nieuwe HS III-afdichting te openen, de vervangende HS III-afdichting te laden en de geladen HS III-afdichting in de gecreëerde aortotomie te plaatsen (procedurevertraging zonder extra interventie)
     - De chirurg acht het het meest gepast om een aortaklem te gebruiken om de anastomose te voltooien, omdat de geplaatste HS III-afdichting niet voor voldoende hemostase zorgde om de anastomose te voltooien en een vervangende HS III-afdichting niet beschikbaar is, of omdat de voorkeur van de chirurg bepaalt dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat en een aortaklem wordt gebruikt om de proximale anastomose te voltooien volgens de traditionele chirurgische techniek. (procedurevertraging met een extra ingreep)
   - **Weefselschade**:Er kan weefselschade ontstaan tijdens het manipuleren van de aangedane HS III-afdichting, tijdens het plaatsen van een tweede geladen HS III-afdichting in dezelfde aortotomie en/of de noodzaak om over te stappen op het gebruik van een aortaklem om de aortotomie te voltooien.
   - **Bloeden:**Een kleine hoeveelheid bloedverlies rond de geplaatste HS III-afdichting is normaal en te verwachten tijdens het plaatsen van de proximale anastomose met een HS III-afdichting. Bij beschadiging van het aortaweefsel kan er meer bloedverlies optreden, wat een aanvullende ingreep vereist, ongeacht de oorzaak.

- **Embolische gebeurtenis(sen):**als gevolg van extra manipulatie van de aorta als gevolg van het onvermogen van de HS III-afdichting om voor voldoende hemostase te zorgen.

Tussen 1 juni 2023 en 22 juli 2025 ontving Getinge de volgende klachten:
• 274 meldingen met betrekking tot het niet laden, wat neerkomt op een klachtenpercentage van 0,386%
• 96 meldingen met betrekking tot het niet ontplooien, wat neerkomt op een klachtenpercentage van 0,135%
• 30 meldingen met betrekking tot onvoldoende hemostase, wat neerkomt op een klachtenpercentage van 0,042%

Aanbevolen maatregelen en acties

Getinge biedt de volgende instructies om de hierboven besproken fouten te voorkomen/minimaliseren.

1. **Falen van de Heartstring Seal om te laden**
    a. Belangrijke herinneringen:

        i. Conform de IFU van het hulpmiddel is de HS III Seal bedoeld om in het laadapparaat te worden geplaatst en daaruit te worden verwijderd, vervolgens te worden geïnspecteerd en indien nodig aangepast om een succesvolle lading te bevestigen, en ten slotte te worden ontgrendeld voordat adventitia uit het geplande anastomosegebied wordt verwijderd en de aortotomie wordt gemaakt. Het laden van de HS III Seal en het bevestigen van een succesvolle lading vóór het maken van de aortotomie minimaliseert het risico voor patiënten, omdat de aorta onaangeroerd blijft totdat een succesvolle lading van de HS III Seal is bevestigd.

        ii. Indien de HS III Seal niet laadt zoals bedoeld, dient het hulpmiddel te worden vervangen.

    b. Hoe het optreden van deze storing te voorkomen/minimaliseren
        i. Raadpleeg vóór gebruik de IFU van het Heartstring-hulpmiddel, vooral als Heartstring niet routinematig wordt gebruikt.

        ii. Laad de HS III Seal door de stapsgewijze instructies voor gebruik (IFU) van het hulpmiddel zorgvuldig te volgen.

        iii. Conform sectie 4.3–4.5 van de IFU dient te worden bevestigd dat de HS III Seal correct in het afleveringshulpmiddel is geladen door de geladen HS III Seal te inspecteren nadat deze in het afleveringshulpmiddel is geplaatst en uit het laadapparaat is verwijderd.

        iv. Een HS III Seal die na verwijdering uit het laadapparaat niet correct wordt geïnspecteerd, kan falen tijdens het ontplooien van de HS III Seal en schade aan de patiënt veroorzaken (zie informatie met betrekking tot het niet ontplooien).

        v. Rond het succesvol laden van de HS III Seal af vóór het reinigen van de adventitia van het aortaoppervlak en het creëren van de aortotomie.

c. Te ondernemen actie als de HS III Seal niet laadt.
    i. Gooi de defecte HS III-afdichting weg.
    ii. Houd altijd een tweede HS III-zegel bij de hand om een defect apparaat te vervangen. Raadpleeg de gebruiksaanwijzing van het apparaat om een succesvolle belading te garanderen.

2. Falen van de Heartstring III-afdichting bij het ontplooien in de aortotomie

a. Belangrijke herinneringen:
    i. Zorg ervoor dat de HS III Seal correct in het afleveringshulpmiddel is geladen zoals beschreven in de bovenstaande sectie.

    ii. Inspecteer, na het verwijderen van de geladen HS III Seal uit het laadapparaat, de geladen HS III Seal overeenkomstig IFU-secties 4.3–4.5 om het volgende te bevestigen:

        1. De geladen HS III Seal is niet gebarsten.
        2. Het gedeelte van de HS III Seal dat niet in de buis van het afleveringshulpmiddel is geladen, wijkt niet verder uit dan de diameter van de buis van het afleveringshulpmiddel.
        3. De uiteinden van de spanningsveer zijn zodanig uitgelijnd dat zij tijdens het inbrengen van de Seal in de aortotomie contact zullen maken met beide proximale randen van de geladen HS III Seal.

b. Hoe u dit falen kunt voorkomen/minimaliseren:
    i. Na bevestiging van succesvol laden van de HS III Seal en het creëren van de aortotomie, dient de geladen HS III Seal in de aortotomie te worden ontplooid door de stappen, voor het ontplooien van de HS III Seal zoals vastgelegd in de IFU van het hulpmiddel, zorgvuldig te volgen.

    ii. Indien de HS III Seal niet wordt ontplooid zoals bedoeld, dient het hulpmiddel te worden vervangen.

c. Maatregelen die moeten worden genomen als de HS III-afdichting niet succesvol in de aorta wordt geplaatst.
    i. Sluit de aortotomie af met de wijsvinger om het bloeden te stoppen.
    ii. Open een tweede HS III-afdichting. Laad de HS III-afdichting volgens de gebruiksaanwijzing van het apparaat. Plaats de geladen HS III-afdichting in de aortotomie en volg de gebruiksaanwijzing om de anastomose te voltooien.
    iii. Als het plaatsen van de tweede HS III-afdichting in de aortotomie niet lukt, of als de chirurg oordeelt dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat, plaatst u een gedeeltelijke occlusieklem op de aorta, waardoor de aortotomie wordt geïsoleerd, en voert u de anastomose uit volgens de traditionele chirurgische techniek.

3. Het falen van de geplaatste Heartstring III Seal om voor voldoende hemostase te zorgen:

a. Hoe kan dit falen worden vermeden/geminimaliseerd:
    i. Laad en inspecteer de geladen HS III-afdichting altijd zorgvuldig om zeker te weten dat de HS III-afdichting succesvol in het plaatsingshulpmiddel is geplaatst, voordat u

de aorta-adventitia vrijmaakt en de aortotomie uitvoert. (Zie de belangrijke opmerkingen hierboven.)

ii. Gebruik het Heartstring Proximal Seal System niet bij patiënten met een dunwandige aorta.

iii. Bij het aanleggen van meervoudige anastomose moet u ervoor zorgen dat alle anastomotische plaatsen minimaal 1,5 cm uit elkaar liggen om hemostase te garanderen.

iv. Dompel de HS III Seal niet onder in een oplossing voordat u hem inzet.

b. Te nemen maatregelen als de HS III-afdichting niet opengaat of niet voor voldoende hemostase zorgt na plaatsing van de afdichting.

i. Bedek de aortotomie met een wijsvinger en pas de spanveer voorzichtig aan om ervoor te zorgen dat de HS III-afdichting volledig is ontplooid.

ii. Indien er sprake blijft van een gebrek aan adequate hemostase:

1. Verwijder de geplaatste HS III-afdichting van de aortotomie volgens de gebruiksaanwijzing van het apparaat.
2. Plaats een tweede HS III Seal en plaats de geladen Seal in de aortotomie volgens de gebruiksaanwijzing van het apparaat en voltooi de anastomose.
3. Als de tweede HS III-afdichting niet succesvol is of als de voorkeur van de chirurg aangeeft dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat, plaatst u een gedeeltelijke occlusieklem op de aorta, isoleert u de aortotomie en voert u de anastomose uit volgens de traditionele chirurgische techniek.

Klantacties

Getinge verzoekt u de volgende acties te ondernemen:

1. Zorg ervoor dat dit bericht wordt doorgestuurd naar alle personen binnen uw organisatie die op de hoogte moeten worden gesteld, of naar organisaties waarnaar de betrokken apparaten zijn overgedragen.

Aanvullende informatie

Getinge geeft deze informatie door aan de bevoegde toezichthoudende instanties.

Onze excuses voor het ongemak. We hechten veel waarde aan de veiligheid van onze patiënten en stellen uw snelle aandacht voor deze kwestie op prijs. Als u vragen hebt over deze communicatie, neem dan contact op met uw Getinge-vertegenwoordiger of de klantenservice van Getinge, van maandag tot en met vrijdag tussen 8.00 en 17.00 uur

Contactgegevens:

Getinge Belgium (Luxembourg)
Info.be@getinge.com
003223202089

Getinge Netherlands
Info.nl@getinge.com
0031353035000

Hoogachtend,

Francisco Vicenty

Directeur Kwaliteit & Regelgeving
Getinge, cardiovasculaire chirurgie

English (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result

in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a

deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

<u>Recommended Mitigations and Actions</u>

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:

        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading <u>prior</u> to creating the aortotomy minimizes risk to patients because the aorta remains untouched until

confirming successful loading of the HS III Seal.

ii. If the HS III Seal fails to load as intended, the device should be replaced.

b. How to avoid/minimize occurrence of this failure

i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. **Failure of the deployed Heartstring III Seal to provide adequate hemostasis:**
    a. How to avoid/minimize occurrence of this failure mode:
        i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
        ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
        iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
        iv. Do not soak the HS III Seal in solution prior to deployment.
    b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
        i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
        ii. If lack of adequate hemostasis persists:
            1. Remove the deployed HS III Seal from the aortotomy per device IFU.
            2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
            3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Aviso de seguridad Urgente
Sistema de obturación proximal Heartstring III
Número de referencia FSCA: 1336551

Número de modelo	UDI	Nombre del modelo	Números de serie/lote
HSK-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de obturación proximal Heartstring III	Todos los lotes no caducados
Fechas de distribución:		1 de julio de 2024 - Actualidad	
Fechas de fabricación:		7 de marzo de 2024 - Actualidad	

Estimado gestor de riesgos,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está emitiendo una corrección urgente de dispositivos médicos para el sistema de sellado proximal Heartstring III (HS III Seal). Según nuestros registros, usted ha recibido uno o varios de los dispositivos afectados por esta notificación.

Descripción del Problema

Se han identificado tres modos de fallo principales.

1. **Fallo en la carga del sello Heartstring**: Este fallo se aplica a cualquier mal funcionamiento del dispositivo que se produzca durante el proceso de carga de cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un sello HS III cargado correctamente y el desbloqueo del dispositivo de administración tras completar con éxito los pasos de carga del sello HS III.
2. **Fallo del sello cardíaco al desplegarse en la aortotomía**: Este fallo se aplica a cualquier mal funcionamiento del sello HS III y/o del dispositivo de implantación desde el momento en que el dispositivo de implantación se desbloquea correctamente hasta que se completa la implantación del sello HS III en la aortotomía y todo el contenido del sello proximal (la correa, el resorte de tensión, el vástago del sello y la lengüeta de anclaje) ha salido del dispositivo de implantación.
3. **Fallo del sellado Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier mal funcionamiento de un sello HS III implantado correctamente que no controle adecuadamente el sangrado en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis, a pesar del ajuste suave del resorte de tensión tras la implantación del sello y/o el uso de un nebulizador, succión o jeringa de solución salina para limpiar el sitio de la anastomosis. Este fallo incluye la identificación por parte del cliente de un sello HS III defectuoso o dañado tras el despliegue correcto del sello HS III en la aorta, lo que da lugar o puede dar lugar a una

hemostasia inadecuada que impide al cirujano completar la anastomosis sin retirar el sello HS III defectuoso.

En estos momentos se está investigando la causa raíz.

Riesgos para la salud

1. **Error al cargar:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un sello HS III que no se carga no supone un riesgo directo para el paciente. Sin embargo, este fallo puede provocar un retraso en la intervención quirúrgica. Este retraso puede variar desde unos minutos para recuperar y cargar un nuevo sello, hasta una posible conversión del uso del sello HS III para realizar la anastomosis proximal al empleo de una pinza aórtica para completar la intervención.
2. **Fallo en la implementación:** Cuando el sello HS III cargado no se despliega desde el dispositivo de administración, ya se han realizado los siguientes pasos del procedimiento, lo que puede contribuir al riesgo potencial de daño al paciente. Si el sello HS III cargado no se despliega desde el dispositivo de administración, ya se habrán completado varios pasos del procedimiento, lo que puede aumentar el riesgo potencial de daño al paciente.
   - Se ha realizado la aortotomía.
   - El extremo distal del tubo del dispositivo de administración se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de administración o se ha intentado presionarlo.
   - El sello HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de administración.
   - Cuando se retira el dispositivo de administración de la aortotomía, el sello HS III no se desplegará y será necesario controlar el sangrado de la aortotomía colocando un dedo sobre ella.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: para retirar el HS III Seal no desplegado, abrir un nuevo HS III Proximal Seal, cargar el Seal en el dispositivo de liberación (Delivery Device) y entregar el HS III Seal cargado en la aortotomía creada (retraso sin intervención adicional) vs. la decisión de utilizar una pinza aórtica para completar la anastomosis debido a que el Seal cargado no se desplegó (retraso con una intervención adicional).
   - **Daño tisular**: puede ocurrir como resultado del despliegue de un HS III Seal cargado que esté ensanchado en la punta. Una punta ensanchada tendrá un diámetro mayor que el tubo distal del dispositivo de liberación. El despliegue de un Seal cargado con la punta ensanchada puede causar daño al tejido de la aortotomía y, si se aplica mayor fuerza para desplegar el Seal afectado, existe un riesgo potencial de perforar la pared posterior de la aorta durante la inserción. El daño tisular también puede ocurrir durante la retirada del dispositivo de liberación de la aortotomía, al desplegar un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** puede producirse una pérdida mínima de sangre al retirar el dispositivo de liberación de la aortotomía, al controlar manualmente el sangrado de la aortotomía y al colocar un HS III Seal de reemplazo. Puede producirse una mayor pérdida de sangre,

que requiera intervención adicional, si ocurre daño tisular.

- **Evento embólico** como resultado de la manipulación adicional de la aorta para abordar la falla en la carga del HS III Seal.

3. **Falla del Heartstring Seal desplegado para proporcionar hemostasia adecuada:** uando un HS III Seal desplegado no logra proporcionar una hemostasia adecuada para que el cirujano complete la anastomosis proximal, varios pasos del uso del Sistema HS III Seal ya se han completado y pueden aumentar el riesgo potencial de daño al paciente. Los siguientes pasos del procedimiento ya se habrán realizado.
   - Se ha creado la aortotomía.
   - El HS III Seal cargado se ha desplegado en la aorta.
   - El sangrado de la aorta es considerado por el cirujano como demasiado abundante para realizar la anastomosis.

   Los siguientes daños potenciales al paciente pueden ocurrir:

   - **Retraso del procedimiento quirúrgico**: puede ocurrir de la siguiente manera:

     Tiempo operatorio adicional necesario para intentar realizar ajustes en el Seal con el fin de mejorar la hemostasia proporcionada por el HS III Seal implantado, retirar el HS III Seal defectuoso, abrir un nuevo HS III Seal, cargar el HS III Seal de reemplazo y colocar el HS III Seal cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional).
     - El cirujano considera más apropiado utilizar una pinza aórtica para completar la anastomosis debido a que el HS III Seal desplegado no logró proporcionar hemostasia adecuada para completarla y no hay un HS III Seal de reemplazo disponible, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo y se utiliza una pinza aórtica para completar la anastomosis proximal según la técnica quirúrgica tradicional. (retraso del procedimiento con intervención adicional)
   - **Daño tisular**: puede ocurrir durante la manipulación del HS III Seal afectado, durante el despliegue de un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** Una pequeña cantidad de pérdida de sangre alrededor del HS III Seal desplegado es normal y esperada al realizar la anastomosis proximal utilizando un HS III Seal. Puede producirse una mayor pérdida de sangre que requiera intervención adicional cuando ocurre daño del tejido aórtico, independientemente de la causa.
   - **Evento(s) embólico(s):** como resultado de la manipulación adicional de la aorta secundaria a la necesidad de abordar la falla del HS III Seal en proporcionar hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge recibió las siguientes quejas:

- 274 reportes relacionados con falla de carga, lo que representa una tasa de quejas del 0,386%
- 96 reportes relacionados con falla de despliegue, lo que representa una tasa de quejas del 0,135%
- 30 reportes relacionados con hemostasia inadecuada, lo que representa una tasa de quejas del 0,042%

Medidas y acciones recomendadas

Getinge proporciona las siguientes instrucciones para evitar/minimizar las fallas descritas anteriormente.

1. **Falla del Heartstring Seal al cargar**
    a. Recordatorios importantes:
        i. Según las Instrucciones de Uso (IFU) del dispositivo, el HS III Seal debe cargarse y retirarse del dispositivo de carga (Loading Device), luego inspeccionarse y ajustarse si es necesario para confirmar una carga exitosa y finalmente desbloquearse antes de retirar cualquier adventicia del área anastomótica planificada y crear la aortotomía. Cargar el HS III Seal y confirmar una carga exitosa antes de crear la aortotomía minimiza el riesgo para los pacientes, ya que la aorta permanece intacta hasta confirmar que la carga del HS III Seal fue exitosa.
        ii. Si el HS III Seal no se carga según lo previsto, el dispositivo debe reemplazarse.
    b. Cómo evitar/minimizar la ocurrencia de esta falla
        i. Revisar las Instrucciones de Uso (IFU) del dispositivo Heartstring antes de su utilización, especialmente si Heartstring no se utiliza de forma rutinaria.
        ii. Cargar el HS III Seal siguiendo cuidadosamente las Instrucciones de Uso (IFU) del dispositivo paso a paso.
        iii. De acuerdo con las Secciones 4.3–4.5 de las IFU, confirmar que el HS III Seal ha sido correctamente cargado en el dispositivo de liberación (Delivery Device) inspeccionando el HS III Seal cargado una vez que haya sido introducido en el Delivery Device y retirado del dispositivo de carga (Loading Device).
        iv. Un HS III Seal que no sea inspeccionado adecuadamente después de retirarlo del dispositivo de carga (Loading Device) puede fallar durante el despliegue del HS III Seal y causar daño al paciente. (Ver la información relacionada con Falla de Despliegue).
        v. Completar la carga exitosa del HS III Seal antes de limpiar la adventicia de la superficie aórtica y crear la aortotomía.
    c. Acción a tomar si el HS III Seal falla al cargarse.
        i. Desechar el HS III Seal defectuoso.
        ii. Tener siempre disponible un segundo HS III Seal para reemplazar un dispositivo defectuoso. Consultar las IFU del dispositivo para asegurar una carga exitosa.
2. **Falla del Heartstring III Seal al desplegarse en la aortotomía**
    a. Recordatorios importantes:
        i. Asegurarse de que el HS III Seal haya sido correctamente cargado en el dispositivo de liberación (Delivery Device), tal como se describe en la sección anterior.
        ii. Después de retirar el HS III Seal cargado del dispositivo de carga (Loading Device), inspeccionar el HS III Seal cargado, de acuerdo con las Secciones 4.3–4.5 de las IFU, para confirmar lo siguiente:
            1. Que el HS III Seal cargado no esté agrietado.
            2. Que la porción del HS III Seal que no está dentro del tubo del

Delivery Device no esté ensanchada más allá del diámetro del tubo del Delivery Device.

3. Que los extremos del resorte de tensión (Tension Spring) estén alineados de modo que contacten ambos bordes proximales del HS III Seal cargado durante la colocación del Seal en la aortotomía.

b. Cómo evitar/minimizar la ocurrencia de esta falla:
   i. Después de confirmar la carga exitosa del HS III Seal y crear la aortotomía, desplegar el HS III Seal cargado en la aortotomía siguiendo cuidadosamente los pasos de despliegue documentados en las IFU del dispositivo.
   ii. Si el HS III Seal no se despliega según lo previsto, el dispositivo debe reemplazarse.
c. Acción a tomar si el HS III Seal no se despliega correctamente en la aorta.
   i. Ocluir la aortotomía para controlar el sangrado utilizando el dedo índice.
   ii. Abrir un segundo HS III Seal. Cargar el HS III Seal de acuerdo con las IFU del dispositivo. Introducir el HS III Seal cargado en la aortotomía y seguir las IFU para completar la anastomosis.
   iii. Si la colocación del segundo HS III Seal en la aortotomía no tiene éxito, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

3. Falla del Heartstring III Seal desplegado para proporcionar hemostasia adecuada:

a. Cómo evitar/minimizar la ocurrencia de este modo de falla:
   i. Cargar siempre e inspeccionar cuidadosamente el HS III Seal cargado para confirmar que la carga en el dispositivo de liberación (Delivery Device) se haya realizado correctamente antes de retirar la adventicia de la aorta y crear la aortotomía. (Ver recordatorios importantes anteriores).
   ii. No utilizar el sistema Heartstring Proximal Seal en pacientes con aorta de pared delgada.
   iii. Al realizar múltiples anastomosis, asegurar que todos los sitios anastomóticos estén separados al menos 1,5 cm para garantizar la hemostasia.
   iv. No sumergir el HS III Seal en solución antes del despliegue.
b. Acción a tomar si el HS III Seal no se abre/no proporciona hemostasia adecuada después del despliegue.
   i. Cubrir la aortotomía con el dedo índice y ajustar suavemente el resorte de tensión (Tension Spring) para asegurar que el HS III Seal se haya desplegado completamente.
   ii. Si persiste la falta de hemostasia adecuada:
      1. Retirar el HS III Seal desplegado de la aortotomía de acuerdo con las IFU del dispositivo.
      2. Cargar un segundo HS III Seal y desplegar el Seal cargado en la aortotomía conforme a las IFU del dispositivo y completar la anastomosis.
      3. Si el segundo HS III Seal no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la

aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

Acciones para el cliente

Getinge solicita que tome las siguientes acciones:

1. Asegúrese de que este mensaje sea reenviado a todas las personas que deban ser notificadas dentro de su organización o en cualquier organización a la que se hayan transferido los dispositivos afectados.

Información adicional

Getinge está comunicando esta información a las agencias regulatorias correspondientes.

Lamentamos cualquier inconveniente que esto pueda ocasionar. Estamos comprometidos con la seguridad del paciente y agradecemos su pronta atención a este asunto. Si tiene alguna pregunta con respecto a esta comunicación, por favor comuníquese con su representante de Getinge o con el Servicio de Atención al Cliente de Getinge.

Cordialmente,

Francisco Vicenty
Director de Calidad y Cumplimiento Regulatorio, Interino
Getinge, Cirugía Cardiovascular

Canada

English (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been

completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.

b. How to avoid/minimize occurrence of this failure
   i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
   ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
   iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
   iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
   v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.
   i. Discard the failed HS III Seal.
   ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
    i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
    ii. If lack of adequate hemostasis persists:
        1. Remove the deployed HS III Seal from the aortotomy per device IFU.
        2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
        3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

French (fr)

Août 2025

Avis de sécurité

Système d'étanchéité proximale Heartstring III

Numéro de référence: DYR 269 (1336551)

Numéro de modèle	IUD	Nom du modèle	Numéros de série/de lot
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Système d'étanchéité proximale Heartstring III	All Unexpired Lots
Dates de distribution:		1er juillet 2024 - à ce jour	
Dates de fabrication:		7 mars 2024 - à ce jour	

Cher gestionnaire de risques,

La présente lettre a pour objet de vous informer que Maquet Cardiovascular, une filiale de Getinge, émet une Correction urgente de dispositif médical concernant le système d'étanchéité proximale Heartstring III (Joint étanche HS III). Nos dossiers indiquent que vous avez reçu un ou plusieurs dispositifs visés par le présent avis.

Description du problème

Trois principaux modes de défaillance ont été identifiés.

1. **Défaillance lors du chargement du joint étanche Heartstring**: Cette défaillance s'applique à tout malfonctionnement du dispositif survenant au cours du processus de chargement en quatre étapes à l'aide du dispositif de chargement Heartstring, de l'inspection visuelle d'un joint étanche HS III correctement chargé, et du déverrouillage du dispositif de pose après exécution complète des étapes de chargement du joint étanche HS III.
2. **Défaillance de déploiement du joint étanche Heartstring dans l'aortotomie**: Cette défaillance s'applique à tout malfonctionnement du joint étanche HS III et/ou du dispositif de pose à partir du moment où le dispositif de pose est déverrouillé avec succès jusqu'à la délivrance complète du joint étanche HS III dans l'aortotomie et tous les éléments du joint étanche proximal (le fil d'attache, le ressort de tension, la tige du joint étanche, la patte d'ancrage) sont sortis du dispositif de pose.
3. **Défaillance du joint étanche Heartstring déployé à assurer une hémostase adéquate:** Cette défaillance s'applique à tout malfonctionnement d'un joint étanche HS III déployé avec qui ne contrôle pas adéquatement le saignement à l'anastomose pour permettre au chirurgien d'effectuer la suture de l'anastomose, malgré un ajustement doux du ressort de tension après le déploiement du joint et/ou l'utilisation d'une soufflette, d'une aspiration à embout fin, ou d'une seringue de solution saline pour dégager le site de l'anastomose. Cette défaillance inclut également l'identification par le client d'un joint étanche HS III défectueux ou endommagé après le déploiement réussi du joint étanche HS III dans l'aorte qui entraîne/ou pourrait entraîner une

hémostase inadéquate qui empêche le chirurgien de compléter l'anastomose sans retirer le joint étanche HS III défectueux.

L'enquête sur les causes profondes est actuellement en cours.

Risques pour la santé

1. **Défaillance de chargement:** Lorsqu'il est utilisé conformément au mode d'emploi de l'instrument, un joint étanche HS III qui ne se charge pas ne présente pas de risque direct pour le patient. Toutefois, cette défaillance peut entraîner un retard dans l'intervention chirurgicale. Ce retard peut aller de quelques minutes pour récupérer et charger un nouveau joint étanche, à une conversion potentielle de l'utilisation du joint étanche HS III pour compléter l'anastomose proximale à l'utilisation d'un clamp aortique pour terminer l'intervention.
2. **Défaillance de déploiement:** Lorsque le joint étanche HS III chargé ne se déploie pas du dispositif de pose, les étapes suivantes de la procédure ont déjà été effectuées et peuvent contribuer au risque potentiel de dommage pour le patient. Si le joint étanche HS III chargé ne se déploie pas du dispositif de pose, plusieurs étapes de la procédure auront déjà été effectuées, ce qui peut augmenter le risque potentiel de dommage pour le patient.
    - L'aortotomie a été réalisée.
    - L'extrémité distale du tube du dispositif de pose a été insérée dans l'aortotomie.
    - Le piston du dispositif de pose a été enfoncé ou une tentative d'enfoncement a été effectuée.
    - Le joint étanche HS III chargé n'a pas été déployé avec succès à partir de l'extrémité distale du tube du dispositif de pose.
    - Lorsque le dispositif de pose est retiré de l'aortotomie, le joint étanche HS III ne sera pas déployé, et il faudra contrôler le saignement en appliquant un doigt sur l'aortotomie.

    Les complications potentielles suivantes peuvent survenir chez les patients:

    - **Retard de l'intervention chirurgicale**: pour retirer le joint étanche HS III non déployé, ouvrir un nouveau joint étanche proximal HS III, charger le joint étanche dans le dispositif de pose, et délivrer le joint étanche HS III chargé dans l'aortotomie réalisée (retard sans intervention supplémentaire) par rapport à la décision d'utiliser un clamp aortique pour compléter l'anastomose en raison de l'échec de déploiement du joint étanche chargé (retard avec intervention supplémentaire)
    - **Lésions tissulaires**: peuvent survenir à la suite du déploiement d'un joint étanche HS III chargé dont la pointe est évasée. Une pointe évasée aura un diamètre supérieur à celui du tube distal du dispositif de pose. Le déploiement d'un joint étanche chargé dont la pointe est évasée peut causer des lésions tissulaires de l'aortotomie et, si une force accrue est utilisée pour déployer le joint étanche concerné, il existe un risque potentiel de transpercement de la paroi postérieure de l'aorte. Des lésions tissulaires peuvent également survenir lors du retrait du dispositif de pose de l'aortotomie, du déploiement d'un second joint étanche HS III chargé dans la même aortotomie et/ou de la nécessité de passer à l'utilisation d'un clamp aortique pour compléter l'aortotomie.
    - **Saignement:** une perte sanguine minimale peut survenir lors du retrait du dispositif de pose de l'aortotomie, du contrôle manuel du saignement de l'aortotomie et du déploiement d'un joint étanche HS III de remplacement. Une perte sanguine plus importante, nécessitant une intervention supplémentaire, peut survenir en cas de lésion tissulaire.

- **Événement embolique** résultant d'une manipulation supplémentaire de l'aorte pour remédier à la défaillance de la charge du joint étanche HS III.

3. **Défaillance du joint étanche Heartstring déployé pour fournir une hémostase adéquate:** Lorsqu'un joint étanche HS III ne parvient pas à assurer une hémostase adéquate permettant au chirurgien de compléter l'anastomose proximale, plusieurs étapes de l'utilisation du système d'étanchéité HS III ont déjà été effectuées et peuvent augmenter le risque potentiel de dommage pour le patient. Les étapes procédurales suivantes ont été réalisées.

   - L'aortotomie a été réalisée.
   - Le joint étanche HS III chargé a été déployé dans l'aorte.
   - Le saignement provenant de l'aorte est jugé par le chirurgien trop important pour compléter l'anastomose.

   Les dommages potentiels suivants pour les patients peuvent survenir:

   - **Retard de l'intervention chirurgicale**: peut se produire comme suit:
     - Temps opératoire supplémentaire requis pour tenter d'ajuster le joint étanche afin d'améliorer l'hémostase assurée par le joint étanche HS III inséré, retirer le joint étanche HS III défectueux, ouvrir un nouveau joint étanche HS III, charger le joint étanche HS III de remplacement, et insérer le joint étanche HS III chargé dans l'aortotomie réalisée (retard de l'intervention chirurgicale sans intervention supplémentaire)
     - Le chirurgien juge plus approprié d'utiliser un clamp aortique pour compléter l'anastomose parce que le joint étanche HS III déployé n'a pas assuré une hémostase adéquate pour compléter l'anastomose et un joint étanche HS III de remplacement n'est pas disponible ou que, selon la préférence du chirurgien, la situation ne permet pas l'utilisation d'un joint étanche HS III de remplacement et un clamp aortique est utilisé pour compléter l'anastomose proximale selon la technique chirurgicale traditionnelle. (retard de l'intervention chirurgicale avec intervention supplémentaire)
   - **Lésions tissulaires**: Des lésions tissulaires peuvent survenir lors de la manipulation du joint étanche HS III affecté, lors du déploiement d'un deuxième joint étanche HS III chargé dans la même aortotomie, et/ou de la nécessité de passer à l'utilisation d'un clamp aortique pour compléter l'aortotomie.
   - **Saignement:** Une légère perte de sang autour du joint étanche HS III déployé est normale et attendue lors de l'anastomose proximale à l'aide d'un joint étanche HS III. Une perte de sang plus importante nécessitant une intervention supplémentaire peut survenir en cas de lésion du tissu aortique, quelle qu'en soit la cause.
   - **Événement(s) embolique(s):** résultant d'une manipulation supplémentaire de l'aorte faisant suite à la défaillance du joint étanche HS III à assurer une hémostase adéquate.

Entre le 1er juin 2023 et le 22 juillet 2025, Getinge a reçu les plaintes suivantes:

- 274 signalements liés à une défaillance de chargement, représentant un taux de réclamation de 0,386 %
- 96 signalements liés à une défaillance de déploiement, représentant un taux de réclamation de 0,135 %

- 30 signalements liés à une hémostase inadéquate, représentant un taux de réclamation de 0,042 %

Mesures correctives et actions recommandées

Getinge fournit les instructions suivantes pour éviter/minimiser les défaillances mentionnées ci-dessus.

1. **Défaillance lors du chargement du joint étanche Heartstring**
    a. Rappels importants:
        i. Selon le mode d'emploi du dispositif, le joint étanche HS III doit être chargé puis retiré du dispositif de pose, puis inspecté et ajusté au besoin afin de confirmer un chargement réussi et enfin déverrouillé avant de nettoyer l'adventice de la zone d'anastomose prévue et de réaliser l'aortotomie. Le chargement du joint étanche HS III et la confirmation du chargement avant la réalisation de l'aortotomie réduit les risques pour les patients, car l'aorte reste intacte jusqu'à ce que le chargement du joint étanche HS III soit confirmé.
        ii. Si le joint étanche HS III ne peut être chargé comme prévu, il doit être remplacé.
    b. Comment éviter/minimiser l'occurrence de cette défaillance
        i. Consulter le mode d'emploi du dispositif Heartstring avant utilisation, surtout si Heartstring n'est pas utilisé régulièrement.
        ii. Charger le joint étanche HS III en suivant attentivement étape par étape le mode d'emploi du dispositif.
        iii. Tel qu'indiqué dans les sections 4.3 à 4.5 du mode d'emploi, confirmez que le joint étanche HS III a été correctement chargé dans le dispositif de pose en inspectant le joint étanche HS III chargé une fois que le joint étanche HS III a été chargé dans le dispositif de pose et qu'il a été retiré du dispositif de pose.
        iv. Un joint étanche HS III qui n'est pas correctement inspecté après avoir été retiré du dispositif de pose peut présenter une défaillance lors du déploiement du joint étanche HS III et causer des dommages au patient. (voir les informations relatives à la défaillance du déploiement).
        v. Compléter le chargement réussi du joint étanche HS III avant de nettoyer l'adventice de la surface aortique et de réaliser l'aortotomie.
    c. Mesures à prendre en cas de défaillance du chargement du joint étanche HS III.
        i. Jeter le joint étanche HS III défectueux.
        ii. Avoir toujours un deuxième joint étanche HS III à disposition pour remplacer un dispositif défectueux. Consulter le mode d'emploi du dispositif pour vous assurer que le chargement s'effectue correctement.
2. **Défaillance de déploiement du joint étanche Heartstring III dans l'aortotomie**
    a. Rappels importants:
        i. S'assurer que le joint étanche HS III a été correctement chargé dans le dispositif de pose, tel que décrit dans la section ci-dessus.
        ii. Après avoir retiré le joint étanche HS III chargé du dispositif de pose, inspectez le joint étanche HS III chargé selon les sections 4.3 à 4.5 du mode d'emploi afin de vérifier les points suivants:
            1. Le joint étanche HS III chargé n'est pas fissuré.

2. La partie du joint étanche HS III qui n'est pas chargée dans le tube du dispositif de pose ne s'évase pas au-delà du diamètre du tube du dispositif de pose.
3. Les extrémités du ressort de tension sont alignées de manière à entrer en contact avec les deux bords proximaux du joint étanche HS III chargé lors de son insertion dans l'aortotomie.

b. Comment éviter/minimiser l'occurrence de cette défaillance :
   i. Après confirmation du chargement réussi du joint étanche HS III et de la réalisation de l'aortotomie, déployez le joint étanche HS III chargé dans l'aortotomie en suivant attentivement les étapes de déploiement du joint étanche HS III décrites dans le mode d'emploi du dispositif.
   ii. Si le joint étanche HS III ne se déploie pas comme prévu, le dispositif doit être remplacé.

c. Mesures à prendre si le joint étanche HS III ne se déploie pas correctement dans l'aorte.
   i. Occlure l'aortotomie pour contrôler le saignement à l'aide de l'index.
   ii. Ouvrir un deuxième joint étanche HS III. Charger le joint étanche HS III conformément au mode d'emploi du dispositif. Insérer le joint étanche HS III chargé dans l'aortotomie et suivre le mode d'emploi pour compléter l'anastomose.
   iii. Si le deuxième joint étanche HS III ne peut être inséré avec succès dans l'aortotomie, ou si la préférence du chirurgien détermine que la situation ne permet pas l'utilisation d'un joint étanche HS III de remplacement, placer un clamp d'occlusion partielle sur l'aorte, isoler l'aortotomie et réaliser l'anastomose selon la technique chirurgicale traditionnelle.

3. Défaillance du joint étanche Heartstring III déployé pour fournir une hémostase adéquate:

a. Comment éviter/minimiser l'occurrence de ce mode de défaillance:
   i. Toujours charger et inspecter soigneusement le joint étanche HS III chargé afin de confirmer le chargement réussi du joint étanche HS III dans le dispositif de pose avant de nettoyer l'adventice aortique et de réaliser l'aortotomie. (Voir les rappels importants ci-dessus.)
   ii. Ne pas utiliser le système d'étanchéité proximale Heartstring chez les patients présentant une aorte à paroi mince.
   iii. Lors de la réalisation de plusieurs anastomoses, veiller à ce que tous les sites anastomotiques soient espacés d'au moins 1,5 cm afin d'assurer l'hémostase.
   iv. Ne pas tremper le joint étanche HS III dans une solution avant le déploiement.

b. Mesures à prendre si le joint étanche HS III ne s'ouvre pas/n'assure pas une hémostase adéquate après déploiement.
   i. Couvrir l'aortotomie avec l'index et ajuster délicatement le ressort de tension pour s'assurer que le joint étanche HS III est complètement déployé.
   ii. Si l'hémostase demeure insuffisante:
      1. Retirer le joint étanche HS III déployé de l'aortotomie selon le mode d'emploi du dispositif.
      2. Charger un deuxième joint étanche HS III et déployer le joint étanche chargé dans l'aortotomie selon le mode d'emploi du dispositif, puis compléter l'anastomose.
      3. Si le deuxième joint étanche HS III n'est pas efficace ou si le chirurgien détermine que la situation ne permet pas l'utilisation d'un joint étanche HS III de remplacement, placer un clamp d'occlusion partielle sur l'aorte,

isoler l'aortotomie et réaliser l'anastomose selon la technique chirurgicale traditionnelle.

Mesures à prendre par le client

Getinge vous demande de prendre les mesures suivantes:

1. Veuillez vous assurer que ce message est transmis à toute personne devant en être informée au sein de votre organisation ou de toute organisation à laquelle les dispositifs concernés ont été transférés.

Informations supplémentaires

Getinge communique ces informations aux organismes de réglementation compétents.

Nous nous excusons pour tout inconvénient que cela pourrait causer. Nous nous engageons à assurer la sécurité des patients et nous vous remercions de votre attention rapide à cette question. Si vous avez des questions concernant cette communication, veuillez communiquer avec votre représentant local de Getinge.

Cordialement,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Chile (es)

Agosto 2025

Aviso de seguridad Urgente
Sistema de obturación proximal Heartstring III
Número de referencia FSCA: 1336551

Número de modelo	UDI	Nombre del modelo	Números de serie/lote
HSK-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de obturación proximal Heartstring III	Todos los lotes no caducados
Fechas de distribución:		1 de julio de 2024 - Actualidad	
Fechas de fabricación:		7 de marzo de 2024 - Actualidad	

Estimado gestor de riesgos,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está emitiendo una corrección urgente de dispositivos médicos para el sistema de sellado proximal Heartstring III (HS III Seal). Según nuestros registros, usted ha recibido uno o varios de los dispositivos afectados por esta notificación.

Descripción del Problema

Se han identificado tres modos de fallo principales.

1. **Fallo en la carga del sello Heartstring**: Este fallo se aplica a cualquier mal funcionamiento del dispositivo que se produzca durante el proceso de carga de cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un sello HS III cargado correctamente y el desbloqueo del dispositivo de administración tras completar con éxito los pasos de carga del sello HS III.
2. **Fallo del sello cardíaco al desplegarse en la aortotomía**: Este fallo se aplica a cualquier mal funcionamiento del sello HS III y/o del dispositivo de implantación desde el momento en que el dispositivo de implantación se desbloquea correctamente hasta que se completa la implantación del sello HS III en la aortotomía y todo el contenido del sello proximal (la correa, el resorte de tensión, el vástago del sello y la lengüeta de anclaje) ha salido del dispositivo de implantación.
3. **Fallo del sellado Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier mal funcionamiento de un sello HS III implantado correctamente que no controle adecuadamente el sangrado en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis, a pesar del ajuste suave del resorte de tensión tras la implantación del sello y/o el uso de un nebulizador, succión o jeringa de solución salina para limpiar el sitio de la anastomosis. Este fallo incluye la identificación por parte del cliente de un sello HS III defectuoso o dañado tras el despliegue correcto del sello HS III en la aorta, lo que da lugar o puede dar lugar a una

hemostasia inadecuada que impide al cirujano completar la anastomosis sin retirar el sello HS III defectuoso.

En estos momentos se está investigando la causa raíz.

Riesgos para la salud

1. **Error al cargar:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un sello HS III que no se carga no supone un riesgo directo para el paciente. Sin embargo, este fallo puede provocar un retraso en la intervención quirúrgica. Este retraso puede variar desde unos minutos para recuperar y cargar un nuevo sello, hasta una posible conversión del uso del sello HS III para realizar la anastomosis proximal al empleo de una pinza aórtica para completar la intervención.
2. **Fallo en la implementación:** Cuando el sello HS III cargado no se despliega desde el dispositivo de administración, ya se han realizado los siguientes pasos del procedimiento, lo que puede contribuir al riesgo potencial de daño al paciente. Si el sello HS III cargado no se despliega desde el dispositivo de administración, ya se habrán completado varios pasos del procedimiento, lo que puede aumentar el riesgo potencial de daño al paciente.
   - Se ha realizado la aortotomía.
   - El extremo distal del tubo del dispositivo de administración se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de administración o se ha intentado presionarlo.
   - El sello HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de administración.
   - Cuando se retira el dispositivo de administración de la aortotomía, el sello HS III no se desplegará y será necesario controlar el sangrado de la aortotomía colocando un dedo sobre ella.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: para retirar el HS III Seal no desplegado, abrir un nuevo HS III Proximal Seal, cargar el Seal en el dispositivo de liberación (Delivery Device) y entregar el HS III Seal cargado en la aortotomía creada (retraso sin intervención adicional) vs. la decisión de utilizar una pinza aórtica para completar la anastomosis debido a que el Seal cargado no se desplegó (retraso con una intervención adicional).
   - **Daño tisular**: puede ocurrir como resultado del despliegue de un HS III Seal cargado que esté ensanchado en la punta. Una punta ensanchada tendrá un diámetro mayor que el tubo distal del dispositivo de liberación. El despliegue de un Seal cargado con la punta ensanchada puede causar daño al tejido de la aortotomía y, si se aplica mayor fuerza para desplegar el Seal afectado, existe un riesgo potencial de perforar la pared posterior de la aorta durante la inserción. El daño tisular también puede ocurrir durante la retirada del dispositivo de liberación de la aortotomía, al desplegar un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** puede producirse una pérdida mínima de sangre al retirar el dispositivo de liberación de la aortotomía, al controlar manualmente el sangrado de la aortotomía y al colocar un HS III Seal de reemplazo. Puede producirse una mayor pérdida de sangre,

que requiera intervención adicional, si ocurre daño tisular.

- **Evento embólico** como resultado de la manipulación adicional de la aorta para abordar la falla en la carga del HS III Seal.

3. **Falla del Heartstring Seal desplegado para proporcionar hemostasia adecuada:** uando un HS III Seal desplegado no logra proporcionar una hemostasia adecuada para que el cirujano complete la anastomosis proximal, varios pasos del uso del Sistema HS III Seal ya se han completado y pueden aumentar el riesgo potencial de daño al paciente. Los siguientes pasos del procedimiento ya se habrán realizado.
   - Se ha creado la aortotomía.
   - El HS III Seal cargado se ha desplegado en la aorta.
   - El sangrado de la aorta es considerado por el cirujano como demasiado abundante para realizar la anastomosis.

   Los siguientes daños potenciales al paciente pueden ocurrir:

   - **Retraso del procedimiento quirúrgico**: puede ocurrir de la siguiente manera:

     Tiempo operatorio adicional necesario para intentar realizar ajustes en el Seal con el fin de mejorar la hemostasia proporcionada por el HS III Seal implantado, retirar el HS III Seal defectuoso, abrir un nuevo HS III Seal, cargar el HS III Seal de reemplazo y colocar el HS III Seal cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional).
     - El cirujano considera más apropiado utilizar una pinza aórtica para completar la anastomosis debido a que el HS III Seal desplegado no logró proporcionar hemostasia adecuada para completarla y no hay un HS III Seal de reemplazo disponible, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo y se utiliza una pinza aórtica para completar la anastomosis proximal según la técnica quirúrgica tradicional. (retraso del procedimiento con intervención adicional)
   - **Daño tisular**: puede ocurrir durante la manipulación del HS III Seal afectado, durante el despliegue de un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** Una pequeña cantidad de pérdida de sangre alrededor del HS III Seal desplegado es normal y esperada al realizar la anastomosis proximal utilizando un HS III Seal. Puede producirse una mayor pérdida de sangre que requiera intervención adicional cuando ocurre daño del tejido aórtico, independientemente de la causa.
   - **Evento(s) embólico(s):** como resultado de la manipulación adicional de la aorta secundaria a la necesidad de abordar la falla del HS III Seal en proporcionar hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge recibió las siguientes quejas:

- 274 reportes relacionados con falla de carga, lo que representa una tasa de quejas del 0,386%
- 96 reportes relacionados con falla de despliegue, lo que representa una tasa de quejas del 0,135%
- 30 reportes relacionados con hemostasia inadecuada, lo que representa una tasa de quejas del 0,042%

<u>Medidas y acciones recomendadas</u>

Getinge proporciona las siguientes instrucciones para evitar/minimizar las fallas descritas anteriormente.

1. **Falla del Heartstring Seal al cargar**
    a. Recordatorios importantes:
        i. Según las Instrucciones de Uso (IFU) del dispositivo, el HS III Seal debe cargarse y retirarse del dispositivo de carga (Loading Device), luego inspeccionarse y ajustarse si es necesario para confirmar una carga exitosa y finalmente desbloquearse antes de retirar cualquier adventicia del área anastomótica planificada y crear la aortotomía. Cargar el HS III Seal y confirmar una carga exitosa antes de crear la aortotomía minimiza el riesgo para los pacientes, ya que la aorta permanece intacta hasta confirmar que la carga del HS III Seal fue exitosa.
        ii. Si el HS III Seal no se carga según lo previsto, el dispositivo debe reemplazarse.
    b. Cómo evitar/minimizar la ocurrencia de esta falla
        i. Revisar las Instrucciones de Uso (IFU) del dispositivo Heartstring antes de su utilización, especialmente si Heartstring no se utiliza de forma rutinaria.
        ii. Cargar el HS III Seal siguiendo cuidadosamente las Instrucciones de Uso (IFU) del dispositivo paso a paso.
        iii. De acuerdo con las Secciones 4.3–4.5 de las IFU, confirmar que el HS III Seal ha sido correctamente cargado en el dispositivo de liberación (Delivery Device) inspeccionando el HS III Seal cargado una vez que haya sido introducido en el Delivery Device y retirado del dispositivo de carga (Loading Device).
        iv. Un HS III Seal que no sea inspeccionado adecuadamente después de retirarlo del dispositivo de carga (Loading Device) puede fallar durante el despliegue del HS III Seal y causar daño al paciente. (Ver la información relacionada con Falla de Despliegue).
        v. Completar la carga exitosa del HS III Seal antes de limpiar la adventicia de la superficie aórtica y crear la aortotomía.
    c. Acción a tomar si el HS III Seal falla al cargarse.
        i. Desechar el HS III Seal defectuoso.
        ii. Tener siempre disponible un segundo HS III Seal para reemplazar un dispositivo defectuoso. Consultar las IFU del dispositivo para asegurar una carga exitosa.
2. **Falla del Heartstring III Seal al desplegarse en la aortotomía**
    a. Recordatorios importantes:
        i. Asegurarse de que el HS III Seal haya sido correctamente cargado en el dispositivo de liberación (Delivery Device), tal como se describe en la sección anterior.
        ii. Después de retirar el HS III Seal cargado del dispositivo de carga (Loading Device), inspeccionar el HS III Seal cargado, de acuerdo con las Secciones 4.3–4.5 de las IFU, para confirmar lo siguiente:
            1. Que el HS III Seal cargado no esté agrietado.
            2. Que la porción del HS III Seal que no está dentro del tubo del

Delivery Device no esté ensanchada más allá del diámetro del tubo del Delivery Device.

3. Que los extremos del resorte de tensión (Tension Spring) estén alineados de modo que contacten ambos bordes proximales del HS III Seal cargado durante la colocación del Seal en la aortotomía.

b. Cómo evitar/minimizar la ocurrencia de esta falla:
   i. Después de confirmar la carga exitosa del HS III Seal y crear la aortotomía, desplegar el HS III Seal cargado en la aortotomía siguiendo cuidadosamente los pasos de despliegue documentados en las IFU del dispositivo.
   ii. Si el HS III Seal no se despliega según lo previsto, el dispositivo debe reemplazarse.
c. Acción a tomar si el HS III Seal no se despliega correctamente en la aorta.
   i. Ocluir la aortotomía para controlar el sangrado utilizando el dedo índice.
   ii. Abrir un segundo HS III Seal. Cargar el HS III Seal de acuerdo con las IFU del dispositivo. Introducir el HS III Seal cargado en la aortotomía y seguir las IFU para completar la anastomosis.
   iii. Si la colocación del segundo HS III Seal en la aortotomía no tiene éxito, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

3. Falla del Heartstring III Seal desplegado para proporcionar hemostasia adecuada:

a. Cómo evitar/minimizar la ocurrencia de este modo de falla:
   i. Cargar siempre e inspeccionar cuidadosamente el HS III Seal cargado para confirmar que la carga en el dispositivo de liberación (Delivery Device) se haya realizado correctamente antes de retirar la adventicia de la aorta y crear la aortotomía. (Ver recordatorios importantes anteriores).
   ii. No utilizar el sistema Heartstring Proximal Seal en pacientes con aorta de pared delgada.
   iii. Al realizar múltiples anastomosis, asegurar que todos los sitios anastomóticos estén separados al menos 1,5 cm para garantizar la hemostasia.
   iv. No sumergir el HS III Seal en solución antes del despliegue.
b. Acción a tomar si el HS III Seal no se abre/no proporciona hemostasia adecuada después del despliegue.
   i. Cubrir la aortotomía con el dedo índice y ajustar suavemente el resorte de tensión (Tension Spring) para asegurar que el HS III Seal se haya desplegado completamente.
   ii. Si persiste la falta de hemostasia adecuada:
      1. Retirar el HS III Seal desplegado de la aortotomía de acuerdo con las IFU del dispositivo.
      2. Cargar un segundo HS III Seal y desplegar el Seal cargado en la aortotomía conforme a las IFU del dispositivo y completar la anastomosis.
      3. Si el segundo HS III Seal no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la

aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

Acciones para el cliente

Getinge solicita que tome las siguientes acciones:

1. Asegúrese de que este mensaje sea reenviado a todas las personas que deban ser notificadas dentro de su organización o en cualquier organización a la que se hayan transferido los dispositivos afectados.

Información adicional

Getinge está comunicando esta información a las agencias regulatorias correspondientes.

Lamentamos cualquier inconveniente que esto pueda ocasionar. Estamos comprometidos con la seguridad del paciente y agradecemos su pronta atención a este asunto. Si tiene alguna pregunta con respecto a esta comunicación, por favor comuníquese con su representante de Getinge o con el Servicio de Atención al Cliente de Getinge.

Cordialmente,

Francisco Vicenty
Director de Calidad y Cumplimiento Regulatorio, Interino
Getinge, Cirugía Cardiovascular

China (zh)

August 2025

区域安全通知
Heartstring III近端吻合系统
Reference Number: 1336551

产品型号	UDI	产品名称	批号
HSK-3038 HSK-3043	00607567700314 00607567700321	Heartstring III近端吻合系统	所有未过期批次
发货日期：		2024年7月1日 - 至今	

尊敬的客户：

本函旨在通知您，生产企业正在对近端吻合系统（Heartstring III）发起紧急纠正。根据我们的记录，您已收到一件或多件受此通知影响的产品。

问题描述

已确定三种主要故障模式。

1. **Heartstring III吻合装置无法装载：**此故障指在使用Heartstring III进行四步装载过程中出现的产品故障，包括在目视检查Heartstring III吻合装置时发现的问题，以及在成功完成Heartstring III吻合装置装载步骤后解锁输送装置时遇到的问题。
2. **Heartstring III吻合装置无法置入到主动脉切口中：**此故障指从输送装置成功解锁后，直至Heartstring III吻合装置完全输送到主动脉切口中，且近端吻合装置的所有组件（系绳、张力簧、吻合装置杆、固定头）完全退出输送装置的整个过程中，Heartstring III吻合装置和/或输送装置出现的故障。
3. **已置入的Heartstring III吻合装置无法充分止血：**此故障指已成功置入的Heartstring III吻合装置出现功能异常，无法在吻合部位充分止血，即使置入后轻轻调整张力簧和/或使用吹雾管、吸引头或盐水注射器清理吻合部位，此问题仍然存在，导致外科医生无法进行顺利吻合。这种故障还包括客户在Heartstring III吻合装置成功置入主动脉后发现装置有故障或损坏的情况，这可能导致止血不足，外科医生必须更换故障的Heartstring III吻合装置才能完成吻合。

潜在危害

1. **装载失败：**若按照产品使用说明书(IFU)操作，吻合装置装载失败不会对患者造成直接风险。但故障可能会导致手术延迟，需要几分钟取出并装载新的吻合装置，或者需要改变吻合方式，从使用Heartstring III吻合装置执行近端吻合改为采用动脉钳完成吻合。
2. **置入失败：**若已经完成了以下部分或全部操作步骤，已装载的Heartstring III吻合装置无法从输送装置中置入时，可能会造成以下患者伤害风险。
   - 主动脉切口已经建立。
   - 输送装置管的远端已经插入主动脉切口。

- 输送装置的活塞已被按下，或已尝试按下。
- 已装载的Heartstring III吻合装置未能成功从输送装置管的远端置入。
- 当输送装置从主动脉切口中取出时，Heartstring III吻合装置未能成功置入，此时需要用手指按压主动脉切口止血。

可能会造成以下患者伤害：

- **手术延迟**：需要移除未成功置入的Heartstring III吻合装置，打开新的Heartstring III近端吻合装置，将其装入输送装置，重新置入已建立的主动脉切口（手术延迟，无需额外干预）；或者因已装载的吻合装置无法置入而决定改用动脉钳完成吻合手术（手术延迟，需额外干预）。
- **组织损伤**：可能由于置入尖端张开的Heartstring III吻合装置而导致。张开的尖端直径大于输送装置管，置入时可能损伤主动脉切口组织。若置入时用力过大，还存可能存在穿透主动脉后壁的风险。在从主动脉切口取出输送装置、重新装载一个Heartstring III吻合装置置入同一主动脉切口，和/或需要改用动脉钳完成吻合操作时，也可能发生组织损伤。
- **出血**：从主动脉切口取出输送装置、手动对主动脉切口止血以及放置替换的Heartstring III吻合装置时，可能发生轻微失血。如果发生组织损伤，则可能因失血量大需要额外干预。
- **栓塞风险**：为了解决Heartstring III吻合装置置入失败而对主动脉进行额外操作可能带来的栓赛风险。

3. **已置入的Heartstring吻合装置无法充分止血**：Heartstring III吻合系统的多个使用操作已经完成，当已置入的Heartstring III吻合装置无法充分止血以协助外科医生完成近端吻合时，可能会增加患者受伤的风险。已经完成的使用操作。
   - 主动脉切口已经建立完成。
   - Heartstring III吻合装置已成功置入主动脉。
   - 外科医生判断主动脉出血程度过大，无法进行吻合操作。

   可能会发生以下患者伤害：

   - **手术延迟**：可能发生如下情况：
     - 需要额外的手术时间来调整已置入的Heartstring III吻合装置以改善止血效果、移除有故障的吻合装置、打开新的Heartstring III吻合装置、重新置入已建立的主动脉切口（手术延迟，无需额外干预）。
     - 已置入的Heartstring III吻合装置未能充分止血，且无替换装置可用，或医生根据临床情况认为不宜使用替换的Heartstring III吻合装置，因而选择采用传统技术动脉钳完成近端吻合。（手术延迟，需额外干预）
   - **组织损伤**：在操作Heartstring III吻合装置过程中、将第二个已装载的Heartstring III吻合装置置入同一主动脉切口期间，和/或需要改用动脉钳完成主动脉切口吻合操作时，均可能导致组织损伤。
   - **出血**：在使用Heartstring III吻合装置进行近端吻合操作时，已置入的Heartstring III吻合装置周围出现少量失血是预期内的正常现象。但当主动脉组织发生损伤时，无论因何种原因，都可能因大量失血导致需要额外的医疗干预。

- **栓塞风险：**为了解决Heartstring III吻合装置置入失败而对主动脉进行额外操作可能带来的栓赛风险。

在2023年6月1日至2025年7月22日期间，生产企业收到相关投诉如下：

- 274例与装载失败相关的报告，投诉率为0.386%
- 96例与置入失败相关的报告，投诉率为0.135%
- 30例与止血效果不足相关的报告，投诉率为0.042%

建议措施和行动

为避免/减少上述故障的发生，生产企业提供以下操作指导。

1. **Heartstring吻合装置无法装载**
    a. 重要提示：
        i. 根据产品使用说明书(IFU)，应先装载Heartstring III吻合装置并从装载装置中取出，然后检查并在必要时调整，以确认装载成功，最后在清洁的主动脉表面，移除疏松组织并确保组织未经改变的主动脉切口前解锁。请先完成Heartstring III吻合装置的装载并确认成功，再建立主动脉切口，这样可以最大限度降低患者风险，因为在确认装载成功前，主动脉能保持完好无损。
        ii. 如果HS III吻合装置未能按预期装载，应更换该装置。
    b. 如何避免/减少此类故障的发生
        i. 遵守Heartstring III产品使用说明书操作，尤其是在不常使用Heartstring III产品的情况下。
        ii. 按照产品使用说明书(IFU)的步骤操作，小心装载Heartstring III吻合装置。
        iii. 根据使用说明书第4.3-4.5节，当Heartstring III吻合装置已装入输送装置并已从装载装置中取出后，通过检查已装载的Heartstring III吻合装置，确认其已正确装入输送装置中。
        iv. 若从装载装置取出后未检查Heartstring IIII吻合装置，可能导致其在置入过程中出现故障，造成患者伤害（请参见置入失败的相关信息）。
        v. 在建立主动脉切口之前，清洁主动脉表面外膜，完成Heartstring IIII吻合装置的成功装载。
    c. 当Heartstring III吻合装置装载失败时应采取的措施。
        i. 丢弃故障的Heartstring III吻合装置。
        ii. 始终备有第二个Heartstring III吻合装置，以便在设备故障时替换。请参考产品使用说明书，并确保正确装载。
2. **Heartstring III吻合装置无法置入主动脉切口中**
    a. 重要提示：
        i. 确保按照上述章节所描述的方法，将Heartstring IIII吻合装置正确装载到输送装置中。
        ii. 从装载装置中取出已装载的Heartstring IIII吻合装置后，根据使用说明书第4.3-4.5节检查已装载的HS III吻合装置，确认以下几点：
            1. 已装载的HS III吻合装置没有开裂。
            2. 确保HS III吻合装置未装入输送装置管中的部分不会张开到大于输送装置管的直径。

3. 确保张力簧末端已对齐，以便在吻合装置给进过程中与 Heartstring IIII 吻合装置的两个近端边缘接触。

b. 如何避免/减少此类故障的发生：
   i. 在确认Heartstring IIII吻合装置成功装载并建立主动脉切口后，按照设备使用说明书(IFU)中的Heartstring IIII吻合装置置入步骤，小心将已装载的Heartstring IIII吻合装置置入主动脉切口中。
   ii. 如果Heartstring IIII吻合装置未能按预期置入，应更换该装置。

c. 当Heartstring IIII吻合装置无法成功置入主动脉时应采取的措施。
   i. 用食指堵住主动脉切口以控制出血。
   ii. 打开第二个Heartstring IIII吻合装置。按照产品使用说明书装载Heartstring IIII吻合装置。将已装载的Heartstring IIII吻合装置置入主动脉切口中，并按照使用说明书完成吻合。
   iii. 如果第二个HS III吻合装置也无法成功置入，或医生根据临床情况判断不宜使用替换的Heartstring IIII吻合装置，则应在主动脉上放置部分咬合夹以隔离主动脉切口，并采用传统手术技术完成吻合操作。

3. 已置入的Heartstring III吻合装置无法提供足够的止血效果：

a. 如何避免/减少此类故障的发生：
   i. 在清洁主动脉表面外膜并建立主动脉切口前，务必先装载Heartstring IIII吻合装置并仔细检查，确保其已成功装入输送装置。（参见上文重要提示）
   ii. 请勿在主动脉壁较薄的患者上使用 Heartstring IIII近端吻合系统。
   iii. 为了确保能够止血，进行多重吻合术前，请确保所有的吻合点都至少分隔 1.5 cm。
   iv. 置入前不要将Heartstring IIII吻合装置浸泡在溶液中。

b. 当Heartstring IIII吻合装置未能打开/置入后无法充分止血时应采取的措施。
   i. 用食指覆盖主动脉切口，轻轻调整张力簧，确保Heartstring IIII吻合装置置放妥当。
   ii. 如果止血效果仍然不理想：
      1. 按照产品使用说明书从主动脉切口中取出已置入的Heartstring IIII吻合装置。
      2. 装载第二个Heartstring IIII吻合装置，并按照产品使用说明书将已装载的吻合装置置入主动脉切口中，完成吻合操作。
      3. 如果第二个Heartstring IIII吻合装置仍然不成功，或医生根据临床情况判断不宜使用替换的Heartstring IIII吻合装置，则应在主动脉上放置部分咬合夹以隔离主动脉切口，并采用传统手术技术完成吻合操作。

<u>客户行动</u>

生产企业要求您采取以下行动：

1. 请将本召回通知转发给贵院相关人员，如果产品已转卖给其他单位，也请将本召回通知转发给相应单位。

<u>其他信息</u>

对由于此问题可能造成的不便我们深表歉意。我们致力于患者的安全，并感谢您对此事的及时关注。如果您对此通信有任何疑问，请联系您的Getinge当地代表或客服热线：800-820-0207。

GETINGE

Croatia

Croatian (hr)

kolovoz 2025.

Sigurnosno upozorenje u terenu
Proksimalni sustav zatvaranja Heartstring III
Referentni broj: 1336551

Broj modela	UDI	Naziv modela	Serijski broj/serija
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proksimalni sustav zatvaranja Heartstring III	Sve serije kojima nije istekao rok trajanja
Datum distribucije:		od 1. srpnja 2024. do danas	
Datum proizvodnje:		od 7. ožujka 2024. do danas	

Poštovani menadžeru za rizike,

svrha ovog pisma je izvijestiti Vas da društvo Maquet Cardiovascular, društvo-kćer društva Getinge, izdaje hitni popravak medicinskog proizvoda Proksimalni sustav zatvaranja Heartstring III (zatvarač HS III). Prema našoj evidenciji ste zaprimili jedan ili više predmetnih medicinskih proizvoda, kojih se tiče ova obavijest.

Opis problema

Identificirana su tri primarna razloga neuspjeha.

1. **Pogreška tijekom uvođenja zatvarača:** ovaj problem se tiče bilo kojeg kvara uređaja, do kojeg dođe tijekom nekog od četiri koraka postupka uvođenja pomoću aplikacijskog uređaja Heartstring, vizualne kontrole uspješno uvedenog zatvarača HS III, te oslobađanja aplikacijskog uređaja nakon uspješnog završetka svih koraka uvođenja zatvarača HS III.
2. **Pogreška tijekom razvijanja zatvarača Heartstring u aortotomiji**: ovaj problem se odnosi na bilo koji kvar zatvarača HS III i/ili aplikacijskog uređaja od trenutka kada je aplikacijski uređaj uspješno oslobođen do trenutka kada je zatvarač HS III u cijelosti postavljen u aortotomiju i svi dijelovi proksimalnog zatvarača (vlakno, zatezna opruga, tijelo zatvarača, prihvatna omča) su uklonjeni iz aplikacijskog uređaja.
3. **Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:** ovaj problem se tiče bilo kojeg kvara uspješno razvijenog zatvarača HS III, koji na mjestu anastomoze ne osigurava adekvatnu kontrolu krvarenja za izvođenje šivenja anastomoze, i to unatoč finom podešavanju zatezne opruge nakon razvijanja zatvarača i/ili uporabe ventilatorske prskalice, usisavanja ili šprice s fiziološkom otopinom za čišćenje mjesta anastomoze. Ovaj kvar obuhvaća i slučaj kada klijent identificira neispravan ili oštećen zatvarač HS III nakon uspješnog razvijanja zatvarača HS III u aortu, ako kvar ima/može imati za posljedicu nedostatnu hemostazu, koja onemogućava da kirurg završi anastomozu bez uklanjanja neispravnog zatvarača HS III.

Trenutno se provodi istraga glavnog uzroka.

Zdravstveni rizici:

1. **Pogreška tijekom uvođenja:** ako se zatvarač HS III upotrebljava sukladno Uputama za uporabu (IFU) proizvoda, pogreška pri uvođenju za pacijenta nije izravan rizik. Međutim, ova pogreška može dovesti do zakašnjenja kirurškog zahvata. Isto kašnjenje može trajati od nekoliko minuti koje su potrebne za vađenje i uvođenje novog zatvarača, sve do potencijalnog prijelaza s korištenja zatvarača HS III na izvođenje proksimalne anastomoze pomoću aortalne kleme radi dovršavanja zahvata.
2. **Pogreška tijekom razvijanja:** ako ne uspijeva razvijanje uvedenog zatvarača HS III iz aplikacijskog uređaja, već su izvedeni slijedni koraci postupka, a isti mogu doprinijeti potencijalnom riziku oštećenja zdravlja pacijenta. Ako se zatvarač HS III ne uspijeva razviti iz aplikacijskog uređaja, izvesti će se nekoliko postupaka koji mogu povećati potencijalni rizik oštećenja zdravlja pacijenta.
   - Izvedena je aortotomija.
   - Distalni kraj cijevi aplikacijskog uređaja je uveden kroz aortotomiju.
   - Klip aplikacijskog uređaja je pritisnut ili je izveden pokušaj njegovog pritiskanja.
   - Nije uspjelo razvijanje umetnutog zatvarača HS III s distalnog kraja cijevi aplikacijskog uređaja.
   - Nakon vađenja aplikacijskog uređaja iz aortotomije se zatvarač HS III ne razvija, te se krvarenje iz aortotomije mora zaustaviti postavljanjem prsta na aortotomiju.

   Mogu nastati sljedeća oštećenja zdravlja pacijenta:

   - **Zakašnjenje kirurškog zahvata**: uklanjanje nerazvijenog zatvarača HS III, otvaranje novog proksimalnog zatvarača HS III, umetanje zatvarača u aplikacijski uređaj te uvođenje umetnutog zatvarača HS III u izvedenu aortotomiju (zakašnjenje bez drugog zahvata) naspram odluke o primjeni aortalne kleme za dovršavanje anastomoze, pošto nije uspjelo razvijanje uvedenog zatvarača (zakašnjenje s drugim zahvatom).
   - **Oštećenje tkiva**: do oštećenja tkiva može doći uslijed razvijanja uvedenog zatvarača HS III, koji je proširen na vrhu. Proširen vrh može imati veći promjer od distalne cijevi aplikacijskog uređaja. Razvijanje uvedenog zatvarača s proširenim vrhom može prouzročiti oštećenje tkiva u oblasti aortotomije, a u slučaju primjene veće sile za razvijanje predmetnog zatvarača pri uvođenju, postoji rizik ozljede zadnjeg zida aorte. Do oštećenja tkiva može doći i tijekom uklanjanja aplikacijskog uređaja iz aortotomije, razvijanja drugog uvedenog zatvarača HS III u istu aortotomiju i/ili neophodnosti primjene aortalne kleme za dovršavanje aortotomije.
   - **Krvarenje:** do minimalnog gubitka krvi može doći tijekom uklanjanja aplikacijskog uređaja iz aortotomije, pri ručnom upravljanju krvarenjem iz aortotomije te aplikacije naknadnog zatvarača HS III. Veći gubitak krvi, koji bi zahtijevao dodatnu intervenciju, može nastati u slučaju oštećenja tkiva.
   - **Embolijski događaj** uslijed dodatne manipulacije aortom pri rješavanju pogreške pri uvođenju zatvarača HS III.
3. **Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:** u slučaju da razvijen zatvarač HS III ne daje dostatnu hemostazu za to da kirurg može dovršiti proksimalnu anastomozu, već su dovršeni određeni koraci u svezi primjene sustava zatvaranja HS III, što može povećati potencijalan rizik oštećenja zdravlja pacijenta. U istom trenutku će već biti izvedeni sljedeći koraci:
   - Izvedena je aortotomija.

- Uveden zatvarač HS III je razvijen u aorti.
- Kirurg smatra da je krvarenje iz aorte prejako za izvođenje anastomoze.

Mogu nastati sljedeća oštećenja zdravlja pacijenta:

- **Zakašnjenje kirurškog zahvata**: do toga može doći na sljedeći način:
    - Dodatno operativno vrijeme potrebno za pokušaj uređenja zatvarača radi poboljšanja hemostaze pomoću uvedenog zatvarača HS III, uklanjanje neispravnog zatvarača HS III, otvaranje novog zatvarača HS III, umetanje naknadnog zatvarača HS III i uvođenje pripremljenog zatvarača HS III u izvedenu aortotomiju (zakašnjenje zahvata bez drugog zahvata).
    - Kirurg smatra da je za dovršavanje anastomoze najprikladnija uporaba aortalne kleme, pošto razvijen zatvarač HS III ne daje dostatnu hemostazu za dovršavanje anastomoze te ili nije na raspolaganju naknadni zatvarač HS III, ili kirurg donosi odluku da situacija ne omogućava primjenu naknadnog zatvarača HS III te upotrebljava aortalnu klemu za dovršavanje proksimalne anastomoze tradicionalnom kirurškom tehnikom (zakašnjenje zahvata s drugim zahvatom).
- **Oštećenje tkiva**: do oštećenja tkiva može doći pri manipulaciji predmetnim zatvaračem HS III, tijekom razvijanja drugog uvedenog zatvarača HS III u istu aortotomiju i/ili u slučaju kada treba prijeći na primjenu aortalne kleme radi dovršavanja aortotomije.
- **Krvarenje:** mali gubitak krvi u okolici razvijenog zatvarača HS III je normalan te se pri izvođenju proksimalne anastomoze primjenom zatvarača HS III može očekivati. Do većeg gubitka krvi, koji bi zahtijevao dodatnu intervenciju, može doći pri oštećenju tkiva, bez obzira na uzrok oštećenja.
- **Embolijski događaj:** nastaje dodatnom manipulacijom aortom pri rješavanju pogreške, kada zatvarač HS III ne daje dostatnu hemostazu.

Od 1. lipnja 2023. do 22. srpnja 2025. je društvo Getinge zaprimilo sljedeće prigovore:

- 274 dojava u svezi pogreške pri uvođenju, što predstavlja količinu prigovora od 0,386 %
- 96 dojava u svezi pogreške pri razvijanju, što predstavlja količinu prigovora od 0,135 %
- 30 dojava u svezi nedostatne hemostaze, što predstavlja količinu prigovora od 0,042 %

<u>Preporučene ublažavajuće mjere i koraci:</u>

Društvo Getinge daje sljedeće upute za izbjegavanje/minimalizaciju gore opisanih pogrešaka.

1. **Pogreška tijekom uvođenja zatvarača Heartstring**
    a. Važne napomene:
        i. U Uputama za uporabu proizvoda se navodi da zatvarač HS III treba biti uveden i izvađen iz aplikacijskog uređaja, nakon toga provjeren, te po potrebi modificiran radi potvrđivanja uspješnog uvođenja, a nakon toga treba biti oslobođen prije uklanjanja adventicije s mjesta planirane anastomoze i izvođenja aortotomije. Uvođenje zatvarača HS III i potvrda uspješnog uvođenja prije izvođenja aortotomije minimalizira rizike za pacijenta, pošto aorta ostaje netaknuta dok se ne potvrdi uspješno uvođenje zatvarača HS III.
        ii. Ako planirano uvođenje zatvarača HS III ne uspije, proizvod bi trebalo zamijeniti.
    b. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:

i. Prije uporabe pročitajte Upute za uporabu proizvoda Heartstring, prije svega ako Heartstring ne koristite redovito.
ii. Pri uvođenju zatvarača HS III postupajte oprezno i poštujte postupno sve korake navedene u Uputama za uporabu (IFU).
iii. Prema uputama u članku 4.3-4.5 Uputa za uporabu provjerite je li zatvarač HS III ispravno umetnut u aplikacijski uređaj tako što ćete provjeriti umetnut zatvarač HS III nakon njegovog umetanja u aplikacijski uređaj i vađenja iz aplikacijskog uređaja.
iv. Zatvarač HS III, koji nakon vađenja iz aplikacijskog uređaja nije uredno provjeren, može tijekom razvijanja zatajiti te prouzročiti ozljedu pacijenta (vidjeti informacije u svezi Pogreške pri razvijanju).
v. Dovršite uspješno uvođenje zatvarača HS III prije čišćenja površine adventicije, površine aorte i izvođenja aortotomije.

c. Mjere koje treba primijeniti u slučaju neuspjeha pri uvođenju zatvarača HS:
i. Zatvarač HS III, čije uvođenje nije uspjelo, uništite.
ii. Uvijek imajte u pripravnosti drugi zatvarač HS III, kojim ćete zamijeniti neispravan uređaj. Radi uspješnog uvođenja poštujte Upute za uporabu.

2. Pogreška tijekom razvijanja zatvarača Heartstring u aortotomiju

a. Važne napomene:
i. Uvjerite se da je zatvarač HS III ispravno umetnut u aplikacijski uređaj, kako je navedeno u prethodnom stavku.
ii. Nakon vađenja umetnutog zatvarača HS III iz aplikacijskog uređaja provjerite umetnut zatvarač HS III prema Uputama za uporabu, dio 4.3.-4.5, kako biste potvrdili da:
1. Umetnut zatvarač HS III nije ispucan.
2. Dio zatvarača HS III, koji nije umetnut u cijev aplikacijskog uređaja, nije širi od promjera cijevi aplikacijskog uređaja.
3. Uvjerite se da su krajevi zatezne opruge poravnani tako da tijekom uvođenja zatvarača HS III u aortotomiju dodiruju obadva njegova proksimalna kraja.

b. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:
i. Čim potvrdite uspješno uvođenje zatvarača HS III i izvođenje aortotomije, razvijte uveden zatvarač HS III u aortotomiju. Precizno poštujte postupak razvijanja zatvarača HS III, koji je opisan u Uputama za uporabu.
ii. Ako se zatvarač HS III ne razvije prema očekivanju, proizvod treba zamijeniti.

c. Mjere koje treba primijeniti u slučaju neuspjeha pri razvijanju zatvarača HS III u aortu:
i. Kažiprstom zatvorite aortotomiju, kako biste zaustavili krvarenje.
ii. Otvorite drugi zatvarač HS III. Umetnite isti zatvarač prema instrukcijama u Uputama za uporabu. Uvedite umetnut zatvarač HS III u aortotomiju te za dovršetak anastomoze poštujte postupak iz Uputa za uporabu.
iii. Ako uvođenje drugog zatvarača HS III u aortotomiju nije uspješno, ili ako kirurg donese odluku da situacija ne dopušta uporabu naknadnog zatvarača HS III, na aortu postavite djelomičnu okluzivnu klemu, čime ćete izolirati aortotomiju, te izvedite anastomozu tradicionalnom kirurškom tehnikom.

3. Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:

a. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:
i. Pri uvođenju zatvarača HS III pažljivo izvedite kontrolu, isto kao i nakon njegovog uvođenja, kako biste potvrdili uspješno uvođenje zatvarača HS III u aplikacijski

uređaj prije čišćenja adventicije aorte i izvođenja aortotomije (vidjeti prethodne važne napomene).

ii. Ne upotrebljavajte Proksimalni sustav zatvaranja Heartstring kod pacijenata s aortom koja ima tanke zidove.

iii. Pri izvođenju višestrukih anastomoza se uvjerite da su sva mjesta anastomoze međusobno udaljena najmanje 1,5 cm, kako bi se osigurala hemostaza.

iv. Prije razvijanja ne potapajte zatvarač HS III u otopinu.

b. Mjere koje treba primijeniti u slučaju da se zatvarač HS III ne otvori / ne daje dostatnu hemostazu nakon razvijanja.

i. Kažiprstom zatvorite aortotomiju te oprezno podesite zateznu oprugu kako biste se uvjerili da je zatvarač HS III u cijelosti razvijen.

ii. Ako nedostatna hemostaza i dalje traje:

1. Izvadite razvijen zatvarač HS III iz aortotomije prema instrukcijama u Uputama za uporabu.
2. Uvedite drugi zatvarač HS III te razvijte uveden zatvarač u aortotomiji prema instrukcijama u Uputama za uporabu i dovršite anastomozu.
3. Ako drugi zatvarač HS III nije uspješan , ili ako kirurg donese odluku da situacija ne dopušta uporabu naknadnog zatvarača HS III, na aortu postavite djelomičnu okluzivnu klemu, čime ćete izolirati aortotomiju, te izvedite anastomozu tradicionalnom kirurškom tehnikom.

Mjere od strane klijenta

Društvo Getinge od Vas traži sljedeće mjere:

1. Osigurajte dostavu ove poruke svim pojedincima koji trebaju ovo upozorenje u okviru Vaše institucije ili druge institucije kojoj su predmetni uređaji predani.

Dodatne informacije

Društvo Getinge priopćava ove informacije nadležnim regulatornim tijelima.

Ispričavamo se za bilo kakve neprijatnosti koje Vam po ovom pitanju mogu nastati. Stalo nam je do sigurnosti pacijenata i cijenimo Vašu brzu reakciju na ovu situaciju. Ako imate bilo kakve nedoumice u svezi ove poruke, obratite se svom predstavniku društva Getinge ili službi za klijente Getinge na broju 1-888-880-2874, od ponedjeljka do petka između 8:00 i 17:00 (pacifička vremenska zona).

S pozdravom,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

English (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural

steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure

i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.
i. Discard the failed HS III Seal.
ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
i. Occlude the aortotomy to control bleeding using an index finger.
ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
i. Always load and carefully inspect the loaded HS III Seal to confirm successful

loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.

iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.

iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.

i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.

ii. If lack of adequate hemostasis persists:

1. Remove the deployed HS III Seal from the aortotomy per device IFU.
2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

srpen 2025

Bezpečnostní upozornění pro terén

Proximální uzavírací systém Heartstring III

Referenční číslo: 1336551

Modelové číslo	UDI	Název modelu	Sériové číslo/šarže
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proximální uzavírací systém Heartstring III	Všechny neprošlé šarže
Data distribuce:		od 1.července 2024 dosud	
Data výroby:		od 7. března 2024 dosud	

Vážený manažere rizik,

účelem tohoto dopisu je informovat vás, že společnost Maquet Cardiovascular, dceřiná společnost společnosti Getinge, vydává naléhavou opravu zdravotnického prostředku Proximální uzavírací systém Heartstring III (uzávěr HS III). Podle našich záznamů jste obdrželi jeden nebo více dotčených zdravotnických prostředků, kterých se toto oznámení týká.

Popis problému

Byly identifikovány tři primární režimy selhání.

1. **Selhání při zavádění uzávěru:** tento problém se týká jakéhokoli selhání zařízení, ke kterému dojde během čtyřkrokového procesu zavádění pomocí zaváděcího zařízení Heartstring, vizuálního kontroly úspěšně zavedeného uzávěru HS III a odjištění aplikačního zařízení po úspěšném dokončení kroků zavádění uzávěru HS III.
2. **Selhání při rozvinutí uzávěru Heartstring do aortomie**: tento problém se vztahuje na jakékoli selhání uzávěru HS III a/nebo aplikačního zařízení od okamžiku, kdy je aplikační zařízení úspěšně odjištěno, do okamžiku, kdy je uzávěr HS III úplně umístěn do aortomie a všechny části proximálního uzávěru (vlákno, napínací pružina, tělo uzávěru, ukotvovací poutko) jsou odstraněny z aplikačního zařízení.
3. **Rozvinutý uzávěr Heartstring neposkytuje dostatečnou hemostázu:** tento problém se týká jakékoli poruchy fungování úspěšně rozvinutého uzávěru HS III, který nezajišťuje v místě anastomózy adekvátní kontrolu krvácení pro provedení šití anastomózy, a to i přes jemné nastavení napínací pružiny po rozvinutí uzávěru a/nebo použití ventilátorového postřikovače, odsávání nebo stříkačky se fyziologickým roztokem k vyčištění místa anastomózy. Tato porucha zahrnuje i případ, kdy zákazník identifikuje vadný nebo poškozený uzávěr HS III po úspěšném

rozvinutí uzávěru HS III do aorty, kdy porucha má/může mít za následek nedostatečnou hemostázu, jež chirurgovi brání v dokončení anastomózy bez odstranění vadného uzávěru HS III.

Momentálně probíhá šetření hlavní příčiny.

Zdravotní rizika:

1. **Selhání při zavádění:** pokud se uzávěr HS III používá podle návodu k použití (IFU) prostředku, nepředstavuje selhání při zavádění pro pacienta přímé riziko. Toto selhání však může vést ke zpoždění chirurgického zákroku. Toto zpoždění se může pohybovat v rozsahu od několika minut potřebných k vyjmutí a zavedení nového uzávěru až po potenciální přechod z použití uzávěru HS III k provedení proximální anastomózy na použití aortální svorky k dokončení zákroku.
2. **Selhání při rozvinutí:** když se nedaří rozvinout zavedený uzávěr HS III z aplikačního zařízení, byly již provedeny následující procedurální kroky a ty mohou přispět k potenciálnímu riziku poškození zdraví pacienta. Pokud se zavedený uzávěr HS III nedaří rozvinout z aplikačního zařízení, bude již provedeno několik procedurálních kroků, které mohou zvýšit potenciální riziko poškození zdraví pacienta.
   - Byla vytvořena aortotomie.
   - Distální konec trubice aplikačního zařízení byl zaveden skrz aortotomii.
   - Píst aplikačního zařízení byl stlačen nebo byl proveden pokus o jeho stlačení.
   - Vložený uzávěr HS III se nepodařilo úspěšně rozvinout z distálního konce trubice aplikačního zařízení.
   - Po vyjmutí aplikačního zařízení z aortomie se uzávěr HS III nerozvine a krvácení z aortomie bude nutné zastavit umístěním prstu přes aortomii.

   Mohou nastat následující újmy na zdraví pacienta:

   - Zpoždění chirurgického zákroku: odstranění nerozvinutého uzávěru HS III, otevření nového proximálního uzávěru HS III, vložení uzávěru do aplikačního zařízení a zavedení vloženého uzávěru HS III do vytvořené aortomie (zpoždění bez dalšího zásahu) vs. rozhodnutí použít aortální svorku k dokončení anastomózy, protože zavedený uzávěr se nepodařilo rozvinout (zpoždění s dalším zásahem).
   - Poškození tkáně: k poškození tkáně může dojít v důsledku rozvinutí zavedeného uzávěru HS III, který je na špičce rozšířený. Rozšířená špička bude mít průměr větší než distální trubice aplikačního zařízení. Rozvinutí zavedeného uzávěru s rozšířeným koncem může způsobit poškození tkáně v oblasti aortomie a v případě použití větší síly k rozvinutí dotčeného uzávěru existuje při zavádění možné riziko poranění zadní stěny aorty. K poškození tkáně může dojít také během odstraňování aplikačního zařízení z aortomie, rozvinutí druhého zavedeného těsnění HS III do stejné aortomie a/nebo nutnosti přechodu na použití aortální svorky k dokončení aortomie.
   - Krvácení: k minimální ztrátě krve může dojít během odstraňování aplikačního zařízení z aortomie, při ovládání krvácení z aortomie manuálně a aplikaci náhradního uzávěru HS III. Větší ztráta krve, která by vyžadovala dodatečnou intervenci, může nastat, dojde-li k poškození tkáně.
   - Embolická **událost** v důsledku dodatečné manipulace s aortou při řešení selhání při zavádění uzávěru HS III.
3. **Rozvinutý uzávěr Heatstring neposkytuje dostatečnou hemostázu:** v případě, že rozvinutý uzávěr HS III neposkytuje hemostázu dostatečnou k tomu, aby mohl chirurg dokončit proximální anastomózu, byly již dokončeny některé kroky související s použitím uzavíracího systému HS III a to

může zvýšit potenciální riziko újmy na zdraví pacienta. V tomto okamžiku již budou provedeny následující kroky:

- Byla provedena aortomie.
- Zavedený uzávěr HS III byl rozvinutý v aortě.
- Chirurg považuje krvácení z aorty za příliš silné, aby mohl provést anastomózu.

Může dojít k následujícím újmám na zdraví pacienta:

- **Zpoždění chirurgického zákroku**: může k němu dojít následovně:
    - Dodatečný operační čas potřebný k pokusu o úpravu uzávěru pro zlepšení hemostázy pomocí zavedeného uzávěru HS III, odstranění vadného uzávěru HS III, otevření nového uzávěru HS III, vložení náhradního uzávěru HS III a zavedení připraveného uzávěru HS III do vytvořené aortomie (Zpoždění zákroku bez dalšího zásahu).
    - Chirurg považuje za nejvhodnější k dokončení anastomózy použít aortální svorku, protože rozvinutý uzávěr HS III neposkytuje hemostázu dostatečnou k dokončení anastomózy a buď není k dispozici náhradní uzávěr HS III nebo chirurg rozhodne, že situace neumožňuje použít náhradní uzávěr HS II a použije aortální svorku k dokončení proximální anastomózy tradiční chirurgickou technikou. (Zpoždění zákroku s dalším zákrokem.)
- **Poškození tkáně**: k poškození tkáně může dojít při manipulaci s dotčeným uzávěrem HS III, během rozvinutí druhého zavedeného uzávěru HS III do stejné aortotomie a/nebo v případě, kdy bude potřeba přejít na použití aortální svorky k dokončení aortomie.
- **Krvácení:** malá ztráta krve v okolí rozvinutého uzávěru HS III je normální a dá se při provádění proximální anastomózy za použití uzávěru HS III očekávat. K větší ztrátě krve, která by vyžadovala dodatečnou intervenci, může dojít při poškození tkáně bez ohledu na jeho příčinu.
- **Embolická událost:** vznikne dodatečnou manipulací s aortou v důsledku řešení selhání, kdy uzávěr HS III neposkytuje dostatečnou hemostázu.

Od 1. června 2023 do 22. července 2025 obdržela společnost Getinge následující stížnosti:

- 274 hlášení souvisejících se selháním při zavádění, což představuje míru stížností 0,386 %
- 96 hlášení souvisejících se selháním při rozvinutí, což představuje míru stížností 0,135 %
- 30 hlášení týkajících se nedostatečné hemostázy, což představuje míru stížností 0,042 %

<u>Doporučená zmírňující opatření a kroky:</u>

Společnost Getinge poskytuje následující pokyny, jak se vyhnout výše popsaná selhání / minimalizovat je.

1. **Selhání při zavádění uzávěru Heartstring**
    a. Důležité připomenutí
        i. Návod k použití prostředku uvádí, že uzávěr HS III má být zavedený a vyjmutý ze zaváděcího zařízení, poté zkontrolován a v případě potřeby upraven, aby bylo možné potvrdit úspěšné zavedení a následně odjištěn před odstraněním adventicie z místa plánované anastomózy a vytvořením aortomie. Zavedení uzávěru HS III a potvrzení úspěšného zavedení před vytvořením aortomie minimalizuje riziko pro

pacienta, protože aorta zůstává nedotčena, dokud se nepotvrdí úspěšné zavedení uzávěru HS III.

ii. Pokud selže plánované zavedení uzávěru HS III, prostředek by se měl vyměnit.

b. Jak se vyhnout tomuto selhání / minimalizovat jeho výskyt.
   i. Před použitím si prostudujte návod k použití prostředku Heartstring, zejména pokud se Heartstring nepoužívá pravidelně.
   ii. Při zavádění uzávěru HS III postupujte opatrně a dodržujte postupně všechny kroky uvedené v návodu k použití. (IFU).
   iii. Podle pokynů v článku 4.3-4.5 návodu k použití zkontrolujte, že uzávěr HS III byl správně vložen do aplikačního zařízení tak, že zkontrolujete vložený uzávěr HS III po jeho vložení do aplikačního zařízení a vyjmutí ze zaváděcího zařízení.
   iv. Uzávěr HS III, který nebyl po vyjmutí ze zaváděcího zařízení řádně zkontrolovaný může během rozvinutí selhat a způsobit pacientovi újmu. (Viz informace související se Selháním při rozvinutí).
   v. Dokončete úspěšné zavedení uzávěru HS III před očištěním povrchu adventicie povrchu aorty a vytvořením aortomie.

c. Opatření, která mají být provedena v případě, že uzávěr HS selže při zavádění.
   i. Uzávěr HS III, který se nepodařilo zavést, zlikvidujte.
   ii. Vždy mějte připravený druhý uzávěr HS III, kterým nahradíte poruchový přístroj. Pro úspěšné zavedení se řiďte návodem k použití.

2. Selhání při rozvinutí uzávěru Heartstring do aortomie

a. Důležitá připomenutí:
   i. Ujistěte se, že uzávěr HS III byl správně vložen do aplikačního zařízení, jak je uvedeno v odstavci výše.
   ii. Po vyjmutí vloženého uzávěru HS III ze zaváděcího zařízení, zkontrolujte vložený uzávěr HS III dle návodu k použití, část 4.3.-4.5, abyste potvrdili, že:
      1. Vložený uzávěr HS III není popraskaný.
      2. Část uzávěru HS III, která není vložena do trubice aplikačního zařízení není širší než průměr trubice aplikačního zařízení.
      3. Ujistěte se, že jsou konce napínací pružiny zarovnány tak, že se během zavádění uzávěru HS III do aortomie dotýkají obou jeho proximálních konců.

b. Jak se vyhnout tomuto selhání / minimalizovat jeho výskyt.
   i. Jakmile potvrdíte úspěšné zavedení uzávěru HS III a vytvoření aortomie, rozviňte zavedený uzávěr HS III do aortomie. Dodržujte pečlivě postup rozvinutí uzávěru HS III popsaný v návodu k použití.
   ii. Pokud se uzávěr HS III nerozvine podle očekávání, prostředek by měl být nahrazen.

c. Opatření, která mají být provedena, pokud se uzávěr HS III nerozvine úspěšně do aorty.
   i. Ukazováčkem uzavřete aortomii, abyste zastavili krvácení.
   ii. Otevřete druhý uzávěr HS III. Vložte tento uzávěr dle pokynů v návodu k použití. Zaveďte vložený uzávěr HS III do aortomie a pro dokončení anastomózy dodržujte postup v návodu k použití.
   iii. Pokud nebude zavedení druhého uzávěru HS III do aortomie úspěšné, nebo pokud chirurg rozhodne, že situace nedovoluje použití náhradního uzávěru HS III, na aortu umístěte částečnou okluzní svorku, čímž izolujete aortomii, a proveďte anastomózu tradiční chirurgickou technikou.

3. **Rozvinutý uzávěr Heatstring neposkytuje dostatečnou hemostázu:**
    a. Jak se vyhnout tomuto selhání / minimalizovat jeho výskyt:
        i. Při zavádění uzávěru HS III proveďte pečlivou kontrolu, stejně tak po jeho zavedení, abyste potvrdili úspěšné zavedení uzávěru HS III do aplikačního zařízení před tím, než očistíte adventicii aorty a vytvoříte aortomii. (viz důležitá připomenutí výše).
        ii. Nepoužívejte Proximální uzavírací systém Heartstring u pacienta s tenkostěnnou aortou.
        iii. Při provádění vícenásobných anastomóz se ujistěte, že všechna místa anastomózy jsou od sebe vzdálena alespoň 1,5 cm, aby byla zajištěna hemostáza.
        iv. Před rozvinutím nenamáčejte uzávěr HS III do roztoku.
    b. Opatření, která mají být provedena, pokud se uzávěr HS III neotevře / neposkytuje po rozvinutí dostatečnou hemostázu.
        i. Ukazováčkem uzavřete aortomii a opatrně upravte napínací pružinu, abyste se ujistili, že je uzávěr HS III úplně rozvinutý.
        ii. Pokud nedostatečná hemostáza přetrvává:
            1. Vyjměte rozvinutý uzávěr HS III z aortomie dle pokynů v návodu k použití.
            2. Zaveďte druhý uzávěr HS III a rozviňte zavedený uzávěr v aortotomii dle pokynů v návodu k použití a dokončete anastomózu.
            3. Pokud není druhý uzávěr HS III úspěšný nebo chirurg rozhodne, že situace nedovoluje použití náhradního uzávěru HS III, na aortu umístěte částečnou okluzní svorku, čímž izolujete aortomii, a proveďte anastomózu tradiční chirurgickou technikou.

Opatření na straně zákazníka

Společnost Getinge po vás požaduje následující opatření:

1. Zajistěte, že tato zpráva bude předána všem jedincům, kteří toto upozornění potřebují v rámci vaší organizace nebo jiné organizace, kam byly dotčené přístroje předány.

Dodatečné informace

Společnost Getinge sděluje tyto informace příslušným regulačním orgánům.

Omlouváme se za jakékoli nepříjemnosti, které vám tato záležitost mohla způsobit. Záleží nám na bezpečnosti pacientů a vážíme si vaší rychlé reakce na tuto záležitost. Máte-li jakékoli dotazy týkající se tohoto sdělení, kontaktujte prosím svého zástupce společnosti Getinge nebo zákaznický servis Getinge na čísle 1-888-880-2874, od pondělí do pátku mezi 8:00 a 17:00 (tichomořské časové pásmo).

S pozdravem,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

S pozdravem
Mgr. Jiri Lacina, MBA
Getinge Czech republic, s.r.o.
Jednatel

Denmark (da)

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Vigtig produktinformation
om Heartstring III proksimalt forseglingssystem

Modelnummer	UDI	Modelnavn	Serie/lotnumre
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	Alle ikke-udløbne lots
Distributionsdatoer:		1. juli 2024 – nu	
Fremstillingsdato		7. marts 2024 - nu	

Kære risikoansvarlige

Formålet med dette brev er at informere dig om, at Maquet Cardiovascular, et datterselskab af Getinge, udsteder en vigtig korrektion af medicinsk udstyr til Heartstring III Proximal Seal System (HS III Seal). Vores optegnelser viser, at du har modtaget en eller flere af de enheder, der er berørt af denne meddelelse.

Beskrivelse af problemet

Der er identificeret tre primære fejltilstande.

1. **Mislykket isættelse af Heartstring-forseglingsanordningen:** Denne fejl gælder for enhver funktionsfejl i enheden, der opstår under firetrins isætningsprocessen ved hjælp af Heartstring-isætningsenheden, den visuelle inspektion af en korrekt isat HS III-forseglingsanordning og oplåsning af indføringsenheden efter vellykket gennemførelse af trinnene til isætning af HS III-forseglingsanordningen.
2. **Fejl ved placering af Heartstring-forseglingsanordningen i forbindelse med aortotomi**: Denne fejl gælder for enhver funktionsfejl i HS III-forseglingsanordningen og/eller indføringsenheden fra det tidspunkt, hvor indføringsenheden er låst op, til det tidspunkt, hvor leveringen af HS III-forseglingsanordningen under aortotomien er fuldført, og alt indhold i den proksimale forseglingsanordning (snor , spændefjeder, forseglingsskaft, ankertap) har forladt indføringsenheden.
3. **Den anlagte Heartstring-forseglingsanordning giver ikke tilstrækkelig hæmostase:** Denne fejl gælder for enhver fejlfunktion i en korrekt anlagt HS III-forseglingsanordning, der ikke kontrollerer blødning ved anastomosen tilstrækkeligt til, at kirurgen kan foretage suturering af anastomosen, på trods af forsigtig justering af spændefjederen efter anlæggelse af forseglingsanordningen og/eller brug af en blowermister, sugning eller saltvandssprøjte til at rense anastomosestedet. Denne fejl omfatter kundeidentifikation af en defekt eller beskadiget HS III-forseglingsanordning efter vellykket anlæggelse af HS III-forseglingsanordningen i aorta, der resulterer i/eller kan resultere i utilstrækkelig hæmostase, der forhindrer kirurgen i at fuldføre anastomosen uden at fjerne den defekte

HS III-forseglingsanordning.

Undersøgelsen af den underliggende årsag er i gang.

Sundhedsrisici

1. **Isættelse mislykkedes:** Ved anvendelse i overensstemmelse med brugsanvisningen til udstyret udgør en HS III-forseglingsanordning, der ikke kan isættes, ikke en direkte risiko for patienten. Denne fejl kan dog føre til en forsinkelse i det kirurgiske indgreb. Denne forsinkelse kan variere fra et par minutter til at hente og isætte en ny forseglingsanordning til et potentielt skift fra at bruge HS III-forseglingsanordningen til at udføre den proksimale anastomose til at bruge en aortaklemme til at fuldføre indgrebet.
2. **Mislykket anlæggelse:** Hvis den isatte HS III-forseglingsanordning ikke udløses fra indføringsenheden, er de følgende proceduretrin allerede udført og kan bidrage til den potentielle risiko for patientskade. Hvis den isatte HS III-forseglingsanordning ikke udløses fra indføringsenheden er flere proceduretrin allerede gennemført, hvilket kan øge den potentielle risiko for patientskade.
   - Aortotomien er blevet etableret.
   - Den distale ende af indføringsenhedens rør er indført gennem aortotomien.
   - Indføringsenhedens stempel er blevet trykket ned, eller der er gjort et forsøg på at trykke det ned.
   - Den isatte HS III-forseglingsanordning er ikke udløst korrekt fra den distale ende af indføringsenhedens rør.
   - Når indføringsenheden fjernes fra aortotomien, er HS III-forseglingsanordningen ikke blevet anlagt, og blødning fra aortotomien skal kontrolleres ved at placere en finger over aortotomien.

   Følgende potentielle patientskader kan forekomme:

   - **Forsinkelse af kirurgisk indgreb**: Fjernelse af den ikke-anlagte HS III-forseglingsanordning, åbning af en ny proksimal HS III-forseglingsanordning, isætning af forseglingsanordningen i indføringsenheden og indføring af den isatte HS III-forseglingsanordning i den etablerede aortotomi (forsinkelse uden yderligere intervention) vs. beslutningen om at bruge en aortaklemme til at fuldføre anastomosen, fordi den isatte forseglingsanordning ikke kunne anlægges (forsinkelse med en yderligere intervention)
   - **Vævsskade**: kan opstå som følge af anlæggelse af en isat HS III-forseglingsanordning, der er konisk udvidet ved spidsen. En konisk udvidet spids vil have en diameter, der er større end den distale indføringsenheds rør. Anlæggelse af en isat forseglingsanordning, der har en konisk udvidet spids, kan forårsage skade på aortotomivævet, og hvis der anvendes større kraft til at anlægge den berørte forseglingsanordning, er der en potentiel risiko for perforation gennem aortas posteriore væg under indføring. Der kan også opstå vævsskade under fjernelse af indføringsenheden fra aortotomien, anlæggelse af en ny isat HS III-forseglingsanordning i samme aortotomi og/eller ved behov for at skifte til brug af en aortaklemme for at fuldføre aortotomien.
   - **Blødning:** Der kan forekomme minimalt blodtab, når indføringsenheden fjernes fra aortotomien, blødningen fra aortotomien kontrolleres manuelt, og der indføres en ny HS III-forseglingsanordning. Der kan forekomme større blodtab, som kræver yderligere intervention, hvis der opstår vævsskade.
   - **Embolisk hændelse** som følge af yderligere manipulation af aorta for at håndtere fejlen med HS III-forseglingsanordningen.
3. **Den anlagte Heartstring-forseglingsanordning giver ikke tilstrækkelig hæmostase:** Når en anlagt HS III-forseglingsanordning ikke giver tilstrækkelig hæmostase til, at kirurgen kan fuldføre den proksimale anastomose, er der allerede udført flere trin i brugen af HS III Seal System, hvilket kan øge den potentielle risiko for patientskade. Følgende proceduretrin er blevet gennemført.
   - Aortotomien er blevet etableret.

- Den isatte HS III-forseglingsanordning er blevet anlagt i aorta.
- Blødning fra aorta vurderes af kirurgen som værende for stor til at foretage anastomosen.

Følgende potentielle patientskader kan forekomme:

- **Forsinkelse af det kirurgiske indgreb**: kan forekomme på følgende måde:
    - Ekstra operationstid brugt på at forsøge at foretage forseglingsjusteringer for at forbedre hæmostase med den indførte HS III-forseglingsanordning, fjernelse af den defekte HS III-forseglingsanordning, åbning af en ny HS III-forseglingsanordning, isættelse af den nye HS III-forseglingsanordning og indføring af den isatte HS III-forseglingsanordning i den etablerede aortotomi (procedureforsinkelse uden yderligere intervention)
    - Kirurgen vurderer, at det er mest hensigtsmæssigt at bruge en aortaklemme til at fuldføre anastomosen, fordi den anlagte HS III-forseglingsanordning ikke giver tilstrækkelig hæmostase til at fuldføre anastomosen, og en erstatnings-HS III-forseglingsanordning er ikke tilgængelig, eller kirurgen beslutter, at situationen ikke tillader brug af en erstatnings-HS III-forseglingsanordning, og der anvendes en aortaklemme til at fuldføre den proksimale anastomose i henhold til traditionel kirurgisk teknik (procedureforsinkelse med yderligere intervention).
- **Vævsskade:** Der kan opstå vævsskade under manipulation af den berørte HS III-forseglingsanordning, under anlæggelse af en ny isat HS III-forseglingsanordning i den samme aortotomi og/eller ved behov for at skifte til brug af en aortaklemme for at fuldføre aortotomien.
- **Blødning:** Et mindre blodtab omkring den anlagte HS III-forseglingsanordning er normalt og forventes, når den proksimale anastomose udføres med en HS III-forseglingsanordning. Større blodtab, der kræver yderligere intervention, kan forekomme, når der opstår skade på aortavæv, uanset årsagen.
- **Embolisk(e) hændelse(r):** Som følge af yderligere manipulation af aorta sekundært til håndtering af den utilstrækkelige hæmostase, der opnås med HS III-forseglingsanordningen.

Mellem 1. juni 2023 og 22. juli 2025 modtog Getinge følgende klager:

- 274 rapporter relateret til mislykket isættelse, hvilket repræsenterer en klagefrekvens på 0,386 %
- 96 rapporter relateret til mislykket anlæggelse, hvilket repræsenterer en klagefrekvens på 0,135 %
- 30 rapporter relateret til utilstrækkelig hæmostase, hvilket repræsenterer en klagefrekvens på 0,042 %

<u>Anbefalede afbødende handlinger og andre handlinger</u>

Getinge giver følgende instruktioner for at undgå/minimere de fejl, der er nævnt ovenfor.

1. **Mislykket isættelse af Heartstring-forseglingsanordningen:**
    a. Vigtige påmindelser:
        i. I henhold til brugsanvisningen til udstyret er det hensigten, at HS III-forseglingsanordningen isættes og fjernes fra isætningsenheden, hvorefter den inspiceres og om nødvendigt justeres for at bekræfte vellykket isætning, og til sidst låses den op, inden eventuelle adventitia fjernes fra det planlagte anastomoseområde, og aortotomien etableres. Isætning af HS III-forseglingsanordningen og bekræftelse af vellykket isætning <u>inden</u> etablering af aortotomien minimerer risikoen for patienterne, da aorta forbliver uberørt, indtil bekræftelse af vellykket isætning af HS III-forseglingsanordningen.
        ii. Hvis HS III-forseglingsanordningen ikke isættes som tilsigtet, skal enheden udskiftes.
    b. Sådan undgår/minimerer du forekomsten af denne fejl
        i. Læs brugsanvisningen til Heartstring-udstyret <u>før</u> brug, især hvis Heartstring ikke bruges rutinemæssigt.
        ii. Isæt HS III-forseglingsanordningen ved omhyggeligt at følge den trinvise

brugsanvisning.

iii. I henhold til afsnit 4.3-4.5 i brugsanvisningen skal det bekræftes, at HS III-forseglingsanordningen er isat korrekt i indføringsenheden ved at inspicere den isatte HS III-forseglingsanordning, når HS III-forseglingsanordningen er isat i indføringsenheden og er blevet fjernet fra isætningsenheden.

iv. En HS III-forseglingsanordning, der ikke inspiceres korrekt efter fjernelse fra isætningsenheden, kan svigte under anlæggelse af HS III-forseglingsanordningen og forårsage patientskade. (se oplysninger vedrørende mislykket anlæggelse).

v. Fuldfør korrekt isætning af HS III-forseglingsanordningen inden fjernelse af adventitia fra aortaoverfladen og etablering af aortotomien.

c. Foranstaltninger, der skal træffes, hvis HS III-forseglingsanordningen ikke kan isættes.
   i. Kasser den defekte HS III-forseglingsanordning.
   ii. Hav altid en ekstra HS III-forseglingsanordning klar til udskiftning af en defekt anordning. Se brugsanvisningen til udstyret for at sikre korrekt isætning.

2. Mislykket anlæggelse af Heartstring III-forseglingsanordningen i aortotomien

a. Vigtige påmindelser:
   i. Sørg for, at HS III-forseglingsanordningen er isat korrekt i indføringsenheden som beskrevet i afsnittet ovenfor.
   ii. Efter fjernelse af den isatte HS III-forseglingsanordning fra indføringsenheden skal den isatte HS III-forseglingsanordning inspiceres i henhold til afsnit 4.3-4.5 i brugsanvisningen for at bekræfte følgende:
      1. At den isatte HS III-forseglingsanordning er ikke revnet.
      2. At den del af HS III-forseglingsanordningen, der ikke er isat i indføringsenhedens rør, ikke er bredere end indføringsenhedens rørdiameter.
      3. At spændefjederens ender er justeret, så de kommer i kontakt med begge proksimale kanter af den isatte HS III-forseglingsanordning under indføring af forseglingsanordnignen i aortotomien.

b. Sådan undgår/minimerer du forekomsten af denne fejl:
   i. Efter bekræftelse af vellykket isætning af HS III-forseglingsanordningen og etablering af aortotomien anlægges den isatte HS III-forseglingsanordning i aortotomien ved omhyggeligt at følge trinene for anlæggelse af HS III-forseglingsanordningen, der er dokumenteret i brugsanvisningen til udstyret.
   ii. Hvis HS III-forseglingsanordningen ikke anlægges som tilsigtet, skal enheden udskiftes.

c. Foranstaltninger, der skal træffes, hvis HS III-forseglingsanordningen ikke kan anlægges korrekt i aorta.
   i. Okkluder aortotomien for at kontrollere blødningen med en pegefinger.
   ii. Åbn en ny HS III-forseglingsanordning. Isæt HS III-forseglingsanordningen i henhold til brugsanvisningen til udstyret. Indfør den isatte HS III-forseglingsanordning i aortotomien, og følg brugsanvisningen for at fuldføre anastomosen.
   iii. Hvis indføringen af den nye HS III-forseglingsanordning i aortotomien ikke lykkes, eller hvis kirurgen beslutter, at situationen ikke tillader brug af en erstatnings-HS III-forseglingsanordning, skal der anbringes en partiel okklusionsklemme på aorta, hvorved aortotomien isoleres, og anastomosen skal udføres i henhold til traditionel kirurgisk teknik.

3. Den anlagte Heartstring III-forseglingsanordning giver ikke tilstrækkelig hæmostase:

a. Sådan undgår/minimerer du forekomsten af denne fejl:
   i. Isæt og inspicer altid omhyggeligt den isatte HS III-forseglingsanordning for at bekræfte, at HS III-forseglingsanordningen er isat korrekt i indføringsenheden før fjernelse af eventuel adventitia fra aorta, og aortotomien dannes. (Se vigtige

påmindelser direkte ovenfor.)

ii. Heartstring Proximal Seal System må ikke anvendes til patienter med en tynd aortavæg.
iii. Ved udførelse af flere anastomoser skal det sikres, at alle anastomosesteder er mindst 1,5 cm fra hinanden for at sikre hæmostase.
iv. HS III-forseglingsanordningen må ikke gennemvædes i en opløsning før anlæggelse.

b. Foranstaltninger, der skal træffes, hvis HS III-forseglingsanordningen ikke åbner/giver tilstrækkelig hæmostase efter anlæggelse.
   i. Dæk aortotomien med en pegefinger, og juster forsigtigt spændefjederen for at sikre, at HS III-forseglingsanordningen er anlagt korrekt.
   ii. Hvis der fortsat ikke er tilstrækkelig hæmostase:
      1. Fjern den anlagte HS III-forseglingsanordning fra aortotomien i henhold til brugsanvisningen til udstyret.
      2. Isæt en ny HS III-forseglingsanordning, og anlæg den isatte forseglingsanordning i aortotomien i henhold til brugsanvisningen til udstyret, og fuldfør anastomosen.
      3. Hvis den nye HS III-forseglingsanordning ikke virker, eller hvis kirurgen beslutter, at situationen ikke tillader brug af en erstatnings-HS III-forseglingsanordning, skal der anbringes en partiel okklusionsklemme på aorta, hvorved aortotomien isoleres, og anastomosen skal udføres i henhold til traditionel kirurgisk teknik.

Handlinger, der skal foretages af kunden

Getinge anmoder dig om at træffe følgende foranstaltninger:

1. Sørg for at videresende denne meddelelse til alle dem, der har brug for at blive underrettet i din virksomhed, eller til enhver virksomhed, hvortil det berørte udstyr er blevet overført.

Supplerende oplysninger

Getinge videregiver disse oplysninger til de relevante tilsynsmyndigheder.

Vi beklager enhver ulejlighed, dette måtte forårsage. Vi har stort fokus på patientsikkerhed og sætter pris på din hurtige hjælp i forbindelse med dette problem. Hvis du har spørgsmål vedrørende denne henvendelse, bedes du kontakte din Getinge-repræsentant eller Getinge-kundesupport på tel. +45 45 93 27 27

Med venlig hilsen

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Aviso de seguridad Urgente
Sistema de obturación proximal Heartstring III
Número de referencia FSCA: 1336551

Número de modelo	UDI	Nombre del modelo	Números de serie/lote
HSK-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de obturación proximal Heartstring III	Todos los lotes no caducados
Fechas de distribución:		1 de julio de 2024 - Actualidad	
Fechas de fabricación:		7 de marzo de 2024 - Actualidad	

Estimado gestor de riesgos,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está emitiendo una corrección urgente de dispositivos médicos para el sistema de sellado proximal Heartstring III (HS III Seal). Según nuestros registros, usted ha recibido uno o varios de los dispositivos afectados por esta notificación.

Descripción del Problema

Se han identificado tres modos de fallo principales.

1. **Fallo en la carga del sello Heartstring**: Este fallo se aplica a cualquier mal funcionamiento del dispositivo que se produzca durante el proceso de carga de cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un sello HS III cargado correctamente y el desbloqueo del dispositivo de administración tras completar con éxito los pasos de carga del sello HS III.
2. **Fallo del sello cardíaco al desplegarse en la aortotomía**: Este fallo se aplica a cualquier mal funcionamiento del sello HS III y/o del dispositivo de implantación desde el momento en que el dispositivo de implantación se desbloquea correctamente hasta que se completa la implantación del sello HS III en la aortotomía y todo el contenido del sello proximal (la correa, el resorte de tensión, el vástago del sello y la lengüeta de anclaje) ha salido del dispositivo de implantación.
3. **Fallo del sellado Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier mal funcionamiento de un sello HS III implantado correctamente que no controle adecuadamente el sangrado en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis, a pesar del ajuste suave del resorte de tensión tras la implantación del sello y/o el uso de un nebulizador, succión o jeringa de solución salina para limpiar el sitio de la anastomosis. Este fallo incluye la identificación por parte del cliente de un sello HS III defectuoso o dañado tras el despliegue correcto del sello HS III en la aorta, lo que da lugar o puede dar lugar a una

hemostasia inadecuada que impide al cirujano completar la anastomosis sin retirar el sello HS III defectuoso.

En estos momentos se está investigando la causa raíz.

Riesgos para la salud

1. **Error al cargar:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un sello HS III que no se carga no supone un riesgo directo para el paciente. Sin embargo, este fallo puede provocar un retraso en la intervención quirúrgica. Este retraso puede variar desde unos minutos para recuperar y cargar un nuevo sello, hasta una posible conversión del uso del sello HS III para realizar la anastomosis proximal al empleo de una pinza aórtica para completar la intervención.
2. **Fallo en la implementación:** Cuando el sello HS III cargado no se despliega desde el dispositivo de administración, ya se han realizado los siguientes pasos del procedimiento, lo que puede contribuir al riesgo potencial de daño al paciente. Si el sello HS III cargado no se despliega desde el dispositivo de administración, ya se habrán completado varios pasos del procedimiento, lo que puede aumentar el riesgo potencial de daño al paciente.
   - Se ha realizado la aortotomía.
   - El extremo distal del tubo del dispositivo de administración se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de administración o se ha intentado presionarlo.
   - El sello HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de administración.
   - Cuando se retira el dispositivo de administración de la aortotomía, el sello HS III no se desplegará y será necesario controlar el sangrado de la aortotomía colocando un dedo sobre ella.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: para retirar el HS III Seal no desplegado, abrir un nuevo HS III Proximal Seal, cargar el Seal en el dispositivo de liberación (Delivery Device) y entregar el HS III Seal cargado en la aortotomía creada (retraso sin intervención adicional) vs. la decisión de utilizar una pinza aórtica para completar la anastomosis debido a que el Seal cargado no se desplegó (retraso con una intervención adicional).
   - **Daño tisular**: puede ocurrir como resultado del despliegue de un HS III Seal cargado que esté ensanchado en la punta. Una punta ensanchada tendrá un diámetro mayor que el tubo distal del dispositivo de liberación. El despliegue de un Seal cargado con la punta ensanchada puede causar daño al tejido de la aortotomía y, si se aplica mayor fuerza para desplegar el Seal afectado, existe un riesgo potencial de perforar la pared posterior de la aorta durante la inserción. El daño tisular también puede ocurrir durante la retirada del dispositivo de liberación de la aortotomía, al desplegar un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** puede producirse una pérdida mínima de sangre al retirar el dispositivo de liberación de la aortotomía, al controlar manualmente el sangrado de la aortotomía y al colocar un HS III Seal de reemplazo. Puede producirse una mayor pérdida de sangre,

que requiera intervención adicional, si ocurre daño tisular.

- **Evento embólico** como resultado de la manipulación adicional de la aorta para abordar la falla en la carga del HS III Seal.

3. **Falla del Heartstring Seal desplegado para proporcionar hemostasia adecuada:** uando un HS III Seal desplegado no logra proporcionar una hemostasia adecuada para que el cirujano complete la anastomosis proximal, varios pasos del uso del Sistema HS III Seal ya se han completado y pueden aumentar el riesgo potencial de daño al paciente. Los siguientes pasos del procedimiento ya se habrán realizado.
   - Se ha creado la aortotomía.
   - El HS III Seal cargado se ha desplegado en la aorta.
   - El sangrado de la aorta es considerado por el cirujano como demasiado abundante para realizar la anastomosis.

   Los siguientes daños potenciales al paciente pueden ocurrir:

   - **Retraso del procedimiento quirúrgico**: puede ocurrir de la siguiente manera:

     Tiempo operatorio adicional necesario para intentar realizar ajustes en el Seal con el fin de mejorar la hemostasia proporcionada por el HS III Seal implantado, retirar el HS III Seal defectuoso, abrir un nuevo HS III Seal, cargar el HS III Seal de reemplazo y colocar el HS III Seal cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional).
     - El cirujano considera más apropiado utilizar una pinza aórtica para completar la anastomosis debido a que el HS III Seal desplegado no logró proporcionar hemostasia adecuada para completarla y no hay un HS III Seal de reemplazo disponible, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo y se utiliza una pinza aórtica para completar la anastomosis proximal según la técnica quirúrgica tradicional. (retraso del procedimiento con intervención adicional)
   - **Daño tisular**: puede ocurrir durante la manipulación del HS III Seal afectado, durante el despliegue de un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** Una pequeña cantidad de pérdida de sangre alrededor del HS III Seal desplegado es normal y esperada al realizar la anastomosis proximal utilizando un HS III Seal. Puede producirse una mayor pérdida de sangre que requiera intervención adicional cuando ocurre daño del tejido aórtico, independientemente de la causa.
   - **Evento(s) embólico(s):** como resultado de la manipulación adicional de la aorta secundaria a la necesidad de abordar la falla del HS III Seal en proporcionar hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge recibió las siguientes quejas:

- 274 reportes relacionados con falla de carga, lo que representa una tasa de quejas del 0,386%
- 96 reportes relacionados con falla de despliegue, lo que representa una tasa de quejas del 0,135%
- 30 reportes relacionados con hemostasia inadecuada, lo que representa una tasa de quejas del 0,042%

Medidas y acciones recomendadas

Getinge proporciona las siguientes instrucciones para evitar/minimizar las fallas descritas anteriormente.

1. **Falla del Heartstring Seal al cargar**
    a. Recordatorios importantes:
        i. Según las Instrucciones de Uso (IFU) del dispositivo, el HS III Seal debe cargarse y retirarse del dispositivo de carga (Loading Device), luego inspeccionarse y ajustarse si es necesario para confirmar una carga exitosa y finalmente desbloquearse antes de retirar cualquier adventicia del área anastomótica planificada y crear la aortotomía. Cargar el HS III Seal y confirmar una carga exitosa antes de crear la aortotomía minimiza el riesgo para los pacientes, ya que la aorta permanece intacta hasta confirmar que la carga del HS III Seal fue exitosa.
        ii. Si el HS III Seal no se carga según lo previsto, el dispositivo debe reemplazarse.
    b. Cómo evitar/minimizar la ocurrencia de esta falla
        i. Revisar las Instrucciones de Uso (IFU) del dispositivo Heartstring antes de su utilización, especialmente si Heartstring no se utiliza de forma rutinaria.
        ii. Cargar el HS III Seal siguiendo cuidadosamente las Instrucciones de Uso (IFU) del dispositivo paso a paso.
        iii. De acuerdo con las Secciones 4.3–4.5 de las IFU, confirmar que el HS III Seal ha sido correctamente cargado en el dispositivo de liberación (Delivery Device) inspeccionando el HS III Seal cargado una vez que haya sido introducido en el Delivery Device y retirado del dispositivo de carga (Loading Device).
        iv. Un HS III Seal que no sea inspeccionado adecuadamente después de retirarlo del dispositivo de carga (Loading Device) puede fallar durante el despliegue del HS III Seal y causar daño al paciente. (Ver la información relacionada con Falla de Despliegue).
        v. Completar la carga exitosa del HS III Seal antes de limpiar la adventicia de la superficie aórtica y crear la aortotomía.
    c. Acción a tomar si el HS III Seal falla al cargarse.
        i. Desechar el HS III Seal defectuoso.
        ii. Tener siempre disponible un segundo HS III Seal para reemplazar un dispositivo defectuoso. Consultar las IFU del dispositivo para asegurar una carga exitosa.
2. **Falla del Heartstring III Seal al desplegarse en la aortotomía**
    a. Recordatorios importantes:
        i. Asegurarse de que el HS III Seal haya sido correctamente cargado en el dispositivo de liberación (Delivery Device), tal como se describe en la sección anterior.
        ii. Después de retirar el HS III Seal cargado del dispositivo de carga (Loading Device), inspeccionar el HS III Seal cargado, de acuerdo con las Secciones 4.3–4.5 de las IFU, para confirmar lo siguiente:
            1. Que el HS III Seal cargado no esté agrietado.
            2. Que la porción del HS III Seal que no está dentro del tubo del

Delivery Device no esté ensanchada más allá del diámetro del tubo del Delivery Device.

3. Que los extremos del resorte de tensión (Tension Spring) estén alineados de modo que contacten ambos bordes proximales del HS III Seal cargado durante la colocación del Seal en la aortotomía.

b. Cómo evitar/minimizar la ocurrencia de esta falla:
   i. Después de confirmar la carga exitosa del HS III Seal y crear la aortotomía, desplegar el HS III Seal cargado en la aortotomía siguiendo cuidadosamente los pasos de despliegue documentados en las IFU del dispositivo.
   ii. Si el HS III Seal no se despliega según lo previsto, el dispositivo debe reemplazarse.
c. Acción a tomar si el HS III Seal no se despliega correctamente en la aorta.
   i. Ocluir la aortotomía para controlar el sangrado utilizando el dedo índice.
   ii. Abrir un segundo HS III Seal. Cargar el HS III Seal de acuerdo con las IFU del dispositivo. Introducir el HS III Seal cargado en la aortotomía y seguir las IFU para completar la anastomosis.
   iii. Si la colocación del segundo HS III Seal en la aortotomía no tiene éxito, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

3. Falla del Heartstring III Seal desplegado para proporcionar hemostasia adecuada:

a. Cómo evitar/minimizar la ocurrencia de este modo de falla:
   i. Cargar siempre e inspeccionar cuidadosamente el HS III Seal cargado para confirmar que la carga en el dispositivo de liberación (Delivery Device) se haya realizado correctamente antes de retirar la adventicia de la aorta y crear la aortotomía. (Ver recordatorios importantes anteriores).
   ii. No utilizar el sistema Heartstring Proximal Seal en pacientes con aorta de pared delgada.
   iii. Al realizar múltiples anastomosis, asegurar que todos los sitios anastomóticos estén separados al menos 1,5 cm para garantizar la hemostasia.
   iv. No sumergir el HS III Seal en solución antes del despliegue.
b. Acción a tomar si el HS III Seal no se abre/no proporciona hemostasia adecuada después del despliegue.
   i. Cubrir la aortotomía con el dedo índice y ajustar suavemente el resorte de tensión (Tension Spring) para asegurar que el HS III Seal se haya desplegado completamente.
   ii. Si persiste la falta de hemostasia adecuada:
      1. Retirar el HS III Seal desplegado de la aortotomía de acuerdo con las IFU del dispositivo.
      2. Cargar un segundo HS III Seal y desplegar el Seal cargado en la aortotomía conforme a las IFU del dispositivo y completar la anastomosis.
      3. Si el segundo HS III Seal no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la

aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

Acciones para el cliente

Getinge solicita que tome las siguientes acciones:

1. Asegúrese de que este mensaje sea reenviado a todas las personas que deban ser notificadas dentro de su organización o en cualquier organización a la que se hayan transferido los dispositivos afectados.

Información adicional

Getinge está comunicando esta información a las agencias regulatorias correspondientes.

Lamentamos cualquier inconveniente que esto pueda ocasionar. Estamos comprometidos con la seguridad del paciente y agradecemos su pronta atención a este asunto. Si tiene alguna pregunta con respecto a esta comunicación, por favor comuníquese con su representante de Getinge o con el Servicio de Atención al Cliente de Getinge.

Cordialmente,

Francisco Vicenty
Director de Calidad y Cumplimiento Regulatorio, Interino
Getinge, Cirugía Cardiovascular

Finland (fi)

lokuu 2025

Turvallisuustiedote

Heartstring III Proximal Seal System -järjestelmä

Mallinumero	UDI	Mallinimi	Sarja-/eränumerot
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	Kaikki vanhentumattomat erät
Jakelupäivämäärät:		1.7.2024 alkaen tähän päivään saakka	
Valmistuspäivämäärät:		7.3.2024 alkaen tähän päivään saakka	

Hyvä riskienhallintapäällikkö

Tämän kirjeen tarkoituksena on ilmoittaa, että Getingen tytäryhtiö Maquet Cardiovascular julkaisee kiireellisen lääkinnällisen laitteen korjauksen Heartstring III Proximal Seal System (HS III Seal) -järjestelmään. Tietojemme mukaan olette vastaanottaneet yhden tai useamman laitteen, jota tämä ilmoitus koskee.

Ongelman kuvaus

Kolme ensisijaista vikatapaa on tunnistettu.

1. **Heartstring Seal ei lataudu:** Tämä ongelma koskee kaikkia laitteen virheitä, joita ilmenee nelivaiheisen latausprosessin aikana käytettäessä Heartstring Loading Device -laitetta, onnistuneesti ladatun HS III Sealin silmämääräisessä tarkastuksessa ja Delivery Device -toimituslaitteen lukituksen avaamisen aikana HS III Sealin latausvaiheiden onnistuneen suorittamisen jälkeen.
2. **Heartstring Sealin laajentuminen aortotomiakohtaan epäonnistuu:** Tämä vika koskee kaikkia HS III Sealin ja/tai Delivery Device -toimituslaitteen virheitä siitä hetkestä, kun Delivery Device on avattu onnistuneesti siihen saakka, kun HS III Seal on viety kokonaan aortotomiaan ja kaikki Proximal Sealin sisällöt (Tether, Tension Spring, Sean Stem, Anchor Tab) on poistunut Delivery Device -toimituslaitteesta.
3. **Laajentunut Heartstring Seal ei muodosta riittävää hemostaasia:** Tämä vikaantuminen koskee mitä tahansa onnistuneesti laajentuneen HS III Sealin virhettä, kun se ei hallitse verenvuotoa anastomoosikohdassa riittävästi, jotta kirurgi voisi suorittaa anastomoosin ompelemisen, huolimatta Tension Spring -jousen hellävaraisesta säätämisestä Sealin laajentumien jälkeen ja/tai puhallussumuttimen, imun tai suolaliuosruiskun käytöstä anastomoosikohdan puhdistamiseen. Tämä virhe sisältää viallisen tai vaurioituneen HS III Sealin tunnistamisen asiakkaan toimesta sen jälkeen, kun HS III Seal on laajentunut onnistuneesti aorttaan, mikä johtaa/tai voi johtaa riittämättömään hemostaasiin, joka estää kirurgia suorittamasta anastomoosia poistamatta viallista HS III Sealia.

Juurisyytä tutkitaan parhaillaan.

Vaara terveydelle:

1. **Lataus epäonnistuu:** HS III Seal, jonka lataus epäonnistuu ei muodosta välitöntä vaaraa potilaalle, kun sitä käytetään laitteen käyttöohjeen mukaisesti. Tämä virhe voi kuitenkin johtaa leikkaustoimenpiteen viivästymiseen. Tämä viive voi vaihdella uuden tiivisteen noutamiseen ja lataamiseen kuluvasta muutamasta minuutista mahdolliseen siirtymiseen HS III Sealin käytöstä proksimaalisen anastomoosin tekemiseen aortan puristimen käyttöön toimenpiteen loppuunsaattamiseksi.

2. **Laajentumisen epäonnistuminen:** Kun ladattu HS III Seal ei laajene Delivery Device -toimituslaitteesta, seuraavat toimenpidevaiheet on jo suoritettu ja ne voivat lisätä potilasvahingon riskiä. Jos ladattu HS III Seal ei laajene Delivery Device -toimituslaitteesta, useita toimenpidevaiheita on jo suoritettu, mikä voi lisätä potilasvahingon riskiä.
   - Aortotomiakohta on luotu.
   - Delivery Device -toimituslaitteen putken distaalipää on viety aortotomiakohdan läpi.
   - Delivery Device -toimituslaitteen mäntää on painettu tai yritetty painaa.
   - Ladattu HS III Seal ei ole laajentunut onnistuneesti Delivery Device -toimituslaitteen putken distaalipäästä.
   - Kun Delivery Device -toimituslaite poistetaan aortotomiakohdasta, HS III Seal ei laajene ja aortotomiakohdasta tulevaa verenvuotoa on hallittava asettamalla sormi aortotomiakohdan päälle.

   Potilaalle voi aiheutua seuraavia mahdollisia haittoja:

   - **Leikkaustoimenpiteen viivästyminen**: laajentumattoman HS III Sealin poistaminen, uuden HS III Proximal Sealin avaaminen, Sealin lataaminen Delivery Device -toimituslaitteeseen ja ladatun HS III Sealin vieminen luotuun aortotomiakohtaan (viive ilman lisätoimenpidettä) verrattuna päätökseen käyttää aortan puristinta anastomoosin viimeistelemiseen, koska ladattu Seal ei laajentunut (viive lisätoimenpiteen kanssa)
   - **Kudosvaurio**: voi aiheutua kärjestä levinneen ladatun HS III Sealin laajentumisesta. Levinneen kärjen halkaisija on suurempi kuin Delivery Device -toimituslaitteen distaalisen putken. Sellaisen Sealin, jonka kärki on levinnyt, laajeneminen voi aiheuttaa kudosvaurion aortotomiakohtaan, ja jos vaurioituneen Sealin laajentamiseen käytetään suurempaa voimaa, on olemassa aortan takaseinämän vaurioitumisriski sisäänviennin aikana. Kudosvaurioita voi esiintyä myös, kun Delivery Device -toimituslaite poistetaan aortotomiakohdasta, kun toinen ladattu HS III Seal laajennetaan samaan aortotomiakohtaan ja/tai jos on siirryttävä aortan puristimen käyttöön aortatomian suorittamiseksi loppuun.
   - **Verenvuoto:** Vähäistä verenhukkaa voi esiintyä, kun Delivery Device -toimituslaite poistetaan aortotomiakohdasta, aortotomiakohdasta tulevaa verenvuotoa hallitaan manuaalisesti ja viedään uusi HS III Seal. Jos kudos vaurioituu, seurauksena voi olla suurempi verenhukka, joka vaatii lisätoimenpiteitä.
   - **Emboliatapahtuma**, joka johtuu aortan lisämanipuloinnista HS III Sealin latausvian korjaamiseksi.

3. **Laajentunut Heartstring Seal ei muodosta riittävää hemostaasia:** Kun laajentunut HS III Seal ei tarjoa kirurgille riittävää hemostaasia proksimaalisen anastomoosin suorittamiseksi, HS III Seal -järjestelmän useita vaiheita on jo suoritettu ja ne voivat lisätä potilasvahingon riskiä. Seuraavat menettelyvaiheet on suoritettu.
   - Aortotomiakohta on luotu.
   - Ladattu HS III Seal on laajennettu aorttaan.
   - Aortan verenvuoto on kirurgin mielestä liian suuri anastomoosin tekemiseen.

   Potilaalle voi aiheutua seuraavia mahdollisia haittoja:

   - **Leikkaustoimenpiteen viivästyminen**: voi tapahtua seuraavasti:

     Ylimääräinen leikkausaika, joka kuluu Sealin säätöjen tekemiseen hemostaasin parantamiseksi viedyn HS III Sealin avulla, viallisen HS III Sealin poistamiseen, uuden

HS III Sealin avaamiseen, korvaavan HS III Sealin lataamiseen ja ladatun HS III Sealin viemiseen luotuun aortotomiaan (toimenpiteen viivästyminen ilman lisätoimenpiteitä)
    - Kirurgin mielestä on sopivinta käyttää aortanpuristinta anastomoosin viimeistelyyn, koska laajentunut HS III Seal ei tarjonnut riittävää hemostaasia anastomoosin viimeistelyyn eikä korvaavaa HS III Sealia ole saatavilla tai kirurgin harkinnan mukaan tilanne ei salli korvaavan HS III Sealin käyttöä ja aortanpuristinta käytetään proksimaalisen anastomoosin viimeistelyyn perinteisen leikkaustekniikan mukaisesti. (toimenpiteen viivästyminen lisätoimenpiteellä)
- **Kudosvauriot:** Kudosvaurioita voi esiintyä käsiteltäessä HS III Sealia, kun toinen ladattu HS III Seal asetetaan samaan aortotomiaan ja/tai kun on siirryttävä aorttapuristimeen aortan sulkemiseksi.
- **Verenvuoto:** Pieni verenhukka laajennetun HS III Sealin ympärillä on normaalia ja odotettavissa suoritettaessa proksimaalista anastomoosia HS III Sealia käyttämällä. Suurempaa verenhukkaa, joka vaatii lisätoimenpiteitä, voi esiintyä, kun aortan kudos vaurioituu syystä riippumatta.
- **Emboliatapahtuma(t):** johtuvat aortan lisämanipuloinnista sen jälkeen, kun HS III Sealilla ei ole saatu riittävää hemostaasia.

1.6.2023 ja 22.7.2025 välisenä aikana Getinge sai seuraavat reklamaatiot:
- 274 raporttia latauksen epäonnistumisesta, reklamaatioaste 0,386 %
- 96 raporttia laajentumisen epäonnistumisesta, reklamaatioaste 0,135 %
- 30 raporttia riittämättömästä hemostaasista, reklamaatioaste 0,042 %

<u>Suositellut lievennystoimet ja toimenpiteet</u>

Getinge antaa seuraavat ohjeet yllä mainittujen vikojen välttämiseksi/minimoimiseksi.

1. **Heartstring Sealin lataaminen epäonnistuu**
    a. Tärkeitä huomautuksia:
        i. Laitteen käyttöohjeiden mukaan HS III Seal on tarkoitettu ladattavaksi ja poistettavaksi Loading Device -laitteesta, sen jälkeen tarkastettavaksi ja tarvittaessa säädettäväksi onnistuneen latauksen varmistamiseksi ja lopulta avattavaksi ennen mahdollisten adventitioiden poistamista suunnitellulta anastomoosialueelta ja aortotomian tekemistä. HS III Sealin lataaminen ja onnistuneen latauksen varmistaminen <u>ennen</u> aortotomian tekemistä minimoi potilaille aiheutuvan riskin, koska aortta pysyy koskemattomana, kunnes HS III Sealin lataamisen onnistuminen on varmistettu.
        ii. Jos HS III Seal ei lataudu tarkoitetulla tavalla, laite on vaihdettava.
    b. Näin vältät tai minimoit tämän vian esiintymisen
        i. Lue Heartstring-laitteen käyttöohjeet <u>ennen</u> käyttöä, erityisesti jos Heartstringiä ei käytetä rutiininomaisesti.
        ii. Lataa HS III Seal noudattamalla huolellisesti laitteen vaiheittaisia käyttöohjeita.
        iii. Varmista käyttöohjeen kohtien 4.3–4.5 mukaisesti, että HS III Seal on asetettu oikein asennuslaitteeseen tarkastamalla asetettu HS III Seal, kun

HS III Seal on ladattu asennuslaitteeseen ja poistettu asennuslaitteesta.

iv. Jos HS III Sealia ei tarkasteta asianmukaisesti Loading Device -laitteesta poistamisen jälkeen, HS III Seal voi pettää laajentamisen aikana ja aiheuttaa potilasvahingon. (Katso tiedot laajentamisen epäonnistumisesta.)

v. Suorita HS III Sealin lataaminen loppuun ennen aortan pinnan adventitian puhdistamista ja aortotomian tekemistä.

c. Toimenpiteet, joihin on ryhdyttävä, jos HS III Sealin lataaminen ei onnistu.

i. Hävitä viallinen HS III Seal.

ii. Pidä aina toinen HS III Seal valmiina viallisen laitteen vaihtamiseksi. Tarkista laitteen käyttöohjeista, että lataus onnistuu.

2. Heartstring III Sealin laajentuminen aortotomiaan epäonnistuu

a. Tärkeitä huomautuksia:

i. Varmista, että HS III Seal on asetettu oikein asennuslaitteeseen edellä kuvatulla tavalla.

ii. Kun ladattu HS III Seal on poistettu asennuslaitteesta, tarkista ladattu HS III Seal käyttöohjeiden kohtien 4.3-4.5 mukaisesti ja varmista seuraavat seikat:

1. Ladattu HS III Seal ei ole murtunut.
2. HS III Sealin osa, jota ei ole ladattu asennuslaitteen putkeen, ei ole leveämpi kuin asennuslaitteen putken halkaisija.
3. Tension Spring -jousen päät on kohdistettu siten, että ne koskettavat ladatun HS III Sealin molempia proksimaalisia reunoja, kun Sealia viedään aortotomiaan.

b. Näin vältät tai minimoit tämän vian esiintymisen:

i. Kun HS III Sealin onnitunut lataaminen ja aortotomian luominen on vahvistettu, laajenna ladattu HS III Seal aortotomiaan noudattamalla huolellisesti laitteen käyttöohjeissa kuvattuja HS III Sealin laajentamisvaiheita.

ii. Jos HS III Seal ei laajene tarkoitetulla tavalla, laite on vaihdettava.

c. Toimenpiteet, joihin on ryhdyttävä, jos HS III Sealin laajentaminen aorttaan ei onnistu.

i. Sulje aortotomia verenvuodon hallitsemiseksi etusormella.

ii. Avaa toinen HS III Seal. Lataa HS III Seal laitteen käyttöohjeiden mukaisesti. Vie ladattu HS III Seal aortotomiaan ja suorita anastomoosi loppuun käyttöohjeiden mukaisesti.

iii. Jos toisen HS III Sealin asettaminen aortatomiaan ei onnistu tai jos kirurgi päättää, että tilanne ei salli korvaavan HS III Sealin käyttöä, aseta osittainen okkluusiopuristin aorttaan, eristä aortotomia ja suorita anastomoosi perinteistä leikkaustekniikkaa käyttäen.

3. Laajentunut Heartstring III Seal ei muodosta riittävää hemostaasia:

a. Tämän vikatilan välttäminen/minimointi:

i. Lataa ja tarkasta ladattu HS III Seal aina huolellisesti varmistaaksesi, että HS III Seal on ladattu onnistuneesti Delivery Device -toimituslaitteeseen ennen aortan adventitian puhdistamista ja aortotomian tekemistä. (Katso tärkeät muistutukset yläpuolelta.)

ii. Heartstring Proximal Seal -järjestelmää ei saa käyttää potilailla, joilla on ohutseinäinen aortta.

iii. Kun suoritetaan useita anastomoosikohtia, varmista, että kaikki anastomoosikohdat ovat vähintään 1,5 cm:n päässä toisistaan hemostaasin varmistamiseksi.
iv. Älä liota HS III Sealia liuoksessa ennen käyttöä.

b. Toimenpiteet, joihin on ryhdyttävä, jos HS III Seal ei avaudu/muodosta riittävää hemostaasia Sealin laajentamisen jälkeen.
   i. Peitä aortotomia etusormella ja säädä Tension Spring -jousta varovasti varmistaaksesi, että HS III Seal on laajentunut kokonaan.
   ii. Jos riittämätön hemostaasi jatkuu:
      1. Poista käytetty HS III Seal aortotomiasta laitteen käyttöohjeiden mukaisesti.
      2. Lataa toinen HS III Seal ja laajenna ladattu Seal aortotomiaan laitteen käyttöohjeiden mukaisesti ja suorita anastomoosi loppuun.
      3. Jos toisen HS III Sealin asentaminen ei onnistu tai jos kirurgi päättää, että tilanne ei salli korvaavan HS III Sealin käyttöä, aseta osittainen okkluusiopuristin aorttaan, eristä aortotomia ja suorita anastomoosi perinteistä leikkaustekniikkaa käyttäen.

Asiakkaalta edellytetyt toimenpiteet

Getinge pyytää sinua toimimaan seuraavasti:

1. Varmistakaa, että tämä tiedote välitetään organisaatiossanne kaikille niille, joiden pitää olla asiasta tietoisia, tai kaikkiin sellaisiin organisaatioihin, joihin kyseisiä laitteita on siirretty.

Lisätietoja

Getinge ilmoittaa nämä tiedot vastaaville sääntelyviranomaisille.

Pahoittelemme mahdollista haittaa, jota tämä tilanne voi aiheuttaa. Olemme sitoutuneet potilasturvallisuuteen ja arvostamme nopeaa ongelmaan paneutumista. Jos sinulla on kysyttävää tästä viestistä, +358 9 6824 120

Ystävällisin terveisin

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

France (fr)

Août 2025

Notification de sécurité
Système d'étanchéité proximale Heartstring III
Numéro de référence : 1336551

Numéro de modèle	IUD	Nom du modèle	Numéros de série/lot
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Système d'étanchéité proximale Heartstring III	`
Dates de distribution :		du 1er juillet 2024 jusqu'à maintenant	
Dates de fabrication :		du 7 mars 2024 jusqu'à maintenant	

Cher(e) professionnel(le) de santé,

Le présent courrier a pour but de vous informer que Maquet Cardiovascular, une filiale de Getinge, initie une notification de sécurité relative au système d'étanchéité proximale Heartstring III (joint HS III). Nos dossiers indiquent que vous avez reçu un ou plusieurs dispositifs affectés concernés par cette notification.

Description du problème

Trois modes de défaillance principaux ont été identifiés.

1. **Échec de chargement du joint Heartstring** : cette défaillance s'applique à tout dysfonctionnement du dispositif qui se produit pendant le processus de chargement en quatre étapes à l'aide du dispositif de chargement Heartstring, pendant l'inspection visuelle d'un joint HS III chargé avec succès et le déverrouillage du dispositif de pose une fois les étapes de chargement du joint HS III terminées avec succès.
2. **Échec du déploiement du joint Heartstring dans l'aortotomie** : cette défaillance s'applique à tout dysfonctionnement du joint HS III et/ou du dispositif de pose à partir du moment où le dispositif de pose est déverrouillé avec succès jusqu'à ce que le joint HS III soit complètement introduit dans l'aortotomie et que tout le contenu du joint proximal (fil d'attache, ressort de tension, tige du joint étanche, patte d'ancrage) ont été libérés du dispositif de pose.
3. **Échec du joint Heartstring à assurer une hémostase adéquate, après déploiement:** cette défaillance s'applique à tout dysfonctionnement d'un joint HS III déployé avec succès qui ne contrôle pas correctement le saignement au niveau de l'anastomose pour permettre au chirurgien de suturer l'anastomose, malgré un léger réglage du ressort de tension après le déploiement du joint et/ou l'utilisation d'un brumisateur souffleur, d'une aspiration ou d'une seringue de sérum physiologique pour dégager le site anastomotique. Cette défaillance inclut l'identification par le client d'un joint HS III défectueux ou endommagé après le déploiement réussi du joint HS III dans l'aorte qui entraîne/peut entraîner une hémostase inadéquate empêchant le chirurgien de terminer l'anastomose sans retirer le joint HS III défectueux.

Une enquête sur les causes profondes est en cours.

Risques pour la santé

1. **Échec du chargement :** lorsqu'il est utilisé conformément au mode d'emploi du dispositif, un joint HS III qui ne se charge pas ne présente pas de risque direct pour le patient. Toutefois, cet échec peut entraîner un retard de l'intervention chirurgicale. Ce délai peut varier de quelques minutes pour récupérer et charger un nouveau joint, à une conversion potentielle de l'utilisation du joint HS III pour réaliser l'anastomose proximale à l'utilisation d'un clamp aortique pour terminer la procédure.
2. **Échec du déploiement :** lorsque le joint HS III chargé ne se déploie pas depuis le dispositif de pose, les étapes de procédure suivantes ont déjà été effectuées et peuvent contribuer au risque potentiel de blessure du patient.
   - L'aortotomie a été créée.
   - L'extrémité distale du tube du dispositif de pose a été insérée dans l'aortotomie.
   - Le piston du dispositif de pose a été enfoncé ou une tentative d'enfoncement a été effectuée.
   - Le joint HS III chargé n'a pas été déployé avec succès depuis l'extrémité distale du tube du dispositif de pose.
   - Lorsque le dispositif de pose est retiré de l'aortotomie, le joint HS III ne sera pas déployé et le saignement de l'aortotomie devra être contrôlé en plaçant un doigt sur l'aortotomie.

   Les risques potentiels pour le patient sont les suivants :

   - **Retard de la procédure chirurgicale** : pour retirer le joint HS III non déployé, ouvrir un nouveau joint proximal HS III, charger le joint dans le dispositif de pose et insérer le joint HS III chargé dans l'aortotomie créée (retard sans intervention supplémentaire) par rapport à la décision d'utiliser un clamp aortique pour terminer l'anastomose, car le joint chargé n'a pas pu être déployé (retard avec une intervention supplémentaire)
   - **Lésions tissulaires** : peuvent survenir à la suite du déploiement d'un joint HS III chargé qui est évasé à l'extrémité. Une extrémité évasée aura un diamètre supérieur à celui du tube distal du dispositif de pose. Le déploiement d'un joint chargé présentant une extrémité évasée peut endommager le tissu de l'aortotomie et, si une force plus importante est utilisée pour déployer le joint affecté, il existe un risque potentiel de perforation (« backwalling ») de l'aorte pendant l'insertion. Des lésions tissulaires peuvent également survenir lors du retrait du dispositif de pose de l'aortotomie, du déploiement d'un second joint HS III chargé dans la même aortotomie et/ou de la nécessité de convertir la procédure en utilisant un clamp aortique pour terminer l'aortotomie.
   - **Saignement :** une perte de sang minimale peut se produire lors du retrait du dispositif de pose de l'aortotomie, du contrôle manuel du saignement de l'aortotomie et de le mise en place d'un joint HS III de remplacement. Une perte de sang plus importante, nécessitant une intervention supplémentaire, peut se produire en cas de lésion tissulaire.
   - **Événement embolique** résultant d'une manipulation supplémentaire de l'aorte pour traiter l'échec du chargement du joint HS III.
3. **Échec du joint Heartstring à assurer une hémostase adéquate, après déploiement:** Lorsqu'un joint HS III déployé ne fournit pas une hémostase adéquate pour que le chirurgien termine l'anastomose proximale, plusieurs étapes de l'utilisation du système de joint HS III ont déjà été effectuées et peuvent augmenter le risque potentiel de préjudice pour le patient. Les étapes suivantes ont été effectuées.

- L'aortotomie a été créée.
- Le joint HS III chargé a été déployé dans l'aorte.
- Le saignement de l'aorte est jugé trop important par le chirurgien pour réaliser l'anastomose.

Les risques potentiels pour le patient sont les suivants :

- **Retard de l'intervention chirurgicale** : peut se produire comme suit :
    - Temps opératoire supplémentaire nécessaire pour tenter d'effectuer des ajustements du joint pour améliorer l'hémostase par le joint HS III fourni, retirer le joint HS III défectueux, ouvrir un nouveau joint HS III, charger le joint HS III de remplacement et insérer le joint HS III chargé dans l'aortotomie créée (retard de la procédure sans intervention supplémentaire)
    - Le chirurgien estime qu'il est plus approprié d'utiliser un clamp aortique pour terminer l'anastomose car le joint HS III déployé n'a pas fourni d'hémostase adéquate pour terminer l'anastomose et qu'un joint HS III de remplacement n'est pas disponible ou que le chirurgien estime que la situation ne permet pas l'utilisation d'un joint HS III de remplacement et qu'un clamp aortique est utilisé pour terminer l'anastomose proximale selon la technique chirurgicale traditionnelle (retard de la procédure avec une intervention supplémentaire).
- **Lésions tissulaires :** des lésions tissulaires peuvent survenir pendant la manipulation du joint HS III concerné, pendant le déploiement d'un deuxième joint HS III chargé dans la même aortotomie et/ou en raison du besoin d'utiliser un clamp aortique pour terminer l'aortotomie .
- **Saignement :** une légère perte de sang autour du joint HS III déployé est normale et attendue lors de la réalisation de l'anastomose proximale à l'aide d'un joint HS III. Une perte de sang plus importante nécessitant une intervention supplémentaire peut survenir en cas de lésion du tissu aortique, quelle qu'en soit la cause.
- **Événement(s) embolique(s) :** résultant d'une manipulation supplémentaire de l'aorte liée au traitement de l'échec du joint HS III à assurer une hémostase adéquate.

Entre le 1er juin 2023 et le 22 juillet 2025, Getinge a reçu les réclamations suivantes :

- 274 signalements liés à l'échec du chargement, représentant un taux de réclamations de 0,386 %
- 96 signalements liés à l'échec du déploiement, représentant un taux de réclamations de 0,135 %
- 30 rapports liés à une hémostase inadéquate, représentant un taux de réclamations de 0,042 %

Mesures d'atténuation et actions recommandées

Getinge fournit les instructions suivantes pour éviter/limiter les défaillances abordées ci-dessus.

1. **Échec de chargement du joint Heartstring**
    a. Rappels importants :
        i. Conformément au mode d'emploi du dispositif, le joint HS III est destiné à être chargé et retiré du dispositif de chargement, puis inspecté et ajusté si nécessaire pour confirmer la réussite du chargement et enfin déverrouillé avant d'éliminer toute adventice de la zone anastomotique prévue et de créer l'aortotomie. Le chargement du joint HS III et la confirmation de la réussite du chargement avant la

création de l'aortotomie minimisent le risque pour les patients, car l'aorte reste intacte jusqu'à la confirmation de la réussite du chargement du joint HS III.

ii. Si le joint HS III ne se charge pas comme prévu, le dispositif doit être remplacé.

b. Comment éviter/limiter cette défaillance

i. Lisez le mode d'emploi du dispositif Heartstring avant utilisation, en particulier si le dispositif Heartstring n'est pas utilisé régulièrement.

ii. Chargez le joint HS III en suivant attentivement le mode d'emploi du dispositif, étape par étape.

iii. Conformément à la section 4.3-4.5 du mode d'emploi, confirmez que le joint HS III a été correctement chargé dans le dispositif de pose en inspectant le joint HS III chargé une fois que le joint HS III a été chargé dans le dispositif de pose et retiré du dispositif de chargement.

iv. Un joint HS III qui n'est pas correctement inspecté après avoir été retiré du dispositif de chargement peut générer une défaillance pendant le déploiement du joint HS III et entrainer un risque pour le patient. (Voir informations relatives à l'échec du déploiement.)

v. Terminez le chargement réussi du joint HS III avant de nettoyer l'adventice de la surface aortique et de créer l'aortotomie.

c. Mesures à prendre si le joint HS III ne se charge pas.

i. Jetez le joint HS III défectueux.

ii. Veillez à toujours disposer d'un deuxième joint HS III pour remplacer un dispositif défectueux. Reportez-vous au mode d'emploi du dispositif pour garantir un chargement réussi.

2. Échec du déploiement du joint Heartstring III dans l'aortotomie

a. Rappels importants :

i. Assurez-vous que le joint HS III a été correctement chargé dans le dispositif de pose comme décrit dans la section ci-dessus.

ii. Après avoir retiré le joint HS III chargé du dispositif de chargement, inspectez le joint HS III chargé, conformément aux sections 4.3-4.5 du mode d'emploi, pour confirmer ce qui suit :

1. Le joint HS III chargé n'est pas fissuré.
2. La partie du joint HS III qui n'est pas insérée dans le tube du dispositif de pose ne présente pas un évasement supérieur au diamètre du tube du dispositif de pose.
3. Les extrémités du ressort de tension sont alignées de manière à ce qu'elles entrent en contact avec les deux bords proximaux du joint HS III chargé pendant l'introduction du joint dans l'aortotomie.

b. Comment éviter/limiter l'apparition de cette défaillance :

i. Après confirmation du chargement réussi du joint HS III et de la création de l'aortotomie, déployez le joint HS III chargé dans l'aortotomie en suivant attentivement les étapes de déploiement du joint HS III documentées dans le mode d'emploi du dispositif.

ii. Si le joint HS III ne se déploie pas comme prévu, le dispositif doit être remplacé.

c. Mesures à prendre si le joint HS III ne se déploie pas correctement dans l'aorte.

i. Obstruer l'aortotomie pour contrôler le saignement à l'aide d'un index.

ii. Ouvrez un deuxième joint HS III. Chargez le joint HS III conformément au mode d'emploi du dispositif. Introduisez le joint HS III chargé dans l'aortotomie et suivez le mode d'emploi pour terminer l'anastomose.
iii. Si la délivrance du second joint HS III dans l'aortotomie échoue ou si le chirurgien estime que la situation ne permet pas l'utilisation d'un joint HS III de remplacement, placez un clamp d'occlusion partielle sur l'aorte, isolez l'aortotomie et réalisez l'anastomose selon la technique chirurgicale traditionnelle.

3. Échec du joint Heartstring à assurer une hémostase adéquate, après déploiement

a. Comment éviter/limiter l'apparition de ce mode de défaillance :
   i. Veillez à toujours charger et inspecter soigneusement le joint HS III chargé pour confirmer le chargement réussi du joint HS III dans le dispositif de pose avant d'éliminer toute adventice aortique et de créer l'aortotomie. (Voir les rappels importants ci-dessus.)
   ii. N'utilisez pas le système d'étanchéité proximale Heartstring chez les patients présentant une aorte à paroi mince.
   iii. Lors de la réalisation d'anastomoses multiples, assurez-vous que tous les sites anastomotiques sont espacés d'au moins 1,5 cm pour assurer l'hémostase.
   iv. Ne faites pas tremper le joint HS III dans une solution avant son déploiement.
b. Mesures à prendre si le joint HS III ne s'ouvre pas/n'assure pas une hémostase adéquate après le déploiement du joint.
   i. Couvrez l'aortotomie avec l'index et ajustez délicatement le ressort de tension pour s'assurer que le joint HS III est complètement déployé.
   ii. Si l'absence d'hémostase adéquate persiste :
      1. Retirez le joint HS III déployé de l'aortotomie conformément au mode d'emploi du dispositif.
      2. Chargez un deuxième joint HS III et déployez le joint chargé dans l'aortotomie conformément au mode d'emploi du dispositif et terminez l'anastomose.
      3. Si le deuxième joint HS III échoue ou si le chirurgien estime que la situation ne permet pas l'utilisation d'un joint HS III de remplacement, placez un clamp d'occlusion partielle sur l'aorte, isolez l'aortotomie et réalisez l'anastomose selon la technique chirurgicale traditionnelle.

Actions à entreprendre par les clients

Getinge vous demande de prendre les mesures suivantes :

1. Veuillez vous assurer que ce message est transmis à toutes les personnes devant en être informées au sein de votre établissement ou à tout établissement où les dispositifs concernés ont été transférés.

Informations complémentaires

Getinge communique ces informations aux autorités compétentes.

Nous regrettons tout désagrément que cette notification pourrait causer. La sécurité du patient est notre plus grande priorité. Nous vous remercions de votre attention immédiate à ce sujet. Pour toute question concernant cette communication, veuillez contacter votre représentant Getinge ou le service clientèle Getinge.

Cordialement,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Germany (de)

August 2025

Sicherheitshinweis
Proximales Versiegelungssystem Heartstring III
Referenznummer: 1336551

Modellnummer	UDI	Modellbezeichnung	Serien-/Losnummern
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proximales Versiegelungssystem Heartstring III	Alle nicht abgelaufenen Chargen
Distributionszeitraum:		1. Juli 2024 – Heute	
Herstellungsdaten:		7. März 2024 – Heute	

Sehr geehrte/r Anwender/in,

Mit diesem Schreiben möchten wir Sie darüber informieren, dass Maquet Cardiovascular, eine Tochtergesellschaft von Getinge, eine dringende Korrekturmaßnahme für das Proximale Versiegelungssystem Heartstring III (HS III Seal) vornimmt. Aus unseren Unterlagen geht hervor, dass Sie mindestens eines der von dieser Mitteilung betroffenen Geräte erhalten haben.

Beschreibung des Problems

Es wurden drei primäre Fehlermodi ermittelt.

1. **Ladeausfall der Heartstring-Versiegelung**: Dieser Fehler betrifft alle Fehlfunktionen des Geräts, die während des vierstufigen Ladevorgangs mit der Heartstring-Beladungsvorrichtung, der Sichtkontrolle einer erfolgreichen Beladung des HS III Seal und der Entriegelung der Einführvorrichtung nach erfolgreicher Beladung des HS III Seal auftreten.
2. **Ausfall der Heartstring-Versiegelung bei der Einführung in die Aortotomie**: Dieser Fehler betrifft alle Fehlfunktionen der HS III Seal und/oder der Einführvorrichtung ab dem Zeitpunkt, zu dem die Einführvorrichtung erfolgreich entriegelt wurde, bis zur vollständigen Einführung der HS III Seal in die Aortotomie und dem Austritt des gesamten Inhalts der proximalen Versiegelung (Anbindung, Zugfeder, Versiegelungsschaft, Verankerungslasche) aus der Einführvorrichtung.
3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Dieser Fehler betrifft jede Fehlfunktion eines erfolgreich eingeführten HS III Seal, welches die Blutung an der Anastomose nicht ausreichend kontrolliert, um dem chirurgischen Personal das Vernähen der Anastomose zu ermöglichen, trotz behutsamer Anpassung der Zugfeder nach der Einbringung der Versiegelung und/oder Verwendung eines Blower Mister, einer Absaugung oder einer Kochsalzlösungsspritze zum Reinigen der Anastomosestelle. Dieser Fehler umfasst die Feststellung eines defekten oder beschädigten HS III Seal durch den Kunden nach erfolgreicher Einbringung des HS III Seals in die Aorta, die zu einer unzureichenden Hämostase führt oder führen kann, sodass das chirurgische Personal die Anastomose nicht abschließen kann, ohne das defekte HS III Seal zu entfernen.

Die Ermittlung der Grundursache ist derzeit noch im Gange.

Gesundheitsrisiken

1. **Fehler bei der Beladung:** Bei Verwendung gemäß der Gebrauchsanweisung des Geräts stellt ein HS III Seal ohne Beladung kein direktes Risiko für Patienten dar. Dieser Fehler kann jedoch zu einer Verzögerung des chirurgischen Eingriffs führen. Diese Verzögerung kann von wenigen Minuten zur Entnahme und Beladung einer neuen Versiegelung bis hin zu einer möglichen Umstellung von der Verwendung des HS III Seal zur Durchführung der proximalen Anastomose auf die Verwendung einer Aortaklemme zum Abschluss des Vorgangs reichen.
2. **Fehlgeschlagene Einbringung:** Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden die folgenden Verfahrensschritte bereits durchgeführt, was zu einem potenziellen Risiko einer Patientenschädigung führen kann. Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden bereits mehrere Verfahrensschritte durchgeführt, was das potenzielle Risiko einer Patientenschädigung erhöhen kann.
    - Die Aortotomie wurde angelegt.
    - Das distale Ende des Schlauchs der Einführvorrichtung wurde durch die Aortotomie eingeführt.
    - Der Kolben der Einführvorrichtung wurde gedrückt oder es wurde versucht, ihn zu drücken.
    - Die geladene HS III Seal konnte nicht erfolgreich vom distalen Ende des Schlauchs der Einführvorrichtung eingesetzt werden.
    - Wenn die Einführvorrichtung aus der Aortotomie entfernt wird, wird das HS III Seal nicht platziert. Blutungen aus der Aortotomie müssen durch Auflegen eines Fingers auf die Aortotomie gestillt werden.

    Die folgenden potenziellen Patientenschäden können auftreten:

    - **Verzögerung des chirurgischen Eingriffs**: Entfernen des nicht platzierten HS III Seal, Öffnen einer neuen HS III-Proximalversiegelung, Einlegen der Versiegelung in die Einführvorrichtung und Einbringung des beladenen HS III Seal in die angelegte Aortotomie (Verzögerung ohne zusätzlichen Eingriff) vs. Entscheidung für die Verwendung einer Aortenklemme, um die Anastomose abzuschließen, da die Einbringung der Versiegelung fehlgeschlagen ist (Verzögerung mit zusätzlichem Eingriff)
    - **Gewebeschädigung**: Kann durch das Platzieren eines geladenen HS III Seal mit zu weit geöffneter Spitze entstehen. Eine aufgeweitete Spitze hat einen größeren Durchmesser als der distale Schlauch der Einführvorrichtung. Das Einsetzen einer beladenen Versiegelung mit aufgeweiteter Spitze kann zu einer Schädigung des Aortotomiegewebes führen. Wird beim Einsetzen der betroffenen Versiegelung mehr Kraft aufgewendet, besteht die Gefahr einer Rückwandbildung in der Aorta während des Einführens. Gewebeschäden können auch beim Entfernen der Einführvorrichtung aus der Aortotomie, beim Einsetzen eines zweiten HS III Seal mit Beladung in dieselbe Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortaklemme zur Durchführung der Aortotomie auftreten.
    - **Blutung:** Es kann zu einem minimalen Blutverlust kommen, wenn die Einführvorrichtung aus der Aortotomie entfernt, die Blutung aus der Aortotomie manuell kontrolliert und ein Ersatz-HS III Seal eingeführt wird. Bei einer Gewebeschädigung kann ein größerer Blutverlust auftreten, der einen zusätzlichen Eingriff erfordert.

- **Embolisches Ereignis** infolge zusätzlicher Manipulation der Aorta zur Behebung der fehlgeschlagenen Beladung des HS III Seal.

3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Wenn ein eingesetztes HS III Seal keine ausreichende Hämostase für chirurgisches Personal zur Fertigstellung der proximalen Anastomose bietet, sind mehrere Schritte der Verwendung des HS III Seal Systems bereits abgeschlossen und können das potenzielle Risiko einer Schädigung von Patienten erhöhen. Die folgenden Verfahrensschritte werden bereits erfolgt sein.

   - Die Aortotomie wurde angelegt.
   - Das HS III Seal mit Beladung wurde in die Aorta eingesetzt.
   - Die Blutung aus der Aorta wird vom chirurgischen Personal als zu groß für die Durchführung der Anastomose erachtet.

   Die folgenden potenziellen Patientenschäden können auftreten:

   - **Verzögerung des chirurgischen Eingriffs**: kann wie folgt eintreten:
     - Zusätzliche operative Zeit, die für den Versuch aufgewendet wird, Anpassungen der Versiegelung vorzunehmen, um die Hämostase durch das eingesetzte HS III Seal zu verbessern, das defekte HS III Seal zu entfernen, ein neues HS III Seal zu öffnen, das Ersatz-HS III Seal zu laden und das geladene HS III Seal in die erstellte Aortotomie einzuführen (Verzögerung des Vorgangs ohne zusätzlichen Eingriff)
     - Das chirurgische Personal hält es für angebracht, für den Abschluss der Anastomose eine Aortenklemme zu verwenden, da das eingesetzte HS III Seal für keine ausreichende Hämostase für den erfolgreichen Abschluss der Anastomose gesorgt hat und entweder kein Ersatz-HS III Seal verfügbar ist oder das chirurgische Personal entscheidet, dass die Verwendung eines Ersatz-HS III Seal in der jeweiligen Situation nicht angebracht ist und eine Aortenklemme für den Abschluss der proximalen Anastomose gemäß der herkömmlichen chirurgischen Technik verwendet wird. (Verzögerung des Vorgangs mit einem zusätzlichen Eingriff)
   - **Gewebeschädigung**: Gewebeschäden können bei der Manipulation des betroffenen HS III Seal, bei der Platzierung eines zweiten HS III Seal mit Beladung in derselben Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortenklemme zur Fertigstellung der Aortotomie auftreten.
   - **Blutung:** Ein geringfügiger Blutverlust um das eingesetzte HS III Seal herum ist normal und bei der Durchführung der proximalen Anastomose mit einem HS III Seal zu erwarten. Ein größerer Blutverlust, der einen zusätzlichen Eingriff erfordert, kann auftreten, wenn eine Schädigung des Aortengewebes auftritt, unabhängig von der Ursache.
   - **Embolische(s) Ereignis(se):** infolge einer zusätzlichen Manipulation der Aorta sekundär zur Behebung des Ausfalls des HS III Seal, um eine angemessene Hämostase zu gewährleisten.

Zwischen dem 1. Juni 2023 und dem 22. Juli 2025 erhielt Getinge die folgenden Beschwerden:

- 274 Meldungen im Zusammenhang mit einer fehlgeschlagenen Beladung, was einer Reklamationsrate von 0,386 % entspricht
- 96 Meldungen im Zusammenhang mit der fehlgeschlagenen Einführung, was einer Reklamationsrate von 0,135 % entspricht

- 30 Meldungen im Zusammenhang mit unzureichender Hämostase, was einer Reklamationsrate von 0,042 % entspricht

Empfohlene Abhilfemaßnahmen

Getinge stellt die folgenden Anweisungen zur Verfügung, um die vorstehend erwähnten Fehler zu vermeiden/minimieren.

1. **Ladeausfall der Heartstring-Versiegelung**
    a. Wichtige Hinweise:
        i. Gemäß der Gebrauchsanweisung des Produkts ist das HS III Seal für das Beladen und Entnehmen aus der Ladevorrichtung vorgesehen. Anschließend wird es überprüft und ggf. angepasst, um die erfolgreiche Beladung zu bestätigen, und schließlich entriegelt, bevor jegliche Adventitia aus dem geplanten Anastomosebereich entfernt und die Aortotomie angelegt wird. Die Beladung des HS III Seal und die Bestätigung der erfolgreichen Beladung vor dem Anlegen der Aortotomie minimieren das Risiko für Patienten, da die Aorta bis zur Bestätigung der erfolgreichen Beladung des HS III Seals unberührt bleibt.
        ii. Wenn die Beladung des HS III Seal nicht wie vorgesehen erfolgt, sollte das Gerät ausgetauscht werden.
    b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers
        i. Lesen Sie die Gebrauchsanweisung des Heartstring-Geräts vor der Verwendung durch, insbesondere wenn Heartstring nicht routinemäßig verwendet wird.
        ii. Beladen Sie das HS III Seal, indem Sie die Schritt-für-Schritt-Gebrauchsanweisung des Geräts sorgfältig befolgen.
        iii. Überprüfen Sie gemäß Abschnitt 4.3-4.5 der Gebrauchsanweisung die ordnungsgemäße Beladung des HS III Seal in die Einführvorrichtung durch Inspektion des beladenen HS III Seal nach dessen Beladung in die Einführvorrichtung und Entnahme aus der Ladevorrichtung.
        iv. Ein HS III Seal, das nach der Entnahme aus der Ladevorrichtung nicht ordnungsgemäß überprüft wird, kann während der Einführung des HS III Seal versagen und zu Verletzungen von Patienten führen. (siehe Informationen zu einer fehlgeschlagenen Einführung).
        v. Die erfolgreiche Beladung des HS III Seal vor der Reinigung der Aortenadventitia und dem Anlegen der Aortotomie fertigstellen.
    c. Zu ergreifende Maßnahmen bei ausbleibender Beladung des HS III Seal.
        i. Entsorgen Sie das defekte HS III Seal.
        ii. Halten Sie immer ein zweites HS III Seal bereit, um ein defektes Gerät zu ersetzen. Beachten Sie die Gebrauchsanweisung des Geräts, um eine erfolgreiche Beladung sicherzustellen.

2. **Ausfall der Heartstring III-Versiegelung bei der Einführung in die Aortotomie**
    a. Wichtige Hinweise:
        i. Stellen Sie sicher, dass das HS III Seal wie vorstehend dargelegt ordnungsgemäß in die Einführvorrichtung eingelegt wurde.

ii. Nachdem Sie das geladene HS III Seal aus der Ladevorrichtung entnommen haben, überprüfen Sie das geladene HS III Seal gemäß den Abschnitten 4.3–4.5 der Gebrauchsanweisung, um Folgendes sicherzustellen:
    1. Das geladene HS III Seal ist nicht gerissen.
    2. Der Teil des HS III Seal, der nicht in den Schlauch der Einführvorrichtung gelegt wird, ist nicht breiter als der Durchmesser des Schlauchs der Einführvorrichtung.
    3. Die Enden der Zugfeder sind so ausgerichtet, dass sie beide proximalen Ränder des beladenen HS III Seal berühren, während die Versiegelung in die Aortotomie eingeführt wird.

b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers:
    i. Nach Bestätigung der erfolgreichen Beladung des HS III Seal und Anlegen der Aortotomie das geladene HS III Seal in die Aortotomie einsetzen, indem die in der Gebrauchsanweisung des Geräts dokumentierten Schritte zur Einführung des HS III Seal sorgfältig befolgt werden.
    ii. Kann das HS III Seal nicht wie vorgesehen eingeführt werden, sollte das Gerät ausgetauscht werden.

c. Zu ergreifende Maßnahmen, wenn das HS III Seal nicht erfolgreich in die Aorta eingeführt werden kann.
    i. Die Aortotomie mit dem Zeigefinger verschließen, um die Blutung zu kontrollieren.
    ii. Ein zweites HS III Seal öffnen. Das HS III Seal gemäß Gebrauchsanweisung des Geräts laden. Das HS III Seal mit Beladung in die Aortotomie einführen und die Anastomose gemäß Gebrauchsanweisung abschließen.
    iii. Wenn das Einsetzen des zweiten HS III Seal in die Aortotomie nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

3. Keine ausreichende Hämostase durch die eingeführte Heartstring III-Versiegelung:

a. So vermeiden/minimieren Sie das Auftreten dieses Fehlermodus:
    i. Das geladene HS III Seal immer sorgfältig laden und prüfen, um sicherzustellen, dass es erfolgreich in die Einführvorrichtung geladen wurde, bevor Sie die Adventitia freilegen und die Aortotomie anlegen. (Siehe die direkt vorstehend aufgeführten wichtigen Hinweise.)
    ii. Die Heartstring Proximalversiegelung nicht bei Patienten mit einer dünnwandigen Aorta verwenden.
    iii. Bei Durchführung einer Mehrfachanastomose sicherstellen, dass alle Anastomosenstellen mindestens 1,5 cm voneinander entfernt sind, um eine Hämostase zu gewährleisten.
    iv. Das HS III Seal nicht vor dem Einsetzen in Lösung einweichen.

b. Zu ergreifende Maßnahmen, wenn sich das HS III Seal nach der Einführung nicht öffnet bzw. keine ausreichende Hämostase gewährleistet.
    i. Decken Sie die Aortotomie mit einem Zeigefinger ab und stellen Sie die Zugfeder vorsichtig ein, um sicherzustellen, dass das HS III Seal vollständig eingeführt wurde.
    ii. Bei anhaltend mangelhafter Hämostase:

1. Entfernen Sie das eingesetzte HS III Seal gemäß der Gebrauchsanweisung des Geräts aus der Aortotomie.
2. Beladen Sie ein zweites HS III Seal und setzen Sie die beladene Versiegelung gemäß der Gebrauchsanweisung des Geräts in die Aortotomie ein, um die Anastomose abzuschließen.
3. Wenn das zweite HS III Seal nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

Von Kund-/innen zu ergreifende Maßnahmen

Getinge bittet Sie, die folgenden Maßnahmen zu ergreifen:

1. Bitte leiten Sie diese Mitteilung an alle Personen in Ihrer Organisation weiter, die darüber informiert werden müssen, oder an alle Organisationen, an die betroffene Produkte weitergegeben wurden.

Weitere Informationen

Getinge leitet diese Informationen an die zuständigen Aufsichtsbehörden weiter.

Wir bedauern etwaige Unannehmlichkeiten, die Ihnen hierdurch entstehen. Wir setzen uns für die Patientensicherheit ein und danken Ihnen, dass Sie sich dieser Angelegenheit umgehend angenommen haben. Wenn Sie Fragen zu dieser Mitteilung haben, wenden Sie sich bitte an Ihre Getinge-Vertretung oder den Getinge-Kundendienst.

Mit freundlichen Grüßen

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Greece (el)

Αύγουστος 2025

Επιτόπια οδηγία ασφάλειας

Εγγύς σύστημα σφράγισης Heartstring III

Αριθμός αναφοράς: 1336551

Αριθμός μοντέλου	**UDI**	**Αριθμός μοντέλου**	**Αριθμός σειράς/παρτίδας:**
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Εγγύς σύστημα σφράγισης Heartstring III	Όλες οι μη ληγμένες παρτίδες
Ημερομηνία διανομής:		από την 1η Ιουλίου 2024 έως σήμερα	
Ημερομηνία κατασκευής:		από τις 7 Μαρτίου 2024 έως σήμερα	

Αξιότιμε διαχειριστή κινδύνου,

σκοπός της παρούσας επιστολής είναι να σας ενημερώσει ότι η Maquet Cardiovascular, θυγατρική της Getinge, εκδίδει επείγουσα διόρθωση του ιατροτεχνολογικού προϊόντος Εγγύς σύστημα σφράγισης Heartstring III (πώμα HS III). Σύμφωνα με τα αρχεία μας, έχετε λάβει ένα ή περισσότερα επηρεαζόμενα ιατροτεχνολογικά προϊόντα τα οποία αφορά η παρούσα κοινοποίηση.

<u>Περιγραφή του προβλήματος</u>

Έχουν εντοπιστεί τρεις κύριοι τρόποι αστοχίας.

1. **Αποτυχία εισαγωγής πώματος :** Το ζήτημα αφορά οποιαδήποτε βλάβη του προϊόντος που προκύπτει κατά τη διάρκεια της τετραβάθμιας διαδικασίας εισαγωγής με χρήση της διάταξης εισαγωγής Heartstring, την οπτική επιθεώρηση του επιτυχώς εισαγμένου πώματος HS III και το ξεκλείδωμα της διάταξης εισαγωγής μετά την επιτυχή ολοκλήρωση των βημάτων εισαγωγής του πώματος HS III.
2. **Αποτυχία ανάπτυξης του πώματος Heartstring στην αορτομή**: Το πρόβλημα αφορά για οποιαδήποτε αστοχία του πώματος ή/και της διάταξης εισαγωγής HS III από τη στιγμή που η διάταξη εισαγωγήςς ξεκλειδώνεται με επιτυχία έως ότου το πώμα HS III τοποθετηθεί εξολοκλήρου στην αορτή και αφαιρεθούν όλα τα εξαρτήματα του εγγύς πώματος (ίνα, ελατήριο τάσης, σώμα πώματος, θηλιά στερέωσης) από την διάταξη εισαγωγής.
3. **Το ανεπτυγμένο πώμα Hearstring δεν παρέχει επαρκή αιμόσταση:** το πρόβλημα αφορά οποιαδήποτε αποτυχία του επιτυχώς ανεπτυγμένου πώματος HS III να παρέχει επαρκή έλεγχο της αιμορραγίας στο σημείο της αναστόμωσης για την εκτέλεση αναστομωτικής συρραφής, παρά τη λεπτή ρύθμιση του ελατηρίου τάσης μετά την ανάπτυξη του πώματος ή/και τη χρήση ψεκαστήρα με ανεμιστήρα, αναρρόφησης ή σύριγγας με φυσιολογικό ορό για τον καθαρισμό του σημείου

της αναστόμωσης. Αυτή η αστοχία περιλαμβάνει επίσης την περίπτωση όπου ο πελάτης εντοπίζει ένα ελαττωματικό ή κατεστραμμένο πώμα HS III μετά την επιτυχή έκπτυξή του στην αορτή, όπου η αστοχία έχει ως αποτέλεσμα/μπορεί να οδηγήσει σε ανεπαρκή αιμόσταση που εμποδίζει τον χειρουργό να ολοκληρώσει την αναστόμωση χωρίς να αφαιρέσει το ελαττωματικό πώμα HS III.

Αυτή τη στιγμή βρίσκεται σε εξέλιξη έρευνα των κύριων αιτίων.

Κίνδυνοι για την υγεία:

1. **Αποτυχία εκκίνησης:** Όταν το πώμα HS III χρησιμοποιείται σύμφωνα με τις οδηγίες χρήσης (IFU) του ιατροτεχνολογικού προϊόντος, η μη εισαγωγή του δεν αποτελεί άμεσο κίνδυνο για τον ασθενή. Ωστόσο, η αποτυχία μπορεί να οδηγήσει σε καθυστέρηση της χειρουργικής επέμβασης. Η καθυστέρηση μπορεί να κυμαίνεται από μερικά λεπτά που απαιτούνται για την αφαίρεση και την εισαγωγή ενός νέου πώματος έως την πιθανή μετάβαση από τη χρήση του πώματος HS III για την εκτέλεση της εγγύς αναστόμωσης στη χρήση ενός αορτικού σφιγκτήρα για την ολοκλήρωση της διαδικασίας.
2. **Αποτυχία ανάπτυξης:** Εάν το ανεπτυγμένο πώμα HS III δεν ξεδιπλωθεί από την διάταξη εισαγωγής, τα ακόλουθα διαδικαστικά βήματα έχουν ήδη εκτελεστεί και ενδέχεται να συμβάλουν στον πιθανό κίνδυνο βλάβης του ασθενούς. Εάν το ανεπτυγμένο πώμα HS III δεν αναπτυχθεί από την διάταξη εισαγωγής, θα έχουν ήδη εκτελεστεί αρκετά διαδικαστικά βήματα που ενδέχεται να αυξήσουν τον πιθανό κίνδυνο βλάβης της υγείας του ασθενούς.
   - Έχει εκτελεστεί αορτοτομή.
   - Το περιφερικό άκρο του σωλήνα της διάταξης εισαγωγής εισάχθηκε από την αορτοτομή.
   - Το έμβολο της διάταξης εισαγωγής έχει πιεστεί ή έχει γίνει προσπάθεια να πιεστεί.
   - Το εισαγόμενο πώμα HS III δεν με επιτυχία από το άπω άκρο του σωλήνα της διάταξης εισαγωγής.
   - Μετά την αφαίρεση της διάταξης εισαγωγής από την αορτή, το πώμα HS III δεν θα ανοίξει και θα πρέπει να σταματήσετε την αιμορραγία από την αορτή βάζοντας το δάχτυλό σας πάνω από την αορτή.

Μπορεί να προκληθούν οι ακόλουθες βλάβες στην υγεία του ασθενούς:

- **Καθυστέρηση χειρουργικής επέμβασης**: αφαίρεση του μη αναπτυγμένου πώματος HS III, άνοιγμα ενός νέου εγγύς πώματος HS III, εισαγωγή του πώματος στη διάταξη εισαγωγήςς και εισαγωγή του αναπτυγμένου πώματος HS III στην δημιουργημένη αορτή (καθυστέρηση χωρίς περαιτέρω παρέμβαση) έναντι απόφασης χρήσης αορτικού σφιγκτήρα για την ολοκλήρωση της αναστόμωσης επειδή το αναπτυγμένο πώμα δεν αναπτύχθηκε (καθυστέρηση με περαιτέρω παρέμβαση).

- **Βλάβη ιστών**: ενδέχεται να προκληθεί βλάβη στους ιστούς λόγω της ανάπτυξης του πώματος HS III, το οποίο είναι διευρυμένο στην άκρη. Η διευρυμένη άκρη θα έχει διάμετρο μεγαλύτερη από τον άπω σωλήνα της διάταξης εισαγωγής. Η ανάπτυξη ενός εισαγόμενου πώματος με διευρυμένο άκρο μπορεί να προκαλέσει βλάβη στους ιστούς στο σημείο της αορτομίας και, εάν χρησιμοποιηθεί υπερβολική δύναμη για την ανάπτυξη του πώματος, υπάρχει πιθανός κίνδυνος τραυματισμού στο οπίσθιο αορτικό τοίχωμα κατά την ανάπτυξη. Βλάβη στους ιστούς μπορεί επίσης να προκληθεί κατά την αφαίρεση της διάταξης εισαγωγής από την αορτομία, την ανάπτυξη μιας δεύτερης σφράγισης HS III που εισάγεται στην ίδια αορτομία ή/και την ανάγκη μετάβασης στη χρήση αορτικού σφιγκτήρα για την ολοκλήρωση της αορτομίας.

- **Αιμορραγία:** Ελάχιστη απώλεια αίματος μπορεί να συμβεί κατά την αφαίρεση της διάταξης εισαγωγής από την αορτομία, τον χειροκίνητο έλεγχο της αιμορραγίας από την αορτομία και

την εφαρμογή του ανταλλακτικού πώματος HS III. Μεγαλύτερη απώλεια αίματος, που απαιτεί πρόσθετη παρέμβαση, μπορεί να συμβεί εάν προκληθεί βλάβη στους ιστούς.

- **Εμβολικό συμβάν** λόγω πρόσθετου χειρισμού της αορτής για την επίλυση του προβλήματος αποτυχίας εισαγωγής πώματος του HS III.

3. **Το ανεπτυγμένο πώμα Heatstring δεν παρέχει επαρκή αιμόσταση:** Εάν το αναπτυγμένο πώμα του HS III δεν παρέχει επαρκή αιμόσταση ώστε ο χειρουργός να ολοκληρώσει την εγγύς αναστόμωση, ορισμένα βήματα που σχετίζονται με τη χρήση του συστήματος πώματος HS III έχουν ήδη ολοκληρωθεί και αυτό μπορεί να αυξήσει τον πιθανό κίνδυνο βλάβης του ασθενούς. Σε αυτό το σημείο, τα ακόλουθα βήματα θα έχουν ήδη εκτελεστεί:
   - Διενεργήθηκε η αορτοτομή.
   - Το πώμα HS III αναπτύχθηκε στην αορτή.
   - Ο χειρουργός θεωρεί ότι η αιμορραγία από την αορτή είναι πολύ σοβαρή παρά να διενεργήσει αναστόμωση.

   Μπορεί να προκληθούν οι ακόλουθες βλάβες στην υγεία του ασθενούς:

   - **Καθυστέρηση χειρουργικής επέμβασης**: μπορεί να προκύψει ακολούθως:
     - Απαιτείται επιπλέον χρόνος επέμβασης για την προσπάθεια τροποποίησης του πώματος για βελτίωση της αιμόστασης χρησιμοποιώντας το εισαγόμενο πώμα HS III, την αφαίρεση του ελαττωματικού πώματος HS III, το άνοιγμα ενός νέου πώματος HS III, την εισαγωγή ενός ανταλλακτικού πώματος HS III και την εισαγωγή του προετοιμασμένου πώματος HS III στην δημιουργημένη αορτή (Καθυστέρηση της διαδικασίας χωρίς περαιτέρω παρέμβαση).
     - Ο χειρουργός θεωρεί καταλληλότερο να χρησιμοποιήσει αορτικό σφιγκτήρα για την ολοκλήρωση της αναστόμωσης, επειδή το ανεπτυγμένο πώμα HS III δεν παρέχει επαρκή αιμόσταση για την ολοκλήρωση της αναστόμωσης και είτε δεν είναι διαθέσιμο ένα ανταλλακτικό πώμα HS III είτε ο χειρουργός αποφασίζει ότι η κατάσταση δεν επιτρέπει τη χρήση ανταλλακτικού πώματος HS II και χρησιμοποιεί έναν αορτικό σφιγκτήρα για να ολοκληρώσει την εγγύς αναστόμωση χρησιμοποιώντας μια παραδοσιακή χειρουργική τεχνική. (Καθυστέρηση μιας παρέμβασης με μια άλλη παρέμβαση.)
   - **Βλάβη ιστών:**Μπορεί να προκληθεί βλάβη στους ιστούς κατά τον χειρισμό του προσβεβλημένου πώματος του HS III, κατά την ανάπτυξη ενός δεύτερου πώματος του HS III στην ίδια αορτοτομή ή/και κατά την αλλαγή σε αορτικό σφιγκτήρα για την ολοκλήρωση της αορτοτομής.

   - **Αιμορραγία:** Μια μικρή απώλεια αίματος γύρω από το ανεπτυγμένο πώμα του HS III είναι φυσιολογική και είναι αναμενόμενη κατά την εκτέλεση εγγύς αναστόμωσης χρησιμοποιώντας πώμα HS III. Μεγάλη απώλεια αίματος που απαιτεί πρόσθετη παρέμβαση μπορεί να προκύψει λόγω βλάβης των ιστών, ανεξάρτητα από την αιτία της.

   - **Εμβολικό συμβάν:** Προκύπτει λόγω περαιτέρω χειρισμού της αορτής ως αποτέλεσμα της επίλυσης μιας βλάβης όταν το πώμα του HS III δεν παρέχει επαρκή αιμόσταση.

Από την 1η Ιουνίου 2023 έως τις 22 Ιουλίου 2025, η Getinge έλαβε τις ακόλουθες καταγγελίες:

- 274 αναφορές αφορούσαν αποτυχίες ανάπτυξης, που παρουσιάζουν 0,386 % των καταγγελιών.
- 96 αναφορές αφορούσαν αποτυχίες ανάπτυξης, που παρουσιάζουν 0,135 % των καταγγελιών.
- 30 αναφορές σχετικά με ανεπαρκή αιμόσταση, που παρουσιάζουν 0,042% των καταγγελιών.

Συνιστώμενα μέτρα και βήματα μετριασμού:

Η Getinge παρέχει τις ακόλουθες οδηγίες για την αποφυγή/ελαχιστοποίηση των βλαβών που περιγράφονται παραπάνω.

1. **Αποτυχία ανάπτυξης πώματος Heartstring**
    a. Σημαντική υπενθύμιση
        i. Οι οδηγίες χρήσης της συσκευής αναφέρουν ότι το πώμα HS III πρέπει να εισάγεται και να αφαιρείται από τη διάταξη εισαγωγής, στη συνέχεια να επιθεωρείται και να ρυθμίζεται εάν είναι απαραίτητο για να επιβεβαιώνεται η επιτυχής εισαγωγή και στη συνέχεια να ξεκλειδώνεται πριν από την αφαίρεση του έξω χιτώνα από το στοχευμένο σημείο αναστόμωσης και τη δημιουργία της αορτομής. Η εισαγωγή του πώματος του HS III και η επιβεβαίωση της επιτυχούς εισαγωγής πριν από τη δημιουργία της αορτομής ελαχιστοποιεί τον κίνδυνο για τον ασθενή, επειδή η αορτή παραμένει άθικτη μέχρι να επιβεβαιωθεί η επιτυχής εισαγωγή του πώματος του HS III.
        ii. Εάν η προγραμματισμένη εισαγωγή του πώματος HS III αποτύχει, το ιατροτεχνολογικό προϊόν θα πρέπει να αντικατασταθεί.
    b. Πώς να αποφύγετε αυτήν την αποτυχία / να ελαχιστοποιήσετε την εμφάνισή της.
        i. Διαβάστε τις οδηγίες χρήσης του Heartstring πριν από τη χρήση, ειδικά εάν το Heartstring δεν χρησιμοποιείται τακτικά.
        ii. Κατά την εισαγωγή του πώματος HS III, προχωρήστε με προσοχή και ακολουθήστε όλα τα βήματα που περιγράφονται στις οδηγίες χρήσης. (IFU).
        iii. Σύμφωνα με τις οδηγίες στην ενότητα 4.3-4.5 των Οδηγιών χρήσης, ελέγξτε ότι το καπάκι HS III έχει εισαχθεί σωστά στη διάταξη εισαγωγής, ελέγχοντας το τοποθετημένο καπάκι HS III αφού το τοποθετήσετε στη διάταξη εισαγωγής και το αφαιρέσετε από τη διάταξη εισαγωγής.
        iv. Το πώμα HS III που δεν έχει ελεγχθεί σωστά μετά την αφαίρεσή του από τη διάταξη εισαγωγής ενδέχεται να παρουσιάσει βλάβη κατά την ανάπτυξη και να προκαλέσει τραυματισμό στον ασθενή. (Δείτε πληροφορίες σχετικά με την αποτυχία ανάπτυξης).
        v. Ολοκληρώστε με επιτυχία την εισαγωγή του πώματος HS III πριν τον καθαρισμό της εξωτερικής επιφάνειας της αορτικής επιφάνειας και τη δημιουργία αορτομής.
    c. Μέτρα που πρέπει να ληφθούν σε περίπτωση που το πώμα του HS αποτύχει κατά την ανάπτυξη.
        i. Απορρίψτε το καπάκι HS III που δεν εισάχθηκε.
        ii. Να έχετε πάντα έτοιμη ένα δεύτερο πώμα HS III για να αντικαταστήσετε την ελαττωματική συσκευή. Για την επιτυχή εισαγωγή, ακολουθήστε τις οδηγίες χρήσης.
2. **Αποτυχία ανάπτυξης πώματος Heartstring στην αορτή**
    a. Σημαντική υπενθύμιση:
        i. Βεβαιωθείτε ότι το πώμα HS III έχει τοποθετηθεί σωστά στη συσκευή εφαρμογής, όπως αναφέρεται στην παραπάνω παράγραφο.
        ii. Αφού αφαιρέσετε το εισαγμένο πώμα HS III από τη διάταξη εισαγωγής, ελέγξτε το εισαγμένο πώμα HS III σύμφωνα με τις Οδηγίες χρήσης, ενότητες 4.3.-4.5, για να βεβαιωθείτε ότι:
            1. Το εισαγμένο πώμα HS III δεν είναι ραγισμένο.

2. Το μέρος του πώματος HS III που δεν εισάγεται στον σωλήνα της διάταξης εισαγωγής δεν είναι ευρύτερο από τη διάμετρο του σωλήνα της διάταξης εισαγωγής.
3. Βεβαιωθείτε ότι τα άκρα του ελατηρίου τάσης είναι ευθυγραμμισμένα έτσι ώστε να εφάπτονται και στα δύο εγγύς άκρα του πώματος HS III κατά την εισαγωγή στην αορτή.

b. Πώς να αποφύγετε αυτήν την αποτυχία / να ελαχιστοποιήσετε την εμφάνισή της.
   i. Μόλις επιβεβαιώσετε την επιτυχή εισαγωγή του πώματος HS III και τη δημιουργία αορτομής, αναπτύξτε το εισαγμένο πώμα HS III στην αορτή. Ακολουθήστε προσεκτικά τη διαδικασία ανάπτυξης του πώματος HS III που περιγράφεται στις Οδηγίες χρήσης.
   ii. Εάν το πώμα HS III δεν αναπτυχθεί όπως αναμένεται, το ιατροτεχνολογικό προϊόν θα πρέπει να αντικατασταθεί.

c. Μέτρα που πρέπει να ληφθούν εάν το πώμα του HS III δεν αναπτυχθεί επιτυχώς στην αορτή.
   i. Χρησιμοποιήστε τον δείκτη σας για να κλείσετε την αορτομή και να σταματήσετε την αιμορραγία.
   ii. Ανοίξτε το δεύτερο πώμα HS III. Εισαγάγετε το πώμα σύμφωνα με τις οδηγίες στις Οδηγίες χρήσης. Εισαγάγετε το εισαγόμενο πώμα HS III στην αορτομή και ακολουθήστε τις οδηγίες χρήσης για να ολοκληρώσετε την αναστόμωση.
   iii. Εάν η τοποθέτηση ενός δεύτερου πώματος HS III στην αορτή δεν είναι επιτυχής ή εάν ο χειρουργός κρίνει ότι η κατάσταση δεν επιτρέπει τη χρήση ενός εφεδρικού πώματος HS III, τοποθετεί έναν σφιγκτήρα μερικής απόφραξης στην αορτή για να απομονώσει την αορτή και να πραγματοποιήσει την αναστόμωση χρησιμοποιώντας παραδοσιακές χειρουργικές τεχνικές.

3. Το ανεπτυγμένο πώμα Heatstring δεν παρέχει επαρκή αιμόσταση:

a. Πώς να αποφύγετε αυτήν την αποτυχία / να ελαχιστοποιήσετε την εμφάνισή της:
   i. Πραγματοποιήστε προσεκτικό έλεγχο κατά την εισαγωγή του πώματος HS III, καθώς και μετά την εισαγωγή, για να επιβεβαιώσετε την επιτυχή εισαγωγή του πώματος HS III στη διάταξη εισαγωγής πριν καθαρίσετε τον αορτικό έξω χιτώνα και προβείτε στην αορτοτομή. (βλ. παραπάνω σημαντικές προειδοποιήσεις).
   ii. Μην χρησιμοποιείτε το σύστημα εγγύς πώματος Heartstring σε ασθενή με αορτή με λεπτό τοίχωμα.
   iii. Όταν εκτελείτε πολλαπλές αναστομώσεις, βεβαιωθείτε ότι όλες οι θέσεις αναστομώσεων απέχουν τουλάχιστον 1,5 cm μεταξύ τους για να διασφαλίσετε την αιμόσταση.
   iv. Μην εμποτίσετε το πώμα HS III σε διάλυμα πριν το αναπτύξετε.

b. Μέτρα που πρέπει να ληφθούν εάν το πώμα του HS III δεν ανοίξει/δεν παρέχει επαρκή αιμόσταση μετά την ανάπτυξη.
   i. Κλείστε την αορτή με τον δείκτη σας και ρυθμίστε προσεκτικά το ελατήριο τάσης για να βεβαιωθείτε ότι το πώμα HS III έχει αναπτυχθεί πλήρως.
   ii. Εάν η ανεπαρκής αιμόσταση επιμένει:
      1. Αφαιρέστε το ανεπτυγμένο πώμα HS III από την αορτή σύμφωνα με τις οδηγίες στις Οδηγίες χρήσης.
      2. Εισαγάγετε το δεύτερο πώμα HS III και αναπτύξτε το εισαγόμενο πώμα στην αορτοτομή σύμφωνα με τις οδηγίες στις Οδηγίες χρήσης και ολοκληρώστε την αναστόμωση.

3. Εάν η τοποθέτηση ενός δεύτερου πώματος HS III στην αορτή δεν είναι επιτυχής ή εάν ο χειρουργός κρίνει ότι η κατάσταση δεν επιτρέπει τη χρήση ενός εφεδρικού πώματος HS III, τοποθετεί έναν σφιγκτήρα μερικής απόφραξης στην αορτή για να απομονώσει την αορτή και να πραγματοποιήσει την αναστόμωση χρησιμοποιώντας παραδοσιακές χειρουργικές τεχνικές.

Μέτρα που λαμβάνονται από τον πελάτη

Η Getinge απαιτεί να λάβετε τα ακόλουθα μέτρα:

1. Βεβαιωθείτε ότι αυτό το μήνυμα θα διαβιβαστεί σε όλα τα άτομα που χρειάζονται αυτήν την ειδοποίηση εντός του οργανισμού σας ή σε οποιονδήποτε άλλο οργανισμό στον οποίο έχουν μεταφερθεί οι επηρεαζόμενες συσκευές.

Συμπληρωματικές πληροφορίες

Η Getinge διαβιβάζει αυτή την πληροφορία στις αρμόδιες ρυθμιστικές αρχές.

Ζητάμε συγγνώμη για την όποια ταλαιπωρία μπορεί να προκαλέσει αυτό το πρόβλημα. Η Datascope/Getinge μεριμνά για την ασφάλεια των ασθενών και εκτιμά την άμεση ανταπόκρισή σας στο θέμα αυτό. Εάν έχετε οποιεσδήποτε ερωτήσεις σχετικά με την παρούσα ειδοποίηση, επικοινωνήστε με τον εκπρόσωπο της Getinge ή την Εξυπηρέτηση Πελατών της Getinge στο 1-888-880-2874, από Δευτέρα έως Παρασκευή, από 8:00 π.μ. μέχρι 5:00 μ.μ. (ώρα Ειρηνικού).

Με εκτίμηση,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Hong Kong (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is

not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

a. Action to be taken if the HS III Seal fails to load.
   i. Discard the failed HS III Seal.
   ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
    i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
    ii. If lack of adequate hemostasis persists:
        1. Remove the deployed HS III Seal from the aortotomy per device IFU.
        2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
        3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

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2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

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Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is

not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

b. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
    i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
    ii. If lack of adequate hemostasis persists:
        1. Remove the deployed HS III Seal from the aortotomy per device IFU.
        2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
        3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Italy (it)

Agosto 2025

Avviso di Sicurezza sul Campo

Sistema di Tenuta Prossimale Heartstring III

Numero di Riferimento: 1336551

Codice prodotto	UDI	Descrizione del prodotto	Numeri di serie/lotto
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema di tenuta prossimale Heartstring III	Tutti i lotti non scaduti
Date di distribuzione:		Dal 1° luglio 2024 ad oggi	
Date di produzione:		Dal 7 marzo 2024 ad oggi	

Gentili clienti,

Lo scopo del presente avviso è quello di informare che Maquet Cardiovascular, una consociata di Getinge, sta emettendo una correzione urgente di dispositivo medico per il sistema di tenuta prossimale Heartstring III (Sigillante HS III). I nostri registri indicano che avete ricevuto uno o più dei dispositivi interessati da questa notifica.

Descrizione del problema

Sono state identificate tre modalità di guasto principali.

1. **Mancato caricamento del sigillante Heartstring:** Questa tipologia di guasto si applica a qualsiasi malfunzionamento del dispositivo che si verifichi durante il processo di caricamento in quattro fasi con il dispositivo di caricamento Heartstring, l'ispezione visiva di un Sigillante HS III caricato correttamente e lo sblocco del dispositivo di erogazione al termine delle fasi di caricamento del sigillante HS III.

2. **Mancato dispiegamento del sigillante Heartstring nell'aortotomia:** Questa tipologia di guasto si applica a qualsiasi malfunzionamento del Sigillante HS III e/o del dispositivo di erogazione dal momento in cui il dispositivo di erogazione viene sbloccato correttamente fino al momento in cui viene completata l'erogazione del sigillante HS III nell'aortotomia e tutto il contenuto del sigillante prossimale (il cavo, la molla elastica, lo stelo del sigillante, la linguetta di ancoraggio) è fuoriuscito dal dispositivo di erogazione.

3. **Mancata anastomosi del sigillante Heartstring III dispiegato:** Questa tipologia di guasto si applica a qualsiasi malfunzionamento di un sigillante HS III dispiegato correttamente che non controlla adeguatamente il sanguinamento in corrispondenza dell'anastomosi per consentire al chirurgo di eseguire la sutura dell'anastomosi, nonostante la delicata regolazione della molla elastica dopo il dispiegamento del sigillante e/o l'uso di una siringa di nebulizzazione, di aspirazione o di soluzione fisiologica per liberare il sito di anastomosi. Questa tipologia di guasto include l'identificazione da parte del cliente di un sigillante HS III difettoso o danneggiato a seguito del corretto dispiegamento del sigillante HS III nell'aorta che comporta/o può comportare un'emostasi inadeguata che impedisce al chirurgo di completare l'anastomosi senza rimuovere il sigillante HS III difettoso.

Al momento sono in corso indagini per scoprire la causa principale.

Rischi per la salute

1. **Mancato caricamento:** Se utilizzato in conformità con le Istruzioni per l'uso (IFU) del dispositivo, un sigillante HS III che non si carica non rappresenta un rischio diretto per il paziente. Tuttavia, questo guasto può portare a un ritardo nella procedura chirurgica. Questo ritardo può variare da pochi minuti per il recupero e il caricamento di nuovo sigillante, a una potenziale conversione dall'utilizzo del sigillante HS III per eseguire l'anastomosi prossimale all'impiego di una pinza aortica per completare la procedura.
2. **Mancato dispiegamento:** Quando il sigillante HS III caricato non riesce a dispiegarsi dal dispositivo di erogazione, le seguenti fasi procedurali sono già state eseguite il che può contribuire al potenziale rischio di danni al paziente:
    - È stata eseguita l'aortotomia.
    - L'estremità distale del tubo del dispositivo di erogazione è stata inserita attraverso l'aortotomia.
    - Lo stantuffo del dispositivo di erogazione è stato premuto o è stato fatto un tentativo di premerlo.
    - Il sigillante HS III caricato non si è dispiegato correttamente dall'estremità distale del tubo del dispositivo di erogazione.
    - Quando il dispositivo di erogazione viene rimosso dall'aortotomia, il sigillante HS III non verrà dispiegato e il sanguinamento dall'aortotomia dovrà essere controllato posizionando un dito sopra l'aortotomia.

    Possono verificarsi i seguenti potenziali danni per il paziente:
    - **Ritardo della procedura chirurgica:** per rimuovere il sigillante HS III non dispiegato, aprire un nuovo sigillante prossimale HS III, caricare il sigillante nel dispositivo di erogazione ed erogare il sigillante HS III caricato nell'aortotomia creata (ritardo senza ulteriore intervento) rispetto alla decisione di utilizzare una pinza aortica per completare l'anastomosi perché il sigillante caricato non è riuscito a dispiegarsi (ritardo con un intervento aggiuntivo)
    - **Danni ai tessuti:** possono verificarsi a seguito del dispiegamento di un sigillante HS III caricato che è svasato sulla punta. Una punta svasata avrà un diametro maggiore del tubo distale del dispositivo di erogazione. Il dispiegamento di un sigillante caricato con punta svasata può causare danni al tessuto aortotomico e, se viene utilizzata una forza maggiore per dispiegare il sigillante interessato, esiste un potenziale rischio di perforazione della parete posteriore dell'aorta durante l'inserimento. Può verificarsi danno tissutale anche durante la rimozione del dispositivo di erogazione dall'aortotomia, il dispiegamento di un secondo sigillante HS III caricato nella stessa aortotomia e/o la necessità di passare all'uso di una pinza aortica per completare l'aortotomia.
    - **Sanguinamento:** si può verificare una perdita di sangue minima quando si rimuove il dispositivo di erogazione dall'aortotomia, si controlla manualmente l'emorragia dall'aortotomia e si eroga un sigillante HS III sostitutivo. Una maggiore perdita di sangue, che richiede un intervento aggiuntivo, può verificarsi se si verifica un danno tissutale.
    - **Evento embolico** derivante da un'ulteriore manipolazione dell'aorta per risolvere il problema di caricamento del sigillante HS III.
3. **Mancata anastomosi del sigillante Heartstring III dispiegato:** Quando un sigillante HS III dispiegato non riesce a fornire un'emostasi adeguata al chirurgo per completare l'anastomosi prossimale, diverse fasi dell'uso del Sistema sigillante emostatico HS III sono già state completate e possono aumentare il potenziale rischio di danni al paziente. Le seguenti fasi procedurali avranno avuto luogo.
    - È stata creata un'aortotomia.

- Il sigillante HS III caricato è stato dispiegato nell'aorta.
- Il sanguinamento dall'aorta è ritenuto dal chirurgo troppo importante per eseguire l'anastomosi.

Possono verificarsi i seguenti potenziali danni per il paziente:

- **Ritardo della procedura chirurgica**: può verificarsi come segue:
  - Un ulteriore tempo operativo impiegato per tentare di effettuare regolazioni del sigillante per migliorare l'emostasi mediante il sigillante HS III erogato, rimuovere il sigillante HS III difettoso, aprire un nuovo sigillante HS III, caricare il sigillante HS III sostitutivo ed erogare il sigillante HS III caricato nell'aortotomia creata (ritardo della procedura senza ulteriore intervento)
  - Il chirurgo ritiene più appropriato utilizzare una pinza aortica per completare l'anastomosi perché il sigillante HS III dispiegato non è riuscito a fornire un'emostasi adeguata a completare l'anastomosi e non è disponibile un sigillante HS III sostitutivo o la preferenza del chirurgo determina che la situazione non consente l'uso di un sigillante HS III sostitutivo e viene utilizzata una pinza aortica per completare l'anastomosi prossimale secondo la tecnica chirurgica tradizionale. (ritardo della procedura con intervento aggiuntivo)
- **Danni ai tessuti**: Può verificarsi danno tissutale può verificarsi durante la manipolazione del sigillante HS III interessato, durante il dispiegamento del sigillante di un secondo sigillante HS III caricato nella stessa aortotomia e/o la necessità di passare all'uso di una pinza aortica per completare l'aortotomia.
- **Sanguinamento:** Una piccola quantità di perdita di sangue intorno al sigillante HS III dispiegato è normale e prevista durante l'esecuzione dell'anastomosi prossimale utilizzando un sigillante HS III. Una perdita di sangue maggiore che richiede un intervento aggiuntivo può verificarsi quando si verifica un danno al tessuto aortico, indipendentemente dalla causa.
- **Evento/i embolico/i:** derivante da un'ulteriore manipolazione dell'aorta secondaria per risolvere l'incapacità del sigillante HS III di fornire un'emostasi adeguata.

Mitigazioni e azioni raccomandate

Getinge fornisce le seguenti istruzioni per evitare/ridurre al minimo i guasti discussi sopra.

1. **Mancato caricamento del Sigillante emostatico Heartstring**
   a. Promemoria importanti:
      i. Secondo le istruzioni per l'uso del dispositivo, il sigillante HS III deve essere caricato e rimosso dal dispositivo di caricamento, quindi ispezionato e regolato se necessario per confermare il corretto caricamento e infine sbloccato prima di eliminare qualsiasi tonaca avventizia dall'area anastomotica pianificata e creare l'aortotomia. Il caricamento del sigillante HS III e la conferma del caricamento riuscito prima della creazione dell'aortotomia riducono al minimo il rischio per i pazienti perché l'aorta rimane intatta fino alla conferma del caricamento riuscito del sigillante HS III.
      ii. Se il sigillante HS III non si carica come previsto, il dispositivo deve essere sostituito.
   b. Come evitare/ridurre al minimo il verificarsi di questo guasto
      i. Esaminare le istruzioni per l'uso del dispositivo Heartstring prima dell'uso, soprattutto se Heartstring non viene utilizzato di routine.
      ii. Caricare il sigillante HS III seguendo attentamente le istruzioni per l'uso passo-passo del dispositivo (IFU).

iii. Per le sezioni 4.3-4.5 delle istruzioni per l'uso, verificare che il sigillante HS III sia stato caricato correttamente nel dispositivo di erogazione ispezionando il sigillante HS III caricato una volta che il sigillante HS III è stato caricato nel dispositivo di erogazione ed è stato rimosso dal dispositivo di caricamento.

iv. Un sigillante HS III che non è adeguatamente ispezionato dopo la rimozione dal dispositivo di caricamento può guastarsi durante l'installazione del sigillante HS III e causare danni al paziente. (vedere le informazioni relative al mancato dispiegamento).

v. Completare correttamente il caricamento del sigillante HS III prima di pulire la tonaca avventizia della superficie aortica e creare l'aortotomia.

c. Azione da intraprendere se il sigillante HS III non si carica.
   i. Eliminare il sigillante HS III guasto.
   ii. Avere sempre a disposizione un secondo sigillante HS III per sostituire un dispositivo guasto. Fare riferimento alle istruzioni per l'uso del dispositivo per garantire il corretto caricamento.

2. Mancato dispiegamento del sigillante Heartstring III nell'aortotomia

a. Promemoria importanti:
   i. Assicurarsi che il sigillante HS III sia stato caricato correttamente nel dispositivo di erogazione come descritto nella sezione precedente.
   ii. Dopo aver rimosso il sigillante HS III caricato dal dispositivo di caricamento, ispezionare il sigillante HS III caricato, secondo le sezioni 4.3-4.5 delle istruzioni per l'uso, per confermare quanto segue:
      1. Il sigillante HS III caricato non è incrinato.
      2. La parte del sigillante HS III che non viene caricata nel tubo del dispositivo di erogazione non si allarga oltre il diametro del tubo del dispositivo di erogazione.
      3. Le estremità della molla elastica sono allineate in modo tale da entrare in contatto con entrambi i bordi prossimali del sigillante HS III caricato durante l'erogazione del sigillante nell'aortotomia.

b. Come evitare/ridurre al minimo il verificarsi di questo guasto:
   i. Dopo la conferma del caricamento del sigillante HS III e la creazione dell'aortotomia, dispiegare il sigillante HS III caricato nell'aortotomia seguendo attentamente i passaggi per il dispiegamento del sigillante HS III documentati nelle istruzioni per l'uso del dispositivo.
   ii. Se il sigillante HS III non si dispiega come previsto, il dispositivo deve essere sostituito.

c. Azione da intraprendere se il sigillante HS III non riesce a dispiegarsi correttamente nell'aorta.
   i. Occludere l'aortotomia per controllare il sanguinamento utilizzando un dito indice.
   ii. Aprire un secondo sigillante HS III. Caricare il sigillante HS III secondo le istruzioni per l'uso del dispositivo. Erogare il sigillante HS III caricato nell'aortotomia e seguire le istruzioni per l'uso per completare l'anastomosi.

iii. Se l'erogazione del secondo sigillante HS III nell'aortotomia non ha esito positivo, o se la preferenza del chirurgo determina che la situazione non consente l'uso di un sigillante HS III sostitutivo, posizionare una pinza di occlusione parziale sull'aorta, isolando l'aortotomia, ed eseguire l'anastomosi secondo la tecnica chirurgica tradizionale.

3. **Mancata anastomosi del sigillante Heartstring III dispiegato:**
    a. Come evitare/ridurre al minimo il verificarsi di questo guasto:
        i. Caricare sempre e ispezionare attentamente il sigillante HS III caricato per confermare il corretto caricamento del sigillante HS III nel dispositivo di erogazione prima di eliminare qualsiasi tonaca avventizia dell'aorta e creare l'aortotomia. (Vedere i promemoria importanti sopra).
        ii. Non utilizzare il Sistema sigillante emostatico prossimale Heartstring in pazienti con aorta a parete sottile.
        iii. Quando si esegue un'anastomosi multipla, assicurarsi che tutti i siti anastomotici siano distanti almeno 1,5 cm per garantire l'emostasi.
        iv. Non immergere il Sistema sigillante HS III nella soluzione prima del dispiegamento.
    b. Azione da intraprendere se il sigillante HS III non si apre/non fornisce un'adeguata emostasi dopo il dispiegamento del sigillante.
        i. Coprire l'aortotomia con un dito indice e regolare delicatamente la molla elastica per assicurarsi che il sigillante HS III sia stata completamente dispiegato.
        ii. Se persiste la mancanza di emostasi adeguata:
            1. Rimuovere il sigillante HS III dispiegato dall'aortotomia secondo le istruzioni dell'uso del dispositivo.
            2. Caricare un secondo sigillante HS III e dispiegare il sigillante caricato nell'aortotomia secondo le istruzioni dell'uso del dispositivo e completare l'anastomosi.
            3. Se il secondo sigillante HS III non ha esito positivo, o se la preferenza del chirurgo determina che la situazione non consente l'uso di un sigillante HS III sostitutivo, posizionare una pinza di occlusione parziale sull'aorta, isolando l'aortotomia, ed eseguire l'anastomosi secondo la tecnica chirurgica tradizionale.

Azioni del cliente

Getinge richiede di intraprendere le seguenti azioni:

1. Assicurarsi che questo messaggio venga inoltrato a tutti i soggetti che necessitano di una notifica all'interno della vostra organizzazione o di qualsiasi organizzazione in cui sono stati trasferiti i dispositivi interessati.

Informazioni aggiuntive

Getinge si sta occupando di comunicare queste informazioni alle agenzie di regolamentazione competenti.
Ci scusiamo per gli eventuali disagi. Siamo impegnati nella sicurezza dei pazienti e apprezziamo la vostra pronta attenzione a questo problema. In caso di domande relative a questa comunicazione, vi preghiamo di contattare il rappresentante locale Getinge o inviare un'e-mail a FSCA.italy@getinge.com .

Cordiali saluti, *

Francisco Vicenty
Director, Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

*Traduzione di cortesia dall'originale in lingua inglese che costituisce il documento ufficiale di Maquet Cardiovascular, LLC

Japan (ja)

August 2025

注意喚起文書
ハートストリング Ⅲ
参照番号: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	ハートストリング Ⅲ	滅菌有効期間中のすべての製品
出荷期間:		2024年7月 1日～ 現在	
製造期間:		2024年3月7日～ 現在	

医療機関ご担当者様

このたび、Getinge社の子会社であるMaquet Cardiovascular社が、ハートストリング Ⅲに関する緊急医療機器是正措置を発出することをお知らせいたします。弊社の記録によると、貴施設に本通知の対象となる製品が一つ以上納入されております。

問題の内容

主に以下の3つの不具合パターンが確認されています。

1. **シールの装填失敗**：この不具合は、ローディングデバイスを用いた4段階の装填プロセス、シールの装填完了後の目視での確認、および装填完了後にデリバリーデバイスの安全ロックを解除する段階で発生するすべての不具合に該当します。

2. **シールの大動脈切開部内への展開失敗**：この不具合は、デリバリーデバイスの安全ロック解除後から、シールが完全に大動脈切開部内へ展開され、プロキシマルシールがデリバリーデバイスから出るまでの間に発生するシールまたはデリバリーデバイスのすべての不具合に該当します。

3. **展開されたシールによる止血不良**：この不具合は、正常に展開されたシールが、テンションスプリングを適切に調整を行った後、あるいはブロワーミスター、吸引器、または生理食塩水を使用して吻合部を洗浄しても、十分な止血が得られず、外科医が吻合を行えない状況を指します。この不具合には、展開後に大動脈内でシールに欠陥または損傷が認められ、その結果、またはその可能性により、外科医が不良品のシールを取り除かない限り吻合を完了できないケースも含まれます。

健康へのリスク

1. **シールの装填失敗**：添付文書に従って使用された場合、シールの装填失敗は患者に直接的なリスクをもたらすものではありません。しかしながら、この不具合は手術の遅延を引き起こす可能性があります。この遅延は、新しいシールを準備し再装填す

るまでの数分程度となる場合もあれば、シール自体の使用を中止し、大動脈クランプによる処置への変更を要する可能性に至る場合もあります。

2. **シールの大動脈切開部内への展開失敗**：装填されたシールがデリバリーデバイスから展開されない場合、すでに以下の手順が行われている場合は、患者への有害事象のリスクを高める可能性があります。
   - 大動脈切開部が作成されている。
   - デリバリーデバイスのチューブ先端が大動脈切開部内に挿入されている。
   - デリバリーデバイスのプランジャーが押し下げられた、または押下げが試みられている。
   - 装填されたシールが、チューブ先端から正常に展開されていない。
   - デリバリーデバイスを切開部から引き抜く際、シールが展開されず、切開部からの出血を指で押さえて止血する必要がある。

想定される患者への有害事象：

- **手術の遅延**：未展開のシールを取り除き、新しいシールを開封・装填・挿入（追加処置を伴わない遅延）する場合と、シールの展開失敗により大動脈クランプによる吻合へ手技を変更する（追加処置を伴う遅延）場合があります。
- **組織損傷**：先端が広がった状態で展開されるシールが原因で発生することがあります。広がった先端は、デリバリーデバイスチューブの直径よりも大きく、無理に展開すると大動脈切開部の組織を損傷する可能性があり、強い力を加えた場合には大動脈後壁を損傷するリスクもあります。また、デリバリーデバイスの取り出し、同一切開部への再挿入、あるいは大動脈クランプへの切り替えにおいても組織損傷が発生する可能性があります。
- **出血**：デリバリーデバイス取り出し時の最小限の出血、手動による止血、代替シール挿入時の出血が含まれます。組織損傷が発生した場合は、追加の処置を要するような多量の出血が発生する可能性があります。
- **塞栓事象**：シール装填失敗に対応するために大動脈を過度に操作することで、塞栓イベントのリスクが生じる可能性があります。

3. **展開されたシールによる止血不良**：展開されたシールが外科医による中枢吻合を可能とする十分な止血を達成できない際に、すでに以下の手順が完了している場合、これが患者への有害事象のリスクを高める可能性があります。
   - 大動脈切開部が作成されている。
   - 装填されたシールが大動脈内に展開されている。
   - 外科医により、出血量が吻合の実施に適さないと判断されている。

想定される患者への有害事象：

- **手術の遅延**：以下のような状況で発生する可能性があります。
  - 出血の改善を図るため、展開済みのシールに調整を加える、欠陥のあるシールを取り除く、新しいシールを開封・装填し、作成済みの大動脈切開部内に再挿入するために追加の手術時間が必要となる場合（追加処置を伴わない遅延）。
  - 展開されたシールでは吻合に十分な止血が得られないと判断され、代替となるシールが使用できない場合、または外科医の判断により再使用が不適切とされた場合に、大動脈クランプを用いて従来の方法で中枢吻合を完了するための処置が選択される場合（追加処置を伴う遅延）。
- **組織損傷**：同一の大動脈切開部内への2つ目のシールの展開時、または大動脈クランプ使用への切り替え時に発生する可能性があります。

- **出血：**シールを用いた中枢吻合中に展開済みシールの周囲から少量の出血が見られるのは正常かつ予想される現象ですが、大動脈組織の損傷が原因で、より多量の出血が生じ、追加の処置が必要となる場合があります。
- **塞栓性事象：**シールによる止血不良に対処するため、大動脈への追加操作を行った結果として、塞栓イベントが発生する可能性があります。

2023年6月1日から2025年7月22日までの間に、Getinge社は以下の苦情を受領しました：

- **装填失敗に関する報告：274件（発生率：0.386%）**
- **展開失敗に関する報告：96件（発生率：0.135%）**
- **止血不良に関する報告：30件（発生率：0.042%）**

<u>推奨される対策および対応措置</u>

Getinge社は、以下の指示に従うことで、上述の不具合を回避または最小限に抑えることを推奨しています。

1. シールの装填失敗

a. 重要な注意事項：

i.添付文書に従い、シールはローディングデバイスに装填・取り外された後、必要に応じて目視で検査・調整を行い、装填が成功したことを確認した上で安全ロックの解除を行います。これは、吻合予定部位の外膜を除去したり大動脈切開を行う前に完了させてください。シールの装填を先に完了させることで、大動脈への不必要な操作を避け、患者へのリスクを最小限に抑えることができます。

ii.シールが正常に装填されない場合は、デバイスを交換してください。

b. この不具合の回避／最小化方法：

i.デバイスを日常的に使用していない場合は特に、使用前に添付文書を確認してください。

ii. 添付文書に記載された手順に従って慎重にシールを装填してください。

iii. 添付文書の【使用方法等】に従い、デリバリーデバイスに装填後にローディングデバイスから取り外したシールを目視検査し、正しく装填されていることを確認してください。

iv. ローディングデバイスから取り外した後に検査されていないシールは、展開時に失敗し、患者への危害をもたらす可能性があります（展開失敗に関する情報を参照）。

v. 大動脈表面の外膜除去および大動脈切開の前に、必ず装填が正常に完了していることを確認してください。

c. 装填に失敗した場合の対応：

i. 不良品は廃棄してください。

ii. 常に代替用のシールを準備しておき、添付文書に従って正しく装填してください。

2.シールの大動脈切開部内への展開失敗

a. 重要な注意事項：

i. 上述のとおり、シールが正しくデリバリーデバイスに装填されていることを確認してください。

ii. ローディングデバイスから取り外した後、以下を確認するために添付文書の【使用方法等】に従って装填済みシールを検査してください。

1. シールに亀裂がないこと
2. デリバリーデバイスチューブに装填されていない部分のシールが、チューブ径より広がっていないこと

3. テンションスプリングのクリンプ部がシールの両端に接触するよう装填されていること

b. この不具合の回避／最小化方法：

i. シール装填完了と大動脈切開後に、添付文書に記載された手順に従って、シールを大動脈切開部内に展開してください。

ii. 正常に展開されない場合は、デバイスを交換してください。

c. 展開失敗時の対応：

i. 出血を防ぐため、切開部を人差し指で押さえてください。

ii. 代替のシールを開封・装填し、添付文書に従って大動脈切開部内に展開し、吻合を完了してください。

iii. 2つ目のシールも展開が失敗する、または外科医の判断で代替シールの使用が適さないとされる場合は、大動脈を部分的に遮断するクランプを使用し、従来の外科技術で吻合を実施してください。

3. 展開されたシールによる止血不良

a. この不具合の回避／最小化方法：

i. 外膜除去や大動脈切開の前に、必ずシールを装填し、デリバリーデバイスへの正しい装填が完了していることを目視で確認してください。

ii. 壁の薄い大動脈を有する患者には本デバイスを使用しないでください。

iii. 複数の吻合を行う場合、各吻合部位の間隔は1.5cm以上確保してください。

iv.シールを展開前に溶液に浸さないでください。

b. 展開後に止血が得られない場合の対応：

i. 切開部を人差し指で覆い、テンションスプリングを適切に調整してシールが完全に展開されているかを確認してください。

ii. 止血不良が継続する場合：

1. 添付文書従って、展開済みシールを大動脈から取り外してください。
2. 新しいシールを装填・展開し、添付文書従って吻合を完了してください。
3. 2つ目のシールでも効果がない、または外科医の判断により代替シールが使用できないとされる場合、大動脈に部分遮断クランプを用いて切開部を分離し、従来の方法で吻合を行ってください。

<u>お客様へのお願い</u>

Getinge社より、以下の対応をお願いいたします：

本通知が、貴医療機関内において本件の周知が必要な関係者、または対象デバイスを使用される可能性のある医療従事者の方にも確実に共有されるようお願いいたします。

<u>追加情報</u>

Getinge社は、本件に関する情報を所管の規制当局にも報告しております。

このたびはご不便をおかけしますことをお詫び申し上げます。当社は患者の安全を最優先に考えており、本件について迅速にご対応いただけますようお願い申し上げます。

本件に関してご質問がございましたら、担当のゲティンゲグループ・ジャパン営業担当者または信頼性保証部市販後安全管理部（03-5781-3844）までご連絡ください。

敬具

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim

Getinge, Cardiovascular Surgery

Kenya (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.
Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)

- Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)

- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

b. Action to be taken if the HS III Seal fails to load.
   i. Discard the failed HS III Seal.
   ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
   i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
   ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
      1. The loaded HS III Seal is not cracked.
      2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
      3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion

clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Montenegro (hr)

kolovoz 2025.

Sigurnosno upozorenje u terenu

Proksimalni sustav zatvaranja Heartstring III

Referentni broj: 1336551

Broj modela	UDI	Naziv modela	Serijski broj/serija
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proksimalni sustav zatvaranja Heartstring III	Sve serije kojima nije istekao rok trajanja
Datum distribucije:		od 1. srpnja 2024. do danas	
Datum proizvodnje:		od 7. ožujka 2024. do danas	

Poštovani menadžeru za rizike,

svrha ovog pisma je izvijestiti Vas da društvo Maquet Cardiovascular, društvo-kćer društva Getinge, izdaje hitni popravak medicinskog proizvoda Proksimalni sustav zatvaranja Heartstring III (zatvarač HS III). Prema našoj evidenciji ste zaprimili jedan ili više predmetnih medicinskih proizvoda, kojih se tiče ova obavijest.

Opis problema

Identificirana su tri primarna razloga neuspjeha.

1. **Pogreška tijekom uvođenja zatvarača:** ovaj problem se tiče bilo kojeg kvara uređaja, do kojeg dođe tijekom nekog od četiri koraka postupka uvođenja pomoću aplikacijskog uređaja Heartstring, vizualne kontrole uspješno uvedenog zatvarača HS III, te oslobađanja aplikacijskog uređaja nakon uspješnog završetka svih koraka uvođenja zatvarača HS III.
2. **Pogreška tijekom razvijanja zatvarača Heartstring u aortotomiji**: ovaj problem se odnosi na bilo koji kvar zatvarača HS III i/ili aplikacijskog uređaja od trenutka kada je aplikacijski uređaj uspješno oslobođen do trenutka kada je zatvarač HS III u cijelosti postavljen u aortotomiju i svi dijelovi proksimalnog zatvarača (vlakno, zatezna opruga, tijelo zatvarača, prihvatna omča) su uklonjeni iz aplikacijskog uređaja.
3. **Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:** ovaj problem se tiče bilo kojeg kvara uspješno razvijenog zatvarača HS III, koji na mjestu anastomoze ne osigurava adekvatnu kontrolu krvarenja za izvođenje šivenja anastomoze, i to unatoč finom podešavanju zatezne opruge nakon razvijanja zatvarača i/ili uporabe ventilatorske prskalice, usisavanja ili šprice s fiziološkom otopinom za čišćenje mjesta anastomoze. Ovaj kvar obuhvaća i slučaj kada klijent identificira neispravan ili oštećen zatvarač HS III nakon uspješnog razvijanja zatvarača HS III u aortu, ako kvar ima/može imati za posljedicu nedostatnu hemostazu, koja onemogućava da kirurg završi anastomozu bez uklanjanja neispravnog zatvarača HS III.

Trenutno se provodi istraga glavnog uzroka.

Zdravstveni rizici:

1. **Pogreška tijekom uvođenja:** ako se zatvarač HS III upotrebljava sukladno Uputama za uporabu (IFU) proizvoda, pogreška pri uvođenju za pacijenta nije izravan rizik. Međutim, ova pogreška može dovesti do zakašnjenja kirurškog zahvata. Isto kašnjenje može trajati od nekoliko minuti koje su potrebne za vađenje i uvođenje novog zatvarača, sve do potencijalnog prijelaza s korištenja zatvarača HS III na izvođenje proksimalne anastomoze pomoću aortalne kleme radi dovršavanja zahvata.
2. **Pogreška tijekom razvijanja:** ako ne uspijeva razvijanje uvedenog zatvarača HS III iz aplikacijskog uređaja, već su izvedeni slijedni koraci postupka, a isti mogu doprinijeti potencijalnom riziku oštećenja zdravlja pacijenta. Ako se zatvarač HS III ne uspijeva razviti iz aplikacijskog uređaja, izvesti će se nekoliko postupaka koji mogu povećati potencijalni rizik oštećenja zdravlja pacijenta.
   - Izvedena je aortotomija.
   - Distalni kraj cijevi aplikacijskog uređaja je uveden kroz aortotomiju.
   - Klip aplikacijskog uređaja je pritisnut ili je izveden pokušaj njegovog pritiskanja.
   - Nije uspjelo razvijanje umetnutog zatvarača HS III s distalnog kraja cijevi aplikacijskog uređaja.
   - Nakon vađenja aplikacijskog uređaja iz aortotomije se zatvarač HS III ne razvija, te se krvarenje iz aortotomije mora zaustaviti postavljanjem prsta na aortotomiju.

   Mogu nastati sljedeća oštećenja zdravlja pacijenta:

   - **Zakašnjenje kirurškog zahvata**: uklanjanje nerazvijenog zatvarača HS III, otvaranje novog proksimalnog zatvarača HS III, umetanje zatvarača u aplikacijski uređaj te uvođenje umetnutog zatvarača HS III u izvedenu aortotomiju (zakašnjenje bez drugog zahvata) naspram odluke o primjeni aortalne kleme za dovršavanje anastomoze, pošto nije uspjelo razvijanje uvedenog zatvarača (zakašnjenje s drugim zahvatom).
   - **Oštećenje tkiva**: do oštećenja tkiva može doći uslijed razvijanja uvedenog zatvarača HS III, koji je proširen na vrhu. Proširen vrh može imati veći promjer od distalne cijevi aplikacijskog uređaja. Razvijanje uvedenog zatvarača s proširenim vrhom može prouzročiti oštećenje tkiva u oblasti aortotomije, a u slučaju primjene veće sile za razvijanje predmetnog zatvarača pri uvođenju, postoji rizik ozljede zadnjeg zida aorte. Do oštećenja tkiva može doći i tijekom uklanjanja aplikacijskog uređaja iz aortotomije, razvijanja drugog uvedenog zatvarača HS III u istu aortotomiju i/ili neophodnosti primjene aortalne kleme za dovršavanje aortotomije.
   - **Krvarenje:** do minimalnog gubitka krvi može doći tijekom uklanjanja aplikacijskog uređaja iz aortotomije, pri ručnom upravljanju krvarenjem iz aortotomije te aplikacije naknadnog zatvarača HS III. Veći gubitak krvi, koji bi zahtijevao dodatnu intervenciju, može nastati u slučaju oštećenja tkiva.
   - **Embolijski događaj** uslijed dodatne manipulacije aortom pri rješavanju pogreške pri uvođenju zatvarača HS III.
3. **Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:** u slučaju da razvijen zatvarač HS III ne daje dostatnu hemostazu za to da kirurg može dovršiti proksimalnu anastomozu, već su dovršeni određeni koraci u svezi primjene sustava zatvaranja HS III, što može povećati potencijalan rizik oštećenja zdravlja pacijenta. U istom trenutku će već biti izvedeni sljedeći koraci:
   - Izvedena je aortotomija.
   - Uveden zatvarač HS III je razvijen u aorti.
   - Kirurg smatra da je krvarenje iz aorte prejako za izvođenje anastomoze.

- **Zakašnjenje kirurškog zahvata**: do toga može doći na sljedeći način:
    - Dodatno operativno vrijeme potrebno za pokušaj uređenja zatvarača radi poboljšanja hemostaze pomoću uvedenog zatvarača HS III, uklanjanje neispravnog zatvarača HS III, otvaranje novog zatvarača HS III, umetanje naknadnog zatvarača HS III i uvođenje pripremljenog zatvarača HS III u izvedenu aortotomiju (zakašnjenje zahvata bez drugog zahvata).
    - Kirurg smatra da je za dovršavanje anastomoze najprikladnija uporaba aortalne kleme, pošto razvijen zatvarač HS III ne daje dostatnu hemostazu za dovršavanje anastomoze te ili nije na raspolaganju naknadni zatvarač HS III, ili kirurg donosi odluku da situacija ne omogućava primjenu naknadnog zatvarača HS III te upotrebljava aortalnu klemu za dovršavanje proksimalne anastomoze tradicionalnom kirurškom tehnikom (zakašnjenje zahvata s drugim zahvatom).
- **Oštećenje tkiva**: do oštećenja tkiva može doći pri manipulaciji predmetnim zatvaračem HS III, tijekom razvijanja drugog uvedenog zatvarača HS III u istu aortotomiju i/ili u slučaju kada treba prijeći na primjenu aortalne kleme radi dovršavanja aortotomije.
- **Krvarenje:** mali gubitak krvi u okolici razvijenog zatvarača HS III je normalan te se pri izvođenju proksimalne anastomoze primjenom zatvarača HS III može očekivati. Do većeg gubitka krvi, koji bi zahtijevao dodatnu intervenciju, može doći pri oštećenju tkiva, bez obzira na uzrok oštećenja.
- **Embolijski događaj:** nastaje dodatnom manipulacijom aortom pri rješavanju pogreške, kada zatvarač HS III ne daje dostatnu hemostazu.

Od 1. lipnja 2023. do 22. srpnja 2025. je društvo Getinge zaprimilo sljedeće prigovore:

- 274 dojava u svezi pogreške pri uvođenju, što predstavlja količinu prigovora od 0,386 %
- 96 dojava u svezi pogreške pri razvijanju, što predstavlja količinu prigovora od 0,135 %
- 30 dojava u svezi nedostatne hemostaze, što predstavlja količinu prigovora od 0,042 %

<u>Preporučene ublažavajuće mjere i koraci:</u>

Društvo Getinge daje sljedeće upute za izbjegavanje/minimalizaciju gore opisanih pogrešaka.

1. **Pogreška tijekom uvođenja zatvarača Heartstring**
    a. Važne napomene:
        i. U Uputama za uporabu proizvoda se navodi da zatvarač HS III treba biti uveden i izvađen iz aplikacijskog uređaja, nakon toga provjeren, te po potrebi modificiran radi potvrđivanja uspješnog uvođenja, a nakon toga treba biti oslobođen prije uklanjanja adventicije s mjesta planirane anastomoze i izvođenja aortotomije. Uvođenje zatvarača HS III i potvrda uspješnog uvođenja prije izvođenja aortotomije minimalizira rizike za pacijenta, pošto aorta ostaje netaknuta dok se ne potvrdi uspješno uvođenje zatvarača HS III.
        ii. Ako planirano uvođenje zatvarača HS III ne uspije, proizvod bi trebalo zamijeniti.
    b. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:
        i. Prije uporabe pročitajte Upute za uporabu proizvoda Heartstring, prije svega ako Heartstring ne koristite redovito.
        ii. Pri uvođenju zatvarača HS III postupajte oprezno i poštujte postupno sve korake navedene u Uputama za uporabu (IFU).
        iii. Prema uputama u članku 4.3-4.5 Uputa za uporabu provjerite je li zatvarač HS III ispravno umetnut u aplikacijski uređaj tako što ćete provjeriti umetnut zatvarač HS III nakon njegovog umetanja u aplikacijski uređaj i vađenja iz aplikacijskog uređaja.

iii. Zatvarač HS III, koji nakon vađenja iz aplikacijskog uređaja nije uredno provjeren, može tijekom razvijanja zatajiti te prouzročiti ozljedu pacijenta (vidjeti informacije u svezi Pogreške pri razvijanju).
iv. Dovršite uspješno uvođenje zatvarača HS III prije čišćenja površine adventicije, površine aorte i izvođenja aortotomije.

c. Mjere koje treba primijeniti u slučaju neuspjeha pri uvođenju zatvarača HS:
i. Zatvarač HS III, čije uvođenje nije uspjelo, uništite.
ii. Uvijek imajte u pripravnosti drugi zatvarač HS III, kojim ćete zamijeniti neispravan uređaj. Radi uspješnog uvođenja poštujte Upute za uporabu.

2. Pogreška tijekom razvijanja zatvarača Heartstring u aortotomiju

a. Važne napomene:
i. Uvjerite se da je zatvarač HS III ispravno umetnut u aplikacijski uređaj, kako je navedeno u prethodnom stavku.
ii. Nakon vađenja umetnutog zatvarača HS III iz aplikacijskog uređaja provjerite umetnut zatvarač HS III prema Uputama za uporabu, dio 4.3.-4.5, kako biste potvrdili da:
1. Umetnut zatvarač HS III nije ispucan.
2. Dio zatvarača HS III, koji nije umetnut u cijev aplikacijskog uređaja, nije širi od promjera cijevi aplikacijskog uređaja.
3. Uvjerite se da su krajevi zatezne opruge poravnani tako da tijekom uvođenja zatvarača HS III u aortotomiju dodiruju obadva njegova proksimalna kraja.

b. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:
i. Čim potvrdite uspješno uvođenje zatvarača HS III i izvođenje aortotomije, razvijte uveden zatvarač HS III u aortotomiju. Precizno poštujte postupak razvijanja zatvarača HS III, koji je opisan u Uputama za uporabu.
ii. Ako se zatvarač HS III ne razvije prema očekivanju, proizvod treba zamijeniti.

c. Mjere koje treba primijeniti u slučaju neuspjeha pri razvijanju zatvarača HS III u aortu:
i. Kažiprstom zatvorite aortotomiju, kako biste zaustavili krvarenje.
ii. Otvorite drugi zatvarač HS III. Umetnite isti zatvarač prema instrukcijama u Uputama za uporabu. Uvedite umetnut zatvarač HS III u aortotomiju te za dovršetak anastomoze poštujte postupak iz Uputa za uporabu.
iii. Ako uvođenje drugog zatvarača HS III u aortotomiju nije uspješno, ili ako kirurg donese odluku da situacija ne dopušta uporabu naknadnog zatvarača HS III, na aortu postavite djelomičnu okluzivnu klemu, čime ćete izolirati aortotomiju, te izvedite anastomozu tradicionalnom kirurškom tehnikom.

3. Razvijen zatvarač Heartstring ne daje dostatnu hemostazu:

a. Kako izbjeći ovu pogrešku / minimalizirati njezinu pojavu:
i. Pri uvođenju zatvarača HS III pažljivo izvedite kontrolu, isto kao i nakon njegovog uvođenja, kako biste potvrdili uspješno uvođenje zatvarača HS III u aplikacijski uređaj prije čišćenja adventicije aorte i izvođenja aortotomije (vidjeti prethodne važne napomene).
ii. Ne upotrebljavajte Proksimalni sustav zatvaranja Heartstring kod pacijenata s aortom koja ima tanke zidove.
iii. Pri izvođenju višestrukih anastomoza se uvjerite da su sva mjesta anastomoze međusobno udaljena najmanje 1,5 cm, kako bi se osigurala hemostaza.
iv. Prije razvijanja ne potapajte zatvarač HS III u otopinu.

b. Mjere koje treba primijeniti u slučaju da se zatvarač HS III ne otvori / ne daje dostatnu hemostazu nakon razvijanja.

i. Kažiprstom zatvorite aortotomiju te oprezno podesite zateznu oprugu kako biste se uvjerili da je zatvarač HS III u cijelosti razvijen.
ii. Ako nedostatna hemostaza i dalje traje:
    1. Izvadite razvijen zatvarač HS III iz aortotomije prema instrukcijama u Uputama za uporabu.
    2. Uvedite drugi zatvarač HS III te razvijte uveden zatvarač u aortotomiji prema instrukcijama u Uputama za uporabu i dovršite anastomozu.
    3. Ako drugi zatvarač HS III nije uspješan , ili ako kirurg donese odluku da situacija ne dopušta uporabu naknadnog zatvarača HS III, na aortu postavite djelomičnu okluzivnu klemu, čime ćete izolirati aortotomiju, te izvedite anastomozu tradicionalnom kirurškom tehnikom.

Mjere od strane klijenta

Društvo Getinge od Vas traži sljedeće mjere:

1. Osigurajte dostavu ove poruke svim pojedincima koji trebaju ovo upozorenje u okviru Vaše institucije ili druge institucije kojoj su predmetni uređaji predani.

Dodatne informacije

Društvo Getinge priopćava ove informacije nadležnim regulatornim tijelima.

Ispričavamo se za bilo kakve neprijatnosti koje Vam po ovom pitanju mogu nastati. Stalo nam je do sigurnosti pacijenata i cijenimo Vašu brzu reakciju na ovu situaciju. Ako imate bilo kakve nedoumice u svezi ove poruke, obratite se svom predstavniku društva Getinge ili službi za klijente Getinge na broju 1-888-880-2874, od ponedjeljka do petka između 8:00 i 17:00 (pacifička vremenska zona).

S pozdravom,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Morocco (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.
Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)

- Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)

- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

b. Action to be taken if the HS III Seal fails to load.
    i. Discard the failed HS III Seal.
    ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:
    i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.
    ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
        1. The loaded HS III Seal is not cracked.
        2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
        3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:
    i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
    ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
    i. Occlude the aortotomy to control bleeding using an index finger.
    ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
    iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
    i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
    ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
    iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
    iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
    i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
    ii. If lack of adequate hemostasis persists:
        1. Remove the deployed HS III Seal from the aortotomy per device IFU.
        2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
        3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion

clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Netherlands (nl)

Augustus 2025

Veiligheidsbericht in het veld
Heartstring III Proximaal Sealsysteem
Referentienummer: 1336551

Modelnummer	UDI	Modelnaam	Serie-/lotnummers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximaal Sealsysteem	Alle niet-verlopen kavels
Distributiedata:		1 juli 2024 - heden	
Productiedata:		7 maart 2024 - heden	

Geachte risicomanager,

Met deze brief willen we u informeren dat Maquet Cardiovascular, een dochteronderneming van Getinge, een dringende medische correctie uitvaardigt voor het Heartstring III Proximal Seal System (HS III Seal).Volgens onze gegevens hebt u een of meer van de apparaten ontvangen waarop deze melding betrekking heeft.

Probleembeschrijving

Er zijn drie primaire faalwijzen geïdentificeerd.

1. **Falen van de Heartstring Seal om te laden**: Deze fout is van toepassing op elke storing van het apparaat die optreedt tijdens het vierstappen-laadproces met behulp van het Heartstring-laadapparaat, de visuele inspectie van een succesvol geladen HS III-zegel en het ontgrendelen van het afgifteapparaat na succesvolle voltooiing van hetStappen voor het laden van HS III-afdichtingen.
2. **Het mislukken van de Heartstring Seal**in de aortotomie: Deze storing is van toepassing op elke storing van de HS III-afdichting en/of het afgiftehulpmiddel vanaf het moment dat het afgiftehulpmiddel succesvol is ontgrendeld tot het moment dat de HS III-afdichting volledig in de aortotomie is geplaatst en alle inhoud van de proximale afdichting (de riem, de spanveer, de afdichtingssteel en het ankerlipje) uit het afgiftehulpmiddel zijn gekomen.
3. **Het falen van de geplaatste Heartstring Seal om voor voldoende hemostase te zorgen:**Tzijn falen geldt voor iedereenEen storing van een succesvol geplaatste HS III-afdichting die de bloeding bij de anastomose niet voldoende onder controle houdt, waardoor de chirurg de anastomose niet kan hechten, ondanks een voorzichtige aanpassing van de spanveer na plaatsing van de afdichting en/of het gebruik van een blaasvernevelaar, zuigpomp of zoutoplossingspuit om de anastomose vrij te maken. Deze storing omvat de identificatie door de klant van een defecte of beschadigde HS III-afdichting na succesvolle plaatsing van de afdichting.HS IIIAfsluiting van de aorta die resulteert/kan resulteren in onvoldoende hemostase waardoor de chirurg de anastomose niet kan voltooien zonder de defecte HS III-afdichting te verwijderen.

Momenteel wordt er onderzoek gedaan naar de oorzaak.

Risico's voor de gezondheid

1. **Laden mislukt:**Bij gebruik volgens de gebruiksaanwijzing (IFU) van het apparaat vormt een HS III Seal die niet goed laadt geen direct risico voor de patiënt. Een dergelijke storing kan echter wel leiden tot vertraging van de chirurgische ingreep. Deze vertraging kan variëren van enkele minuten voor het ophalen en laden van een nieuwe Seal tot een mogelijke overstap van de HS III Seal voor het aanbrengen van de proximale anastomose naar het gebruik van een aortaklem om de ingreep te voltooien.
2. **Mislukte implementatie:**Wanneer de geladen HS III Seal niet uit het plaatsingshulpmiddel kan worden geplaatst, zijn de volgende procedurestappen al uitgevoerd en kunnen deze bijdragen aan het potentiële risico op letsel bij de patiënt. Als de geladen HS III Seal niet uit het plaatsingshulpmiddel kan worden geplaatst, zijn er al verschillende procedurestappen uitgevoerd, wat het potentiële risico op letsel bij de patiënt kan vergroten.
    - De aortotomie is aangelegd.
    - Het distale uiteinde van de toedieningsbuis is via de aortotomie ingebracht.
    - De zuiger van het toedieningshulpmiddel is ingedrukt, of er is een poging gedaan om deze in te drukken.
    - De geladen HS III-afdichting is niet succesvol geplaatst vanaf het distale uiteinde van de toedieningsbuis.
    - Wanneer het toedieningshulpmiddel uit de aortotomie wordt verwijderd, wordt de HS III-afdichting niet geplaatst en moet bloeding uit de aortotomie worden gestopt door een vinger op de aortotomie te plaatsen.

    De volgende mogelijke schade kan voor de patiënt optreden:

    - **Vertraging van de chirurgische ingreep**: om de niet-geplaatste HS III-afdichting te verwijderen, een nieuwe HS III-proximale afdichting te openen, de afdichting in het plaatsingsapparaat te laden en de geladen HS III-afdichting in de gecreëerde aortotomie te plaatsen (vertraging zonder aanvullende interventie) versus de beslissing om een aortaklem te gebruiken om de anastomose te voltooien omdat de geladen afdichting niet kon worden geplaatst (vertraging met een aanvullende interventie)
    - **Weefselschade**: kan optreden als gevolg van het plaatsen van een geladen HS III-afdichting met een uitlopende punt. Een uitlopende punt heeft een diameter die groter is dan de distale buis van het toedieningshulpmiddel. Het plaatsen van een geladen afdichting met een uitlopende punt kan schade aan het aortotomieweefsel veroorzaken en als er meer kracht wordt gebruikt om de aangetaste afdichting te plaatsen, bestaat er een potentieel risico op terugslag in de aorta tijdens het inbrengen. Weefselschade kan ook optreden tijdens het verwijderen van het toedieningshulpmiddel uit de aortotomie, het plaatsen van een tweede geladen HS III-afdichting in dezelfde aortotomie en/of de noodzaak om over te stappen op het gebruik van een aortaklem om de aortotomie te voltooien.
    - **Bloeden:** Er kan minimaal bloedverlies optreden bij het verwijderen van het toedieningshulpmiddel uit de aortotomie, het handmatig onder controle houden van de bloeding uit de aortotomie en het plaatsen van een vervangende HS III-afdichting. Er kan meer bloedverlies optreden, waarvoor aanvullende interventie nodig is, indien er weefselschade optreedt.
    - **Embolische gebeurtenis**als gevolg van extra manipulatie van de aorta om het falen van de HS III-afdichtingslading aan te pakken.
3. **Het falen van de geplaatste Heartstring Seal om voor voldoende hemostase te zorgen:**Wanneer een geplaatste HS III Seal niet voldoende hemostase biedt voor de chirurg om de proximale anastomose te voltooien, zijn verschillende stappen van het HS III Seal-systeem al uitgevoerd en kan dit het potentiële risico op letsel voor de patiënt vergroten. De volgende procedurestappen hebben plaatsgevonden.
    - De aortotomie is aangelegd.
    - De geladen HS III Seal is in de aorta geplaatst.

- De chirurg is van mening dat de bloeding uit de aorta te ernstig is om een anastomose aan te brengen.

De volgende mogelijke schade kan voor de patiënt optreden:

- **Vertraging van de chirurgische ingreep**: kan als volgt optreden:
    - AExtra operatietijd die nodig is om de afdichting aan te passen om de hemostase te verbeteren door de geplaatste HS III-afdichting, de defecte HS III-afdichting te verwijderen, een nieuwe HS III-afdichting te openen, de vervangende HS III-afdichting te laden en de geladen HS III-afdichting in de gecreëerde aortotomie te plaatsen (procedurevertraging zonder extra interventie)
    - De chirurg acht het het meest gepast om een aortaklem te gebruiken om de anastomose te voltooien, omdat de geplaatste HS III-afdichting niet voor voldoende hemostase zorgde om de anastomose te voltooien en een vervangende HS III-afdichting niet beschikbaar is, of omdat de voorkeur van de chirurg bepaalt dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat en een aortaklem wordt gebruikt om de proximale anastomose te voltooien volgens de traditionele chirurgische techniek. (procedurevertraging met een extra ingreep)
- **Weefselschade**:Er kan weefselschade ontstaan tijdens het manipuleren van de aangedane HS III-afdichting, tijdens het plaatsen van een tweede geladen HS III-afdichting in dezelfde aortotomie en/of de noodzaak om over te stappen op het gebruik van een aortaklem om de aortotomie te voltooien.
- **Bloeden:**Een kleine hoeveelheid bloedverlies rond de geplaatste HS III-afdichting is normaal en te verwachten tijdens het plaatsen van de proximale anastomose met een HS III-afdichting. Bij beschadiging van het aortaweefsel kan er meer bloedverlies optreden, wat een aanvullende ingreep vereist, ongeacht de oorzaak.
- **Embolische gebeurtenis(sen):**als gevolg van extra manipulatie van de aorta als gevolg van het onvermogen van de HS III-afdichting om voor voldoende hemostase te zorgen.

Tussen 1 juni 2023 en 22 juli 2025 ontving Getinge de volgende klachten:
• 274 meldingen met betrekking tot het niet laden, wat neerkomt op een klachtenpercentage van 0,386%
• 96 meldingen met betrekking tot het niet ontplooien, wat neerkomt op een klachtenpercentage van 0,135%
• 30 meldingen met betrekking tot onvoldoende hemostase, wat neerkomt op een klachtenpercentage van 0,042%

<u>Aanbevolen maatregelen en acties</u>

Getinge biedt de volgende instructies om de hierboven besproken fouten te voorkomen/minimaliseren.

1. **Falen van de Heartstring Seal om te laden**
    a. Belangrijke herinneringen:

        i. Conform de IFU van het hulpmiddel is de HS III Seal bedoeld om in het laadapparaat te worden geplaatst en daaruit te worden verwijderd, vervolgens te worden geïnspecteerd en indien nodig aangepast om een succesvolle lading te bevestigen, en ten slotte te worden ontgrendeld voordat adventitia uit het geplande anastomosegebied wordt verwijderd en de aortotomie wordt gemaakt. Het laden van de HS III Seal en het bevestigen van een succesvolle lading vóór het maken van de aortotomie minimaliseert het risico voor patiënten, omdat de aorta onaangeroerd blijft totdat een succesvolle lading van de HS III Seal is bevestigd.

        ii. Indien de HS III Seal niet laadt zoals bedoeld, dient het hulpmiddel te worden vervangen.

b. Hoe het optreden van deze storing te voorkomen/minimaliseren
    i. Raadpleeg vóór gebruik de IFU van het Heartstring-hulpmiddel, vooral als Heartstring niet routinematig wordt gebruikt.

    ii. Laad de HS III Seal door de stapsgewijze instructies voor gebruik (IFU) van het hulpmiddel zorgvuldig te volgen.

    iii. Conform sectie 4.3–4.5 van de IFU dient te worden bevestigd dat de HS III Seal correct in het afleveringshulpmiddel is geladen door de geladen HS III Seal te inspecteren nadat deze in het afleveringshulpmiddel is geplaatst en uit het laadapparaat is verwijderd.

    iv. Een HS III Seal die na verwijdering uit het laadapparaat niet correct wordt geïnspecteerd, kan falen tijdens het ontplooien van de HS III Seal en schade aan de patiënt veroorzaken (zie informatie met betrekking tot het niet ontplooien).

    v. Rond het succesvol laden van de HS III Seal af vóór het reinigen van de adventitia van het aortaoppervlak en het creëren van de aortotomie.

c. Te ondernemen actie als de HS III Seal niet laadt.
    i. Gooi de defecte HS III-afdichting weg.
    ii. Houd altijd een tweede HS III-zegel bij de hand om een defect apparaat te vervangen. Raadpleeg de gebruiksaanwijzing van het apparaat om een succesvolle belading te garanderen.

2. Falen van de Heartstring III-afdichting bij het ontplooien in de aortotomie

a. Belangrijke herinneringen:
    i. Zorg ervoor dat de HS III Seal correct in het afleveringshulpmiddel is geladen zoals beschreven in de bovenstaande sectie.
    ii. Inspecteer, na het verwijderen van de geladen HS III Seal uit het laadapparaat, de geladen HS III Seal overeenkomstig IFU-secties 4.3–4.5 om het volgende te bevestigen:
        1. De geladen HS III Seal is niet gebarsten.

        2. Het gedeelte van de HS III Seal dat niet in de buis van het afleveringshulpmiddel is geladen, wijkt niet verder uit dan de diameter van de buis van het afleveringshulpmiddel.
        3. De uiteinden van de spanningsveer zijn zodanig uitgelijnd dat zij tijdens het inbrengen van de Seal in de aortotomie contact zullen maken met beide proximale randen van de geladen HS III Seal.

b. Hoe u dit falen kunt voorkomen/minimaliseren:
    i. Na bevestiging van succesvol laden van de HS III Seal en het creëren van de aortotomie, dient de geladen HS III Seal in de aortotomie te worden ontplooid door de stappen, voor het ontplooien van de HS III Seal zoals vastgelegd in de IFU van het hulpmiddel, zorgvuldig te volgen.

    ii. Indien de HS III Seal niet wordt ontplooid zoals bedoeld, dient het hulpmiddel te worden vervangen.

c. Maatregelen die moeten worden genomen als de HS III-afdichting niet succesvol in de aorta wordt geplaatst.
    i. Sluit de aortotomie af met de wijsvinger om het bloeden te stoppen.
    ii. Open een tweede HS III-afdichting. Laad de HS III-afdichting volgens de gebruiksaanwijzing van het apparaat. Plaats de geladen HS III-afdichting in de aortotomie en volg de gebruiksaanwijzing om de anastomose te voltooien.
    iii. Als het plaatsen van de tweede HS III-afdichting in de aortotomie niet lukt, of als de chirurg oordeelt dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat, plaatst u een gedeeltelijke occlusieklem op de aorta, waardoor de aortotomie wordt geïsoleerd, en voert u de anastomose uit volgens de traditionele chirurgische techniek.

3. Het falen van de geplaatste Heartstring III Seal om voor voldoende hemostase te zorgen:

a. Hoe kan dit falen worden vermeden/geminimaliseerd:
    i. Laad en inspecteer de geladen HS III-afdichting altijd zorgvuldig om zeker te weten dat de HS III-afdichting succesvol in het plaatsingshulpmiddel is geplaatst, voordat u de aorta-adventitia vrijmaakt en de aortotomie uitvoert. (Zie de belangrijke opmerkingen hierboven.)
    ii. Gebruik het Heartstring Proximal Seal System niet bij patiënten met een dunwandige aorta.
    iii. Bij het aanleggen van meervoudige anastomose moet u ervoor zorgen dat alle anastomotische plaatsen minimaal 1,5 cm uit elkaar liggen om hemostase te garanderen.
    iv. Dompel de HS III Seal niet onder in een oplossing voordat u hem inzet.
b. Te nemen maatregelen als de HS III-afdichting niet opengaat of niet voor voldoende hemostase zorgt na plaatsing van de afdichting.
    i. Bedek de aortotomie met een wijsvinger en pas de spanveer voorzichtig aan om ervoor te zorgen dat de HS III-afdichting volledig is ontplooid.
    ii. Indien er sprake blijft van een gebrek aan adequate hemostase:
        1. Verwijder de geplaatste HS III-afdichting van de aortotomie volgens de gebruiksaanwijzing van het apparaat.
        2. Plaats een tweede HS III Seal en plaats de geladen Seal in de aortotomie volgens de gebruiksaanwijzing van het apparaat en voltooi de anastomose.
        3. Als de tweede HS III-afdichting niet succesvol is of als de voorkeur van de chirurg aangeeft dat de situatie het gebruik van een vervangende HS III-afdichting niet toelaat, plaatst u een gedeeltelijke occlusieklem op de aorta, isoleert u de aortotomie en voert u de anastomose uit volgens de traditionele chirurgische techniek.

Klantacties

Getinge verzoekt u de volgende acties te ondernemen:

1. Zorg ervoor dat dit bericht wordt doorgestuurd naar alle personen binnen uw organisatie die op de hoogte moeten worden gesteld, of naar organisaties waarnaar de betrokken apparaten zijn overgedragen.

Aanvullende informatie

Getinge geeft deze informatie door aan de bevoegde toezichthoudende instanties.

Onze excuses voor het ongemak. We hechten veel waarde aan de veiligheid van onze patiënten en stellen uw snelle aandacht voor deze kwestie op prijs. Als u vragen hebt over deze communicatie, neem dan contact op met uw Getinge-vertegenwoordiger of de klantenservice van Getinge, van maandag tot en met vrijdag tussen 8.00 en 17.00 uur

Contactgegevens:

Getinge Belgium (Luxembourg)
Info.be@getinge.com
003223202089

Getinge Netherlands
Info.nl@getinge.com
0031353035000

Hoogachtend,

Francisco Vicenty
Directeur Kwaliteit & Regelgeving
Getinge, cardiovasculaire chirurgie

New Zealand (en)

5th February 2026

Urgent Medical Device Product Alert

SUBJECT	**Heartstring III Proximal Seal System – Version 2**
LETTER ADDRESSED TO	Users of the medical device listed above
DEVICES CONCERNED	HS-3045, HSK-3038, and HSK-3043 All Unexpired Lots Manufacturing Dates: March 7, 2024 - Present
WAND #	090305-WAND-66C8W3
Medsafe#	35715

GETINGE New Zealand, after consultation with Medsafe, Ministry of Health wishes to advise you of an UrgentMedical Device Product Alert for the Heartstring III Proximal Seal System due to 3 failure modes.

Problem Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device thatoccurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successfulcompletion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction,or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to

Getinge New Zealand
Level 2, Building B
Millennium Centre
600 Great South Road
Ellerslie Auckland 1051
New Zealand
Phone: 0800 1 438 4643
www.getinge.com

load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depressit.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. Aflared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: may occur as follows:
     - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III

       seal into the created aortotomy (procedure delay without additional intervention)
     - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
   - **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an

aortic clamp to complete the aortotomy.

- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimise the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loadingof the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimise occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not usedon a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions forUse (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the LoadingDevice.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Devicemay fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surfaceadventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.
        i. Discard the failed HS III Seal.
        ii. Always have a second HS III Seal available to replace a failed device. Refer to thedevice IFU to ensure successful loading.
2. **Failure of the Heartstring III Seal to Deploy into the aortotomy**
    a. Important reminders:
        i. Ensure the HS III Seal has been properly loaded into the Delivery Device asdescribed in the section above.
        ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:
            1. The loaded HS III Seal is not cracked.

Getinge New Zealand
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Phone: 0800 1 438 4643
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2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimise the occurrence of this failure:
   i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.
   ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.
   i. Occlude the aortotomy to control bleeding using an index finger.
   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimise occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.

      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.

If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organisation or any organisation where the affected devices have been transferred.

Please complete this document and email to your local Getinge New Zealand office.

Email: Quality.AUNZ@getinge.com

We apologise for any inconvenience this Urgent Medical Device Product Alert may cause. If you have any questions, please contact your Getinge representative or call the Getinge Customer Support 0800 1 438 4643.

Getinge New Zealand
Level 2, Building B
Millennium Centre
600 Great South Road
Ellerslie Auckland 1051
New Zealand
Phone: 0800 1 438 4643
www.getinge.com

Yours Sincerely,

Nicole Ditrich
QRC Manager

Australia & New Zealand

Getinge New Zealand
Level 2, Building B
Millennium Centre
600 Great South Road
Ellerslie Auckland 1051
New Zealand

Phone: 0800 1 438 4643
www.getinge.com

GETINGE

Norway (no)

August 2025

Sikkerhetsvarsel Heartstring III Proximal Seal System
Referansenummer: 1336551

Modellnummer	UDI	Modellnavn	Serie-/partinumre
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	Alle ikke-utløpte partier
Distribusjonsdatoer:		1. juli 2024 – nå	
Fabrikasjonsdatoer:		7. mars 2024 – nå	

Kjære kunde.

Formålet med dette brevet er å informere deg om at Maquet Cardiovascular, et datterselskap av Getinge, iverksetter en kritisk korrigering av medisinsk utstyr for Heartstring III Proximal Seal System (HS III Seal). Våre registre viser at dere har mottatt ett eller flere av produktene som er berørt av dette varselet.

Beskrivelse av problemet

Det er identifisert tre primære feilmoduser.

1. **Mislykket innlasting av Heartstring-forseglingen:** Denne feilen gjelder enhver funksjonsfeil på enheten som oppstår under firetrinns innlastingssprosessen med Heartstring-innlastingsenheten, visuell inspeksjon av riktig innlastet HS III Seal-forsegling og opplåsing av leveringsenheten etter at innlastingstrinnene for HS III Seal er utført.
2. **Mislykket utplassering av Heartstring Seal i aortotomien**: Denne feilen gjelder enhver funksjonsfeil på HS III Seal og/eller leveringsenheten fra tidspunktet der leveringsenheten er låst opp, til tidspunktet der leveringen av HS III Seal-forseglingen i aortotomien er fullført og alt innholdet i Proximal Seal (festet, strammefjæren, forseglingsskaftet, forankringsfliken) har kommet ut av leveringsenheten.
3. **Den utplasserte Heartstring Seal-forseglingen gir ikke tilstrekkelig hemostase:** Denne feilen gjelder enhver funksjonsfeil der HS III Seal-forseglingen er utplassert på riktig måte, men ikke kontrollerer blødningen ved anastomosen tilstrekkelig til at kirurgen kan suturere anastomosen, til tross for forsiktig justering av strammefjæren etter utplassering av forseglingen og/eller bruk av sårskylling, sug eller saltvannssprøyte for å rengjøre anastomosestedet. Denne feilen inkluderer HS III Seal-forsegling som identifiseres som defekt eller skadet etter vellykket utplassering av HS III Seal-forsegling i aorta, som fører til eller kan føre til utilstrekkelig hemostase og som hindrer kirurgen i å fullføre anastomosen uten å fjerne den defekte HS III Seal-forseglingen.

En undersøkelse av den underliggende årsaken pågår for øyeblikket.

Helsefare

1. **Mislykket innlasting:** En HS III Seal-forsegling som ikke lastes inn på riktig måte, utgjør ingen direkte risiko for

pasienten ved bruk i henhold til bruksanvisningen for enheten. Denne feilen kan imidlertid føre til forsinkelse i den kirurgiske prosedyren. Denne forsinkelsen kan variere fra noen få minutter for å hente ut og laste inn en ny Seal-enhet, til potensiell metodeendring fra å bruke HS III Seal til å utføre den proksimale anastomosen til å bruke en aortaklemme for å fullføre prosedyren.

2. **Mislykket utplassering:** Hvis den innlastede HS III Seal-forseglingen ikke blir utplassert av leveringsenheten, er de følgende prosedyretrinnene allerede utført, og kan bidra til potensiell risiko for pasientskade. Hvis den innlastede HS III Seal-forseglingen ikke kunne plasseres av leveringsenheten, er flere prosedyretrinn allerede fullført, noe som kan øke den potensielle risikoen for pasientskade.
   - Aortotomien er opprettet.
   - Den distale enden av røret på leveringsenheten er satt inn gjennom aortotomien.
   - Stempelet på leveringsenheten er trykket ned, eller det er gjort et forsøk på å trykke det ned.
   - Den innlastede HS III Seal-forseglingen ble ikke utplassert fra den distale enden av røret på leveringsenheten.
   - Når leveringsenheten fjernes fra aortotomien, vil HS III Seal-forseglingen ikke være utplassert, og blødningen fra aortotomien må kontrolleres ved å sette en finger over aortotomien.

   Følgende potensielle pasientskader kan oppstå:

   - **Forsinkelse av den kirurgiske prosedyren**: For å fjerne HS III Seal-forseglingen som ikke ble utplassert, skal du åpne en ny HS III Proximal Seal-forsegling, laste den inn i leveringsenheten og utplassere den innlastede HS III Seal-forseglingen i den opprettede aortotomien (forsinkelse uten ytterligere inngrep) i motsetning til beslutningen om å bruke en aortaklemme for å fullføre anastomosen fordi den innlastede Seal-forseglingen ikke ble utplassert (forsinkelse med ytterligere inngrep)
   - **Vevsskade**: kan oppstå som følge av utplassering av en innlastet HS III Seal-forsegling som er utvidet ved spissen. En utvidet spiss vil ha en diameter som er større enn det distale røret på leveringsenheten. Utplassering av en innlastet Seal-forsegling med utvidet spiss kan forårsake skade på aortotomivevet, og hvis det brukes mer kraft for å løse ut den berørte Seal-forseglingen, er det en potensiell risiko for å treffe motsatt aortavegg under plasseringen. Vevsskade kan også oppstå når leveringsenheten fjernes fra aortotomien, ved utplassering av en ny innlastet HS III Seal-forsegling i samme aortotomi, og/eller ved behov for å endre metode og bruke en aortaklemme for å fullføre aortotomien.
   - **Blødning:** Minimalt blodtap kan forekomme ved fjerning av leveringsenheten fra aortotomien, manuell kontroll av blødningen og plassering av en ny HS III Seal-forsegling. Større blodtap, som krever ytterligere inngrep, kan forekomme hvis det oppstår vevsskade.
   - **Embolisk hendelse** som følge av ytterligere manipulering av aorta for å håndtere HS III Seal-forsegling som er feil innlastet.

3. **Den utplasserte Heartstring Seal-forseglingen gir ikke tilstrekkelig hemostase:** Hvis en utplassert HS III Seal-forsegling ikke gir tilstrekkelig hemostase til at kirurgen kan fullføre den proksimale anastomosen, er flere trinn i bruken av HS III Seal-systemet allerede utført, og det kan øke den potensielle risikoen for pasientskade. Følgende prosedyretrinn vil være utført.
   - Aortotomien er opprettet.
   - Den innlastede HS III Seal-forseglingen er utplassert i aorta.
   - Blødningen fra aorta vurderes av kirurgen som for stor til å utføre anastomosen.

   Følgende potensielle pasientskader kan oppstå:

   - **Forsinkelse av den kirurgiske prosedyren:** kan oppstå på følgende måte:
     - Ytterligere tidsbruk i operasjonen ved forsøk på å justere en Seal-forsegling for å forbedre hemostasen med en plassert HS III Seal-forsegling, fjerne en defekt HS III Seal-forsegling, åpne en ny HS III Seal-forsegling, laste inn en ny HS III Seal-forsegling og plassere den innlastede HS III Seal-forseglingen i den opprettede aortotomien (prosedyreforsinkelse uten ytterligere inngrep)
     - Kirurgen anser det som mest hensiktsmessig å bruke en aortaklemme for å fullføre anastomosen fordi den utplasserte HS III Seal-forseglingen ikke gir tilstrekkelig hemostase til å fullføre anastomosen og en ny HS III Seal-forsegling ikke er tilgjengelig, eller kirurgen vurderer at situasjonen ikke tillater bruk av en ny HS III Seal-forsegling, og en aortaklemme brukes til å fullføre den proksimale

anastomosen i henhold til tradisjonell kirurgisk teknikk. (prosedyreforsinkelse med et ekstra inngrep)

- **Vevsskade:** Vevsskade kan oppstå under manipulering av den berørte HS III Seal-forseglingen, under utplassering av Seal-forseglingen fra en ny innlastet HS III Seal-forsegling i den samme aortotomien, og/eller ved behov for å endre metode til bruk av aortaklemme for å fullføre aortotomien.
- **Blødning:** Et mindre blodtap rundt den utplasserte HS III Seal-forseglingen er normalt og forventes når den proksimale anastomosen utføres med en HS III Seal-forsegling. Større blodtap som krever ytterligere inngrep kan forekomme hvis det oppstår skade på aortavevet, uansett årsak.
- **Emboliske hendelser:** som følge av ytterligere manipulering av aorta etter at HS III Seal-forseglingen ikke har gitt tilstrekkelig hemostase.

Mellom 1. juni 2023 og 22. juli 2025 mottok Getinge følgende klager:

- 274 rapporter relatert til feil ved lasting, representerer en klagefrekvens på 0,386 %
- 96 rapporter relatert til manglende utplassering, noe som representerer en klagefrekvens på 0,135 %
- 30 rapporter relatert til utilstrekkelig hemostase, noe som representerer en klagefrekvens på 0,042 %

Anbefalte tiltak

Getinge gir følgende instruksjoner for å unngå/minimere de ovennevnte feilene .

1. **Mislykket innlasting av Heartstring Seal-forsegling**
    a. Viktige merknader:
        i. I henhold til bruksanvisningen for enheten skal HS III Seal-forseglingen lastes inn og fjernes fra innlastingsenheten, og deretter inspiseres og justeres om nødvendig for å bekrefte vellykket innlasting og til slutt låses opp før eventuell adventitia fjernes fra det planlagte anastomoseområdet og aortotomien opprettes. Innlasting av HS III Seal og bekreftelse av vellykket innlasting før aortotomien opprettes minimerer risikoen for pasientene fordi aorta forblir uberørt til det er bekreftet at innlastingen av HS III Seal-forseglingen er vellykket.
        ii. Hvis HS III Seal-forseglingen ikke lastes som tiltenkt, må enheten skiftes ut.
    b. Hvordan unngå/minimere forekomsten av denne feilen
        i. Les bruksanvisningen for Heartstring før bruk, spesielt hvis Heartstring ikke brukes rutinemessig.
        ii. Last inn HS III Seal-forseglingen ved å følge trinnene i bruksanvisningen for enheten nøye.
        iii. Bekreft at HS III Seal-forseglingen er riktig lastet inn i leveringsenheten i henhold til avsnitt 4.3-4.5. Gjør dette ved å inspisere den innlastede HS III Seal-forseglingen når HS III Seal-forseglingen er lastet inn i leveringssenheten og fjernet fra innlastingsenheten.
        iv. En HS III Seal-forsegling som ikke inspiseres på riktig måte etter at den er fjernet fra innlastingsenheten, kan svikte under utplassering av HS III Seal-forseglingen og forårsake pasientskade. (se informasjon om mislykket utplassering).
        v. Utfør riktig innlasting av HS III Seal-forseglingen før adventitia fjernes fra aortaoverflaten og aortotomien opprettes.
    a. Tiltak som skal iverksettes hvis innlasting av HS III Seal-forseglingen mislykkes.
        i. Kast den defekte HS III Seal-forseglingen.
        ii. Ha alltid en ekstra HS III Seal-forsegling tilgjengelig for å erstatte en eventuell defekt enhet. Se bruksanvisningen for enheten for å sikre vellykket innlasting.
2. **Mislykket utplassering av Heartstring III Seal-forseglingen i aortotomien**
    a. Viktige merknader:
        i. Kontroller at HS III-forseglingen er riktig lastet inn i leveringsenheten som beskrevet i avsnittet ovenfor.
        ii. Etter at den lastede HS III-forseglingen er fjernet fra lasteenheten, inspiserer du den lastede HS III-forseglingen i henhold til avsnitt 4.3-4.5 i bruksanvisningen for å bekrefte følgende:

1. Den innlastede HS III Seal-forseglingen er ikke sprukket.
2. Delen av HS III Seal-forseglingen som ikke er lastet inn i røret i leveringsenheten, er ikke videre enn leveringsenhetens rørdiameter.
3. Endene av strammefjæren er innrettet slik at de berører begge de proksimale kantene på den innlastede HS III Seal-forseglingen når Seal-forseglingen settes inn i aortotomien.

b. Hvordan unngå/minimere forekomsten av denne feilen:
   i. Etter at vellykket innlasting av HS III Seal-forseglingen er bekreftet og aortotomien er opprettet, utplasseres den innlastede HS III Seal-forseglingen i aortotomien ved å følge trinnene for plassering av HS III Seal-forseglingen i bruksanvisningen for enheten.
   ii. Hvis HS III Seal-forseglingen ikke blir utplassert som tiltenkt, må enheten skiftes ut.

c. Tiltak som skal iverksettes hvis utplassering av HS III Seal-forseglingen i aorta mislykkes.
   i. Okkluder aortotomien med pekefingeren for å kontrollere blødningen.
   ii. Åpne en ny HS III Seal-forsegling. Last inn HS III Seal-forseglingen i henhold til bruksanvisningen for enheten. Utplasser den innlastede HS III Seal-forseglingen i aortotomien og følg bruksanvisningen for å fullføre anastomosen.
   iii. Hvis innsetting av den andre HS III Seal-forseglingen i aortotomien mislykkes, eller hvis kirurgen vurderer at situasjonen ikke tillater bruk av en ny HS III Seal-forsegling, okkluderes aorta delvis med en klemme for å isolere aortotomien, og anastomosen utføres i henhold til tradisjonell kirurgisk teknikk.

3. Hvis Heartstring III Seal-forseglingen ikke gir tilstrekkelig hemostase:

a. Hvordan unngå/minimere forekomsten av denne feilmodusen:
   i. Last inn HS III Seal-forseglingen og inspiser den alltid nøye for å bekrefte vellykket innlasting av HS III Seal-forseglingen i leveringsenheten før adventitia fjernes fra aorta og aortotomien opprettes. (Se viktige merknader ovenfor.)
   ii. Ikke bruk Heartstring Proximal Seal System på pasienter med tynne aortavegger.
   iii. Ved utføring av flere anastomoser må det sikres at alle anastomosestedene er minst 1,5 cm fra hverandre for å sikre hemostase.
   iv. HS III Seal skal ikke bløtlegges i væske før bruk.

b. Tiltak som skal iverksettes hvis HS III Seal-forseglingen ikke åpnes/gir tilstrekkelig hemostase etter at forseglingen er utplassert.
   i. Dekk aortotomien med pekefingeren og juster strammefjæren forsiktig for å sikre at HS III Seal-forseglingen er fullstendig utplassert.
   ii. Hvis det fortsatt ikke er tilstrekkelig hemostase:
      1. Fjern den utplasserte HS III Seal-forseglingen fra aortotomien i henhold til bruksanvisningen for enheten.
      2. Last inn en annen HS III Seal-forsegling og utplasser den innlastede forseglingen i aortotomien i henhold til bruksanvisningen for enheten, og fullfør anastomosen.
      3. Hvis plassering av den andre HS III Seal-forseglingen mislykkes, eller hvis kirurgen vurderer at situasjonen ikke tillater bruk av en ny HS III Seal-forsegling, okkluderes aorta delvis med en klemme for å isolere aortotomien, og anastomosen utføres i henhold til tradisjonell kirurgisk teknikk.

<u>Kundetiltak</u>

Getinge ber om at følgende tiltak gjennomføres:

1. Videresend denne meldingen til alle som trenger å bli varslet i din organisasjon eller eventuelle andre organisasjoner som har mottatt de aktuelle enhetene.

<u>Ytterligere opplysninger</u>

Getinge formidler denne informasjonen til relevante tilsynsmyndigheter.

Vi beklager eventuelle ulemper dette medfører. Pasientsikkerhet er viktig for oss, og vi setter pris på raskt svar i denne saken. Hvis du har spørsmål angående denne informasjonen, kan du kontakte din Getinge-representant eller Getinges kundeservice på tel. +47 23 03 52 00
Vennlig hilsen

Francisco Vicenty
Director, Quality & Regulatory Compliance
Getinge, Cardiovascular Surgery

Paraguay (es)

Agosto 2025

Aviso de seguridad Urgente
Sistema de obturación proximal Heartstring III
Número de referencia FSCA: 1336551

Número de modelo	UDI	Nombre del modelo	Números de serie/lote
HSK-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de obturación proximal Heartstring III	Todos los lotes no caducados
Fechas de distribución:		1 de julio de 2024 - Actualidad	
Fechas de fabricación:		7 de marzo de 2024 - Actualidad	

Estimado gestor de riesgos,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está emitiendo una corrección urgente de dispositivos médicos para el sistema de sellado proximal Heartstring III (HS III Seal). Según nuestros registros, usted ha recibido uno o varios de los dispositivos afectados por esta notificación.

Descripción del Problema

Se han identificado tres modos de fallo principales.

1. **Fallo en la carga del sello Heartstring**: Este fallo se aplica a cualquier mal funcionamiento del dispositivo que se produzca durante el proceso de carga de cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un sello HS III cargado correctamente y el desbloqueo del dispositivo de administración tras completar con éxito los pasos de carga del sello HS III.
2. **Fallo del sello cardíaco al desplegarse en la aortotomía**: Este fallo se aplica a cualquier mal funcionamiento del sello HS III y/o del dispositivo de implantación desde el momento en que el dispositivo de implantación se desbloquea correctamente hasta que se completa la implantación del sello HS III en la aortotomía y todo el contenido del sello proximal (la correa, el resorte de tensión, el vástago del sello y la lengüeta de anclaje) ha salido del dispositivo de implantación.
3. **Fallo del sellado Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier mal funcionamiento de un sello HS III implantado correctamente que no controle adecuadamente el sangrado en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis, a pesar del ajuste suave del resorte de tensión tras la implantación del sello y/o el uso de un nebulizador, succión o jeringa de solución salina para limpiar el sitio de la anastomosis. Este fallo incluye la identificación por parte del cliente de un sello HS III defectuoso o dañado tras el despliegue correcto del sello HS III en la aorta, lo que da lugar o puede dar lugar a una hemostasia inadecuada que impide al cirujano completar la anastomosis sin retirar el sello HS III defectuoso.

En estos momentos se está investigando la causa raíz.

Riesgos para la salud

1. **Error al cargar:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un sello HS III que no se carga no supone un riesgo directo para el paciente. Sin embargo, este fallo puede provocar un retraso en la intervención quirúrgica. Este retraso puede variar desde unos minutos para recuperar y cargar un nuevo sello, hasta una posible conversión del uso del sello HS III para realizar la anastomosis proximal al empleo de una pinza aórtica para completar la intervención.
2. **Fallo en la implementación:** Cuando el sello HS III cargado no se despliega desde el dispositivo de administración, ya se han realizado los siguientes pasos del procedimiento, lo que puede contribuir al riesgo potencial de daño al paciente. Si el sello HS III cargado no se despliega desde el dispositivo de administración, ya se habrán completado varios pasos del procedimiento, lo que puede aumentar el riesgo potencial de daño al paciente.
   - Se ha realizado la aortotomía.
   - El extremo distal del tubo del dispositivo de administración se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de administración o se ha intentado presionarlo.
   - El sello HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de administración.
   - Cuando se retira el dispositivo de administración de la aortotomía, el sello HS III no se desplegará y será necesario controlar el sangrado de la aortotomía colocando un dedo sobre ella.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: para retirar el HS III Seal no desplegado, abrir un nuevo HS III Proximal Seal, cargar el Seal en el dispositivo de liberación (Delivery Device) y entregar el HS III Seal cargado en la aortotomía creada (retraso sin intervención adicional) vs. la decisión de utilizar una pinza aórtica para completar la anastomosis debido a que el Seal cargado no se desplegó (retraso con una intervención adicional).
   - **Daño tisular**: puede ocurrir como resultado del despliegue de un HS III Seal cargado que esté ensanchado en la punta. Una punta ensanchada tendrá un diámetro mayor que el tubo distal del dispositivo de liberación. El despliegue de un Seal cargado con la punta ensanchada puede causar daño al tejido de la aortotomía y, si se aplica mayor fuerza para desplegar el Seal afectado, existe un riesgo potencial de perforar la pared posterior de la aorta durante la inserción. El daño tisular también puede ocurrir durante la retirada del dispositivo de liberación de la aortotomía, al desplegar un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** puede producirse una pérdida mínima de sangre al retirar el dispositivo de liberación de la aortotomía, al controlar manualmente el sangrado de la aortotomía y al colocar un HS III Seal de reemplazo. Puede producirse una mayor pérdida de sangre, que requiera intervención adicional, si ocurre daño tisular.
   - **Evento embólico** como resultado de la manipulación adicional de la aorta para abordar la falla en la carga del HS III Seal.
3. **Falla del Heartstring Seal desplegado para proporcionar hemostasia adecuada:** uando un HS III Seal desplegado no logra proporcionar una hemostasia adecuada para que el cirujano complete la anastomosis proximal, varios pasos del uso del Sistema HS III Seal ya se han completado y pueden aumentar el riesgo potencial de daño al paciente. Los siguientes pasos del procedimiento ya se habrán realizado.
   - Se ha creado la aortotomía.

- El HS III Seal cargado se ha desplegado en la aorta.
- El sangrado de la aorta es considerado por el cirujano como demasiado abundante para realizar la anastomosis.

Los siguientes daños potenciales al paciente pueden ocurrir:

- **Retraso del procedimiento quirúrgico**: puede ocurrir de la siguiente manera:

  Tiempo operatorio adicional necesario para intentar realizar ajustes en el Seal con el fin de mejorar la hemostasia proporcionada por el HS III Seal implantado, retirar el HS III Seal defectuoso, abrir un nuevo HS III Seal, cargar el HS III Seal de reemplazo y colocar el HS III Seal cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional).
  - El cirujano considera más apropiado utilizar una pinza aórtica para completar la anastomosis debido a que el HS III Seal desplegado no logró proporcionar hemostasia adecuada para completarla y no hay un HS III Seal de reemplazo disponible, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo y se utiliza una pinza aórtica para completar la anastomosis proximal según la técnica quirúrgica tradicional. (retraso del procedimiento con intervención adicional)
- **Daño tisular**: puede ocurrir durante la manipulación del HS III Seal afectado, durante el despliegue de un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
- **Sangrado:** Una pequeña cantidad de pérdida de sangre alrededor del HS III Seal desplegado es normal y esperada al realizar la anastomosis proximal utilizando un HS III Seal. Puede producirse una mayor pérdida de sangre que requiera intervención adicional cuando ocurre daño del tejido aórtico, independientemente de la causa.
- **Evento(s) embólico(s):** como resultado de la manipulación adicional de la aorta secundaria a la necesidad de abordar la falla del HS III Seal en proporcionar hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge recibió las siguientes quejas:

- 274 reportes relacionados con falla de carga, lo que representa una tasa de quejas del 0,386%
- 96 reportes relacionados con falla de despliegue, lo que representa una tasa de quejas del 0,135%
- 30 reportes relacionados con hemostasia inadecuada, lo que representa una tasa de quejas del 0,042%

<u>Medidas y acciones recomendadas</u>

Getinge proporciona las siguientes instrucciones para evitar/minimizar las fallas descritas anteriormente.

1. **Falla del Heartstring Seal al cargar**
   a. Recordatorios importantes:
      i. Según las Instrucciones de Uso (IFU) del dispositivo, el HS III Seal debe cargarse y retirarse del dispositivo de carga (Loading Device), luego inspeccionarse y ajustarse si es necesario para confirmar una carga exitosa y finalmente desbloquearse antes de retirar cualquier adventicia del área anastomótica planificada y crear la aortotomía. Cargar el HS III Seal y confirmar una carga exitosa antes de crear la aortotomía minimiza el riesgo para los pacientes, ya que la aorta permanece intacta hasta confirmar que la carga del HS III Seal fue exitosa.
      ii. Si el HS III Seal no se carga según lo previsto, el dispositivo debe reemplazarse.
   b. Cómo evitar/minimizar la ocurrencia de esta falla
      i. Revisar las Instrucciones de Uso (IFU) del dispositivo Heartstring antes de su utilización, especialmente si Heartstring no se utiliza de forma rutinaria.

ii. Cargar el HS III Seal siguiendo cuidadosamente las Instrucciones de Uso (IFU) del dispositivo paso a paso.

iii. De acuerdo con las Secciones 4.3–4.5 de las IFU, confirmar que el HS III Seal ha sido correctamente cargado en el dispositivo de liberación (Delivery Device) inspeccionando el HS III Seal cargado una vez que haya sido introducido en el Delivery Device y retirado del dispositivo de carga (Loading Device).

iv. Un HS III Seal que no sea inspeccionado adecuadamente después de retirarlo del dispositivo de carga (Loading Device) puede fallar durante el despliegue del HS III Seal y causar daño al paciente. (Ver la información relacionada con Falla de Despliegue).

v. Completar la carga exitosa del HS III Seal antes de limpiar la adventicia de la superficie aórtica y crear la aortotomía.

c. Acción a tomar si el HS III Seal falla al cargarse.
   i. Desechar el HS III Seal defectuoso.
   ii. Tener siempre disponible un segundo HS III Seal para reemplazar un dispositivo defectuoso. Consultar las IFU del dispositivo para asegurar una carga exitosa.

2. Falla del Heartstring III Seal al desplegarse en la aortotomía

a. Recordatorios importantes:
   i. Asegurarse de que el HS III Seal haya sido correctamente cargado en el dispositivo de liberación (Delivery Device), tal como se describe en la sección anterior.
   ii. Después de retirar el HS III Seal cargado del dispositivo de carga (Loading Device), inspeccionar el HS III Seal cargado, de acuerdo con las Secciones 4.3–4.5 de las IFU, para confirmar lo siguiente:
      1. Que el HS III Seal cargado no esté agrietado.
      2. Que la porción del HS III Seal que no está dentro del tubo del Delivery Device no esté ensanchada más allá del diámetro del tubo del Delivery Device.
      3. Que los extremos del resorte de tensión (Tension Spring) estén alineados de modo que contacten ambos bordes proximales del HS III Seal cargado durante la colocación del Seal en la aortotomía.

b. Cómo evitar/minimizar la ocurrencia de esta falla:
   i. Después de confirmar la carga exitosa del HS III Seal y crear la aortotomía, desplegar el HS III Seal cargado en la aortotomía siguiendo cuidadosamente los pasos de despliegue documentados en las IFU del dispositivo.
   ii. Si el HS III Seal no se despliega según lo previsto, el dispositivo debe reemplazarse.

c. Acción a tomar si el HS III Seal no se despliega correctamente en la aorta.
   i. Ocluir la aortotomía para controlar el sangrado utilizando el dedo índice.
   ii. Abrir un segundo HS III Seal. Cargar el HS III Seal de acuerdo con las IFU del dispositivo. Introducir el HS III Seal cargado en la aortotomía y seguir las IFU para completar la anastomosis.
   iii. Si la colocación del segundo HS III Seal en la aortotomía no tiene éxito, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

3. Falla del Heartstring III Seal desplegado para proporcionar hemostasia adecuada:

a. Cómo evitar/minimizar la ocurrencia de este modo de falla:

i. Cargar siempre e inspeccionar cuidadosamente el HS III Seal cargado para confirmar que la carga en el dispositivo de liberación (Delivery Device) se haya realizado correctamente antes de retirar la adventicia de la aorta y crear la aortotomía. (Ver recordatorios importantes anteriores).
ii. No utilizar el sistema Heartstring Proximal Seal en pacientes con aorta de pared delgada.
iii. Al realizar múltiples anastomosis, asegurar que todos los sitios anastomóticos estén separados al menos 1,5 cm para garantizar la hemostasia.
iv. No sumergir el HS III Seal en solución antes del despliegue.

b. Acción a tomar si el HS III Seal no se abre/no proporciona hemostasia adecuada después del despliegue.
    i. Cubrir la aortotomía con el dedo índice y ajustar suavemente el resorte de tensión (Tension Spring) para asegurar que el HS III Seal se haya desplegado completamente.
    ii. Si persiste la falta de hemostasia adecuada:
        1. Retirar el HS III Seal desplegado de la aortotomía de acuerdo con las IFU del dispositivo.
        2. Cargar un segundo HS III Seal y desplegar el Seal cargado en la aortotomía conforme a las IFU del dispositivo y completar la anastomosis.
        3. Si el segundo HS III Seal no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

Acciones para el cliente

Getinge solicita que tome las siguientes acciones:

1. Asegúrese de que este mensaje sea reenviado a todas las personas que deban ser notificadas dentro de su organización o en cualquier organización a la que se hayan transferido los dispositivos afectados.

Información adicional

Getinge está comunicando esta información a las agencias regulatorias correspondientes.

Lamentamos cualquier inconveniente que esto pueda ocasionar. Estamos comprometidos con la seguridad del paciente y agradecemos su pronta atención a este asunto. Si tiene alguna pregunta con respecto a esta comunicación, por favor comuníquese con su representante de Getinge o con el Servicio de Atención al Cliente de Getinge.

Cordialmente,

Francisco Vicenty
Director de Calidad y Cumplimiento Regulatorio, Interino
Getinge, Cirugía Cardiovascular

Poland (pl)

363 Październik 2025

Komunikat dotyczący bezpieczeństwa wyrobu medycznego
System uszczelnienia proksymalnego Heartstring III
Numer referencyjny: 1336551

Nr modelu	UDI	Nazwa modelu	Numery seryjne/partii
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	System uszczelnienia proksymalnego Heartstring III	Wszystkie nieprzeterminowane partie
Daty dystrybucji:		1 lipca 2024 r. - obecnie	
Daty produkcji:		7 marca 2024 r. - obecnie	

Szanowni Państwo,

Firma Maquet Cardiovascular, spółka zależna firmy Getinge, niniejszym informuje, że wydaje pismo dotyczące pilnej korekty wyrobu medycznego dla systemu uszczelnienia proksymalnego Heartstring III (uszczelnienie HS III). Z naszych danych wynika, że otrzymali Państwo co najmniej jeden z Wyrobów, których dotyczy niniejsze powiadomienie.

Opis sprawy

Zidentyfikowano trzy podstawowe tryby awarii.

1. **Brak możliwości załadowania uszczelnienia Heartstring Seal**: Awaria ta dotyczy wszelkich nieprawidłowości w działaniu wyrobu, które wystąpią podczas czteroetapowego procesu ładowania przy użyciu urządzenia do ładowania Heartstring, kontroli wzrokowej poprawnie załadowanego uszczelnienia HS III oraz odblokowania urządzenia do ładowania po pomyślnym zakończeniu etapów ładowania uszczelnienia HS III.
2. **Brak możliwości rozwinięcia uszczelnienia Heartstring Seal w aortotomii**: Awaria ta dotyczy wszelkich nieprawidłowości w działaniu uszczelnienia HS III i/lub urządzenia do wprowadzania od momentu pomyślnego odblokowania urządzenia do wprowadzania do momentu całkowitego wprowadzenia uszczelnienia HS III do aortotomii i usunięcia wszystkich elementów uszczelnienia proksymalnego (uwięzi, sprężyny napinającej, trzpienia uszczelnienia, zakładki kotwiczącej) z urządzenia do wprowadzania.
3. **Niezdolność rozwiniętego uszczelnienia Heartstring Seal do zapewnienia odpowiedniej hemostazy:** Awaria ta dotyczy każdego nieprawidłowego działania pomyślnie rozwiniętego uszczelnienia HS III, które nie kontroluje odpowiednio krwawienia w miejscu zespolenia, aby umożliwić chirurgowi zszycie zespolenia, pomimo delikatnej regulacji sprężyny napinającej po rozwinięciu uszczelnienia i/lub użycia dmuchawy, odsysania lub strzykawki z solą fizjologiczną w celu oczyszczenia miejsca zespolenia. Awaria ta obejmuje identyfikację przez klienta wadliwego lub uszkodzonego uszczelnienia HS III po pomyślnym rozwinięciu uszczelnienia HS III w aorcie, co skutkuje lub może skutkować nieodpowiednią hemostazą, która uniemożliwia chirurgowi ukończenie zespolenia bez usunięcia wadliwego uszczelnienia HS III.

Obecnie trwa dochodzenie w celu ustalenia przyczyn źródłowych.

Zagrożenia dla zdrowia

1. **Brak możliwości załadowania:** Jeśli wyrób jest używany zgodnie z Instrukcją użytkowania (IFU), uszczelnienie HS III, którego nie można załadować, nie stanowi bezpośredniego zagrożenia dla pacjenta. Awaria ta może jednak prowadzić do opóźnienia zabiegu chirurgicznego. Opóźnienie to może wynosić od kilku minut, niezbędnych na pobranie i załadowanie nowego uszczelnienia, po ewentualne zastąpienie uszczelnienia HS III do wykonania zespolenia proksymalnego zaciskiem aortalnym w celu dokończenia zabiegu.
2. **Brak możliwości rozwinięcia:** Jeśli załadowane uszczelnienie HS III nie zostanie rozwinięte z urządzenia do wprowadzania, wykonano już następujące etapy zabiegu, które mogą przyczynić się do potencjalnego ryzyka uszkodzenia ciała pacjenta. Jeśli załadowane uszczelnienie HS III nie zostanie rozwinięte z urządzenia dostarczającego, kilka etapów zabiegu będzie już zakończonych, co może zwiększyć potencjalne ryzyko uszkodzenia ciała pacjenta.
    - Utworzenie aortotomii;
    - Wprowadzenie przez aortotomię dystalnego końca rurki wyrobu do wprowadzania;
    - Wciśnięcie tłoka urządzenia do wprowadzania lub podjęcie próby jego wciśnięcia;
    - Załadowane uszczelnienie HS III nie zostało pomyślnie rozwinięte z dystalnego końca rurki urządzenia do wprowadzania;
    - Po wyjęciu urządzenia do wprowadzania z aortotomii uszczelnienie HS III nie zostanie rozwinięte, a krwawienie z aortotomii trzeba będzie kontrolować poprzez umieszczenie palca na aortotomii.

    Mogą wystąpić następujące potencjalne szkody dla pacjenta:

    - **Opóźnienie zabiegu chirurgicznego**: usunięcie nierozwiniętego uszczelnienia HS III, otwarcie nowego systemu uszczelniania proksymalnego HS III, załadowanie uszczelnienia do urządzenia do wprowadzania i wprowadzenie załadowanego uszczelnienia HS III do wytworzonej aortotomii (opóźnienie bez dodatkowej interwencji) vs. decyzja o użyciu zacisku aortalnego w celu dokończenia zespolenia, ponieważ załadowane uszczelnienie nie rozwinęło się (opóźnienie z dodatkową interwencją).
    - **Uszkodzenie tkanek**: może wystąpić w wyniku rozwijania załadowanego uszczelnienia HS III, które jest rozszerzone na końcu. Rozszerzona końcówka będzie miała średnicę większą niż dystalna część rurki urządzenia do wprowadzania. Rozwinięcie załadowanego uszczelnienia, które ma rozszerzoną końcówkę, może spowodować uszkodzenie tkanki aortotomijnej, a w przypadku użycia większej siły do rozwinięcia uszkodzonego uszczelnienia istnieje potencjalne ryzyko uszkodzenia tylnej ściany aorty podczas wprowadzania. Uszkodzenie tkanek może również wystąpić podczas usuwania urządzenia do wprowadzania z aortotomii, rozwijania drugiego załadowanego uszczelnienia HS III w tej samej aortotomii i/lub konieczności zastosowania zacisku aortalnego w celu zakończenia aortotomii.
    - **Krwawienie:** może wystąpić minimalna utrata krwi podczas usuwania urządzenia do wprowadzania z aortotomii, ręcznego kontrolowania krwawienia z aortotomii i wprowadzania zastępczego uszczelnienia HS III. W przypadku uszkodzenia tkanek może dojść do większej utraty krwi, wymagającej dodatkowej interwencji.
    - **Incydent zatorowy** wynikający z dodatkowej manipulacji aortą w celu wyeliminowania braku możliwości załadowania uszczelnienia HS III.
3. **Niezdolność rozwiniętego uszczelnienia Heartstring Seal do zapewnienia odpowiedniej hemostazy:** Gdy rozwinięte uszczelnienie HS III nie zapewnia chirurgowi hemostazy wystarczającej do ukończenia zespolenia proksymalnego, zakończono już kilka etapów stosowania systemu uszczelniania HS III, co może zwiększać potencjalne zagrożenie dla pacjenta. Podczas zabiegu wykonano następujące kroki.
    - Utworzenie aortotomii;

- Załadowane uszczelnienie HS III zostało rozwinięte w aorcie.
- Chirurg uzna, że krwawienie z aorty jest zbyt duże, aby wykonać zespolenie.

Mogą wystąpić następujące potencjalne szkody dla pacjenta:

- **Opóźnienie zabiegu chirurgicznego**: może wystąpić w następujący sposób:
    - Wymagany dodatkowy czas podczas zabiegu na próbę dostosowania uszczelnienia w celu poprawy hemostazy przez wprowadzone uszczelnienie HS III, usunięcie uszkodzonego uszczelnienia HS III, otwarcie nowego uszczelnienia HS III, załadowanie zastępczego uszczelnienia HS III i wprowadzenie załadowanego uszczelnienia HS III do wytworzonej aortotomii (opóźnienie zabiegu bez dodatkowej interwencji).
    - Chirurg uznaje za najwłaściwsze użycie zacisku aortalnego w celu zakończenia zespolenia, ponieważ rozwinięte uszczelnienie HS III nie zapewniło odpowiedniej hemostazy w celu zakończenia zespolenia, a zastępcze uszczelnienie HS III nie jest dostępne lub chirurg uznaje, że sytuacja nie pozwala na użycie zastępczego uszczelnienia HS III, i używa zacisku aortalnego do zakończenia zespolenia proksymalnego zgodnie z tradycyjną techniką chirurgiczną. (opóźnienie zabiegu z dodatkową interwencją)
- **Uszkodzenie tkanek**: Uszkodzenie tkanek może wystąpić podczas manipulacji uszkodzonym uszczelnieniem HS III, podczas wprowadzania drugiego załadowanego uszczelnienia HS III do tej samej aortotomii i/lub konieczności użycia zacisku aortalnego w celu wykonania aortotomii.
- **Krwawienie:** Niewielka utrata krwi wokół rozwiniętego uszczelnienia HS III jest zjawiskiem normalnym i przewidywanym podczas wykonywania zespolenia proksymalnego przy użyciu uszczelnienia HS III. Większa utrata krwi wymagająca dodatkowej interwencji może wystąpić w przypadku uszkodzenia tkanki aorty, niezależnie od przyczyny.
- **Zdarzenie(-a) zatorowe:** wynikające z dodatkowej manipulacji w obrębie aorty w następstwie niezapewnienia odpowiedniej hemostazy przez uszczelnienie HS III.

W okresie od 1 czerwca 2023 r. do 22 lipca 2025 r. firma Getinge otrzymała 274 zgłoszone reklamacje związane z brakiem możliwości załadowania, 96 reklamacji związanych z brakiem możliwości rozwinięcia oraz 30 reklamacji związanych z brakiem odpowiedniej hemostazy.

<u>Zalecane środki zaradcze i działania</u>

Firma Getinge udostępnia następujące instrukcje w celu uniknięcia/zminimalizowania opisanych powyżej awarii.

1. **Brak możliwości załadowania uszczelnienia Heartstring Seal**
    a. Ważne przypomnienie:
        i. Zgodnie z instrukcją użytkowania, uszczelnienie HS III należy załadować i wyjąć z urządzenia do ładowania, a następnie sprawdzić i w razie potrzeby wyregulować, aby upewnić się, że ładowanie zakończyło się powodzeniem, a na koniec odblokować <u>przed</u> usunięciem przydanki z obszaru planowanego zespolenia i wykonaniem aortotomii.
        ii. Krok ten zapewnia ograniczony czas między wykonaniem aortotomii a wprowadzeniem załadowanego uszczelnienia HS III do aorty. Zgodnie z instrukcją użytkowania urządzenia, **przewidywany okres użytkowania systemu uszczelnienia proksymalnego Heartstring III wynosi do 15 minut.**

iii. Załadowanie uszczelnienia HS III i sprawdzenie, czy zostało ono prawidłowo załadowane przed wykonaniem aortotomii minimalizuje ryzyko dla pacjentów, ponieważ aorta pozostaje nienaruszona do momentu sprawdzenia, czy uszczelnienie HS III zostało prawidłowo załadowane.

iv. Brak możliwości załadowania uszczelnienia HS III zgodnie z założeniami wymaga jego wymiany.

b. Jak uniknąć/zminimalizować występowanie tej awarii?

i. Załadować uszczelnienie HS III, postępując dokładnie zgodnie z instrukcją użytkowania urządzenia.

ii. Przed użyciem należy zapoznać się z instrukcją użytkowania urządzenia Heartstring, zwłaszcza jeśli nie jest ono używany rutynowo.

iii. Upewnić się, że uszczelnienie HS III zostało prawidłowo załadowane do urządzenia do wprowadzania, sprawdzając załadowane uszczelnienie HS III po załadowaniu go do urządzenia do wprowadzania i wyjęciu z urządzenia do wprowadzania.

iv. Zakończyć proces ładowania uszczelnienia HS III przed oczyszczeniem przydanki aorty i wykonaniem aortotomii.

v. Uszczelnienie HS III, które nie zostanie odpowiednio sprawdzone po wyjęciu z urządzenia ładującego, może ulec uszkodzeniu podczas rozwijania i spowodować obrażenia u pacjenta (patrz informacje dotyczące braku możliwości rozwinięcia).

c. Działania, które należy podjąć w przypadku braku możliwości załadowania.

i. Wyrzucić wadliwe uszczelnienie HS III.

ii. Zawsze należy dysponować drugim uszczelnieniem HS III, aby móc zastąpić wadliwe urządzenie. Aby mieć pewność, że ładowanie przebiegnie pomyślnie, należy zapoznać się z instrukcją użytkowania.

2. Brak możliwości rozwinięcia uszczelnienia Heartstring Seal III w aortotomii:

a. Ważne przypomnienie:

i. Należy upewnić się, że uszczelnienie HS III zostało prawidłowo załadowane do urządzenia do wprowadzania.

ii. Kontrola załadowanego uszczelnienia HS III po wyjęciu z urządzenia do ładowania ma na celu potwierdzenie, że:

1. załadowane uszczelnienie HS III nie jest pęknięte;
2. część uszczelnienia HS III, która nie została załadowana do rurki urządzenia dostarczającego, nie jest szersza niż średnica rurki urządzenia dostarczającego;
3. Końce sprężyny napinającej są ustawione w taki sposób, aby stykały się z obiema proksymalnymi krawędziami załadowanego uszczelnienia HS III podczas wprowadzania do aortotomii.

b. Jak uniknąć/zminimalizować występowanie tej awarii:

i. Po potwierdzeniu pomyślnego załadowania uszczelnienia HS III i utworzeniu aortotomii, wprowadzić załadowane uszczelnienie HS III do aortotomii, postępując dokładnie zgodnie z krokami wprowadzania uszczelnienia HS III udokumentowanymi w instrukcji użytkowania.

ii. Brak możliwości rozwinięcia uszczelnienia HS III zgodnie z założeniami wymaga jego wymiany.

c. Działania, które należy podjąć, jeśli uszczelnienie HS III nie zostanie pomyślnie rozwinięte w aorcie.

i. Zamknąć aortotomię w celu opanowania krwawienia za pomocą palca wskazującego.

ii. Otworzyć drugie uszczelnienie HS III. Załadować uszczelnienie HS III zgodnie z instrukcją użytkowania. Wprowadzić załadowane uszczelnienie HS III do aortotomii i postępować zgodnie z instrukcją użytkowania, aby dokończyć zespolenie.
iii. Jeśli wprowadzenie drugiego uszczelnienia HS III do aortotomii nie powiedzie się lub chirurg uzna, że sytuacja nie pozwala na użycie zastępczego uszczelnienia HS III, należy założyć zacisk na aortę, izolując aortotomię i wykonać zespolenie zgodnie z tradycyjną techniką chirurgiczną.

3. **Niezdolność rozwiniętego uszczelnienia Heartstring Seal III do zapewnienia odpowiedniej hemostazy:**
   a. Ważne przypomnienie: Zgodnie z instrukcją użytkowania urządzenia, **przewidywany okres użytkowania systemu uszczelnienia proksymalnego Heartstring III wynosi do 15 minut.**
   b. Jak uniknąć/zminimalizować występowanie tego trybu awarii?:
      i. Zawsze należy załadować i dokładnie sprawdzić załadowane uszczelnienie HS III, aby upewnić się, że zostało ono prawidłowo załadowane do urządzenia do wprowadzania przed usunięciem przydanki aorty i wykonaniem aortotomii. (Zobacz ważne przypomnienia bezpośrednio powyżej).
      ii. Nie stosować systemu uszczelnienia proksymalnego Heartstring u pacjentów z cienkościenną aortą.
      iii. W przypadku wykonywania zespolenia wielokrotnego należy upewnić się, że wszystkie miejsca zespolenia są oddalone od siebie o co najmniej 1,5 cm w celu zapewnienia hemostazy.
      iv. Nie należy moczyć uszczelnienia HS III w roztworze przed rozwinięciem.
   c. Działania, które należy podjąć, jeśli uszczelnienie HS III nie otwiera się/zapewnia odpowiedniej hemostazy po rozwinięciu.
      i. Należy zakryć aortotomię palcem wskazującym i delikatnie wyregulować sprężynę napinającą, aby upewnić się, że uszczelnienie HS III zostało w pełni rozwinięte.
      ii. Jeśli brak odpowiedniej hemostazy utrzymuje się:
         1. Usunąć rozwinięte uszczelnienie HS III z aortotomii zgodnie z instrukcją użytkowania wyrobu.
         2. Załadować drugie uszczelnienie HS III i wprowadzić je do aortotomii zgodnie z instrukcją użytkowania wyrobu, a następnie dokończyć zespolenie.
         3. Jeśli wprowadzenie drugiego uszczelnienia HS III do aortotomii nie powiedzie się lub chirurg uzna, że sytuacja nie pozwala na użycie zastępczego uszczelnienia HS III, należy założyć zacisk na aortę, izolując aortotomię i wykonać zespolenie zgodnie z tradycyjną techniką chirurgiczną.

Działania wymagane od klienta

Firma Getinge prosi o podjęcie następujących działań:

1. Należy upewnić się, że ta wiadomość została przekazana do wszystkich osób, które wymagają powiadomienia w Państwa organizacji lub w każdej organizacji, do której zostały przeniesione urządzenia, których dotyczy problem.

Informacje dodatkowe

Firma Getinge przekazuje te informacje odpowiednim agencjom regulacyjnym.

Wyrażamy ubolewanie z powodu wszelkich niedogodności związanych z tym problemem. Dbamy o bezpieczeństwo pacjentów i dziękujemy za szybkie podjęcie odpowiednich działań. W przypadku jakichkolwiek pytań dotyczących tego komunikatu prosimy o kontakt z przedstawicielem firmy Getinge.

Z poważaniem,

Agnieszka Pietras
Quality & Regulatory Compliance Manager
Getinge Polska Sp. z o.o.
ul. Żwirki i Wigury 18
02-092 Warszawa
plssu.qrc@getinge.com

Portugal (pt)

18 de fevereiro de 2026

Aviso de Segurança
Sistema de vedação proximal Heartstring III
Número de referência FSCA: 1336551

Número do modelo	UDI	Nome do modelo	Números de série/lote
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de vedação proximal Heartstring III	Todos os lotes não expirados
Datas de distribuição:		1 de julho de 2024 - Presente	
Datas de fabrico:		7 de março de 2024 - Presente	

Caro cliente,

O objetivo desta carta é informar que a Maquet Cardiovascular, uma subsidiária da Getinge, está a emitir uma ação corretiva urgente de dispositivo médico para o sistema de vedação proximal Heartstring III (vedante HS III). Os nossos registos indicam que recebeu um ou mais dos dispositivos afetados por esta notificação.

Descrição do problema

Foram identificados três modos de falha principais.

1. **Falha no carregamento do vedante Heartstring:** Esta falha aplica-se a qualquer avaria do dispositivo que ocorra durante o processo de carregamento em quatro passos utilizando o dispositivo de carregamento Heartstring, a inspeção visual de um vedante HS III carregado com sucesso e o desbloqueio do dispositivo de aplicação após a conclusão bem-sucedida dos passos de carregamentodo vedante HS III.
2. **Falha na colocação do vedante Heartstring na aortotomia:** Esta falha aplica-se a qualquer falha do vedante HS III e/ou avaria do dispositivo de aplicação a partir do momento em que o dispositivo de aplicação é desbloqueado com sucesso até uma vez concluída a aplicação do vedante HS III na aortotomia e todo o conteúdo do vedante proximal (fio de ligação, mola de tensão, haste do vedante, lingueta de fixação) tiver saído do dispositivo de aplicação.
3. **Falha do vedante Heartstring colocado em fornecer uma hemóstase adequada:** Esta falha aplica-se a qualquer funcionamento incorreto de um vedante HS III colocado com sucesso que não controle adequadamente a hemorragia na anastomose para permitir que o cirurgião realize a sutura da anastomose, apesar do ajuste suave da mola de tensão após a colocação do vedante e/ou da utilização de um soprador nebulizador, aspiração ou seringa salina para limpar o local da anastomose. Esta falhainclui a identificação pelo cliente de um vedante HS III defeituoso ou danificado após a colocação bem-sucedida do vedante HS III na aorta que resulta ou pode resultar numa hemostasia inadequada que impede o cirurgião de concluir a anastomose sem remover o vedante HS III defeituoso.

A investigação da causa principal está a decorrer.

Risco para a saúde

1. **Falha ao carregar:** Quando utilizado de acordo com as instruções de utilização do dispositivo (IFU), um vedante HS III que não carregue não representa um risco direto para o doente. No entanto, esta falha pode resultar num atraso no procedimento cirúrgico. Este atraso pode variar entre alguns minutos para recuperar e carregar um novo vedante e a necessidade de passar a utilizar um clampe aórtico para concluir o procedimento em vez do vedante HS III para realizar o procedimento.
2. **Falha ao colocar:** Quando o carregamento do vedante HS III falha com o dispositivo de aplicação, os seguintes passos do procedimento já foram realizados e podem contribuir para o risco potencial de lesões no doente. Se houver falha no carregamento do vedante HS III com o dispositivo de aplicação, vários passos do procedimento já terão sido concluídos, o que pode aumentar o risco potencial de lesões no doente.
   - A aortotomia foi criada.
   - A extremidade distal do tubo do dispositivo de aplicação foi inserida através da aortotomia.
   - O êmbolo do dispositivo de aplicação foi pressionado ou foi feita uma tentativa de o pressionar.
   - O vedante HS III carregado não foi colocado com sucesso a partir da extremidade distal do tubo do dispositivo de aplicação.
   - Quando o dispositivo de aplicação é removido da aortotomia, o vedante HS III não será colocado e a hemorragia da aortotomia terá de ser controlada colocando um dedo sobre a aortotomia.

   Podem ocorrer os seguintes potenciais danos para o doente:

   - **Atraso no procedimento cirúrgico**: para remover o vedante HS III não colocado, abra um novo vedante proximal HS III, carregue o vedante no dispositivo de aplicação e aplique o vedante HS III carregado na aortotomia criada (atraso sem intervenção adicional) vs. a decisão de utilizar um clampe aórtico para concluir a anastomose porque o vedante carregado não foi colocado (atraso com uma intervenção adicional)
   - **Danos nos tecidos**: podem ocorrer como resultado da colocação de um vedante HS III carregado que esteja alargado na ponta. Uma ponta alargada terá um diâmetro maior do que o tubo distal do dispositivo de aplicação. A colocação de um vedante carregado com uma ponta alargada pode causar danos no tecido da aortotomia e, se for utilizada mais força para colocar o vedante afetado, existe um risco potencial de danos na parede posterior da aorta durante a inserção. Também podem ocorrer danos nos tecidos durante a remoção do dispositivo de aplicação da aortotomia, colocando um segundo vedante HS III carregado na mesma aortotomia e/ou sendo necessário passar a utilizar um clampe aórtico para concluir a aortotomia.
   - **Hemorragia:** pode ocorrer uma perda mínima de sangue quando se remove o dispositivo de aplicação da aortotomia, controlando manualmente a hemorragia da aortotomia e aplicando um vedante HS III de substituição. Se os tecidos forem danificados, pode ocorrer uma maior perda de sangue, exigindo intervenção adicional.
   - **Evento embólico** resultante da manipulação adicional da aorta para resolver a falha de carregamento do vedante HS III.
3. **Falha em fornecer uma hemóstase adequada por parte do vedante Heartstring colocado:** Quando um vedante HS III colocado não permite uma hemóstase adequada para o cirurgião concluir a anastomose proximal, vários passos da utilização do sistema de vedação HS III já foram concluídos e podem aumentar o risco potencial de lesões no doente. Os seguintes passos processuais terão sido realizados.
   - A aortotomia foi criada.
   - O vedante HS III carregado foi colocado na aorta.
   - O cirurgião considera que a hemorragia da aorta é demasiado grande para realizar a anastomose.

   Podem ocorrer os seguintes potenciais danos para o doente:

   - **Atraso no procedimento cirúrgico**: pode ocorrer da seguinte forma:

     Um tempo operatório adicional necessário para tentar fazer ajustes no vedante para melhorar a hemóstase

pelo vedante HS III aplicado, remover o vedante HS III defeituoso, abrir um novovedante HS III, carregar o vedante HS III de substituição e aplicar o vedante HS III carregado na aortotomia criada (atraso do procedimento sem intervenção adicional)

- O cirurgião considera que é mais apropriado utilizar um clampe aórtico para concluir a anastomose, porque o vedante HS III colocado não permitiu uma hemostase adequada paraconcluir a anastomose e um vedante HS III de substituição não está disponível ou a preferência do cirurgião determina que a situação não permita a utilização de um vedante HS III de substituição e que é utilizado um clampe aórtico para concluir a anastomose proximal de acordo com a técnica cirúrgica tradicional (atraso do procedimento com uma intervençãoadicional)

- **Danos nos tecidos:** Podem ocorrer danos nos tecidos durante a manipulação do vedante HS III afetado, durante a colocação do vedante de um segundo vedante HS III carregado na mesma aortotomia e/ou a necessidade de converter para a utilização de um clampe aórtico para concluir a aortotomia.
- **Hemorragia:** Uma pequena quantidade de perda de sangue à volta do vedante HS III colocado é normal e esperada ao realizar a anastomose proximal utilizando um vedante HS III. Quando os tecidos aórticos são danificados, pode ocorrer uma maior perda de sangue que exija intervenção adicional, independentemente da causa.
- **Evento(s) embólico(s):** resultante(s) da manipulação adicional da aorta resultante da tentativa deresolver a falha do vedante HS III em permitir uma hemóstase adequada.

Entre 1 de junho de 2023 e 22 de julho de 2025, a Getinge recebeu as siguientes reclamações:

- 274 reclamações comunicadas associadas a uma falha de carregamento, representando uma tasa de reclamações de 0,386%
- 96 reclamações associadas a uma falha de colocação, representando uma tasa de reclamações de 0,135%
- 30 reclamações associadas a uma falta de hemóstase adequada, , representando uma tasa de reclamaçõesde 0,042%

<u>Ações e mitigações recomendadas</u>

A Getinge fornece as seguintes instruções para evitar/minimizar as falhas mencionadas acima.

1. **Falha no carregamento do vedante Heartstring**
   a. Lembretes importantes:
      i. De acordo com as instruções de utilização do dispositivo, o vedante HS III destina-se a ser carregado e removido do dispositivo de carregamento, depois inspecionado e ajustado, se necessário, para confirmar o carregamento bem-sucedido e, finalmente, desbloqueado <u>antes</u> de se limpar quaisquer adventícias da área anastomótica planeada e criar a aortotomia.
      ii. Carregar o vedante HS III e confirmar o carregamento bem-sucedido <u>antes</u> de criar a aortotomia minimiza o risco para os doentes, uma vez que a aorta permanece intacta até confirmar o carregamento bem-sucedido do vedante HS III.
      iii. Se o vedante HS III não for carregado conforme previsto, é necessário substituí-lo.

   b. Como evitar/minimizar a ocorrência desta falha
      i. Reveja as instruções de utilização do dispositivo Heartstring <u>antes</u> da utilização, especialmente

se o Heartstring não for utilizado de forma rotineira.

ii. Carregue o vedante HS III seguindo cuidadosamente as instruções de utilização (IFU) passo a passo do dispositivo.

iii. De acordo com a secções 4.3-4.5, confirme que o vedante HS III foi devidamente carregado nodispositivo de aplicação inspecionando o vedante HS III carregado assim que este tenha sido carregado no dispositivo de aplicação e removido do dispositivo de carregamento.

iv. Um vedante HS III que não seja devidamente inspecionado após a remoção do dispositivo de carregamento pode falhar durante a colocação do vedante HS III e causar lesões no doente(consulte as informações em "Falha na colocação").

v. Conclua o carregamento bem-sucedido do vedante HS III antes de limpar a adventícia da superfície aórtica e criar a aortotomia.

c. Ação a tomar se não for possível carregar o vedante HS III.

i. Elimine o vedante HS III com falha.

ii. Tenha sempre disponível um segundo vedante HS III para substituir um dispositivo avariado.Consulte as instruções de utilização do dispositivo para garantir um carregamento bem-sucedido.

2. Falha na colocação do vedante Heartstring III na aortotomia

a. Lembretes importantes:

i. Certifique-se de que o vedante HS III foi devidamente carregado no dispositivo de aplicação, deacordo com o indicado na secção anterior.

ii. Depios de retirar do vedante HS III carregado do dispositivo de carregamento, inspecione oobturador HS III carragado de acordo com as secções 4.3-4.5 das instruções de uso para confrimaro seguinte:

1. O vedante HS III carregado não está rachado.
2. A porção do vedante HS III não carregada no tubo do dispositivo de aplicação não émais larga do que o diâmetro do tubo do dispositivo de aplicação.
3. As extremidades da mola de tensão estão alinhadas de forma a entrarem em contacto com ambas as extremidades proximais do vedante HS III carregado durante a aplicaçãodo vedante na aortotomia.

b. Como evitar/minimizar a ocorrência desta falha:

i. Depois de confirmar o carregamento bem-sucedido do vedante HS III e a criação da aortotomia,coloque o vedante HS III carregado na aortotomia seguindo cuidadosamente os passos para acolocação do vedante HS III documentados nas instruções de utilização do dispositivo.

ii. Se o vedante HS III não for colocado conforme previsto, é necessário substituí-lo.

c. Ação a tomar se o vedante HS III não for colocado com sucesso na aorta.

i. Oclua a aortotomia para controlar a hemorragia utilizando um dedo indicador.

ii. Abra um segundo vedante HS III. Carregue o vedante HS III de acordo com as instruções deutilização do dispositivo. Aplique o vedante HS III carregado na aortotomia e siga as instruções de utilização para concluir a anastomose.

iii. Se a aplicação do segundovedante HSIII na aortotomia nãofor bem-sucedida, ou sea preferência do cirurgião determinar que a situação não permite a utilização de um vedante HS III de substituição, coloque um clampe de oclusão parcial na aorta, isolando a aortotomia e realize a anastomose de acordo com a técnica cirúrgica tradicional.

3. Falha do vedante Heartstring III colocado em fornecer uma hemóstase adequada:

a. Como evitar/minimizar a ocorrência deste modo de falha:

i. Carregue sempre e inspecione cuidadosamente o vedante HS III carregado para confirmar o carregamento bem-sucedido do vedante HS III no dispositivo de aplicação antes de limpar quaisquer adventícias da aorta e criar a aortotomia. (Consulte os lembretes importantes diretamente acima.)
ii. Não utilize o sistema de vedação proximal Heartstring em doentes com uma aorta de parede fina.
iii. Ao realizar várias anastomoses, certifique-se de que todos os locais de anastomose têm uma distância mínima de 1,5 cm entre si para garantir a hemóstase.
iv. Não mergulhe o vedante HS III na solução antes da colocação.

b. Ação a tomar se o vedante HS III não se abrir/permitir uma hemóstase adequada após a colocação do vedante.
   i. Tape a aortotomia com um dedo indicador e ajuste suavemente a mola de tensão paragarantir que o vedante HS III está colocado na totalidade.
   ii. Se a falta de hemóstase adequada persistir:
      1. Retire o vedante HS III colocado da aortotomia de acordo com as instruções de utilização do dispositivo.
      2. Carregue um segundo vedante HS III e coloque o vedante carregado na aortotomia de acordo com as instruções de utilização do dispositivo e concluaa anastomose.
      3. Se o segundo vedante HS III não for bem-sucedido, ou se a preferência do cirurgião determinar que a situação não permite a utilização de um vedante HS III de substituição, coloque um clampe de oclusão parcial na aorta, isolando a aortotomia e realize a anastomose de acordo com a técnicacirúrgica tradicional.

Ações por parte do cliente
A Getinge solicita que tome as seguintes medidas:

1. Certifique-se de que esta mensagem é transmitida a todas as pessoas que têm de ser informadas dentro da sua organização ou a qualquer organização para onde os dispositivos afetados tenham sido transferidos.

Informação adicional
A Getinge está a divulgar esta informação às agências reguladoras apropriadas.

Lamentamos qualquer inconveniente que isto lhe possa causar. Estamos empenhados na segurança dos doentes e apreciamos a sua atenção imediata a este assunto. Em caso de dúvidas acerca desta comunicação, contacte o seu representante local da Getinge.

Com os melhores cumprimentos,

Francisco Vicenty
Diretor, Conformidade Regulamentar e de Qualidade
Getinge, Cirurgia cardiovascular

Detahles do seu representante local:

Francisco Noronha
Responsável Técnico
Getinge Group Portugal, Unipessoal Lda
Rua Dr. António Loureiro Borges, 9/9A, Arquiparque, Miraflores, 1495-131Algés, Portugalf.noronha@bizaffairs.pt
00 (351) 211 579 890

Puerto Rico (es)

Agosto 2025

Aviso de Seguridad en Campo
Sistema de Sellado Proximal
Heartstring III

Número de Modelo	UDI	Nombre del modelo	Números de serie/lote
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de sellado proximal Heartstring III	Todos los lotes no vencidos
Fechas de distribución:		1 de julio de 2024 - Actualidad	
Fechas de fabricación:		7 de marzo de 2024 - Actualidad	

Estimado gestor de riesgos,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está emitiendo una corrección urgente de dispositivos médicos para el sistema de sellado proximal Heartstring III (HS III Seal). Según nuestros registros, usted ha recibido uno o varios de los dispositivos afectados por esta notificación.

Descripción del Problema

Se han identificado tres modos de fallo principales.

1. **Fallo en la carga del sello Heartstring**: Este fallo se aplica a cualquier mal funcionamiento del dispositivo que se produzca durante el proceso de carga de cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un sello HS III cargado correctamente y el desbloqueo del dispositivo de administración tras completar con éxito los pasos de carga del sello HS III.
2. **Fallo del sello cardíaco al desplegarse en la aortotomía**: Este fallo se aplica a cualquier mal funcionamiento del sello HS III y/o del dispositivo de implantación desde el momento en que el dispositivo de implantación se desbloquea correctamente hasta que se completa la implantación del sello HS III en la aortotomía y todo el contenido del sello proximal (la correa, el resorte de tensión, el vástago del sello y la lengüeta de anclaje) ha salido del dispositivo de implantación.
3. **Fallo del sellado Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier mal funcionamiento de un sello HS III implantado correctamente que no controle adecuadamente el sangrado en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis, a pesar del ajuste suave del resorte de tensión tras la implantación del sello y/o el uso de un nebulizador, succión o jeringa de solución salina para limpiar el sitio de la anastomosis. Este fallo incluye la identificación por parte del cliente de un sello HS III defectuoso o dañado tras el despliegue correcto del sello HS III en la aorta, lo que da lugar o puede dar lugar a una hemostasia inadecuada que impide al cirujano completar la anastomosis sin retirar el sello HS III defectuoso.

En estos momentos se está investigando la causa raíz.

Riesgos para la salud

1. **Error al cargar:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un sello HS III que no se carga no supone un riesgo directo para el paciente. Sin embargo, este fallo puede provocar un retraso en la intervención quirúrgica. Este retraso puede variar desde unos minutos para recuperar y cargar un nuevo sello, hasta una posible conversión del uso del sello HS III para realizar la anastomosis proximal al empleo de una pinza aórtica para completar la intervención.
2. **Fallo en la implementación:** Cuando el sello HS III cargado no se despliega desde el dispositivo de administración, ya se han realizado los siguientes pasos del procedimiento, lo que puede contribuir al riesgo potencial de daño al paciente. Si el sello HS III cargado no se despliega desde el dispositivo de administración, ya se habrán completado varios pasos del procedimiento, lo que puede aumentar el riesgo potencial de daño al paciente.
   - Se ha realizado la aortotomía.
   - El extremo distal del tubo del dispositivo de administración se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de administración o se ha intentado presionarlo.
   - El sello HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de administración.
   - Cuando se retira el dispositivo de administración de la aortotomía, el sello HS III no se desplegará y será necesario controlar el sangrado de la aortotomía colocando un dedo sobre ella.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: para retirar el HS III Seal no desplegado, abrir un nuevo HS III Proximal Seal, cargar el Seal en el dispositivo de liberación (Delivery Device) y entregar el HS III Seal cargado en la aortotomía creada (retraso sin intervención adicional) vs. la decisión de utilizar una pinza aórtica para completar la anastomosis debido a que el Seal cargado no se desplegó (retraso con una intervención adicional).
   - **Daño tisular**: puede ocurrir como resultado del despliegue de un HS III Seal cargado que esté ensanchado en la punta. Una punta ensanchada tendrá un diámetro mayor que el tubo distal del dispositivo de liberación. El despliegue de un Seal cargado con la punta ensanchada puede causar daño al tejido de la aortotomía y, si se aplica mayor fuerza para desplegar el Seal afectado, existe un riesgo potencial de perforar la pared posterior de la aorta durante la inserción. El daño tisular también puede ocurrir durante la retirada del dispositivo de liberación de la aortotomía, al desplegar un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
   - **Sangrado:** puede producirse una pérdida mínima de sangre al retirar el dispositivo de liberación de la aortotomía, al controlar manualmente el sangrado de la aortotomía y al colocar un HS III Seal de reemplazo. Puede producirse una mayor pérdida de sangre, que requiera intervención adicional, si ocurre daño tisular.
   - **Evento embólico** como resultado de la manipulación adicional de la aorta para abordar la falla en la carga del HS III Seal.
3. **Falla del Heartstring Seal desplegado para proporcionar hemostasia adecuada:** uando un HS III Seal desplegado no logra proporcionar una hemostasia adecuada para que el cirujano complete la anastomosis proximal, varios pasos del uso del Sistema HS III Seal ya se han completado y pueden aumentar el riesgo potencial de daño al paciente. Los siguientes pasos del procedimiento ya se habrán realizado.
   - Se ha creado la aortotomía.
   - El HS III Seal cargado se ha desplegado en la aorta.
   - El sangrado de la aorta es considerado por el cirujano como demasiado abundante para realizar la anastomosis.

Los siguientes daños potenciales al paciente pueden ocurrir:

- **Retraso del procedimiento quirúrgico**: puede ocurrir de la siguiente manera:

  Tiempo operatorio adicional necesario para intentar realizar ajustes en el Seal con el fin de mejorar la hemostasia proporcionada por el HS III Seal implantado, retirar el HS III Seal defectuoso, abrir un nuevo HS III Seal, cargar el HS III Seal de reemplazo y colocar el HS III Seal cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional).
  - El cirujano considera más apropiado utilizar una pinza aórtica para completar la anastomosis debido a que el HS III Seal desplegado no logró proporcionar hemostasia adecuada para completarla y no hay un HS III Seal de reemplazo disponible, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo y se utiliza una pinza aórtica para completar la anastomosis proximal según la técnica quirúrgica tradicional. (retraso del procedimiento con intervención adicional)
- **Daño tisular**: puede ocurrir durante la manipulación del HS III Seal afectado, durante el despliegue de un segundo HS III Seal cargado en la misma aortotomía y/o al necesitar convertir el procedimiento al uso de una pinza aórtica para completar la aortotomía.
- **Sangrado:** Una pequeña cantidad de pérdida de sangre alrededor del HS III Seal desplegado es normal y esperada al realizar la anastomosis proximal utilizando un HS III Seal. Puede producirse una mayor pérdida de sangre que requiera intervención adicional cuando ocurre daño del tejido aórtico, independientemente de la causa.
- **Evento(s) embólico(s):** como resultado de la manipulación adicional de la aorta secundaria a la necesidad de abordar la falla del HS III Seal en proporcionar hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge recibió las siguientes quejas:

- 274 reportes relacionados con falla de carga, lo que representa una tasa de quejas del 0,386%
- 96 reportes relacionados con falla de despliegue, lo que representa una tasa de quejas del 0,135%
- 30 reportes relacionados con hemostasia inadecuada, lo que representa una tasa de quejas del 0,042%

<u>Medidas y acciones recomendadas</u>

Getinge proporciona las siguientes instrucciones para evitar/minimizar las fallas descritas anteriormente.

1. **Falla del Heartstring Seal al cargar**
   a. Recordatorios importantes:
      i. Según las Instrucciones de Uso (IFU) del dispositivo, el HS III Seal debe cargarse y retirarse del dispositivo de carga (Loading Device), luego inspeccionarse y ajustarse si es necesario para confirmar una carga exitosa y finalmente desbloquearse antes de retirar cualquier adventicia del área anastomótica planificada y crear la aortotomía. Cargar el HS III Seal y confirmar una carga exitosa antes de crear la aortotomía minimiza el riesgo para los pacientes, ya que la aorta permanece intacta hasta confirmar que la carga del HS III Seal fue exitosa.
      ii. Si el HS III Seal no se carga según lo previsto, el dispositivo debe reemplazarse.

   b. Cómo evitar/minimizar la ocurrencia de esta falla
      i. Revisar las Instrucciones de Uso (IFU) del dispositivo Heartstring antes de su utilización, especialmente si Heartstring no se utiliza de forma rutinaria.
      ii. Cargar el HS III Seal siguiendo cuidadosamente las Instrucciones de

Uso (IFU) del dispositivo paso a paso.

iii. De acuerdo con las Secciones 4.3–4.5 de las IFU, confirmar que el HS III Seal ha sido correctamente cargado en el dispositivo de liberación (Delivery Device) inspeccionando el HS III Seal cargado una vez que haya sido introducido en el Delivery Device y retirado del dispositivo de carga (Loading Device).

iv. Un HS III Seal que no sea inspeccionado adecuadamente después de retirarlo del dispositivo de carga (Loading Device) puede fallar durante el despliegue del HS III Seal y causar daño al paciente. (Ver la información relacionada con Falla de Despliegue).

v. Completar la carga exitosa del HS III Seal antes de limpiar la adventicia de la superficie aórtica y crear la aortotomía.

c. Acción a tomar si el HS III Seal falla al cargarse.
   i. Desechar el HS III Seal defectuoso.
   ii. Tener siempre disponible un segundo HS III Seal para reemplazar un dispositivo defectuoso. Consultar las IFU del dispositivo para asegurar una carga exitosa.

2. Falla del Heartstring III Seal al desplegarse en la aortotomía

a. Recordatorios importantes:
   i. Asegurarse de que el HS III Seal haya sido correctamente cargado en el dispositivo de liberación (Delivery Device), tal como se describe en la sección anterior.
   ii. Después de retirar el HS III Seal cargado del dispositivo de carga (Loading Device), inspeccionar el HS III Seal cargado, de acuerdo con las Secciones 4.3–4.5 de las IFU, para confirmar lo siguiente:
      1. Que el HS III Seal cargado no esté agrietado.
      2. Que la porción del HS III Seal que no está dentro del tubo del Delivery Device no esté ensanchada más allá del diámetro del tubo del Delivery Device.
      3. Que los extremos del resorte de tensión (Tension Spring) estén alineados de modo que contacten ambos bordes proximales del HS III Seal cargado durante la colocación del Seal en la aortotomía.

b. Cómo evitar/minimizar la ocurrencia de esta falla:
   i. Después de confirmar la carga exitosa del HS III Seal y crear la aortotomía, desplegar el HS III Seal cargado en la aortotomía siguiendo cuidadosamente los pasos de despliegue documentados en las IFU del dispositivo.
   ii. Si el HS III Seal no se despliega según lo previsto, el dispositivo debe reemplazarse.

c. Acción a tomar si el HS III Seal no se despliega correctamente en la aorta.
   i. Ocluir la aortotomía para controlar el sangrado utilizando el dedo índice.
   ii. Abrir un segundo HS III Seal. Cargar el HS III Seal de acuerdo con las IFU del dispositivo. Introducir el HS III Seal cargado en la aortotomía y seguir las

IFU para completar la anastomosis.

iii. Si la colocación del segundo HS III Seal en la aortotomía no tiene éxito, o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

3. **Falla del Heartstring III Seal desplegado para proporcionar hemostasia adecuada:**
    a. Cómo evitar/minimizar la ocurrencia de este modo de falla:
        i. Cargar siempre e inspeccionar cuidadosamente el HS III Seal cargado para confirmar que la carga en el dispositivo de liberación (Delivery Device) se haya realizado correctamente antes de retirar la adventicia de la aorta y crear la aortotomía. (Ver recordatorios importantes anteriores).
        ii. No utilizar el sistema Heartstring Proximal Seal en pacientes con aorta de pared delgada.
        iii. Al realizar múltiples anastomosis, asegurar que todos los sitios anastomóticos estén separados al menos 1,5 cm para garantizar la hemostasia.
        iv. No sumergir el HS III Seal en solución <u>antes</u> del despliegue.
    b. Acción a tomar si el HS III Seal no se abre/no proporciona hemostasia adecuada después del despliegue.
        i. Cubrir la aortotomía con el dedo índice y ajustar suavemente el resorte de tensión (Tension Spring) para asegurar que el HS III Seal se haya desplegado completamente.
        ii. Si persiste la falta de hemostasia adecuada:
            1. Retirar el HS III Seal desplegado de la aortotomía de acuerdo con las IFU del dispositivo.
            2. Cargar un segundo HS III Seal y desplegar el Seal cargado en la aortotomía conforme a las IFU del dispositivo y completar la anastomosis.
            3. Si el segundo HS III Seal no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un HS III Seal de reemplazo, colocar una pinza de oclusión parcial en la aorta, aislando la aortotomía, y realizar la anastomosis según la técnica quirúrgica tradicional.

<u>Acciones para el cliente</u>

Getinge solicita que tome las siguientes acciones:

1. Asegúrese de que este mensaje sea reenviado a todas las personas que deban ser notificadas dentro de su organización o en cualquier organización a la que se hayan transferido los dispositivos afectados.

<u>Información adicional</u>

Getinge está comunicando esta información a las agencias regulatorias correspondientes.

Lamentamos cualquier inconveniente que esto pueda ocasionar. Estamos comprometidos con la seguridad del paciente y agradecemos su pronta atención a este asunto. Si tiene alguna pregunta con respecto a esta comunicación, por favor comuníquese con su representante de Getinge o con el Servicio de Atención al Cliente de Getinge.

Cordialmente,

Francisco Vicenty
Director de Calidad y Cumplimiento Regulatorio, Interino
Getinge, Cirugía Cardiovascular

Saudi Arabia (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:
   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly

loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Singapore (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:
   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

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Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly

loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Slovakia (sk)

august 2025

Bezpečnostný oznam

Proximálny uzatvárací systém Heartstring III

Referenčné číslo: 1336551

Modelové číslo	UDI	Názov modelu	Sériové číslo/šarža
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proximálny uzatvárací systém Heartstring III	Všetky neexspirované šarže
Dátumy distribúcie:		od 1. júla 2024 doteraz	
Dátumy výroby:		od 7. marca 2024 doteraz	

Vážený manažér rizík,

účelom tohto listu je informovať vás, že spoločnosť Maquet Cardiovascular, dcérska spoločnosť spoločnosti Getinge, vydáva naliehavú opravu zdravotníckej pomôcky Proximálny uzatvárací systém Heartstring III (uzáver HS III). Podľa našich záznamov ste dostali jednu alebo viac dotknutých zdravotníckych pomôcok, ktorých sa tento oznam týka.

Opis problému

Boli identifikované tri primárne režimy zlyhania.

1. **Zlyhanie pri zavádzaní uzáveru:** tento problém sa týka akéhokoľvek zlyhania zariadenia, ku ktorému dôjde počas štvorkrokového procesu zavádzania pomocou zavádzacieho zariadenia Heartstring, vizuálnej kontroly úspešne zavedeného uzáveru HS III a odistenia aplikačného zariadenia po úspešnom dokončení krokov zavádzania uzáveru HS III.
2. **Zlyhanie pri rozvinutí uzáveru Heartstring do aortotómie**: tento problém sa vzťahuje na akékoľvek zlyhanie uzáveru HS III a/alebo aplikačného zariadenia od okamihu, čo je aplikačné zariadenie úspešne odistené, do okamihu, čo je uzáver HS III úplne umiestnený do aortotómie, a všetky časti proximálneho uzáveru (vlákno, napínacia pružina, telo uzáveru, ukotvovacie pútko) sú odstránené z aplikačného zariadenia.
3. **Rozvinutý uzáver Heartstring neposkytuje dostatočnú hemostázu:** tento problém sa týka akejkoľvek poruchy fungovania úspešne rozvinutého uzáveru HS III, ktorý nezaisťuje v mieste anastomózy adekvátnu kontrolu krvácania na uskutočnenie šitia anastomózy, a to aj napriek jemnému nastaveniu napínacej pružiny po rozvinutí uzáveru a/alebo použití ventilátorového postrekovača, odsávania alebo striekačky s fyziologickým roztokom na vyčistenie miesta anastomózy. Táto porucha zahŕňa aj prípad, keď zákazník identifikuje chybný alebo poškodený

uzáver HS III po úspešnom rozvinutí uzáveru HS III do aorty, keď porucha má/môže mať za následok nedostatočnú hemostázu, ktorá chirurgovi bráni v dokončení anastomózy bez odstránenia chybného uzáveru HS III.

Momentálne prebieha šetrenie hlavnej príčiny.

Zdravotné riziká:

1. **Zlyhanie pri zavádzaní:** ak sa uzáver HS III používa podľa návodu na použitie (IFU) pomôcky, nepredstavuje zlyhanie pri zavádzaní pre pacienta priame riziko. Toto zlyhanie však môže viesť k oneskoreniu chirurgického zákroku. Toto oneskorenie sa môže pohybovať v rozsahu od niekoľkých minút potrebných na vybratie a zavedenie nového uzáveru až po potenciálny prechod z použitia uzáveru HS III k vykonaniu proximálnej anastomózy na použitie aortálnej svorky na dokončenie zákroku.
2. **Zlyhanie pri rozvinutí:** keď sa nedarí rozvinúť zavedený uzáver HS III z aplikačného zariadenia, boli už vykonané nasledujúce procedurálne kroky a tie môžu prispieť k potenciálnemu riziku poškodenia zdravia pacienta. Ak sa zavedený uzáver HS III nedarí rozvinúť z aplikačného zariadenia, bude už vykonaných niekoľko procedurálnych krokov, ktoré môžu zvýšiť potenciálne riziko poškodenia zdravia pacienta.
   - Bola vytvorená aortotómia.
   - Distálny koniec trubice aplikačného zariadenia bol zavedený cez aortotómiu.
   - Piest aplikačného zariadenia bol stlačený alebo sa uskutočnil pokus o jeho stlačenie.
   - Vložený uzáver HS III sa nepodarilo úspešne rozvinúť z distálneho konca trubice aplikačného zariadenia.
   - Po vybratí aplikačného zariadenia z aortotómie sa uzáver HS III nerozvinie a krvácanie z aortotómie bude nutné zastaviť umiestnením prsta cez aortotómiu.

   Môžu nastať nasledujúce ujmy na zdraví pacienta:

   - **Oneskorenie chirurgického zákroku**: odstránenie nerozvinutého uzáveru HS III, otvorenie nového proximálneho uzáveru HS III, vloženie uzáveru do aplikačného zariadenia a zavedenie vloženého uzáveru HS III do vytvorenej aortotómie (oneskorenie bez ďalšieho zásahu) v. rozhodnutie použiť aortálnu svorku na dokončenie anastomózy, pretože zavedený uzáver sa nepodarilo rozvinúť (oneskorenie s ďalším zásahom).
   - **Poškodenie tkaniva**: k poškodeniu tkaniva môže dôjsť v dôsledku rozvinutia zavedeného uzáveru HS III, ktorý je na špičke rozšírený. Rozšírená špička bude mať priemer väčší než distálna trubica aplikačného zariadenia. Rozvinutie zavedeného uzáveru s rozšíreným koncom môže spôsobiť poškodenie tkaniva v oblasti aortotómie a v prípade použitia väčšej sily na rozvinutie dotknutého uzáveru existuje pri zavádzaní možné riziko poranenia zadnej steny aorty. K poškodeniu tkaniva môže dôjsť aj počas odstraňovania aplikačného zariadenia z aortotómie, rozvinutia druhého zavedeného tesnenia HS III do tej istej aortotómie a/alebo nutnosti prejsť na použitie aortálnej svorky na dokončenie aortotómie.
   - **Krvácanie:** k minimálnej strate krvi môže dôjsť počas odstraňovania aplikačného zariadenia z aortotómie, pri ovládaní krvácania z aortotómie manuálne a aplikácii náhradného uzáveru HS III. Väčšia strata krvi, ktorá by vyžadovala dodatočnú intervenciu, môže nastať, ak dôjde k poškodeniu tkaniva.
   - **Embolická udalosť** v dôsledku dodatočnej manipulácie s aortou pri riešení zlyhania pri zavádzaní uzáveru HS III.
3. **Rozvinutý uzáver Heartstring neposkytuje dostatočnú hemostázu:** v prípade, že rozvinutý uzáver HS III neposkytuje hemostázu dostatočnú na to, aby mohol chirurg dokončiť proximálnu anastomózu, boli už dokončené niektoré kroky súvisiace s použitím uzatváracieho systému HS III

a to môže zvýšiť potenciálne riziko ujmy na zdraví pacienta. V tomto okamihu už budú vykonané nasledujúce kroky:

- Bola vykonaná aortotómia.
- Zavedený uzáver HS III bol rozvinutý v aorte.
- Chirurg považuje krvácanie z aorty za príliš silné, aby mohol vykonať anastomózu.

Môže dôjsť k nasledujúcim ujmám na zdraví pacienta:

- **Oneskorenie chirurgického zákroku**: môže k nemu dôjsť nasledovne:
    - Dodatočný operačný čas potrebný na pokus o úpravu uzáveru s cieľom zlepšiť hemostázu pomocou zavedeného uzáveru HS III, odstránenie chybného uzáveru HS III, otvorenie nového uzáveru HS III, vloženie náhradného uzáveru HS III a zavedenie pripraveného uzáveru HS III do vytvorenej aortotómie (Oneskorenie zákroku bez ďalšieho zásahu).
    - Chirurg považuje za najvhodnejšie použiť na dokončenie anastomózy aortálnu svorku, pretože rozvinutý uzáver HS III neposkytuje hemostázu dostatočnú na dokončenie anastomózy a buď nie je k dispozícii náhradný uzáver HS III, alebo chirurg rozhodne, že situácia neumožňuje použiť náhradný uzáver HS III a použije aortálnu svorku na dokončenie proximálnej anastomózy tradičnou chirurgickou technikou. (Oneskorenie zákroku s ďalším zákrokom.)
- **Poškodenie tkaniva**: k poškodeniu tkaniva môže dôjsť pri manipulácii s dotknutým uzáverom HS III, počas rozvinutia druhého zavedeného uzáveru HS III do tej istej aortotómie a/alebo v prípade, keď bude treba prejsť na použitie aortálnej svorky na dokončenie aortotómie.
- **Krvácanie:** malá strata krvi v okolí rozvinutého uzáveru HS III je normálna a dá sa pri vykonávaní proximálnej anastomózy použitím uzáveru HS III očakávať. K väčšej strate krvi, ktorá by vyžadovala dodatočnú intervenciu, môže dôjsť pri poškodení tkaniva bez ohľadu na jeho príčinu.
- **Embolická udalosť:** vznikne dodatočnou manipuláciou s aortou v dôsledku riešenia zlyhania, keď uzáver HS III neposkytuje dostatočnú hemostázu.

Od 1. júna 2023 do 22. júla 2025 dostala spoločnosť Getinge nasledujúce sťažnosti:

- 274 hlásení súvisiacich so zlyhaním pri zavádzaní, čo predstavuje mieru sťažností 0,386 %
- 96 hlásení súvisiacich so zlyhaním pri rozvinutí, čo predstavuje mieru sťažností 0,135 %
- 30 hlásení týkajúcich sa nedostatočnej hemostázy, čo predstavuje mieru sťažností 0,042 %

<u>Odporúčané zmierňujúce opatrenia a kroky:</u>
Spoločnosť Getinge poskytuje nasledujúce pokyny, ako sa vyhnúť vyššie opísaným zlyhaniam / minimalizovať ich.

1. **Zlyhanie pri zavádzaní uzáveru Heartstring**
    a. Dôležité pripomenutie
        i. Návod na použitie pomôcky uvádza, že uzáver HS III sa má zaviesť a vybrať zo zavádzacieho zariadenia, potom skontrolovať a v prípade potreby upraviť, aby bolo možné potvrdiť úspešné zavedenie, a následne odistiť pred odstránením adventicie z miesta plánovanej anastomózy a vytvorením aortotómie. Zavedenie uzáveru HS III

a potvrdenie úspešného zavedenia pred vytvorením aortotómie minimalizuje riziko pre pacienta, pretože aorta zostáva nedotknutá, pokým sa nepotvrdí úspešné zavedenie uzáveru HS III.

ii. Ak zlyhá plánované zavedenie uzáveru HS III, pomôcka by sa mala vymeniť.

b. Ako sa vyhnúť tomuto zlyhaniu / minimalizovať jeho výskyt.

i. Pred použitím si preštudujte návod na použitie pomôcky Heartstring, najmä ak sa Heartstring nepoužíva pravidelne.

ii. Pri zavádzaní uzáveru HS III postupujte opatrne a dodržujte postupne všetky kroky uvedené v návode na použitie. (IFU).

iii. Podľa pokynov v článku 4.3 – 4.5 návodu na použitie skontrolujte, že uzáver HS III bol správne vložený do aplikačného zariadenia tak, že skontrolujete vložený uzáver HS III po jeho vložení do aplikačného zariadenia a vybratí zo zavádzacieho zariadenia.

iv. Uzáver HS III, ktorý nebol po vybratí zo zavádzacieho zariadenia riadne skontrolovaný, môže počas rozvinutia zlyhať a spôsobiť pacientovi ujmu. (Pozri informácie súvisiace so zlyhaním pri rozvinutí).

v. Dokončite úspešné zavedenie uzáveru HS III pred očistením povrchu adventicie aorty a vytvorením aortotómie.

c. Opatrenia, ktoré je nutné vykonať v prípade, že uzáver HS zlyhá pri zavádzaní.

i. Uzáver HS III, ktorý sa nepodarilo zaviesť, zlikvidujte.

ii. Vždy majte pripravený druhý uzáver HS III, ktorým nahradíte poruchovú pomôcku. S cieľom dosiahnuť úspešné zavedenie sa riaďte návodom na použitie.

2. Zlyhanie pri rozvinutí uzáveru Heartstring do aortotómie

a. Dôležité pripomenutia:

i. Uistite sa, že uzáver HS III bol správne vložený do aplikačného zariadenia, ako je uvedené v odseku vyššie.

ii. Po vybratí vloženého uzáveru HS III zo zavádzacieho zariadenia skontrolujte vložený uzáver HS III podľa návodu na použitie (časť 4.3. – 4.5), aby ste potvrdili, že:

1. Vložený uzáver HS III nie je popraskaný.
2. Časť uzáveru HS III, ktorá nie je vložená do trubice aplikačného zariadenia, nie je širšia než priemer trubice aplikačného zariadenia.
3. Uistite sa, že sú konce napínacej pružiny zarovnané tak, že sa počas zavádzania uzáveru HS III do aortotómie dotýkajú oboch jeho proximálnych koncov.

b. Ako sa vyhnúť tomuto zlyhaniu / minimalizovať jeho výskyt.

i. Hneď ako potvrdíte úspešné zavedenie uzáveru HS III a vytvorenie aortotómie, rozviňte zavedený uzáver HS III do aortotómie. Dôkladne dodržujte postup rozvinutia uzáveru HS III opísaný v návode na použitie.

ii. Ak sa uzáver HS III nerozvinie podľa očakávania, pomôcka by sa mala nahradiť.

c. Opatrenia, ktoré je nutné vykonať, ak sa uzáver HS III nerozvinie úspešne do aorty.

i. Ukazovákom uzatvorte aortotómiu, aby ste zastavili krvácanie.

ii. Otvorte druhý uzáver HS III. Vložte tento uzáver podľa pokynov v návode na použitie. Zaveďte vložený uzáver HS III do aortotómie a na dokončenie anastomózy dodržujte postup v návode na použitie.

iii. Ak nebude zavedenie druhého uzáveru HS III do aortotómie úspešné, alebo ak chirurg rozhodne, že situácia nedovoľuje použiť náhradný uzáver HS III, na aortu umiestnite čiastočnú oklúznu svorku, čím izolujete aortotómiu, a vykonajte anastomózu tradičnou chirurgickou technikou.

3. **Rozvinutý uzáver Heartstring neposkytuje dostatočnú hemostázu:**
    a. Ako sa vyhnúť tomuto zlyhaniu / minimalizovať jeho výskyt:
        i. Pri zavádzaní uzáveru HS III vykonajte dôkladnú kontrolu, takisto po jeho zavedení, aby ste potvrdili úspešné zavedenie uzáveru HS III do aplikačného zariadenia pred tým, ako očistíte adventiciu aorty a vytvoríte aortotómiu. (pozri dôležité pripomenutia vyššie).
        ii. Nepoužívajte Proximálny uzatvárací systém Heartstring u pacienta s tenkostennou aortou.
        iii. Pri vykonávaní viacnásobných anastomóz sa uistite, že všetky miesta anastomózy sú od seba vzdialené aspoň 1,5 cm, aby bola zaistená hemostáza.
        iv. Pred rozvinutím nenamáčajte uzáver HS III do roztoku.
    b. Opatrenia, ktoré je nutné vykonať, ak sa uzáver HS III neotvorí / neposkytuje po rozvinutí dostatočnú hemostázu.
        i. Ukazovákom uzatvorte aortotómiu a opatrne upravte napínaciu pružinu, aby ste sa uistili, že je uzáver HS III úplne rozvinutý.
        ii. Ak nedostatočná hemostáza pretrváva:
            1. Vyberte rozvinutý uzáver HS III z aortotómie podľa pokynov v návode na použitie.
            2. Zaveďte druhý uzáver HS III a rozviňte zavedený uzáver v aortotómii podľa pokynov v návode na použitie a dokončite anastomózu.
            3. Ak nie je druhý uzáver HS III úspešný alebo chirurg rozhodne, že situácia nedovoľuje použiť náhradný uzáver HS III, na aortu umiestnite čiastočnú oklúznu svorku, čím izolujete aortotómiu, a vykonajte anastomózu tradičnou chirurgickou technikou.

Opatrenia na strane zákazníka

Spoločnosť Getinge po vás požaduje nasledujúce opatrenia:

1. Zaistite, že táto správa bude odovzdaná všetkým jedincom, ktorí toto upozornenie potrebujú v rámci vašej organizácie alebo inej organizácie, kam boli dotknuté pomôcky odovzdané.

Dodatočné informácie

Spoločnosť Getinge oznamuje tieto informácie príslušným regulačným orgánom.

Ospravedlňujeme sa za akékoľvek nepríjemnosti, ktoré vám táto záležitosť mohla spôsobiť. Záleží nám na bezpečnosti pacientov a vážime si vašu rýchlu reakciu na túto záležitosť. Ak máte akékoľvek otázky týkajúce sa tohto oznamu, kontaktujte, prosím, svojho zástupcu spoločnosti Getinge alebo zákaznícky servis Getinge na čísle 1-888-880-2874, od pondelka do piatka medzi 8.00 a 17.00 hod. (tichomorské časové pásmo).

S pozdravom,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Slovenia (sl)

avgust 2025

Varnostno opozorilo za teren

Proksimalni zapiralni sistem Heartstring III

Referenčna številka: 1336551

Številka modela	**UDI**	**Ime modela**	**Serijska številka/serija**
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proksimalni zapiralni sistem Heartstring III	Vse serije, ki jim še ni potekel rok uporabe
Datumi distribucije:		od 1.julija 2024 do danes	
Datumi proizvodnje:		od 7. marca 2024 do danes	

Spoštovani upravitelj tveganj,

namen tega dopisa je, obvestiti vas, da podjetje Maquet Cardiovascular, hčerinska družba podjetja Getinge, izdaja nujno popravilo medicinskega pripomočka Proksimalni zapiralni sistem Heartstring III (zapiralo HS III). Po naših podatkih ste prejeli enega ali več prizadetih medicinskih pripomočkov, na katere se nanaša to obvestilo.

Opis težave

Opredeljeni so bili trije glavni načini odpovedi.

1. **Odpoved pri vstavljanju zapirala:** ta težava se nanaša na katerokoli okvaro naprave, do katere pride med štiristopenjskim postopkom vstavljanja z uporabo vsadljive naprave Heartstring, vizualnim pregledom uspešno vstavljenega zapirala HS III in sprostitve aplikacijske naprave po uspešnem zaključku korakov vstavljanja zapirala HS III.
2. **Odpoved pri raztegnitvi zapirala Heartstring v arteriotomijo**: ta težava se nanaša na kakršnokoli okvaro zapirala HS III in/ali aplikacijske naprave od trenutka, ko je aplikacijska naprava uspešno aktivirana, do popolne namestitve zapirala HS III v aorto in odstranitve vseh delov proksimalnega zapirala (vlakno, napenjalna vzmet, ohišje zapirala, sidrna zanka) iz aplikacijske naprave.
3. **Raztegnjeno zapiralo Heartstring ne zagotavlja zadostne hemostaze:** ta težava se nanaša na vsako okvaro uspešno nameščenega zapirala HS III, ki ne zagotavlja ustreznega nadzora krvavitve na mestu anastomoze za izvedbo šivanja anastomoze, kljub natančni nastavitvi napenjalne vzmeti po raztegu zapirala in/ali uporabi ventilatorskega pršilnika, sesanja ali brizge s fiziološko raztopino za čiščenje mesta anastomoze. Ta okvara vključuje tudi primer, ko stranka po uspešni namestitvi zapirala HS III v aorto ugotovi okvaro ali poškodbo zapirala HS III, pri čemer je/bi lahko okvara povzročila neustrezno hemostazo, ki kirurgu preprečuje dokončanje anastomoze brez odstranitve okvarjene zapirala HS III.

Trenutno poteka preiskava osnovnega vzroka.

Tveganja za zdravje:

1. **Odpoved pri vstavljanju:** če se zapiralo HS III uporablja v skladu z navodili za uporabo (IFU) pripomočka, odpoved med vstavljanjem ne predstavlja neposrednega tveganja za bolnika. Vendar pa lahko ta napaka povzroči zamudo pri kirurškem posegu. Ta zamuda lahko traja od nekaj minut, potrebnih za odstranitev in vstavitev novega zapirala, do morebitnega prehoda od uporabe zapirala HS III za izvedbo proksimalne anastomoze k uporabi aortne sponke za dokončanje posega.
2. **Odpoved pri raztegu:** če vstavljenega zapirala HS III ne uspe raztegniti iz aplikacijske naprave, so bili naslednji postopkovni koraki že opravljeni in lahko prispevajo k morebitnemu tveganju za poškodbo bolnikovega zdravja. Če vstavljeno zapiralo HS III ne uspe raztegniti iz aplikacijske naprave, je bilo že izvedenih več postopkovnih korakov, ki lahko povečajo potencialno tveganje za škodo na zdravju bolnika.
    - Ustvarjena je bila arteriotomija.
    - Distalni konec cevke aplikacijske naprave je bil vstavljen skozi arteriotomijo.
    - Bat aplikacijske naprave je bil pritisnjen ali se ga je poskušalo pritisniti.
    - Vstavljenega zapirala HS III ni uspelo uspešno raztegniti z distalnega konca cevke aplikacijske naprave.
    - Po odstranitvi aplikacijske naprave iz arteriotomije se zapiralo HS III ne raztegne, krvavitev iz arteriotomije pa je treba zaustaviti s namestitvijo prsta preko arteriotomije.

    Pride lahko do naslednjih škodljivih posledic za bolnikovo zdravje:

    - **Zamuda pri kirurškem posegu**: odstranitev neraztegnjenega zapirala HS III, odprtje novega proksimalnega zapirala HS III, vstavitev zapirala v aplikacijsko napravo in vstavitev vstavljenega zapirala HS III v ustvarjeno arteriotomijo (zamuda brez nadaljnjega posega) v primerjavi z odločitvijo za uporabo aortne sponke za dokončanje anastomoze, ker se vstavljeno zapiralo ni raztegnilo (zamuda z nadaljnjim posegom).
    - **Poškodba tkiva**: do poškodbe tkiva lahko pride zaradi raztega zapirala HS III, ki je na konici razširjeno. Premer razširjene konice je večji od premera distalne cevi aplikacijske naprave. Raztegovanje vstavljenega zapirala z razširjenim koncem lahko povzroči poškodbo tkiva na mestu arteriotomije, med vstavljanjem pa obstaja potencialna nevarnost poškodbe zadnje stene aorte, če se za odvijanje zapirala uporabi večja sila. Do poškodbe tkiva lahko pride tudi med odstranjevanjem aplikacijske naprave iz arteriotomije, raztegom drugega vstavljenega tesnila HS III, ki se uvaja v isto arteriotomijo, in/ali potrebo po prehodu na uporabo aortne sponke za dokončanje arteriotomije.
    - **Krvavitev:** do minimalne izgube krvi lahko pride med odstranjevanjem aplikacijske naprave iz arteriotomije ročno in aplikacijo nadomestnega zapirala HS III. Če pride do poškodbe tkiva, lahko pride do večje izgube krvi, ki zahteva dodaten poseg.
    - **Embolični dogodek** zaradi dodatnega rokovanja z aorto pri zdravljenju neuspešne vstavitve zapirala HS III.
3. **Raztegnjeno zapiralo Heatstring ne zagotavlja zadostne hemostaze:** če raztegnjeno zapiralo HS III ne zagotavlja zadostne hemostaze, da bi kirurg lahko dokončal proksimalno anastomozo, so bili nekateri

koraki, povezani z uporabo zapiralnega sistema HS III, že opravljeni, kar lahko poveča morebitno tveganje za poškodbe zdravja bolnika. Na tej točki so bili že opravljeni naslednji koraki:

- Izvedena je bila arteriotomija.
- Vstavljeno zapiralo HS III je bilo raztegnjeno v aorti.
- Kirurg meni, da je krvavitev iz aorte prehuda za izvedbo anastomoze.

Pride lahko do naslednjih škodljivih posledic za bolnikovo zdravje:

- **Zamuda pri kirurškem posegu**: pojavi se lahko na naslednji način:
    - Dodatni čas operacije, potreben za poskus spremembe zapirala za izboljšanje hemostaze z uporabo vzpostavljenega zapirala HS III, odstranitev okvarjenega zapirala HS III, odprtje novega zapirala HS III, vstavitev nadomestnega zapirala HS III in vstavitev pripravljene zapirala HS III v ustvarjeno arteriotomijo (Zamuda pri posegu brez nadaljnjega posega).
    - Kirurg meni, da je za dokončanje anastomoze najprimerneje uporabiti aortno sponko, ker raztegnjeno zapiralo HS III ne zagotavlja zadostne hemostaze za dokončanje anastomoze in nadomestno zapiralo HS III ni na voljo ali pa se kirurg odloči, da razmere ne dovoljujejo uporabe nadomestnega zapirala HS III, in uporabi aortno sponko za dokončanje proksimalne anastomoze s tradicionalno kirurško tehniko (Zamuda pri posegu brez nadaljnjega posega.)
- **Poškodba tkiva**: Do poškodbe tkiva lahko pride med rokovanjem z zadevnim zapiralom HS III, med raztegom drugega zapirala HS III v isto arteriotomijo in/ali pri prehodu na uporabo aortne sponke za dokončanje arteriotomije.
- **Krvavitev:** majhna izguba krvi okoli raztegnjenega zapirala HS III je normalna in pričakovana pri izvajanju proksimalne anastomoze z uporabo zapirala HS III. Pri poškodbi tkiva se lahko pojavi večja izguba krvi, ki zahteva dodaten poseg, ne glede na vzrok.
- **Embolični dogodek:** nastane zaradi dodatnega rokovanja z aorto zaradi razrešitve okvare, pri kateri zapiralo HS III ne zagotovi zadostne hemostaze.

Od 1. junija 2023 do 22. julija 2025 je družba Getinge prejela naslednje pritožbe:

- 274 poročil, povezanih z napakami pri vstavljanju, kar predstavlja stopnjo pritožb 0,386 %
- 96 poročil, povezanih z napako pri raztegovanju, kar predstavlja stopnjo pritožb 0,135 %
- 30 poročil, povezanih z neustrezno hemostazo, kar predstavlja stopnjo pritožb 0,042 %

<u>Priporočeni omilitveni ukrepi in dejavnosti:</u>

Družba Getinge zagotavlja naslednja navodila za preprečevanje/zmanjševanje zgoraj opisanih napak.

1. **Odpoved pri vstavljanju Heartstring**
    a. Pomembna opozorila
        i. V navodilih za uporabo pripomočka je navedeno, da je treba zapiralo HS III vstaviti in odstraniti iz pripomočka za vstavljanje, nato preveriti in po potrebi prilagoditi, da se potrdi uspešna vstavitev, in nato odkleniti, preden se odstrani adventicija z načrtovanega mesta anastomoze in ustvari arteriotomija. Z vstavitvijo zapirala HS III in potrditvijo uspešne vstavitve pred izdelavo arteriotomije se zmanjša tveganje za

bolnika, saj aorta ostane nedotaknjena, dokler ni potrjena uspešna vstavitev zapirala HS III.

ii. Če načrtovana vstavitev zapirala HS III ni uspešna, je treba pripomoček zamenjati

b. Kako preprečiti ali čim bolj zmanjšati pojav te napake.
   i. Pred uporabo preberite navodila za uporabo pripomočka Heartstring, zlasti če Heartstring ne uporabljate redno.
   ii. Pri vstavljanju zapirala HS III ravnajte previdno in postopno upoštevajte vse korake, navedene v navodilih za uporabo. (IFU).
   iii. V skladu z navodili iz poglavja 4.3-4.5 navodil za uporabo preverite, ali je bilo zapiralo HS III pravilno vstavljeno v aplikacijsko napravo, tako da preverite vstavljeno zapiralo HS III, potem ko je bil vstavljeno v aplikacijsko napravo in odstranjeno iz naprave za vstavljanje.
   iv. Zapiralo HS III, ki po odstranitvi iz naprave za vstavljanje ni bilo ustrezno pregledano, lahko med raztegovanjem odpove in bolniku povzroči poškodbe (glejte informacije v zvezi z napako pri vstavljanju).
   v. Dokončajte uspešno vstavitev zapirala HS III pred čiščenjem površine adventicije aorte in ustvarjanjem arteriotomije.

c. Ukrepi, ki jih je treba izvesti, če zapiralo HS odpove med vstavljanjem.
   i. Zapiralo HS III, ki ga ni uspelo vstaviti, odstranite.
   ii. Vedno imejte pripravljeno drugo zapiralo HS III, s katerim pokvarjen instrument nadomestite. Za uspešno vstavitev upoštevajte navodila za uporabo.

2. Odpoved pri raztegovanju pokrova Heartstring v arteriotomijo

a. Pomembna opozorila:
   i. Prepričajte se, da je zapiralo HS III pravilno vstavljeno v aplikacijsko napravo, kot je navedeno v zgornjem odstavku.
   ii. Po odstranitvi vstavljenega zapirala HS III iz naprave za vstavljanje preverite vstavljeno zapiralo HS III v skladu z navodili za uporabo, oddelek 4.3.-4.5, da potrdite, da:
      1. Vstavljeno zapiralo HS III ni razpokano.
      2. Del zapirala HS III, ki ni vstavljen v cevko aplikacijske naprave, ni širši od premera cevke aplikacijske naprave.
      3. Prepričajte se, da sta konca napenjalne vzmeti poravnana tako, da se med vstavljanjem zapirala HS III v arteriotomijo dotikata obeh njegovih proksimalnih koncev.

b. Kako preprečiti ali čim bolj zmanjšati pojav te napake.
   i. Ko ste potrdili uspešno vstavitev zapirala HS III in oblikovanje arteriotomije, raztegnite vstavljeno zapiralo HS III v arteriotomijo. Previdno upoštevajte postopek odvijanja zapirala HS III, opisan v navodilih za uporabo.
   ii. Če se zapiralo HS III ne raztegne v skladu s pričakovanji, je treba pripomoček zamenjati.

c. Ukrepi, ki jih je treba sprejeti, če se zapiralo HS III ne raztegne uspešno v aorto.
   i. S kazalcem zaprite arteriotomijo in ustavite krvavitev.
   ii. Odprite drugo zapiralo HS III. Zapiralo vstavite v skladu z napotki v navodilih za uporabo. Vstavljeno zapiralo HS III vstavite v arteriotomijo in v skladu z navodili za uporabo dokončajte anastomozo.
   iii. Če vstavitev drugega zapirala HS III v arteriotomijo ni uspešna ali če kirurg ugotovi, da razmere ne dopuščajo uporabe nadomestnega zapirala HS III, namestite na aorto delno

okluzijsko sponko, da izolirate arteriotomijo, in izvede anastomozo s tradicionalno kirurško tehniko.

3. **Raztegnjeno zapiralo Heatstring ne zagotavlja zadostne hemostaze:**
    a. Kako preprečiti ali čim bolj zmanjšati pojav te napake:
        i. Med vstavljanjem zapirala HS III in po vstavitvi le-tega skrbno preverite, ali je bilo zapiralo HS III uspešno vstavljeno v aplikacijsko napravo, preden odstranite adventicijo aorte in naredite arteriotomijo. (glejte pomembna opozorila zgoraj).
        ii. Proksimalnega zapiralnega sistema Heartstring ne uporabljajte pri bolniku s tanko steno aorte.
        iii. Pri več anastomozah poskrbite, da so vsa mesta anastomoze med seboj oddaljena vsaj 1,5 cm, da zagotovite hemostazo.
        iv. Zapirala HS III pred raztegovanjem ne namočite v raztopino.
    b. Ukrepi, ki jih je treba izvesti, če se zapiralo HS III po namestitvi ne odpre/ne zagotovi zadostne hemostaze.
        i. S kazalcem zaprite arteriotomijo in previdno prilagodite napenjalno vzmet, da je zapiralo HS III popolnoma raztegnjeno.
        ii. Če se nezadostna hemostaza nadaljuje:
            1. V skladu z napotki v navodilih za uporabo z arteriotomije raztegnjeno zapiralo HS III.
            2. Vstavite drugo zapiralo HS III in raztegnite vstavljeno zapiralo v arteriotomijo v skladu z napotki v navodilih za uporabo ter dokončajte anastomozo.
            3. Če drugo zapiralo HS III ni uspešno ali če kirurg presodi, da razmere ne dopuščajo uporabe nadomestnega zapirala HS III, na aorto namestite delno okluzijsko sponko, da izolirate arteriotomijo in izvedete anastomozo s tradicionalno kirurško tehniko.

Ukrepi na strani stranke

Družba Getinge od vas zahteva, da izvedete naslednje ukrepe:

1. Zagotovite, da bodo o tem sporočilu obveščeni vsi posamezniki, ki to obvestilo potrebujejo v vaši organizaciji ali drugi organizaciji, v katero so bile prizadete naprave izročene.

Dodatne informacije

Družba Getinge te informacije poroča pristojnim regulativnim organom.

Opravičujemo se za vse nevšečnosti, ki so vam nastale zaradi tega. Skrbimo za varnost bolnikov in cenimo vaš hiter odziv na to zadevo. Če imate kakršnakoli vprašanja v zvezi s tem sporočilom, se obrnite na svojega predstavnika družbe Getinge ali na službo za pomoč strankam družbe Getinge na številko 1-888-880-2874 od ponedeljka do petka med 8.00 in 17.00 (pacifiški časovni pas).

Lep pozdrav.

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

South Africa (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.

- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled

aorta.

iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.

iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.

i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.

ii. If lack of adequate hemostasis persists:

1. Remove the deployed HS III Seal from the aortotomy per device IFU.
2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

South Korea (ko)

현장 안전성 공지 (Field Safety Notice, FSN)

Heartstring III Proximal Seal System

수신: 위험관리 책임자(Risk Manager) 귀하

1. 본 공지의 목적

본 공지는 Getinge 그룹의 자회사인 **Maquet Cardiovascular**가 Heartstring III Proximal Seal System (이하 "HS III")과 관련하여 시급한 의료기기 시정조치(Urgent Medical Device Correction)를 시행함에 따라, 해당 제품을 공급받은 고객에게 관련 정보를 제공하기 위한 것입니다. 당사 기록에 따르면 귀 기관은 본 공지의 대상이 되는 HS III 제품을 수령하였거나 수령했을 가능성이 있습니다.

2. 대상 제품 정보

- **제품명:** Heartstring III Proximal Seal System
- **모델 번호:** HS-3045 / HSK-3038 / HSK-3043
- **UDI:**
  - 00607567700307
  - 00607567700314
  - 00607567700321
- **대상 Lot:** 유효기간이 만료되지 않은 모든 Lot
- **유통 기간:** 2024년 7월 1일 ~ 현재
- **제조 기간:** 2024년 3월 7일 ~ 현재

3. 확인된 문제 사항 (Issue Description)

HS III 사용 과정에서 다음의 **3가지 주요 고장 유형**이 확인되었습니다.

1) **Seal 로딩 실패 (Failure to Load)**
   - Loading Device를 이용한 4단계 로딩 과정 중 Seal이 정상적으로 장착되지 않거나, 장착 후 육안 확인 또는 잠금 해제 단계에서 이상이 발생하는 경우

2) **Seal 전개 실패 (Failure to Deploy)**
   - Delivery Device 잠금 해제 후, Seal이 대동맥 절개부(aortotomy)로 정상적으로 전개되지 않는 경우

3) **지혈 불충분 (Failure to Provide Adequate Hemostasis)**
   - Seal이 전개되었음에도 불구하고 출혈이 충분히 조절되지 않아 문합(anastomosis)을 완료할 수 없는 경우

※ 현재 해당 문제에 대한 **근본 원인 분석은 진행 중**입니다.

4. 환자에게 미칠 수 있는 잠재적 위험

위 문제로 인해 다음과 같은 위험이 발생할 수 있습니다.

- 수술 시간 지연
- 대동맥 조직 손상 가능성
- 출혈 증가
- 추가적인 대동맥 조작으로 인한 색전(embolism) 위험
- HS III 사용 중단 후 대동맥 클램프를 이용한 기존 수술법으로 전환 필요

단, **기기 사용설명서(IFU)를 준수할 경우 직접적인 환자 위해 위험은 제한적**이며,
주로 수술 지연 및 추가 처치 가능성에 해당합니다.

5. 발생 최소화를 위한 권장 사항

Getinge는 다음 사항을 준수할 것을 권고합니다.

1) Seal 로딩 단계

- HS III Seal은 **대동맥 절개 전 반드시 로딩 및 육안 확인**을 완료하십시오.
- IFU 4.3~4.5절에 따라:
    - Seal의 균열 여부
    - Seal 팁이 Delivery Device 튜브 직경보다 벌어지지 않았는지
    - Tension Spring 정렬 상태를 확인하십시오.
- 로딩 실패 시 해당 Seal은 **폐기**하고 새로운 Seal을 사용하십시오.

2) Seal 전개 단계

- 로딩이 정상적으로 완료된 후 IFU에 따라 전개하십시오.
- 전개 실패 시:
    - 손가락으로 대동맥 절개부를 눌러 출혈을 조절
    - 새로운 HS III Seal로 교체 시도
    - 필요 시 대동맥 클램프를 이용한 기존 수술법 적용

3) 지혈 불충분 발생 시

- Tension Spring을 부드럽게 조정하여 완전 전개 여부 확인
- 지혈이 확보되지 않을 경우:
    - Seal 제거
    - 새 Seal 재적용
    - 필요 시 기존 수술 기법으로 전환

6. 고객 요청 사항 (Customer Actions)

- 본 공지 내용을 **귀 기관 내 관련 의료진 및 담당자에게 공유**하여 주시기 바랍니다.

- 본 제품이 타 기관으로 이전된 경우, 해당 기관에도 본 공지를 전달해 주시기 바랍니다.

※ 본 FSN은 **제품 박스의 QR 코드를 통해 제공**되며, 신규 공급 제품에 대해서는 별도의 고객 확인서(acknowledgement form) 제출이 요구되지 않습니다.

7. 규제기관 보고

Getinge는 본 안전성 정보에 대해 **관련 규제기관에 이미 통보**하였습니다.

8. 문의처 본 공지와 관련하여 추가 문의사항이 있는 경우,
귀사의 Getinge 담당자 또는 Getinge 고객지원으로 문의하시기 바랍니다.

감사합니다.

Francisco Vicenty
Director, Quality & Regulatory Compliance (Interim)
Getinge – Cardiovascular Surgery

Spain (es)

18 de febrero de 2026

Aviso de seguridad Urgente
Sistema de obturación proximal Heartstring III
Número de referencia FSCA: 1336551

Número de modelo	UDI	Nombre del modelo	Números de serie/lote
HSK-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema de obturación proximal Heartstring III	Todos los lotes no caducados
Fechas de distribución:		1 de julio de 2024 - hasta la fecha	
Fechas de fabricación:		7 de marzo de 2024 - hasta la fecha	

Estimado cliente,

El objetivo de esta carta es informarle de que Maquet Cardiovascular, una filial de Getinge, está inciando una acción correctiva de seguridad urgente de productos sanitarios para el sistema de obturación proximal Heartstring III (obturador HS III). Nuestros registros indican que ha recibido uno o más de los dispositivos afectados por esta notificación.

Descripción del problema

Se han identificado tres modos de fallo principales.

1. **Fallo de carga del obturador Heartstring III:** Este fallo se aplica a cualquier funcionamiento incorrecto del dispositivo que se produzca durante el proceso de carga en cuatro pasos utilizando el dispositivo de carga Heartstring, la inspección visual de un obturador HS III cargado correctamente y el desbloqueo del dispositivo de colocación tras completar correctamente los pasos de carga del obturador HS III.
2. **Fallo de despliegue del obturador Heartstring en la aortotomía**: Este fallo se aplica a cualquier funcionamiento incorrecto del obturador HS III y/o del dispositivo de colocación desde el momento en que el dispositivo de colocación se desbloquea correctamente hasta que se completa la colocación del obturador HS III en la aortotomía y todo el contenido del obturador proximal (ligadura, el resorte de tensión, base del obturador, lengüeta de fijación) ha salido del dispositivo de colocación.
3. **Incapacidad del obturador Heartstring desplegado para proporcionar una hemostasia adecuada:** Este fallo se aplica a cualquier funcionamiento incorrecto de un obturador HS III desplegado correctamente que no controla adecuadamente la hemostasia en la anastomosis para permitir al cirujano realizar la sutura de la anastomosis; a pesar del ajuste suave del resorte de tensión después del despliegue del obturador y/o el uso de un atomizador con soplador, aspirador o jeringa de solución salina para despejar el punto de la anastomosis. Este fallo incluye la identificación por parte del cliente de un obturador HS III defectuoso o dañado tras el despliegue satisfactorio del obturador HS III en la aorta que provoca o podría dar lugar a una

hemostasia inadecuada que impida al cirujano completar la anastomosis sin retirar el obturador HS III defectuoso.

La investigación de las causas raízes está en curso.

Riesgos para la salud

1. **Fallo de carga:** Cuando se utiliza de acuerdo con las instrucciones de uso (IFU) del dispositivo, un obturador HS III que no se carga no supone un riesgo directo para el paciente. No obstante, este fallo puede provocar un retraso en el procedimiento quirúrgico. Este retraso puede variar desde unos pocos minutos para recuperar y cargar un nuevo obturador HS III para realizar la anastomosis proximalhasta emplear un clamp aórtico para completar el procedimiento.
2. **Fallo de despliegue:** Cuando el obturador HS III cargado no se despliega desde el dispositivo de colocación, ya se habrán completado varios pasos del procedimiento; lo que podría aumentar el riesgopotencial de daño al paciente.
   - La aortotomía se ha creado.
   - El extremo distal del tubo del dispositivo de colocación se ha insertado a través de la aortotomía.
   - Se ha presionado el émbolo del dispositivo de colocación o se ha intentado presionarlo.
   - El obturador HS III cargado no se ha desplegado correctamente desde el extremo distal del tubo del dispositivo de colocación.
   - Cuando se retire el dispositivo de colocación de la aortotomía, el obturador HS III no se desplegaráy la hemostasia de la aortotomía deberá controlarse colocando un dedo sobre la propia aortotomía.

   Pueden producirse los siguientes daños potenciales para el paciente:

   - **Retraso del procedimiento quirúrgico**: retirada del obturador HS III no desplegado, apertura de un nuevo obturador proximal HS III, carga del obturador en el dispositivo de colocación y colocación del obturador HS III cargado en la aortotomía creada (retraso sin intervención adicional) frente a la decisión de utilizar un clamp aórtico para completar la anastomosis porque el obturador cargado no se despliega (retraso con intervención adicional)
   - **Daños tisulares**: pueden producirse como resultado del despliegue de un obturador HS III cargadoque está abocardado en la punta. Una punta abocardada tendrá un diámetro mayor que el tubo distal del dispositivo de colocación. El despliegue de un obturador cargado con una puntaabocardada puede causar daños en el tejido de la aortotomía y, si se utiliza una fuerza mayor paradesplegar el obturador afectado, existe el riesgo potencial de que la pared posterior de la aorta se rompa durante la inserción. También podría producirse daño tisular durante la extracción del dispositivo de colocación de la aortotomía, el despliegue de un segundo obturador HS III cargadoen la misma aortotomía y/o requiriendo de pasar al uso de un clamp aórtico para completar la anastomosis.
   - **Hemorragia:** podría producirse una pérdida mínima de sangre al retirar el dispositivo de colocación de la aortotomía, al controlar manualmente la hemorragia de la aortotomía y al colocarun obturador HS III de sustitución. Si se producen daños tisulares, podría producirse una mayor pérdida de sangre que requeriría una intervención adicional.
   - **Evento embólico** provocado por una manipulación adicional de la aorta para abordar el fallo de carga del obturador HS III.
3. **Incapacidad del obturador Heartstring desplegado para proporcionar una hemostasia adecuada:** Cuando un obturador HS III desplegado no proporciona una hemostasia adecuada para que el cirujanocomplete la anastomosis proximal y ya se han completado varios pasos del

uso del obturador HS III y esto podría aumentar el riesgo potencial de daño al paciente. En esta situación se han llevado a cabolos siguientes pasos del proceso.

- La aortotomía se ha creado.
- El obturador HS III cargado se ha desplegado en la aorta.
- El cirujano considera que la hemorragia de la aorta es demasiado grande para realizar la anastomosis.

Pueden producirse los siguientes daños potenciales para el paciente:

- **Retraso en el procedimiento quirúrgico**: podría producirse de la siguiente manera:
    - Tiempo operativo adicional necesario para intentar realizar ajustes en el obturador HS IIIpara mejorar la hemostasia mediante el obturador HS III colocado, retirada del HS III defectuoso, apertura de un nuevo HS III, carga del obturador HS III de sustitución y colocación del obturador HS III cargado en la aortotomía creada (retraso del procedimiento sin intervención adicional)
    - El cirujano considera que es más adecuado utilizar un clamp aórtico para completar la anastomosis porque el obturador HS III desplegado no proporcionó una hemostasia adecuada para completar la anastomosis y no hay disponible un obturador HS III de sustitución o la preferencia del cirujano determina que la situación no permite el uso de un obturador HS III de sustitución y se utiliza un clamp aórtico para completar la anastomosis proximal según la técnica quirúrgica tradicional (retraso del procedimiento con intervención adicional)
- **Daños tisulares:** Podrían producirse daños tisulares durante la manipulación del obturador HS III afectado, durante el despliegue de un segundo obturador HS III cargado en la misma aortotomía y/o la necesidad de pasar al uso de un clamp aórtico para completar la anastomosis.
- **Hemorragia:** Una pequeña cantidad de pérdida de sangre alrededor del obturador HS III desplegado es normal y previsible mientras se realiza la anastomosis proximal con un obturador HS III. Podría producirse una mayor pérdida de sangre que requiera una intervención adicional si se producen daños en el tejido aórtico, independientemente de la causa.
- **Evento(s) embólico(s):** provocado(s) por una manipulación adicional de la aorta posterior al tratamiento de un fallo en el obturador HS III para proporcionar una hemostasia adecuada.

Entre el 1 de junio de 2023 y el 22 de julio de 2025, Getinge ha recibido las reclamaciones siguientes:

- 274 quejas relacionadas con un fallo de carga, representando un tasa de reclamación del 0,386%
- 96 quejas relacionadas con un fallo de despliegue, representando una tasa de reclamación del 0,135%
- 30 quejas relacionadas con una falta de hemostasia adecuada, representando una tasa de reclamacióndel 0,042%

<u>Mitigaciones y acciones recomendadas</u>

Getinge proporciona las siguientes instrucciones para evitar/minimizar los fallos mencionados anteriormente.

1. **Fallo de carga del obturador Heartstring**
    a. Recordatorios importantes:
        i. De acuerdo con las instrucciones de uso del dispositivo, el obturador HS III está

diseñado para cargarse y retirarse del dispositivo de carga, luego se debe inspeccionar y ajustar sifuera necesario para confirmar que la carga se ha realizado correctamente y, finalmente, se debe desbloquear antes de despejar cualquier adventicia del área anastomótica planificada y crear la aortotomía.

ii. La carga del obturador HS III y la confirmación de la carga correcta antes de crear la aortotomía minimizan el riesgo para los pacientes, ya que la aorta permanece intacta hasta que se confirma la carga correcta del obturador HS III.

iii. Si el obturador HS III no se carga según lo previsto, será necesario sustituirlo.

b. Cómo evitar/minimizar la aparición de este fallo

i. Revise las IFU del dispositivo Heartstring antes de su uso, especialmente si no se utilizade forma rutinaria.

ii. Cargar con cuidado el obturador HS III siguiendo las instrucciones de uso paso a paso.

iii. De acuerdo con las secciones 4.3-4.5, confirme que el obturador HS III se ha cargado correctamente en el dispositivo de colocación inspeccionando el obturador HS III una vez que se ha cargado en el dispositivo de colocación y se ha retirado del dispositivo de carga.

iv. Un obturador HS III que no se inspeccione adecuadamente después de retirarlo del dispositivo de carga puede fallar durante el despliegue del obturador HS III y causar lesiones al paciente (consulte la información relacionada con el fallo en el despliegue).

v. Complete correctamente la carga del obturador HS III antes de la limpieza de la adventicia de la superficie aórtica y la creación de la aortotomía.

c. Acción que se debe llevar a cabo si el obturador HS III no se carga.

i. Deseche el obturador HS III defectuoso.

ii. Tenga siempre disponible un segundo obturador HS III para sustituir un dispositivodefectuoso. Consulte las IFU del dispositivo para garantizar una carga correcta.

2. Fallo de despliegue del obturador Heartstring III en la aortotomía

a. Recordatorios importantes:

i. Asegúrese de que el obturador HS III se haya cargado correctamente en el dispositivo de colocación de acuerdo con lo indicado en la sección anterior.

ii. Despues de retirar el obturador HS III cargado del dispositivo de carga, inspeccione el obturador HS III cargado de acuerdo con las secciones 4.3-4.5 de las instrucciones de uso para confirmar lo siguiente:

1. El obturador HS III cargado no está agrietado.
2. La porción del obturador HS III que no está cargada en el tubo del dispositivode colocación no es más ancha que el diámetro del tubo del dispositivo de colocación.
3. Los extremos del resorte de tensión están alineados de manera que entren en contacto con los dos bordes proximales del obturador HS III cargado durante la colocación del obturador en la aortotomía.

b. Cómo evitar/minimizar la aparición de este fallo:
    i. Después de confirmar la carga correcta del obturador HS III y la creación de la aortotomía, despliegue el obturador HS III cargado en la aortotomía siguiendo atentamente los pasos de despliegue del obturador HS III documentados en las IFU deldispositivo.
    ii. Si el obturador HS III no se despliega según lo previsto, será necesario sustituirlo.

c. Acción que se debe llevar a cabo si el obturador HS III no se despliega correctamente en la aorta.
    i. Ocluya la aortotomía para controlar la hemorragia con el dedo índice.
    ii. Abra un segundo obturador HS III. Cargue el obturador HS III de acuerdo con las IFU del dispositivo. Introduzca el obturador HS III cargado en la aortotomía y siga las IFU para completar la anastomosis.
    i. Si la colocación del segundo obturador HS III en la aortotomía no tiene éxito, o si la preferencia del cirujano determina que la situación no permite el uso de un obturador HS III de sustitución, coloque un clamp de oclusión parcial en la aorta, aísle la aortotomía y realice la anastomosis según la técnica quirúrgica tradicional.

3. Incapacidad del obturador Heartstring III desplegado para proporcionar una hemostasia adecuada:

a. Cómo evitar/minimizar la aparición de este modo de fallo:
    i. Cargue e inspeccione siempre cuidadosamente el obturador HS III cargado para confirmar la correcta carga del obturador HS III en el dispositivo de colocación antes de despejar cualquier adventicia aórtica y crear la aortotomía. (Consulte los recordatorios importantes más arriba.)
    ii. No utilice el sistema de obturación proximal Heartstring en pacientes con una aorta depared fina.
    iii. Cuando realice varias anastomosis, asegúrese de que todos los puntos de anastomosisestén separados al menos 1,5 cm para garantizar la hemostasia.
    iv. No sumerja el obturador HS III en solución antes de su despliegue.

b. Acción que se debe llevar a cabo si el obturador HS III no se abre/proporciona una hemostasiaadecuada después de su despliegue.
    i. Cubra la aortotomía con el dedo índice y ajuste suavemente el resorte de tensión paraasegurarse de que el obturador HS III se haya desplegado por completo.
    ii. Si persiste la falta de hemostasia adecuada:
        1. Retire el obturador HS III desplegado de la aortotomía según las IFU del dispositivo.
        2. Cargue un segundo obturador HS III y despliegue el obturador cargado en la aortotomía de acuerdo con las IFU del dispositivo y complete la anastomosis.
        3. Si el segundo obturador HS III no tiene éxito o la preferencia del cirujano determina que la situación no permite el uso de un obturador HS III de sustitución, coloque un clamp de oclusión parcial en la aorta, aísle la aortotomía y realice la anastomosis según la técnica quirúrgica tradicional.

Medidas que deben tomar los clientes

Getinge le solicita que tome las siguientes medidas:

1. Le rogamos que se asegure de que este mensaje se reenvíe a todas las personas que deban ser informadas dentro de su organización o a cualquier organización a la que se hayan transferido los dispositivos afectados.

Información adicional

Getinge ha comunicado esta alerta sanitaria de seguridad a la Agencia Española de medicamentos y ProductosSanitarios (AEMPS).

Lamentamos las posibles molestias que esta incidencia pueda ocasionarle. Estamos comprometidos con la seguridad del paciente y agradecemos su atención inmediata a este asunto. Si tiene alguna pregunta acerca de esta comunicación, póngase en contacto con su representante local de Getinge.

Atentamente,

Francisco Vicenty
Director de Calidad y Conformidad Normativa
Getinge, Cirugía Cardiovascular

Datos de contacto de su representante local:
Séverine Moine
QARA Manager –Responsable
TécnicoGetinge Group Spain
S.L.U.
C/ Marie Curie, 5, Edificio Alfa, Pl 6, Ofic.
6,1-6,228521 Rivas Vaciamadrid
severine.moine@getinge.com
Tel: 639 779 945

Sweden (sv)

Augusti 2025

Brådskande Säkerhetsmeddelande till marknaden
Heartstring III Proximal Seal System
Referensnummer: 1336551

Modellnummer	UDI	Modellnamn	Serienummer/Partinummer
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	Alla ej utgångna partinummer
Distributionsdatum:		1 juli 2024 – Nuvarande	
Tillverkningsdatum:		7 mars 2024 - Nuvarande	

Bästa Risk Manager,

Syftet med detta brev är att informera dig om att Maquet Cardiovascular, ett dotterbolag till Getinge, utfärdar en brådskande korrigering av medicinteknisk produkt för Heartstring III Proximal Seal System (HS III Seal). Våra uppgifter visar att du har mottagit en eller flera av de produkter som berörs av detta meddelande.

Beskrivning av problemet

Tre primära fellägen har identifierats.

1. **Heartstring Seal kunde inte laddas:** Detta fel gäller för alla funktionsfel på enheten som inträffar under laddningsprocessen i fyra steg då man använder Heartstring-laddaren, gör en visuell inspektion av en framgångsrikt laddad HS III Seal och frigör införingsenheten när laddningen av HS III Seal har avslutats.
2. **Heartstring Seal kan inte aktiveras i aortotomin**: Detta fel gäller vid funktionsfel på HS III Seal och/eller införingsenheten från det att införingsenheten har frigjorts till dess att införingen av HS III Seal i aortotomin har slutförts och allt innehåll i den proximala tätningen (förankring, spännfjäder, tätningsskaft, ankarfliken) har lämnat införingsenheten.
3. **Om den aktiverade Heartstring Seal inte ger tillräcklig hemostas:** Detta fel gäller alla funktionsfel hos en framgångsrikt aktiverad HS III Seal som inte kontrollerar blödning vid anastomosen på ett adekvat sätt så att kirurgen kan suturera anastomosen, trots försiktig justering av spännfjädern efter aktivering av tätningen och/eller användning av en blåsspray, sug eller saltlösningsspruta för att rensa anastomosstället. Detta fel inkluderar kundidentifiering av en defekt eller skadad HS III Seal efter framgångsrik aktivering av HS III Seal i aorta som resulterar i/eller kan resultera i otillräcklig hemostas som hindrar kirurgen från att slutföra anastomosen utan att ta bort den defekta HS III Seal.

Grundorsaken utreds för närvarande.

Hälsorisker

1. **Misslyckad laddning:** När HS III Seal används i enlighet med produktens bruksanvisning utgör den ingen direkt risk för patienten om den inte laddas. Detta fel kan dock leda till en fördröjning av operationen. Denna fördröjning kan variera från några minuter för att hämta och ladda en ny försegling till en möjlig konvertering från att använda HS III Seal för att utföra den proximala anastomosen till att använda en aortaklämma för att slutföra ingreppet.

2. **Misslyckande av aktivering:** Om den laddade HS III Seal inte aktiveras från införingsenheten har följande procedursteg redan utförts och kan bidra till potentiell risk för patientskada. Om den laddade HS III Seal inte aktiveras från införingsenheten har flera procedursteg redan slutförts, vilket kan öka den potentiella risken för patientskada.
   - Aortotomin har skapats.
   - Den distala änden av införingsenhetens slang har förts in genom aortotomin.
   - Införingsenhetens kolv har tryckts in eller ett försök har gjorts att trycka in den.
   - Den laddade HS III Seal har inte aktiverats från den distala änden av leveransenhetens slang.
   - När införingsenheten avlägsnas från aortotomin kommer HS III Seal inte att aktiveras och blödningen från aortotomin måste kontrolleras genom att ett finger placeras över aortotomin.

   Följande potentiella patientskador kan uppstå:

   - **Fördröjning av operation**: För att ta bort den ej aktiverade HS III Seal, öppna en ny HS III Proximal Seal, ladda den i införingsenheten och för in den laddade HS III Seal i den skapade aortotomin (fördröjning utan ytterligare intervention), alternativt: om den laddade HS III Proximal Seal inte kan aktiveras kan beslut fattas om att använda en aortaklämma för att slutföra anastomosen (fördröjning med ytterligare intervention)
   - **Vävnadsskada:** kan uppstå som ett resultat av aktivering av en laddad HS III-försegling som utvidgas vid spetsen. En utsvängd spets har en diameter som är större än den distala införingsenhetens slang. Aktivering av en laddad HS III Seal som har en utsvängd spets kan orsaka skador på aortotomivävnaden och om större kraft används för att aktivera den berörda HS III Seal finns det en potentiell risk för att aortans bakre vägg skadas under införandet. Vävnadsskada kan också uppstå när införingsenheten avlägsnas från aortotomin, vid aktivering av en andra laddad HS III Seal i samma aortotomi och/eller vid behov av att konvertera till användning av en aortaklämma för att slutföra aortotomin.
   - **Blödning:** minimal blodförlust kan uppstå när införingsenheten avlägsnas från aortotomin, blödningen från aortotomin kontrolleras manuellt och en ersättnings-HS III Seal förs in. Större blodförlust, som kräver ytterligare intervention, kan uppstå om vävnadsskada uppstår.
   - **Embolisk händelse** till följd av ytterligare manipulation av aorta för att åtgärda HS III Seals laddningsfel.

3. **Om den aktiverade Heartstring Seal inte ger tillräcklig hemostas:** När en aktiverad HS III Seal inte ger tillräcklig hemostas för att kirurgen ska kunna slutföra den proximala anastomosen har flera steg i användningen av HS III Seal-systemet redan slutförts vilket kan öka den potentiella risken för patientskada. Följande procedursteg har genomförts.
   - Aortotomin har skapats.
   - Den laddade HS III Seal har aktiverats in i aorta.
   - Blödning från aorta bedöms av kirurgen vara för stor för att utföra anastomosen.

   Följande potentiella patientskador kan uppstå:

   - **Fördröjning av operationen:** kan inträffa på följande sätt:
     - Ytterligare operationstid som krävs för att försöka göra tätningsjusteringar för att förbättra hemostasen med den levererade HS III Seal, ta bort den defekta HS III Seal, öppna en ny HS III Seal, ladda ersättnings-HS III Seal och leverera den laddade HS III Seal i den skapade aortotomin (fördröjning av ingreppet utan ytterligare ingrepp)
     - Kirurgen anser att det är lämpligast att använda en aortaklämma för att

slutföra anastomosen eftersom den aktiverade HS III Seal inte ger tillräcklig hemostas för att slutföra anastomosen och en ersättnings-HS III Seal inte finns tillgänglig eller för att kirurgen bestämmer att situationen inte tillåter användning av en ersättnings-HS III Seal, och en aortaklämma används för att slutföra den proximala anastomosen enligt traditionell kirurgisk teknik (procedurfördröjning med ytterligare intervention)

- **Vävnadsskada:** Vävnadsskada kan uppstå under hantering av den berörda HS III Seal, under aktivering av en andra laddad HS III Seal i samma aortotomi och/eller vid behov av att konvertera till användning av en aortaklämma för att slutföra aortotomin.
- **Blödning:** En liten mängd blodförlust runt den aktiverade HS III Seal är normalt och förväntas när den proximala anastomosen utförs med en HS III Seal. Större blodförlust som kräver ytterligare intervention kan uppstå när vävnadsskada på aorta uppstår, oavsett orsak.
- **Embolisk(a) händelse(r):** till följd av ytterligare manipulation av aorta sekundärt till att HS III Seal inte ger tillräcklig hemostas.

Mellan den 1 juni 2023 och den 22 juli 2025 mottog Getinge följande klagomål:

- 274 rapporter relaterade till misslyckad laddning, vilket representerar en reklamationsfrekvens på 0,386 %
- 96 rapporter relaterade till misslyckad aktivering, vilket motsvarar en klagomålsfrekvens på 0,135 %
- 30 rapporter om otillräcklig hemostas, vilket representerar en klagomålsfrekvens på 0,042 %

Rekommenderade begränsningar och åtgärder

Getinge tillhandahåller följande instruktioner för att undvika/minimera de fel som diskuteras ovan.

1. **Heartstring Seal kunde inte laddas**
    a. Viktigt att tänka på:
        i. Enligt enhetens bruksanvisning är HS III Seal avsedd att laddas och tas bort från laddningsenheten, sedan inspekteras och justeras vid behov för att bekräfta lyckad laddning och slutligen frigöras innan eventuella adventitia avlägsnas från det planerade anastomosområdet och aortotomin skapas. Att ladda HS III Seal och bekräfta att den har laddats korrekt innan aortotomin skapas minimerar risken för patienten eftersom aorta förblir orörd tills det bekräftats att HS III Seal har laddats korrekt.
        ii. Om HS III Seal inte laddas som avsett bör enheten bytas ut.
    b. Hur man undviker/minimerar förekomsten av detta fel
        i. Läs bruksanvisningen för Heartstring-enheten före användning, särskilt om Heartstring inte används rutinmässigt.
        ii. Ladda HS III Seal genom att noga följa produktens bruksanvisning steg för steg.
        iii. Enligt avsnitt 4.3–4.5 i bruksanvisningen, bekräfta att HS III Seal har laddats korrekt i införingsenheten genom att inspektera den laddade HS III Seal när HS III Seal har laddats i införingsenheten och tagits bort från laddenheten.
        iv. En HS III Seal som inte inspekteras ordentligt efter att den tagits bort från laddningsenheten kan misslyckas under aktiveringen av HS III Seal

och orsaka patientskada. (se information om misslyckande av aktivering).

v. Ladda HS III Seal fullständigt före rengöring av aortaytans adventitia och skapande av aortotomin.

c. Åtgärder som ska vidtas om HS III Seal inte laddar.
   i. Kassera den trasiga HS III Seal.
   ii. Ha alltid en andra HS III Seal tillgänglig för att ersätta en trasig enhet. Se enhetens bruksanvisning för att säkerställa korrekt laddning.

2. Heartstring III Seal kunde inte aktiveras i aortotomin

a. Viktigt att tänka på:
   i. Kontrollera att HS III Seal har laddats korrekt i införingsenheten enligt beskrivningen i avsnittet ovan.
   ii. Kontrollera följande efter att den laddade HS III har tagits bort från laddenheten enligt avsnitt 4.3-4.5 i bruksanvisningen:
      1. Den laddade HS III Seal är inte sprucken.
      2. Den del av HS III Seal som inte är laddad i införingsenhetens slang är inte bredare än införingsenhetens slangdiameter.
      3. Spännfjäderns ändar är inriktade så att de kommer i kontakt med båda proximala kanterna på den laddade HS III Seal under införseln av HS III Seal i aortotomin.

b. Hur man undviker/minimerar förekomsten av detta fel:
   i. När du har bekräftat att HS III Seal har laddats och att aortotomin har skapats aktiverar du den laddade HS III Seal i aortotomin genom att noggrant följa stegen för placering av HS III Seal som finns dokumenterade i enhetens bruksanvisning.
   ii. Om HS III Seal inte aktiveras som avsett ska enheten bytas ut.

c. Åtgärder som ska vidtas om HS III Seal inte lyckas aktiveras i aorta.
   i. Ockludera aortotomin för att kontrollera blödningen med pekfingret.
   ii. Öppna en andra HS III Seal. Ladda HS III Seal enligt enhetens bruksanvisning. För in den laddade HS III Seal i aortotomin och följ bruksanvisningen för att slutföra anastomosen.
   iii. Om införingen av den andra HS III Seal i aortotomin inte lyckas, eller om kirurgen bedömer att situationen inte tillåter användning av en ersättnings-HS III Seal, placera en partiell ocklusionsklämma på aorta, isolera aortotomin och utför anastomosen enligt traditionell kirurgisk teknik.

3. Om aktiverad Heartstring III Seal inte ger adekvat hemostas:

a. Så här undviker/minimerar du förekomsten av detta felläge:
   i. Innan aorta adventitia rensas och aortotomin skapas ska den laddade HS III Seal alltid inspekteras noggrant för att bekräfta att HS III Seal har laddats korrekt i införingsenheten. (Se viktiga påminnelser direkt ovan.)
   ii. Använd inte Heartstring Proximal Seal System på patienter med en tunnväggig aorta.
   iii. När flera anastomoser utförs, se till att alla anastomosställen är minst 1,5 cm från varandra för att säkerställa hemostas.
   iv. Blötlägg inte HS III Seal i lösning före aktivering.

b. Åtgärder som ska vidtas om HS III Seal inte öppnar/ger tillräcklig hemostas efter att

den har aktiverats.

i. Täck aortotomin med pekfingret och justera försiktigt spännfjädern för att säkerställa att HS II Seal helt har aktiverats.
ii. Om tillräcklig hemostas kvarstår:
    1. Ta bort den aktiverade HS III Seal från aortotomin enligt enhetens bruksanvisning.
    2. Ladda en andra HS III Seal och aktivera laddad HS III Seal i aortotomin enligt enhetens bruksanvisning och slutför anastomosen.
    3. Om en andra HS III Seal inte lyckas eller om kirurgen bedömer att situationen inte tillåter användning av en ersättnings-HS III Seal, placera en partiell ocklusionsklämma på aorta, isolera aortotomin och utför anastomosen enligt traditionell kirurgisk teknik.

Åtgärder som ska vidtas av kunden

Getinge ber dig att vidta följande åtgärder:

1. Se till att detta meddelande vidarebefordras till alla som behöver känna till det inom din organisation eller till alla organisationer dit de berörda enheterna har överförts.

Ytterligare information

Getinge kommunicerar denna information till relevanta tillsynsmyndigheter.

Vi ber om ursäkt för eventuella olägenheter som detta kan ha orsakat. Vi är engagerade i patientsäkerheten och uppskattar din omedelbara uppmärksamhet i denna fråga. Om du har några frågor är du välkommen att kontakta din Getinge-representant eller ringa Getinges kundsupport på 010 335 3000 måndag till fredag mellan kl. 8.00 och 17.00.

Med vänlig hälsning,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, kardiovaskulär kirurgi

Switzerland

German (de)

August 2025

Sicherheitshinweis
Proximales Versiegelungssystem Heartstring III
Referenznummer: 1336551

Modellnummer	UDI	Modellbezeichnung	Serien-/Losnummern
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Proximales Versiegelungssystem Heartstring III	Alle nicht abgelaufenen Chargen
Distributionszeitraum:		1. Juli 2024 – Heute	
Herstellungsdaten:		7. März 2024 – Heute	

Sehr geehrte/r Anwender/in,

Mit diesem Schreiben möchten wir Sie darüber informieren, dass Maquet Cardiovascular, eine Tochtergesellschaft von Getinge, eine dringende Korrekturmaßnahme für das Proximale Versiegelungssystem Heartstring III (HS III Seal) vornimmt. Aus unseren Unterlagen geht hervor, dass Sie mindestens eines der von dieser Mitteilung betroffenen Geräte erhalten haben.

Beschreibung des Problems

Es wurden drei primäre Fehlermodi ermittelt.

1. **Ladeausfall der Heartstring-Versiegelung**: Dieser Fehler betrifft alle Fehlfunktionen des Geräts, die während des vierstufigen Ladevorgangs mit der Heartstring-Beladungsvorrichtung, der Sichtkontrolle einer erfolgreichen Beladung des HS III Seal und der Entriegelung der Einführvorrichtung nach erfolgreicher Beladung des HS III Seal auftreten.
2. **Ausfall der Heartstring-Versiegelung bei der Einführung in die Aortotomie**: Dieser Fehler betrifft alle Fehlfunktionen der HS III Seal und/oder der Einführvorrichtung ab dem Zeitpunkt, zu dem die Einführvorrichtung erfolgreich entriegelt wurde, bis zur vollständigen Einführung der HS III Seal in die Aortotomie und dem Austritt des gesamten Inhalts der proximalen Versiegelung (Anbindung, Zugfeder, Versiegelungsschaft, Verankerungslasche) aus der Einführvorrichtung.
3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Dieser Fehler betrifft jede Fehlfunktion eines erfolgreich eingeführten HS III Seal, welches die Blutung an der Anastomose nicht ausreichend kontrolliert, um dem chirurgischen Personal das Vernähen der Anastomose zu ermöglichen, trotz behutsamer Anpassung der Zugfeder nach der Einbringung der Versiegelung und/oder Verwendung eines Blower Mister, einer Absaugung oder einer Kochsalzlösungsspritze zum Reinigen der Anastomosestelle. Dieser Fehler umfasst die Feststellung eines defekten oder beschädigten HS III Seal durch den Kunden nach erfolgreicher Einbringung des HS III Seals in die Aorta, die zu einer unzureichenden Hämostase führt oder führen kann, sodass

das chirurgische Personal die Anastomose nicht abschließen kann, ohne das defekte HS III Seal zu entfernen.

Die Ermittlung der Grundursache ist derzeit noch im Gange.

Gesundheitsrisiken

1. **Fehler bei der Beladung:** Bei Verwendung gemäß der Gebrauchsanweisung des Geräts stellt ein HS III Seal ohne Beladung kein direktes Risiko für Patienten dar. Dieser Fehler kann jedoch zu einer Verzögerung des chirurgischen Eingriffs führen. Diese Verzögerung kann von wenigen Minuten zur Entnahme und Beladung einer neuen Versiegelung bis hin zu einer möglichen Umstellung von der Verwendung des HS III Seal zur Durchführung der proximalen Anastomose auf die Verwendung einer Aortaklemme zum Abschluss des Vorgangs reichen.
2. **Fehlgeschlagene Einbringung:** Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden die folgenden Verfahrensschritte bereits durchgeführt, was zu einem potenziellen Risiko einer Patientenschädigung führen kann. Wenn das geladene HS III Seal nicht aus der Einführvorrichtung eingebracht werden kann, wurden bereits mehrere Verfahrensschritte durchgeführt, was das potenzielle Risiko einer Patientenschädigung erhöhen kann.

    - Die Aortotomie wurde angelegt.
    - Das distale Ende des Schlauchs der Einführvorrichtung wurde durch die Aortotomie eingeführt.
    - Der Kolben der Einführvorrichtung wurde gedrückt oder es wurde versucht, ihn zu drücken.
    - Die geladene HS III Seal konnte nicht erfolgreich vom distalen Ende des Schlauchs der Einführvorrichtung eingesetzt werden.
    - Wenn die Einführvorrichtung aus der Aortotomie entfernt wird, wird das HS III Seal nicht platziert. Blutungen aus der Aortotomie müssen durch Auflegen eines Fingers auf die Aortotomie gestillt werden.

    Die folgenden potenziellen Patientenschäden können auftreten:

    - **Verzögerung des chirurgischen Eingriffs**: Entfernen des nicht platzierten HS III Seal, Öffnen einer neuen HS III-Proximalversiegelung, Einlegen der Versiegelung in die Einführvorrichtung und Einbringung des beladenen HS III Seal in die angelegte Aortotomie (Verzögerung ohne zusätzlichen Eingriff) vs. Entscheidung für die Verwendung einer Aortenklemme, um die Anastomose abzuschließen, da die Einbringung der Versiegelung fehlgeschlagen ist (Verzögerung mit zusätzlichem Eingriff)
    - **Gewebeschädigung**: Kann durch das Platzieren eines geladenen HS III Seal mit zu weit geöffneter Spitze entstehen. Eine aufgeweitete Spitze hat einen größeren Durchmesser als der distale Schlauch der Einführvorrichtung. Das Einsetzen einer beladenen Versiegelung mit aufgeweiteter Spitze kann zu einer Schädigung des Aortotomiegewebes führen. Wird beim Einsetzen der betroffenen Versiegelung mehr Kraft aufgewendet, besteht die Gefahr einer Rückwandbildung in der Aorta während des Einführens. Gewebeschäden können auch beim Entfernen der Einführvorrichtung aus der Aortotomie, beim Einsetzen eines zweiten HS III Seal mit Beladung in dieselbe Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortaklemme zur Durchführung der Aortotomie auftreten.
    - **Blutung:** Es kann zu einem minimalen Blutverlust kommen, wenn die Einführvorrichtung aus der Aortotomie entfernt, die Blutung aus der Aortotomie manuell kontrolliert und ein Ersatz-

HS III Seal eingeführt wird. Bei einer Gewebeschädigung kann ein größerer Blutverlust auftreten, der einen zusätzlichen Eingriff erfordert.

- **Embolisches Ereignis** infolge zusätzlicher Manipulation der Aorta zur Behebung der fehlgeschlagenen Beladung des HS III Seal.

3. **Keine ausreichende Hämostase durch die eingeführte Heartstring-Versiegelung:** Wenn ein eingesetztes HS III Seal keine ausreichende Hämostase für chirurgisches Personal zur Fertigstellung der proximalen Anastomose bietet, sind mehrere Schritte der Verwendung des HS III Seal Systems bereits abgeschlossen und können das potenzielle Risiko einer Schädigung von Patienten erhöhen. Die folgenden Verfahrensschritte werden bereits erfolgt sein.

   - Die Aortotomie wurde angelegt.
   - Das HS III Seal mit Beladung wurde in die Aorta eingesetzt.
   - Die Blutung aus der Aorta wird vom chirurgischen Personal als zu groß für die Durchführung der Anastomose erachtet.

   Die folgenden potenziellen Patientenschäden können auftreten:

   - **Verzögerung des chirurgischen Eingriffs**: kann wie folgt eintreten:
     - Zusätzliche operative Zeit, die für den Versuch aufgewendet wird, Anpassungen der Versiegelung vorzunehmen, um die Hämostase durch das eingesetzte HS III Seal zu verbessern, das defekte HS III Seal zu entfernen, ein neues HS III Seal zu öffnen, das Ersatz-HS III Seal zu laden und das geladene HS III Seal in die erstellte Aortotomie einzuführen (Verzögerung des Vorgangs ohne zusätzlichen Eingriff)
     - Das chirurgische Personal hält es für angebracht, für den Abschluss der Anastomose eine Aortenklemme zu verwenden, da das eingesetzte HS III Seal für keine ausreichende Hämostase für den erfolgreichen Abschluss der Anastomose gesorgt hat und entweder kein Ersatz-HS III Seal verfügbar ist oder das chirurgische Personal entscheidet, dass die Verwendung eines Ersatz-HS III Seal in der jeweiligen Situation nicht angebracht ist und eine Aortenklemme für den Abschluss der proximalen Anastomose gemäß der herkömmlichen chirurgischen Technik verwendet wird. (Verzögerung des Vorgangs mit einem zusätzlichen Eingriff)
   - **Gewebeschädigung**: Gewebeschäden können bei der Manipulation des betroffenen HS III Seal, bei der Platzierung eines zweiten HS III Seal mit Beladung in derselben Aortotomie und/oder bei der Umstellung auf die Verwendung einer Aortenklemme zur Fertigstellung der Aortotomie auftreten.
   - **Blutung:** Ein geringfügiger Blutverlust um das eingesetzte HS III Seal herum ist normal und bei der Durchführung der proximalen Anastomose mit einem HS III Seal zu erwarten. Ein größerer Blutverlust, der einen zusätzlichen Eingriff erfordert, kann auftreten, wenn eine Schädigung des Aortengewebes auftritt, unabhängig von der Ursache.
   - **Embolische(s) Ereignis(se):** infolge einer zusätzlichen Manipulation der Aorta sekundär zur Behebung des Ausfalls des HS III Seal, um eine angemessene Hämostase zu gewährleisten.

Zwischen dem 1. Juni 2023 und dem 22. Juli 2025 erhielt Getinge die folgenden Beschwerden:

- 274 Meldungen im Zusammenhang mit einer fehlgeschlagenen Beladung, was einer Reklamationsrate von 0,386 % entspricht

- 96 Meldungen im Zusammenhang mit der fehlgeschlagenen Einführung, was einer Reklamationsrate von 0,135 % entspricht
- 30 Meldungen im Zusammenhang mit unzureichender Hämostase, was einer Reklamationsrate von 0,042 % entspricht

Empfohlene Abhilfemaßnahmen

Getinge stellt die folgenden Anweisungen zur Verfügung, um die vorstehend erwähnten Fehler zu vermeiden/minimieren.

1. **Ladeausfall der Heartstring-Versiegelung**
    a. Wichtige Hinweise:
        i. Gemäß der Gebrauchsanweisung des Produkts ist das HS III Seal für das Beladen und Entnehmen aus der Ladevorrichtung vorgesehen. Anschließend wird es überprüft und ggf. angepasst, um die erfolgreiche Beladung zu bestätigen, und schließlich entriegelt, bevor jegliche Adventitia aus dem geplanten Anastomosebereich entfernt und die Aortotomie angelegt wird. Die Beladung des HS III Seal und die Bestätigung der erfolgreichen Beladung vor dem Anlegen der Aortotomie minimieren das Risiko für Patienten, da die Aorta bis zur Bestätigung der erfolgreichen Beladung des HS III Seals unberührt bleibt.
        ii. Wenn die Beladung des HS III Seal nicht wie vorgesehen erfolgt, sollte das Gerät ausgetauscht werden.
    b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers
        i. Lesen Sie die Gebrauchsanweisung des Heartstring-Geräts vor der Verwendung durch, insbesondere wenn Heartstring nicht routinemäßig verwendet wird.
        ii. Beladen Sie das HS III Seal, indem Sie die Schritt-für-Schritt-Gebrauchsanweisung des Geräts sorgfältig befolgen.
        iii. Überprüfen Sie gemäß Abschnitt 4.3-4.5 der Gebrauchsanweisung die ordnungsgemäße Beladung des HS III Seal in die Einführvorrichtung durch Inspektion des beladenen HS III Seal nach dessen Beladung in die Einführvorrichtung und Entnahme aus der Ladevorrichtung.
        iv. Ein HS III Seal, das nach der Entnahme aus der Ladevorrichtung nicht ordnungsgemäß überprüft wird, kann während der Einführung des HS III Seal versagen und zu Verletzungen von Patienten führen. (siehe Informationen zu einer fehlgeschlagenen Einführung).
        v. Die erfolgreiche Beladung des HS III Seal vor der Reinigung der Aortenadventitia und dem Anlegen der Aortotomie fertigstellen.
    c. Zu ergreifende Maßnahmen bei ausbleibender Beladung des HS III Seal.
        i. Entsorgen Sie das defekte HS III Seal.
        ii. Halten Sie immer ein zweites HS III Seal bereit, um ein defektes Gerät zu ersetzen. Beachten Sie die Gebrauchsanweisung des Geräts, um eine erfolgreiche Beladung sicherzustellen.
2. **Ausfall der Heartstring III-Versiegelung bei der Einführung in die Aortotomie**
    a. Wichtige Hinweise:
        i. Stellen Sie sicher, dass das HS III Seal wie vorstehend dargelegt ordnungsgemäß in die Einführvorrichtung eingelegt wurde.

ii. Nachdem Sie das geladene HS III Seal aus der Ladevorrichtung entnommen haben, überprüfen Sie das geladene HS III Seal gemäß den Abschnitten 4.3–4.5 der Gebrauchsanweisung, um Folgendes sicherzustellen:
    1. Das geladene HS III Seal ist nicht gerissen.
    2. Der Teil des HS III Seal, der nicht in den Schlauch der Einführvorrichtung gelegt wird, ist nicht breiter als der Durchmesser des Schlauchs der Einführvorrichtung.
    3. Die Enden der Zugfeder sind so ausgerichtet, dass sie beide proximalen Ränder des beladenen HS III Seal berühren, während die Versiegelung in die Aortotomie eingeführt wird.

b. So vermeiden/minimieren Sie das Auftreten dieses Fehlers:
    i. Nach Bestätigung der erfolgreichen Beladung des HS III Seal und Anlegen der Aortotomie das geladene HS III Seal in die Aortotomie einsetzen, indem die in der Gebrauchsanweisung des Geräts dokumentierten Schritte zur Einführung des HS III Seal sorgfältig befolgt werden.
    ii. Kann das HS III Seal nicht wie vorgesehen eingeführt werden, sollte das Gerät ausgetauscht werden.

c. Zu ergreifende Maßnahmen, wenn das HS III Seal nicht erfolgreich in die Aorta eingeführt werden kann.
    i. Die Aortotomie mit dem Zeigefinger verschließen, um die Blutung zu kontrollieren.
    ii. Ein zweites HS III Seal öffnen. Das HS III Seal gemäß Gebrauchsanweisung des Geräts laden. Das HS III Seal mit Beladung in die Aortotomie einführen und die Anastomose gemäß Gebrauchsanweisung abschließen.
    iii. Wenn das Einsetzen des zweiten HS III Seal in die Aortotomie nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

3. Keine ausreichende Hämostase durch die eingeführte Heartstring III-Versiegelung:

a. So vermeiden/minimieren Sie das Auftreten dieses Fehlermodus:
    i. Das geladene HS III Seal immer sorgfältig laden und prüfen, um sicherzustellen, dass es erfolgreich in die Einführvorrichtung geladen wurde, bevor Sie die Adventitia freilegen und die Aortotomie anlegen. (Siehe die direkt vorstehend aufgeführten wichtigen Hinweise.)
    ii. Die Heartstring Proximalversiegelung nicht bei Patienten mit einer dünnwandigen Aorta verwenden.
    iii. Bei Durchführung einer Mehrfachanastomose sicherstellen, dass alle Anastomosenstellen mindestens 1,5 cm voneinander entfernt sind, um eine Hämostase zu gewährleisten.
    iv. Das HS III Seal nicht vor dem Einsetzen in Lösung einweichen.

b. Zu ergreifende Maßnahmen, wenn sich das HS III Seal nach der Einführung nicht öffnet bzw. keine ausreichende Hämostase gewährleistet.
    i. Decken Sie die Aortotomie mit einem Zeigefinger ab und stellen Sie die Zugfeder vorsichtig ein, um sicherzustellen, dass das HS III Seal vollständig eingeführt wurde.
    ii. Bei anhaltend mangelhafter Hämostase:

1. Entfernen Sie das eingesetzte HS III Seal gemäß der Gebrauchsanweisung des Geräts aus der Aortotomie.
2. Beladen Sie ein zweites HS III Seal und setzen Sie die beladene Versiegelung gemäß der Gebrauchsanweisung des Geräts in die Aortotomie ein, um die Anastomose abzuschließen.
3. Wenn das zweite HS III Seal nicht erfolgreich ist oder das chirurgische Personal die Situation so beurteilt, dass die Verwendung eines Ersatz-HS III Seal nicht möglich ist, eine Klemme zur teilweisen Okklusion auf die Aorta setzen, um die Aortotomie zu isolieren, und die Anastomose gemäß der herkömmlichen chirurgischen Technik durchführen.

Von Kund-/innen zu ergreifende Maßnahmen

Getinge bittet Sie, die folgenden Maßnahmen zu ergreifen:

1. Bitte leiten Sie diese Mitteilung an alle Personen in Ihrer Organisation weiter, die darüber informiert werden müssen, oder an alle Organisationen, an die betroffene Produkte weitergegeben wurden.

Weitere Informationen

Getinge leitet diese Informationen an die zuständigen Aufsichtsbehörden weiter.

Wir bedauern etwaige Unannehmlichkeiten, die Ihnen hierdurch entstehen. Wir setzen uns für die Patientensicherheit ein und danken Ihnen, dass Sie sich dieser Angelegenheit umgehend angenommen haben. Wenn Sie Fragen zu dieser Mitteilung haben, wenden Sie sich bitte an Ihre Getinge-Vertretung oder den Getinge-Kundendienst.

Mit freundlichen Grüßen

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Italian (it)

Agosto 2025

Avviso di sicurezza
Sistema di tenuta prossimale Heartstring III
Codice prodotto: 1336551

Numero di modello	UDI	Nome del modello	Numeri di serie/di lotto
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Sistema di tenuta prossimale Heartstring III	Tutti i lotti non scaduti
Date di distribuzione:		1 luglio 2024 - Oggi	
Date di produzione:		7 marzo 2024 - Oggi	

Gentile cliente,

la presente lettera ha lo scopo di informarla che Maquet Cardiovascular, una consociata di Getinge, sta emettendo un'azione correttiva urgente relativa a un dispositivo medico per il sistema di tenuta prossimale Heartstring III (HS III Seal). Dai nostri registri risulta che ha ricevuto uno o più dei dispositivi interessati da questa notifica.

Descrizione del problema

Sono state identificate tre modalità di guasto principali.

1. **Mancato caricamento del sistema di tenuta Heartstring:** questo guasto si verifica in caso di malfunzionamento del dispositivo durante il processo di caricamento in quattro fasi che prevede l'utilizzo del dispositivo di caricamento Heartstring, l'ispezione visiva di un sistema di tenuta HS III correttamente caricato e lo sblocco del dispositivo di erogazione al completamento con successo delle fasi di caricamento della tenuta HS III.
2. **Errore nel posizionamento del sistema di tenuta Heartstring nell'aortotomia:** questo errore riguarda qualsiasi malfunzionamento del sistema di tenuta HS III e/o del dispositivo di posizionamento dal momento in cui il dispositivo di posizionamento viene sbloccato correttamente fino al completamento del rilascio del sistema di tenuta HS III nell'aortotomia e all'uscita dell'intero contenuto del sistema di tenuta prossimale (il cavo di collegamento, la molla di tensione, lo stelo di tenuta, la linguetta di fissaggio) dal dispositivo di posizionamento.
3. **Mancata capacità del sistema di tenuta Heartstring posizionato di garantire un'emostasi adeguata:** questo errore riguarda qualsiasi malfunzionamento di un sistema di tenuto HS III posizionato correttamente che non controlla adeguatamente il sanguinamento in corrispondenza dell'anastomosi per consentire al chirurgo di eseguire la sutura dell'anastomosi, nonostante la leggera regolazione della molla di tensione dopo il posizionamento della tenuta e/o l'uso di un nebulizzatore a soffiaggio, aspirazione o siringa fisiologica per pulire la sede anastomotica. Questo guasto include anche i casi in cui il cliente identifica un sistema di tenuta HS III difettoso o danneggiato dopo il posizionamento corretto della tenuta HS III nell'aorta, che comporta o può

comportare un'emostasi inadeguata tale da impedire al chirurgo di completare l'anastomosi senza rimuovere il sistema di tenuta HS III difettoso.

L'indagine sulla causa principale è attualmente in corso.

Rischi per la salute

1. **Mancato caricamento:** se utilizzato in conformità alle Istruzioni per l'uso (IFU) del dispositivo, un sistema di tenuta HS III che non si carica non rappresenta un rischio diretto per il paziente. Tuttavia, tale guasto può causare un ritardo nell'intervento chirurgico. Questo ritardo può variare da pochi minuti, necessari per recuperare e preparare una nuova tenuta, fino a una possibile conversione dall'impiego del sistema HS III per eseguire l'anastomosi prossimale al ricorso a una pinza aortica per completare la procedura.
2. **Guasto durante il posizionamento:** quando il sistema di tenuta HS III caricato non si posiziona correttamente dal dispositivo di posizionamento, le seguenti fasi procedurali sono già state eseguite e possono contribuire al rischio potenziale di lesioni al paziente. Se la tenuta HS III caricata non si dispiega dal dispositivo di posizionamento, diverse fasi procedurali saranno già state completate, il che può aumentare il rischio potenziale di lesioni al paziente.
    - L'aortotomia è stata creata.
    - L'estremità distale del tubo del dispositivo di posizionamento è stata inserita mediante aortotomia.
    - Lo stantuffo del dispositivo di posizionamento è stato premuto o si è tentato di premerlo.
    - Il sistema di tenuta HS III caricato non si è posizionato correttamente dall'estremità distale del tubo del dispositivo di posizionamento.
    - Quando il dispositivo di posizionamento viene rimosso dall'aortotomia, il sistema di tenuta HS III non verrà rilasciato e il sanguinamento dall'aortotomia dovrà essere controllato applicando pressione digitale (con un dito) sull'aortotomia.

    Possono verificarsi i seguenti potenziali danni a carico del paziente:

    - **Ritardo nella procedura chirurgica**: per rimuovere il sistema di tenuta HS III non posizionatosi, aprire un nuovo sistema di tenuta HS III, caricare il sistema nel dispositivo di posizionamento e posizionare il sistema di tenuta HS III caricato nell'aortotomia creata (ritardo senza interventi aggiuntivi) rispetto alla decisione di utilizzare una pinza aortica per completare l'anastomosi, poiché il sistema di tenuta caricato non si è posizionato correttamente (ritardo con ulteriore intervento).
    - **Danni ai tessuti**: possono verificarsi in seguito al posizionato di un sistema di tenuta HS III caricato con punta svasata (all'estremità). Una punta svasata avrà un diametro maggiore rispetto al tubo distale del dispositivo di posizionamento. Il posizionamento di un sistema di tenuta caricato con punta svasata può causare danni ai tessuti a livello dell'aortotomia e, se per rilasciare il sistema di tenuta interessato si applica una forza maggiore, vi è un rischio potenziale di danneggiare la parete posteriore dell'aorta durante l'inserimento. Danni ai tessuti possono inoltre verificarsi durante la rimozione del dispositivo di posizionamento dall'aortotomia, durante il rilascio di un secondo sistema di tenuta HS III caricato nella stessa aortotomia e/o qualora si renda necessario passare all'uso di una pinza aortica per completare l'aortotomia.
    - **Sanguinamento:** può verificarsi una perdita minima di sangue durante la rimozione del dispositivo di posizionamento dall'aortotomia, il controllo manuale dell'emorragia

dall'aortotomia e il rilascio di un sistema di tenuta HS III sostitutivo. In caso di danni ai tessuti, può verificarsi una maggiore perdita di sangue che richiede un intervento aggiuntivo.

- **Evento embolico** derivante da un'ulteriore manipolazione dell'aorta per risolvere il problema di caricamento del sistema di tenuta HS III.

3. **Mancata capacità del sistema di tenuta Heartstring posizionato di garantire un'emostasi adeguata:** quando un sistema di tenuta HS III non riesce a ottenere un'emostasi adeguata che consenta al chirurgo di completare l'anastomosi prossimale, diverse fasi di utilizzo del sistema di tenuta HS III sono già state completate e possono aumentare il rischio potenziale di lesioni al paziente. Sono già state eseguite le seguenti fasi procedurali.

   - L'aortotomia è stata creata.
   - Il sistema di guarnizione HS III caricato è stata posizionato nell'aorta.
   - Il chirurgo ritiene che il sanguinamento dall'aorta sia troppo grave per eseguire l'anastomosi.

   Possono verificarsi i seguenti potenziali danni a carico del paziente:

   - **Ritardo nell'intervento chirurgico**: può verificarsi come segue:
     - Tempo aggiuntivo per l'intervento chirurgico necessario per tentare di regolare il sistema di tenuta al fine di migliorare l'emostasi mediante il sistema di tenuta HS III rilasciato, rimuovere il sistema di tenuta HS III difettoso, aprire un nuovo sistema HS III, caricare il sistema HS III sostitutivo e rilasciare il sistema di tenuta HS III caricato nell'aortotomia creata (ritardo della procedura senza intervento aggiuntivo)
     - Il chirurgo ritiene più opportuno utilizzare una clamp aortica per completare l'anastomosi poiché il sistema di tenuta HS III utilizzato non è riuscito a garantire un'emostasi adeguata al fine di completare l'anastomosi e non è disponibile un sistema di tenuta HS III sostitutivo oppure il chirurgo ritiene che la situazione non consenta l'uso di un sistema di tenuta HS III sostitutivo e si utilizza una clamp aortica per completare l'anastomosi prossimale secondo la tecnica chirurgica tradizionale. (ritardo della procedura con intervento aggiuntivo).
   - **Danno ai tessuti:** possono verificarsi danni ai tessuti durante la manipolazione della tenuta HS III interessata, durante il posizionamento di un secondo sistema di tenuta HS III caricato nella stessa aortotomia e/o la necessità di passare all'uso di una clamp aortica per completare l'aortotomia.
   - **Sanguinamento:** una piccola perdita di sangue intorno al sistema di tenuta HS III posizionato è normale e prevedibile durante l'esecuzione dell'anastomosi prossimale utilizzando un sistema HS III. Una perdita di sangue maggiore che richiede un intervento aggiuntivo può verificarsi in caso di danni al tessuto aortico, indipendentemente dalla causa.
   - **Eventi embolici:** derivanti da un'ulteriore manipolazione dell'aorta secondaria alla risoluzione del problema del sistema di tenuta HS III per eseguire un'emostasi adeguata.

Tra il 1 giugno 2023 e il 22 luglio 2025, Getinge ha ricevuto i seguenti reclami:

- 274 segnalazioni di guasti durante il caricamento, che rappresentano un tasso di reclami dello 0,386%
- 96 segnalazioni di guasti durante il posizionamento, che rappresentano un tasso di reclami dello 0,135%

- 30 segnalazioni relative a un'emostasi inadeguata, che rappresentano un tasso di reclami dello 0,042%

Azioni e mitigazioni consigliate

Getinge fornisce le seguenti istruzioni per evitare/ridurre al minimo i guasti di cui sopra.

1. **Mancato caricamento del sistema di tenuta Heartstring**
    a. Promemoria importanti:
        i. Secondo le Istruzioni per l'uso del dispositivo, il sistema di tenuta HS III è destinato a essere caricato e rimosso dal dispositivo di caricamento, quindi ispezionato e regolato se necessario per confermare l'esito positivo del caricamento e infine sbloccato prima di rimuovere l'avventizia dall'area anastomotica prevista e creare l'aortotomia. Il caricamento del sistema di tenuta HS III e la conferma del caricamento riuscito prima della creazione dell'aortotomia riducono al minimo il rischio per i pazienti, poiché l'aorta rimane intatta fino alla conferma dell'avvenuto caricamento del sistema di tenuta HS III.
        ii. Se il sistema di tenuta HS III non si carica come previsto, occorre sostituire il dispositivo.
    b. Come evitare/ridurre al minimo l'insorgenza di questo guasto
        i. Leggere le Istruzioni per l'uso del dispositivo Heartstring prima dell'uso, specialmente se Heartstring non viene utilizzato regolarmente.
        ii. Caricare il sistema di tenuta HS III seguendo attentamente le Istruzioni per l'uso (IFU) del dispositivo.
        iii. Conformemente alla sezione 4.3-4.5 delle Istruzioni per l'uso, confermare che il sistema HS III sia stato caricato correttamente nel dispositivo di posizionamento ispezionando il sistema di tenuta HS III caricato una volta che il sistema di tenuta HS III è stato caricato nel dispositivo di posizionamento e rimosso dal dispositivo di caricamento.
        iv. Un sistema di tenuta HS III che non viene ispezionato correttamente dopo essere stato rimosso dal dispositivo di caricamento potrebbe non funzionare correttamente durante l'attivazione e causare lesioni al paziente. (vedere le informazioni relative al mancato posizionamento).
        v. Completare correttamente il caricamento del sistema di tenuta HS III prima di rimuovere l'avventizia aortica e creare l'aortotomia.
    c. Azione da intraprendere se il sistema di tenuta HS III non si carica.
        i. Smaltire il sistema di tenuta HS III difettoso.
        ii. Tenere sempre a disposizione un secondo sistema di tenuta HS III per sostituire un dispositivo guasto. Fare riferimento alle Istruzioni per l'uso del dispositivo per garantire un caricamento corretto.
2. **Errore nel posizionamento del sistema di tenuta Heartstring III nell'aortotomia**
    a. Promemoria importanti:
        i. Assicurarsi che il sistema di tenuta HS III sia stato caricato correttamente nel dispositivo di posizionamento come descritto nella sezione precedente.
        ii. Dopo aver rimosso il sistema di tenuta HS III caricato dal dispositivo di caricamento, ispezionare il sistema HS III caricato, conformemente alle sezioni 4.3-4.5 delle Istruzioni per l'uso, per confermare quanto segue:

1. Il sistema di tenuta HS III caricato non è rotto.
2. La porzione del sistema di tenuta HS III che non si è caricato nel tubo del dispositivo di posizionamento non si allarga oltre il diametro del tubo del dispositivo di posizionamento.
3. Le estremità della molla di tensione sono allineate in modo che entrino in contatto con entrambi i bordi prossimali del sistema di tenuta HS III caricato durante il posizionamento della tenuta nell'aortotomia.

b. Come evitare/ridurre al minimo l'insorgenza di questo guasto:
   i. Dopo aver confermato il corretto caricamento del sistema di tenuta HS III e la creazione dell'aortotomia, posizionare la tenuta HS III caricata nell'aortotomia seguendo attentamente i passaggi per il posizionamento del sistema di tenuta HS III documentati nelle Istruzioni per l'uso del dispositivo.
   ii. Se il sistema di tenuta HS III non si posiziona come previsto, occorre sostituire il dispositivo.

c. Azioni da intraprendere se il sistema di tenuta HS III non si posiziona correttamente nell'aorta.
   i. Occludere l'aortotomia per controllare il sanguinamento utilizzando un dito indice.
   ii. Aprire un secondo sistema di tenuta HS III. Caricare la tenuta HS III secondo le Istruzioni per l'uso del dispositivo. Inserire la tenuta HS III caricata nell'aortotomia e seguire le Istruzioni per l'uso per completare l'anastomosi.
   iii. Se il posizionamento del secondo sistema di tenuta HS III nell'aortotomia non riesce o se il chirurgo ritiene che il caso non consente l'uso di un sistema di tenuta HS III sostitutivo, posizionare una clamp di occlusione parziale sull'aorta isolando l'aortotomia ed eseguire l'anastomosi secondo la tecnica chirurgica tradizionale.

3. Mancata capacità del sistema di tenuta Heartstring III posizionato di garantire un'emostasi adeguata:

a. Come evitare/ridurre al minimo l'insorgenza di questa modalità di guasto:
   i. Caricare sempre e ispezionare attentamente il sistema di tenuta HS III caricato per confermare il corretto caricamento della tenuta HS III nel dispositivo di posizionamento prima di rimuovere l'avventizia aortica e creare l'aortotomia. (Vedere i promemoria importanti qui sopra.)
   ii. Non utilizzare il sistema di tenuta prossimale Heartstring in pazienti con aorta a parete sottile.
   iii. Quando si esegue un'anastomosi multipla, assicurarsi che tutti i siti anastomotici siano distanti almeno 1,5 cm per garantire l'emostasi.
   iv. Non immergere il sistema di tenuta HS III nella soluzione prima del posizionamento.

b. Azione da intraprendere se il sistema di tenuta HS III non si apre/non fornisce un'emostasi adeguata dopo il posizionamento della tenuta.
   i. Coprire l'aortotomia con il dito indice e regolare delicatamente la molla di tensione per assicurarsi che il sistema di tenuta HS III sia posizionato correttamente.
   ii. Se l'emostasi non è sufficiente:
      1. Rimuovere il sistema di tenuta HS III posizionato dall'aortotomia conformemente alle Istruzioni per l'uso del dispositivo.
      2. Caricare un secondo sistema di tenuta HS III e posizionarlo nell'aortotomia secondo le Istruzioni per l'uso del dispositivo e completare l'anastomosi.
      3. Se il secondo sistema di tenuta HS III fallisce o se il chirurgo ritiene che il caso non consente l'uso di un sistema di tenuta HS III sostitutivo, posizionare una clamp di occlusione parziale sull'aorta isolando

l'aortotomia ed eseguire l'anastomosi secondo la tecnica chirurgica tradizionale.

Azioni del cliente

Getinge richiede di intraprendere le seguenti azioni:

1. Si prega di trasmettere il presente avviso a chiunque debba esserne a conoscenza all'interno della propria organizzazione/struttura o di qualsiasi organizzazione in cui sono stati trasferiti i dispositivi interessati.

Informazioni aggiuntive

Getinge sta comunicando queste informazioni alle autorità di regolamentazione competenti.

Ci scusiamo per il disagio. Ci impegniamo a garantire la sicurezza dei pazienti e apprezziamo la vostra immediata attenzione al problema. In caso di domande sulla presente comunicazione, contatti il rappresentante Getinge o l'assistenza clienti Getinge

Cordiali saluti

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

French (fr)

Août 2025

Avis relatif à la sécurité
Système d'étanchéité proximale Heartstring III
Réf. pièce : 1336551

Numéro de modèle	**UDI**	**Désignation de modèle**	Numéro de série/lot
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Système d'étanchéité proximale Heartstring III	Tous les lots non périmés
Période de distribution:		Du 1er juillet 2024 à aujourd'hui	
Période de fabrication:		**Du 7 mars 2024 à aujoud'hui**	

Cher utilisateur, cher client,

Le présent courrier a pour but de vous informer que Maquet Cardiovascular, filiale de Getinge, a publié une correction urgente de dispositif médical pour le système d'étanchéité proximale Heartstring III (HS III Seal). Nos dossiers indiquent que vous avez reçu au moins un des dispositifs concernés par cette notification.

Description du problème

Trois modes d'anomalie primaire ont été identifiés.

1. **Échec de chargement du système d'étanchéité Heartstring**: Cette anomalie s'applique à tout dysfonctionnement du dispositif qui se produit pendant le processus de chargement en quatre étapes à l'aide du dispositif de chargement Heartstring, l'inspection visuelle d'un système d'étanchéité HS III chargé avec succès et le déverrouillage du dispositif d'administration une fois les étapes de chargement du système d'étanchéité HS III terminées avec succès.
2. **Échec du déploiement du système d'étanchéité Heartstring dans l'aortotomie**: Cette anomalie s'applique à tout dysfonctionnement du système d'étanchéité HS III et/ou du dispositif d'administration à partir du moment où le dispositif d'administration est déverrouillé avec succès jusqu'à ce que le système d'étanchéité HS III soit complètement introduit dans l'aortotomie et que tout le contenu du système d'étanchéité proximal (attache, ressort de tension, tige du système d'étanchéité, languette d'ancrage) ait quitté le dispositif d'administration.
3. **Échec de l'hémostase par le système d'étanchéité Heartstring déployé:** Cette anomalie s'applique à tout dysfonctionnement d'un système d'étanchéité HS III déployé avec succès qui ne contrôle pas adéquatement le saignement au niveau de l'anastomose pour permettre au chirurgien d'effectuer la suture de l'anastomose, malgré un léger réglage du ressort de tension après le déploiement du système d'étanchéité et/ou l'utilisation d'un vaporisateur, d'une aspiration ou d'une seringue de sérum physiologique pour dégager le site anastomotique. Cette anomalie inclut l'identification par le client d'un système d'étanchéité HS III défectueux ou endommagé après le déploiement réussi du système d'étanchéité HS III dans l'aorte qui entraîne/peut entraîner une hémostase inadéquate empêchant le chirurgien de terminer l'anastomose sans retirer le système d'étanchéité HS III défectueux.

L'enquête sur les causes profondes est en cours.

Risque pour la santé

1. **Échec du chargement:** Lorsqu'il est utilisé conformément au mode d'emploi du dispositif, un système d'étanchéité HS III qui ne se charge pas ne présente aucun risque direct pour le patient. Toutefois, cette anomalie peut retarder l'intervention chirurgicale. Un tel retard peut aller de quelques minutes pour récupérer et charger un nouveau système d'étanchéité, à une conversion potentielle de l'utilisation du système d'étanchéité HS III pour effectuer l'anastomose proximale à l'utilisation d'une pince aortique pour terminer la procédure.
2. **Échec du déploiement:** Lorsque le système d'étanchéité HS III chargé ne se déploie pas à partir du dispositif d'administration, les étapes de procédure suivantes ont déjà été effectuées et peuvent contribuer au risque de blesser le patient. Si le système d'étanchéité HS III chargé ne se déploie pas à partir du dispositif d'administration, plusieurs étapes de la procédure auront déjà été effectuées, ce qui peut augmenter le risque de blesser le patient.
    - L'aortotomie a été créée.
    - L'extrémité distale du tube du dispositif d'introduction a été insérée dans l'aortotomie.
    - Le piston du dispositif d'administration a été enfoncé ou une tentative a été faite de l'enfoncer.
    - Le système d'étanchéité HS III chargé n'a pas été déployé avec succès depuis l'extrémité distale du tube du dispositif d'administration.
    - Lorsque le dispositif d'introduction est retiré de l'aortotomie, le système d'étanchéité HS III ne sera pas déployé et le saignement de l'aortotomie devra être contrôlé en plaçant un doigt sur l'aortotomie.

    Les risques pour le patient sont les suivants:

    - **Retard de l'intervention chirurgicale**: pour retirer le système d'étanchéité HS III non déployé, ouvrir un nouveau système d'étanchéité proximal HS III, charger le système d'étanchéité dans le dispositif d'administration et délivrer le système d'étanchéité HS III chargé dans l'aortotomie créée (retard sans intervention supplémentaire) par rapport à la décision d'utiliser une pince aortique pour terminer l'anastomose parce que le système d'étanchéité chargé n'a pas pu être déployé (retard dû à une intervention supplémentaire)
    - **Lésions tissulaires**: peuvent survenir à la suite du déploiement d'un système d'étanchéité HS III chargé qui est évasé au niveau de l'embout. Un embout évasé aura un diamètre supérieur à celui du tube distal du dispositif d'introduction. Le déploiement d'un système d'étanchéité chargé avec une extrémité évasée peut endommager le tissu de l'aortotomie et, si une force plus importante est exercée pour déployer le système d'étanchéité touché, il existe un risque de retour de l'aorte pendant l'insertion. Des lésions tissulaires peuvent également se produire pendant le retrait du dispositif d'introduction de l'aortotomie, le déploiement d'un deuxième système d'étanchéité HS III chargé dans la même aortotomie, et/ou la nécessité de passer à l'utilisation d'une pince aortique pour terminer l'aortotomie.
    - **Hémorragie:** une perte de sang minimale peut se produire lors du retrait du dispositif d'introduction de l'aortotomie, du contrôle manuel du saignement de l'aortotomie et de l'administration d'un système d'étanchéité HS III de remplacement. Une saignement plus important, nécessitant une intervention supplémentaire, peut se produire en cas de lésion tissulaire.

- **Événement embolique** résultant d'une manipulation supplémentaire de l'aorte pour résoudre l'échec du chargement du système d'étanchéité HS III.

3. **Échec de l'hémostase par le système d'étanchéité Heartstring déployé:** Si un système d'étanchéité HS III déployé n'assure pas une hémostase adéquate pour que le chirurgien termine l'anastomose proximale, plusieurs étapes de l'utilisation du système de système d'étanchéité HS III ont déjà été effectuées et peuvent augmenter le risque de blessure du patient. Les étapes suivantes ont été effectuées.

   - L'aortotomie a été créée.
   - Le système d'étanchéité HS III chargé a été déployé dans l'aorte.
   - L'hémorragie de l'aorte est jugé trop importante par le chirurgien pour effectuer l'anastomose.

   Les risques pour le patient sont les suivants:

   - **Retard d'intervention chirurgicale**: peut se produire comme suit:
     - P rolongation de la durée d'opération nécessaire pour tenter d'effectuer des ajustements du système d'étanchéité pour améliorer l'hémostase par le système d'étanchéité HS III fourni, retirer le système d'étanchéité HS III défectueux, ouvrir un nouveau système d'étanchéité HS III, charger le système d'étanchéité HS III de remplacement et transmettre le système d'étanchéité HS III chargé dans l'aortotomie créée (retard de la procédure sans intervention supplémentaire)
     - Le chirurgien estime qu'il est plus approprié d'utiliser un clamp aortique pour terminer l'anastomose car le système d'étanchéité HS III déployé n'a pas fourni d'hémostase adéquate pour terminer l'anastomose et qu'un système d'étanchéité HS III de remplacement n'est pas disponible ou que le chirurgien détermine que la situation ne permet pas l'utilisation d'un système d'étanchéité HS III de remplacement et qu'un clamp aortique est utilisé pour terminer l'anastomose proximale suivant la technique chirurgicale traditionnelle. (retard de la procédure avec une intervention supplémentaire)
   - **Dommages tissulaires :** Des lésions tissulaires peuvent se produire pendant la manipulation du système d'étanchéité HS III concerné, pendant le déploiement du système d'étanchéité d'un second système d'étanchéité HS III chargé dans la même aortotomie et/ou nécessitant l'utilisation d'une pince aortique pour terminer l'aortotomie.
   - **Hémorragie :** Une légère perte de sang autour du système d'étanchéité HS III déployé est normale et attendue lors de l'anastomose proximale au moyen d'un système d'étanchéité HS III. Une perte de sang plus importante nécessitant une intervention supplémentaire peut survenir en cas de lésion du tissu aortique, quelle qu'en soit la cause.
   - **Événement(s) embolique(s):** résultant d'une manipulation supplémentaire de l'aorte secondaire au traitement de l'échec de l'étanchéité HS III pour assurer une hémostase adéquate.

Entre le 1er juin 2023 et le 22 juillet 2025, Getinge a reçu les réclamations suivantes:

- 274 signalements liés à l'échec du chargement, représentant un taux de réclamations de 0,386 %
- 96 signalements liés à l'échec du déploiement, représentant un taux de réclamations de 0,135 %
- 30 rapports liés à une hémostase inadéquate, représentant un taux de plaintes de 0,042 %

Mesures et actions recommandées

Getinge fournit les instructions suivantes pour éviter/minimiser les anomalies abordées ci-dessus.

1. **Échec de chargement du système d'étanchéité Heartstring**
    a. Rappels importants:
        i. Conformément au mode d'emploi du dispositif, le système d'étanchéité HS III est destiné à être chargé et retiré du dispositif de chargement, puis inspecté et ajusté si nécessaire pour confirmer le chargement réussi et enfin déverrouillé avant de dégager toute adventice de la zone anastomotique prévue et de créer l'aortotomie. Le chargement du système d'étanchéité HS III et la confirmation du chargement réussi avant la création de l'aortotomie minimisent le risque pour les patients car l'aorte reste intacte jusqu'à la confirmation du chargement réussi du système d'étanchéité HS III.
        ii. Si le système d'étanchéité HS III ne se charge pas comme prévu, le dispositif doit être remplacé.
    b. Comment éviter/minimiser l'occurrence de cette anomalie
        i. Lisez le mode d'emploi du dispositif Heartstring avant utilisation, en particulier si Heartstring n'est pas utilisé de manière routinière.
        ii. Chargez le système d'étanchéité HS III en suivant attentivement le mode d'emploi du dispositif.
        iii. Conformément à la section 4,3-4,5 du mode d'emploi, confirmez que le système d'étanchéité HS III a été correctement chargé dans le dispositif d'administration en inspectant le système d'étanchéité HS III chargé une fois le système d'étanchéité HS III chargé dans le dispositif d'administration et retiré du dispositif de chargement.
        iv. Un système d'étanchéité HS III qui n'est pas correctement inspecté après avoir été retiré du dispositif de chargement peut tomber en panne pendant le déploiement du système d'étanchéité HS III et nuire au patient. (voir informations relatives à l'échec du déploiement).
        v. Terminez le chargement réussi du système d'étanchéité HS III avant de nettoyer l'adventice de la surface aortique et de créer l'aortotomie.
    c. Mesures à prendre si le système d'étanchéité HS III ne se charge pas.
        i. Éliminez le système d'étanchéité HS III défectueux.
        ii. Il faut toujours disposer d'un deuxième système d'étanchéité HS III pour remplacer un dispositif défectueux. Reportez-vous au mode d'emploi du dispositif pour garantir un chargement réussi.

2. **Échec du déploiement du système d'étanchéité Heartstring III dans l'aortotomie**
    a. Rappels importants:
        i. Vérifiez que le système d'étanchéité HS III a été correctement chargé dans le dispositif d'administration comme décrit dans la section ci-dessus.
        ii. Après avoir retiré le système d'étanchéité HS III chargé du dispositif de chargement, inspectez le système d'étanchéité HS III chargé, conformément aux sections 4.3-4.5 du mode d'emploi, pour confirmer ce qui suit:
            1. Le système d'étanchéité HS III chargé n'est pas fissuré.

2. La partie du système d'étanchéité HS III qui n'est pas chargée dans le tube du dispositif d'administration ne s'élargit pas au-delà du diamètre du tube du dispositif d'administration.
3. Les extrémités du ressort de tension sont alignées de sorte qu'elles entrent en contact avec les deux bords proximaux du système d'étanchéité HS III chargé pendant l'introduction du système d'étanchéité dans l'aortotomie.

b. Comment éviter/minimiser l'occurrence de cette anomalie:
   i. Après confirmation du chargement réussi du système d'étanchéité HS III et de la création de l'aortotomie, déployez le système d'étanchéité HS III chargé dans l'aortotomie en suivant attentivement les étapes de déploiement du système d'étanchéité HS III énoncées dans le mode d'emploi du dispositif.
   ii. Si le système d'étanchéité HS III ne se déploie pas comme prévu, le dispositif doit être remplacé.

c. Mesures à prendre si le système d'étanchéité HS III ne se déploie pas correctement dans l'aorte.
   i. Occluez l'aortotomie pour contrôler le saignement à l'aide d'un index.
   ii. Ouvrez un deuxième système d'étanchéité HS III. Chargez le système d'étanchéité HS III conformément au mode d'emploi du dispositif. Introduisez le système d'étanchéité HS III chargé dans l'aortotomie et suivez le mode d'emploi pour terminer l'anastomose.
   iii. Si la pose du deuxième système d'étanchéité HS III dans l'aortotomie échoue ou si l'avis du chirurgien détermine que la situation ne permet pas l'utilisation d'un système d'étanchéité HS III de remplacement, placez un clamp d'occlusion partielle sur l'aorte, isolez l'aortotomie et effectuez l'anastomose suivant la technique chirurgicale traditionnelle.

3. Échec de l'hémostase du système d'étanchéité Heartstring III déployé:

a. Comment éviter/minimiser l'occurrence de ce mode d'anomalie:
   i. Il faut toujours charger et inspecter soigneusement le système d'étanchéité HS III chargé pour confirmer le chargement réussi du système d'étanchéité HS III dans le dispositif d'introduction avant de dégager toute adventice aortique et de créer l'aortotomie. (Voir les rappels importants ci-dessus.)
   ii. Veillez à ne pas utiliser le système d'étanchéité proximale Heartstring chez les patients présentant une aorte à paroi mince.
   iii. Lors d'anastomoses multiples, assurez-vous que tous les sites d'anastomose sont espacés d'au moins 1,5 cm pour assurer l'hémostase.
   iv. N'immergez pas le système d'étanchéité HS III dans la solution avant son déploiement.

b. Mesures à prendre si le système d'étanchéité HS III ne s'ouvre pas/n'assure pas une hémostase adéquate après le déploiement du système d'étanchéité.
   i. Couvrez l'aortotomie avec l'index et ajustez délicatement le ressort de tension pour s'assurer que le système d'étanchéité HS III est complètement déployé.
   ii. Si l'absence d'hémostase adéquate persiste:
      1. Retirez le système d'étanchéité HS III déployé de l'aortotomie conformément au mode d'emploi du dispositif.

2. Chargez un deuxième système d'étanchéité HS III et déployez le système d'étanchéité chargé dans l'aortotomie conformément au mode d'emploi du dispositif et terminez l'anastomose.
3. Si le second système d'étanchéité HS III n'est pas efficace ou si le chirurgien détermine que la situation ne permet pas l'utilisation d'un système d'étanchéité HS III de remplacement, placez un clamp d'occlusion partielle sur l'aorte, isolez l'aortotomie et effectuez l'anastomose suivant la technique chirurgicale traditionnelle.

Mesures du client

Getinge vous invite à prendre les mesures suivantes:

1. Veuillez vous assurer que ce message est transmis à toutes les personnes devant en être informées au sein de votre établissement ou tout autre où les dispositifs concernés ont été transférés.

Pour plus d'informations

Getinge communique ces informations aux organismes de réglementation appropriés.

Veuillez nous excuser pour tout éventuel désagrément. Nous nous engageons à assurer la sécurité des patients et apprécions votre attention immédiate à ce sujet. Pour toute question au sujet de cet avis, veuillez contacter votre représentant Getinge ou appeler le service client Getinge.

Nous vous prions de recevoir nos respectueuses salutations,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Turkey (tr)

Ağustos 2025

Saha Güvenlik Bildirimi
Heartstring III Proksimal Sızdırmazlık Sistemi
Referans Numarası: 1336551

Model Numarası	UDI	Model Adı	Seri / Lot Numaraları
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	Süresi Dolmamış Tüm Lotlar
Dağıtım Tarihleri:		1 Temmuz 2024 - Günümüz	
Üretim Tarihleri:		7 Mart 2024 - Halen	

Sayın Risk Yöneticisi,

Bu mektubun amacı, Getinge'nin bir iştiraki olan Maquet Cardiovascular'ın Heartstring III Proksimal Sızdırmazlık Elemanı Sistemi (HS III Sızdırmazlık Elemanı) için Acil Tıbbi Cihaz Düzeltmesi yayınladığını size bildirmektir. Kayıtlarımız, bu bildirimin kapsadığı bir veya daha fazla cihaz aldığınızı göstermektedir.

Sorun Açıklaması

Üç ana arıza modu tespit edilmiştir.

1. **Heartstring Sızdırmazlık Elemanı'nın Yüklenememesi:** Bu arıza, Heartstring Yükleme Cihazı kullanılarak dört aşamalı yükleme işlemi sırasında cihazda meydana gelen herhangi bir arıza, başarıyla yüklenmiş HS III Sızdırmazlık Elemanı'nın görsel kontrolü ve HS III Sızdırmazlık Elemanı yükleme adımlarının başarıyla tamamlanmasının ardından Yerleştirme Cihazının kilidinin açılması için geçerlidir.
2. **Heartstring Sızdırmazlık Elemanının aortotomi içine yerleştirilememesi**: Bu arıza, Yerleştirme Cihazının başarıyla kilidinin açılmasından itibaren, HS III Sızdırmazlık Elemanının aortotomi içine tamamen yerleştirilmesine ve Proksimal Sızdırmazlık Sisteminin tüm bileşenlerinin (Tether, Gergi Yayı, Sızdırmazlık Gövdesi, Ankraj Sekmesi) Yerleştirme Cihazından tamamen çıkmasına kadar geçen süre içinde HS III Sızdırmazlık Elemanı ve/veya Yerleştirme Cihazında meydana gelen her türlü arızayı kapsar.
3. **Yerleştirilen Heartstring Sızdırmazlık Elemanı'nın yeterli hemostaz sağlayamaması:** Bu durum, Sızdırmazlık Elemanı yerleştirildikten sonra Gergi Yayının nazikçe ayarlanmasına ve/veya anastomoz bölgesini temizlemek için püskürtücü, aspirasyon veya salin şırıngası kullanılmasına rağmen, cerrahın anastomozu dikmesini sağlayacak şekilde anastomoz bölgesindeki kanamayı yeterince kontrol edemeyen, başarıyla yerleştirilmiş HS III Sızdırmazlık Elemanı'nın herhangi bir arızası için geçerlidir. Bu arıza, HS III Sızdırmazlık Elemanı'nın aortaya başarılı bir şekilde yerleştirilmesinin ardından, müşteri tarafından tespit edilen arızalı veya hasarlı bir HS III Sızdırmazlık Elemanı'nı kapsar. Bu durum,

yetersiz hemostaza yol açarak cerrahın anastomozu tamamlamasının engellenmesine neden olur ve/veya neden olabilir; bu durumda hasarlı HS III Sızdırmazlık Elemanı'nın çıkarılması gerekebilir.

Şu anda temel neden araştırması devam etmektedir.

Sağlık Riskleri

1. **Yükleme Arızası:** Cihazın Kullanım Talimatlarına (IFU) uygun olarak kullanıldığında, yüklenemeyen bir HS III Sızdırmazlık Elemanı hastaya doğrudan bir risk oluşturmaz. Ancak bu durum cerrahi prosedürün gecikmesine neden olabilir. Bu gecikme, yeni bir Sızdırmazlık Elemanının alınması ve yüklenmesi için birkaç dakikadan, proksimal anastomozu gerçekleştirmek için HS III Sızdırmazlık Elemanının kullanılmasından, prosedürü tamamlamak için aort kelepçesinin kullanılmasına kadar değişebilir.
2. **Yerleştirilememe:** Yüklenen HS III Sızdırmazlık Elemanı, Yerleştirme Cihazından yerleştirilemediğinde aşağıdaki prosedür adımları önceden uygulanmış olup hastanın zarar görme riskine katkıda bulunabilir. Yüklenen HS III Sızdırmazlık Elemanı, Yerleştirme Cihazından çıkmazsa birkaç prosedür adımı zaten tamamlanmış olacak ve bu da hastaya zarar verme riskini artıracaktır.
   - Aortotomi gerçekleştirilmiştir.
   - Yerleştirme Cihazı Tüpünün distal ucu aortotomi yoluyla yerleştirilmiştir.
   - Yerleştirme Cihazının Pistonuna basılmış veya basılmaya çalışılmıştır.
   - Yüklenen HS III Sızdırmazlık Elemanı, Yerleştirme Cihazı Tüpünün distal ucundan başarıyla yerleştirilememiştir.
   - Yerleştirme Cihazı aortotomiden çıkarıldığında HS III Sızdırmazlık Elemanı açılmayacaktır ve aortotomiden kaynaklanan kanamayı aortotominin üzerine baskı uygulayarak kontrol altına almak gerekecektir.

   Aşağıdaki potansiyel hasta zararları meydana gelebilir:

   - **Cerrahi prosedür gecikmesi:** Yerleştirilememiş HS III Proksimal Sızdırmazlık Elemanının çıkarılması, yeni bir HS III Proximal Seal açılması, Sızdırmazlık Elemanının Yerleştirme Cihazına yüklenmesi ve Sızdırmazlık Elemanının oluşturulan aortotomiye yerleştirilmesine (ek bir müdahale olmadan gecikme) karşılık Sızdırmazlık Elemanının yerleşmemesi nedeniyle aort kıskaç kullanarak anastomozun tamamlanması kararı (ek bir müdahale ile gecikme).
   - **Doku hasarı:** Uç kısmı açılmış bir HS III Sızdırmazlık Elemanının yerleştirilmesi sonucunda meydana gelebilir. Açılmış uç, Yerleştirme Cihazı Tüpü'nün distal kısmından daha büyük bir çapta olacaktır. Açılmış uçlu yüklenmiş bir Sızdırmazlık Elemanının yerleştirilmesi, aortotomi dokusunda hasara yol açabilir ve etkilenen Sızdırmazlık Elemanının yerleştirilmesi sırasında daha fazla kuvvet kullanılması durumunda aortanın arka duvarının delinmesi (backwalling) riski olabilir. Doku hasarı, Yerleştirme Cihazının aortotomiden çıkarılması sırasında aynı aortotomiye ikinci bir yüklenmiş HS III Sızdırmazlık Elemanı yerleştirilmesi sırasında ve/veya aortotomi tamamlamak için aort kıskaç kullanmaya dönüşme sırasında da meydana gelebilir.
   - **Kanama:** Aortotomi bölgesinden Yerleştirme Cihazı çıkarılırken bu bölgedeki kanamayı manuel olarak kontrol ederken ve yedek HS III Sızdırmazlık Elemanı yerleştirirken minimal kan kaybı meydana gelebilir. Doku hasarı meydana gelirse daha fazla kan kaybı meydana gelebilir ve ek müdahale gerekebilir.
   - HS III Sızdırmazlık Elemanının yüklenememesi sorununu gidermek amacıyla aortaya ek manipülasyon yapılması sonucu gelişen **embolik olay**.

3. **Yerleştirilen Heartstring Sızdırmazlık Elemanının yeterli hemostaz sağlayamaması**: Yerleştirilmiş bir HS III Sızdırmazlık Elemanının, cerrahın proksimal anastomozu tamamlayabilmesi için yeterli hemostazı sağlayamaması durumunda, HS III Sızdırmazlık Sistemi kullanımına ilişkin birkaç adım halihazırda tamamlanmış olup bu durum hastaya zarar verme potansiyel riskini artırabilir. Aşağıdaki prosedür adımları gerçekleştirilmiş olacaktır.
   - Aortotomi gerçekleştirilmiştir.
   - Yüklenmiş HS III Sızdırmazlık Elemanı aorta içine yerleştirilmiştir.
   - Aortta meydana gelen kanama, cerrah tarafından anastomoz işlemi için çok fazla olduğu değerlendirilmektedir.

   Aşağıdaki potansiyel hasta zararları meydana gelebilir:

   - **Cerrahi işlemin gecikmesi:** aşağıdaki şekilde meydana gelebilir**:**
     - Yeterli hemostaz sağlamak amacıyla yerleştirilmiş HS III Sızdırmazlık Elemanında ayarlama yapılmasına çalışılması, kusurlu HS III Sızdırmazlık Elemanının çıkarılması, yeni bir HS III Sızdırmazlık Elemanının açılması, yedek HS III Sızdırmazlık Elemanının yüklenmesi ve yüklenen HS III Sızdırmazlık Elemanının oluşturulan aortotomi içine yerleştirilmesi için geçen ilave operasyon süresi (ek müdahale olmaksızın prosedür gecikmesi)
     - Cerrah, anastomozu tamamlamak için aort kelepçesi kullanmanın en uygun olduğunu düşünür çünkü yerleştirilen HS III Sızdırmazlık Elemanı anastomozu tamamlamak için yeterli hemostaz sağlamamıştır ve yedek HS III Sızdırmazlık Elemanı mevcut değildir veya cerrahın tercihi, durumun yedek HS III Sızdırmazlık Elemanı kullanımına izin vermeyen bir durum olduğunu belirler ve geleneksel cerrahi teknikle proksimal anastomozu tamamlamak için aort kelepçesi kullanılır. (ek müdahale ile prosedür gecikmesi)
   - **Doku hasarı:** Etkilenen HS III Sızdırmazlık Elemanı'nın kullanımı sırasında, aynı aortotomide ikinci bir yüklenmiş HS III Sızdırmazlık Elemanı'nın yerleştirilmesi ve/veya aortotomiyi tamamlamak için aort kelepçesi kullanımına geçilmesi gerektiğinde doku hasarı meydana gelebilir.
   - **Kanama:** HS III Sızdırmazlık Elemanı kullanılarak proksimal anastomoz gerçekleştirilirken yerleştirilen HS III Sızdırmazlık Elemanı çevresinde az miktarda kan kaybı olması normaldir ve beklenen bir durumdur. Aort dokusunda hasar meydana geldiğinde, nedeni ne olursa olsun ek müdahale gerektiren daha fazla kan kaybı meydana gelebilir.
   - **Embolik olay(lar):** HS III Sızdırmazlık Elemanının yeterli hemostaz sağlayamamasının giderilmesine bağlı olarak aortanın ek manipülasyonu sonucu ortaya çıkan embolik olay(lar).

1 Haziran 2023 ile 22 Temmuz 2025 tarihleri arasında Getinge aşağıdaki şikayetleri almıştır:
- Yükleme hatasıyla ilgili 274 rapor, şikayet oranı %0,386
- Yerleşim hatasıyla ilgili 96 rapor, şikayet oranı %0,135
- Yetersiz hemostazla ilgili 30 rapor, şikayet oranı %0,042

<u>Önerilen Azaltıcı Önlemler ve Eylemler</u>

Getinge, yukarıda bahsedilen hataları önlemek/en aza indirmek için aşağıdaki talimatları vermektedir.

1. **Heartstring Sızdırmazlık Elemanı'nın Yüklenememesi**
   a. Önemli hatırlatmalar:

i. Cihazın kullanım talimatına göre HS III Sızdırmazlık Elemanı, Yükleme Cihazına yüklenip cihazdan çıkarılmalı, ardından başarılı bir şekilde yüklendiğini doğrulamak için incelenmeli, gerekirse ayarlanmalı ve son olarak planlanan anastomoz alanından herhangi bir adventisya temizlenmeden ve aortotomi oluşturulmadan önce kilidi açılmalıdır. HS III Sızdırmazlık Elemanı'nı yüklemek ve aortotomi oluşturmadan önce yüklemenin başarılı olduğunu doğrulamak, HS III Sızdırmazlık Elemanı'nın başarılı bir şekilde yüklendiğini doğrulayana kadar aort dokunulmadan kaldığı için hastalar için riski en aza indirir.

ii. HS III Sızdırmazlık Elemanı beklendiği gibi yüklenemezse cihaz değiştirilmelidir.

b. Bu arızanın oluşmasını nasıl önleyebilir/en aza indirebilirsiniz?

i. Kullanmadan önce özellikle Heartstring cihazını rutin olarak kullanmıyorsanız Heartstring cihazının kullanım talimatlarını inceleyin.

ii. HS III Sızdırmazlık Elemanını, cihazın adım adım Kullanım Talimatlarını (IFU) dikkatlice izleyerek yükleyin.

iii. Kullanım Talimatının 4.3-4.5 bölümlerine göre HS III Sızdırmazlık Elemanı, Yerleştirme Cihazına düzgün bir şekilde yerleştirildiğini, HS III Sızdırmazlık Elemanı Yerleştirme Cihazına yerleştirildikten ve Yükleme Cihazından çıkarıldıktan sonra kontrol ederek teyit edin.

iv. Yükleme Cihazından çıkarıldıktan sonra düzgün bir şekilde incelenmeyen bir HS III Sızdırmazlık Elemanı, HS III Sızdırmazlık Elemanı Yerleştirme işlemi sırasında arızalanabilir ve hastaya zarar verebilir. (Yerleştirme Arızası ile ilgili bilgilere bakın).

v. Aort yüzeyinin adventisya kısmını temizlemeden ve aortotomi oluşturmadan önce HS III Sızdırmazlık Elemanının yüklenmesini tam olarak tamamlayın.

c. HS III Sızdırmazlık Elemanı yüklenmezse alınacak önlemler.

i. Arızalı HS III Sızdırmazlık Elemanını atın.

ii. Arızalı bir cihazı değiştirmek için her zaman ikinci bir HS III Sızdırmazlık Elemanı bulundurun. Başarılı bir yükleme için cihazın kullanım kılavuzuna bakın.

2. Heartstring III Sızdırmazlık Elemanının aortotomiye yerleştirilememesi

a. Önemli hatırlatmalar:

i. HS III Sızdırmazlık Elemanının yukarıdaki bölümde açıklanan şekilde Yerleştirme Cihazına doğru şekilde yerleştirildiğinden emin olun.

ii. Yükleme Cihazından yüklenmiş HS III Sızdırmazlık Elemanı çıkarıldıktan sonra, aşağıdakilerin doğrulanması amacıyla Kullanım Talimatları (IFU) Bölüm 4.3–4.5 uyarınca yüklenmiş HS III Sızdırmazlık Elemanını inceleyiniz:

1. Yüklenen HS III Sızdırmazlık Elemanı çatlak olmamalıdır.
2. Yerleştirme Cihazı Tüpüne yerleştirilmeyen HS III Sızdırmazlık Elemanı kısmı, Yerleştirme Cihazı Tüpünün çapından daha geniş olmamalıdır.
3. Gergi Yayı uçları, Sızdırmazlık Elemanı aortotomide yerleştirilirken yüklenen HS III Sızdırmazlık Elemanının her iki proksimal kenarına temas edecek şekilde hizalanmalıdır.

b. Bu arızanın oluşmasını önlemek/en aza indirmek için:
    i. HS III Sızdırmazlık Elemanının başarılı bir şekilde yüklendiği ve aortotomi oluşturulduğu doğrulandıktan sonra cihazın kullanım talimatlarında belirtilen HS III Sızdırmazlık Elemanı yerleştirme adımlarını dikkatlice izleyerek yüklenen HS III Sızdırmazlık Elemanını aortotominin içine yerleştirin.
    ii. HS III Sızdırmazlık Elemanı istenen şekilde yerleştirilemezse cihaz değiştirilmelidir.
c. HS III Sızdırmazlık Elemanı aorta içine başarıyla yerleştirilemezse alınacak önlemler.
    i. Kanamayı kontrol etmek için aortotomi bölgesini işaret parmağınızla kapatın.
    ii. İkinci bir HS III Sızdırmazlık Elemanı açın. Cihazın kullanım talimatına göre HS III Sızdırmazlık Elemanını yükleyin. Yüklenen HS III Sızdırmazlık Elemanını aortotomiye yerleştirin ve kullanım talimatını izleyerek anastomozu tamamlayın.
    iii. İkinci HS III Sızdırmazlık Elemanının aortotomiye yerleştirilmesi başarılı olmazsa veya cerrahın tercihi, durumun yedek HS III Sızdırmazlık Elemanı kullanımına izin vermediğine karar verirse aortotomiye kısmi oklüzyon kıskaç yerleştirin, aortotomiyi izole edin ve geleneksel cerrahi teknikle anastomozu gerçekleştirin.

3. Yerleştirilen Heartstring III Sızdırmazlık Elemanının yeterli hemostaz sağlamaması:

a. Bu arıza durumunun oluşmasını önlemek/en aza indirmek için:
    i. Aort adventisya temizlenmeden ve aortotomi oluşturulmadan önce HS III Sızdırmazlık Elemanının Yerleştirme Cihazına başarıyla yerleştirildiğini doğrulamak için her zaman HS III Sızdırmazlık Elemanını yükleyin ve dikkatlice inceleyin. (Yukarıdaki önemli hatırlatmalara bakın.)
    ii. İnce duvarlı aortu olan hastalarda Heartstring Proximal Seal System'i kullanmayın.
    iii. Birden fazla anastomoz gerçekleştirirken hemostazı sağlamak için tüm anastomoz bölgelerinin birbirinden en az 1,5 cm uzaklıkta olmasını sağlayın.
    iv. HS III Sızdırmazlık Elemanı yerleştirmeden önce solüsyona batırmayın.
b. HS III Sızdırmazlık Elemanı açılmadığında/yerleştirildikten sonra yeterli hemostaz sağlamadığında alınacak önlemler.
    i. Aortotomiyi işaret parmağınızla kapatın ve HS III Sızdırmazlık Elemanının tamamen yerleştirildiğinden emin olmak için Gergi Yayını nazikçe ayarlayın.
    ii. Yeterli hemostaz sağlanamadığı durumlarda:
        1. Cihazın kullanım talimatına göre yerleştirilen HS III Sızdırmazlık Elemanını aortotomiden çıkarın.
        2. İkinci bir HS III Sızdırmazlık Elemanı yükleyin ve yüklenen Sızdırmazlık Elemanını cihaz kullanım talimatına göre aortotomide yerleştirin ve anastomozu tamamlayın.
        3. İkinci HS III Sızdırmazlık Elemanı başarılı olmazsa veya cerrahın tercihi, durumun yedek HS III Sızdırmazlık Elemanı kullanımına izin vermediğine karar verirse aortotomiye izole ederek aort üzerine kısmi oklüzyon kıskacı yerleştirin ve geleneksel cerrahi teknikle anastomozu gerçekleştirin.

Müşteri Eylemleri

Getinge, aşağıdaki işlemleri gerçekleştirmenizi rica eder:

1. Bu bildirimin, kuruluşunuzda veya etkilenen cihazların transfer edildiği herhangi bir kuruluşta bildirim gerektiren tüm kişilere iletildiğinden emin olun.

Ek Bilgi

Getinge bu bilgileri ilgili düzenleyici kurumlara iletmektedir.

Bu durumun neden olabileceği rahatsızlıktan dolayı özür dileriz. Hasta güvenliğine büyük önem veriyoruz ve bu konuya gösterdiğiniz ilgi için teşekkür ederiz. Bu bildirimle ilgili herhangi bir sorunuz olması halinde, lütfen Getinge temsilcinizle veya Pazartesi–Cuma günleri arasında 08:00–17:00 saatleri (Pasifik Saat Dilimi) içinde 1-888-880-2874 numaralı telefondan Getinge Müşteri Hizmetleri ile iletişime geçiniz.

Saygılarımızla,

Francisco Vicenty
Geçici Kalite ve Mevzuata Uyum Direktörü
Getinge, Kardiyovasküler Cerrahi

Thailand (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.

- The aortotomy has been created.
- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
  - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
  - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

Recommended Mitigations and Actions

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
   a. Important reminders:
      i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading prior to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
      ii. If the HS III Seal fails to load as intended, the device should be replaced.
   b. How to avoid/minimize occurrence of this failure
      i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used

on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta

adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.

iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.

iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.

i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.

ii. If lack of adequate hemostasis persists:

1. Remove the deployed HS III Seal from the aortotomy per device IFU.
2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

Ukraine (uk)

Серпень 2025 року

Консультативне повідомлення
Системи блокування при анастомозі артерії Heartstring III Proximal Seal System

Довідковий номер: 1336551

Номер Моделі	ЄДІ	Назва моделі	Серійний номер/номер партії
HS-3045 HSK-3038 HSK - 3043	00607567700307 00607567700314 00607567700321	Система блокування при анастомозі артерії Heartstring III Proximal Seal System	Усі продукти, що мають дійний термін
Розповсюдження Дати:		Липень 1, 2024 рік – донині	
Виробництво Дати:		Березень 7, 2024 рік - донині	

Шановний Клієнте,

Мета цього листа — повідомити Вас, що Maquet Cardiovascular, дочірня компанія Getinge, видає термінове Консультативне повідомлення, щодо Системи блокування при анастомозі артерії Heartstring III Proximal Seal System (HS III Seal). Наш записи вказують на те, що ви отримали один або декілька пристроїв, на які поширюється це консультативне повідомлення.

Опис проблеми

Було індефіковано три первинні режими невдачі.

1. **Невдача при завантажені Heartstring Seal** : Ця несправність стосується будь-якої несправності пристрою, що виникає під час чотириетапного процесу завантаження за допомогою пристрою завантаження Heartstring, візуального огляду успішно завантаженої пломби HS III та розблокування пристрою доставки після успішного завершення етапів завантаження пломби HS III.
2. **Невдача при розкритті Heartstring Seal в аортотомію**: Ця несправність стосується будь-якої несправності ущільнювача HS III та/або пристрою доставки з моменту успішного розблокування пристрою доставки до моменту повного введення ущільнювача HS III в аортотомію, коли весь вміст проксимального ущільнювача (тросик, пружина натягу, шток ущільнювача, анкерний виступ) вийшов з пристрою доставки.
3. **Нездатність розгорнутого ущільнювача Heartstring забезпечити належний гемостаз:** Ця несправність стосується будь-якої несправності успішно розгорнутого ущільнювача HS III, який не забезпечує належної зупинки кровотечі в анастомозі, щоб хірург міг виконати ушивання анастомозу, незважаючи на обережне регулювання пружини натягу після розгортання ущільнювача та/або використання

розпилювача, відсмоктувача або шприца з фізіологічним розчином для очищення місця анастомозу. Ця несправність включає виявлення клієнтом дефектного або пошкодженого ущільнювача HS III після успішного розгортання ущільнювача HS III в аорту, що призводить/або може призвести до недостатнього гемостазу, що перешкоджає хірургу завершити анастомоз без видалення дефектного ущільнювача HS III.

Ризики до Здоров'я

1. **Невдача при завантажені** : За умови використання відповідно до інструкцій із застосування пристрою (IFU), ущільнювач HS III, який не завантажується, не становить прямої небезпеки для пацієнта. Однак ця нездатність може призвести до затримки хірургічної процедури. Ця затримка може коливатися від кількох хвилин для вилучення та завантаження нового ущільнювача до потенційного переходу від використання ущільнювача HS III для виконання проксимального анастомозу до використання аортального затискача для завершення процедури.

2. **Невдача при розкритті Heartstring Seal в аортотомію:** Якщо заряджена пломба HS III не розгортається з пристрою доставки, наступні процедурні кроки вже виконано, і це може призвести до потенційного ризику травмування пацієнта. Якщо заряджена пломба HS III не розгортається з пристрою доставки, це означає, що кілька процедурних кроків вже виконано, що може збільшити потенційний ризик травмування пацієнта. • Аортотомію створено. • Дистальний кінець трубки пристрою доставки введено через аортотомію. • Поршень пристрою доставки натиснуто або було зроблено спробу його натиснути. • Завантажена пломба HS III не розгорнулася успішно з дистального кінця трубки пристрою доставки. • Після видалення пристрою доставки з аортотомії пломба HS III не розгорнеться, і кровотечу з аортотомії потрібно буде зупинити, помістивши палець на аортотомію.

Потенційна шкода для пацієнтів:

- **Затримка хірургічної процедури** : видалити нерозгорнуту пломбу HS III, відкрити нову проксимальну пломбу HS III, завантажити пломбу в пристрій доставки та доставити завантажену пломбу HS III у створену аортотомію (затримка без додаткового втручання) порівняно з рішенням використовувати аортальний затискач для завершення анастомозу, оскільки завантажена пломба не розгорнулася (затримка з додатковим втручанням)

- **Пошкодження тканин** : може виникнути в результаті розгортання завантаженого ущільнювача HS III з розширеним кінчиком. Розширений кінчик матиме діаметр, більший за діаметр дистальної трубки пристрою доставки. Розгортання завантаженого ущільнювача з розширеним кінчиком може спричинити пошкодження тканин аорти, і якщо для розгортання пошкодженого ущільнювача застосувати більшу силу, існує потенційний ризик утворення задньої стінки аорти під час введення. Пошкодження тканин також може виникнути під час видалення пристрою доставки з аортотомії, розгортання другого завантаженого ущільнювача HS III у ту саму аортотомію та/або необхідності переходу на використання аортального затискача для завершення аортотомії.

- **Кровотеча:** Мінімальна крововтрата може виникнути під час видалення пристрою доставки з аортотомії, ручної зупинки кровотечі з аортотомії та встановлення заміни ущільнювача HS III. Більша крововтрата, що потребує додаткового втручання, може виникнути, якщо станеться пошкодження тканин.

- **Емболічна подія** , в результаті додаткових маніпуляцій з аортою для усунення несправності навантаження ущільнення HS III.

3. **Нездатність розгорнутого ущільнювача Heartstring забезпечити належний гемостаз:** Якщо розгорнуте ущільнення HS III не забезпечує належного гемостазу для хірурга, щоб завершити проксимальний анастомоз, це означає, що кілька етапів використання системи ущільнень HS III вже виконано, що може збільшити потенційний ризик пошкодження пацієнта. Наступні процедурні кроки мають бути виконані.

   - Аортотомія створена.
   - Завантажене ущільнення HS III розгорнуто в аорту.
   - Хірург вважає кровотечу з аорти занадто великою для виконання анастомозу.

   Потенційна шкода для пацієнтів:

   • **Затримка хірургічної процедури**: може виникнути в таких випадках: o Додатковий час під час операції, витрачений на спробу коригування ущільнення для покращення гемостазу за допомогою наданого ущільнення HS III, видалення дефектного ущільнення HS III, відкриття нового ущільнення HS III, встановлення запасного ущільнення HS III та встановлення завантаженого ущільнення HS III у створену аортотомію (затримка процедури без додаткового втручання)
   o Хірург вважає за найбільш доцільне використовувати аортальний затискач для завершення анастомозу, оскільки розгорнуте ущільнення HS III не забезпечило належного гемостазу для завершення анастомозу, а запасне ущільнення HS III недоступне, або хірург, на думку, не може використовувати запасне ущільнення HS III, і для завершення проксимального анастомозу використовується аортальний затискач за традиційною хірургічною технікою. (затримка процедури з додатковим втручанням)

   - **Пошкодження тканини** : Пошкодження тканин може виникнути під час маніпуляцій з ураженим ущільнювачем HS III, під час розгортання ущільнювача другого завантаженого ущільнювача HS III у ту саму аортотомію та/або при необхідності переходу на використання аортального затискача для завершення аортотомії.
   - **Кровотеча:** Невелика крововтрата навколо розгорнутого ущільнювача HS III є нормальною та очікуваною під час виконання проксимального анастомозу з використанням ущільнювача HS III. Більша крововтрата, що потребує додаткового втручання, може виникнути при пошкодженні тканини аорти, незалежно від причини.
   - **Емболічна подія(ї):** внаслідок додаткових маніпуляцій з аортою, що сталися внаслідок усунення невдалого завершення ущільнення HS III для забезпечення адекватного гемостазу.

Між 1 червня 2023 року та 22 липня 2025 року компанія Getinge отримала такі скарги: • 274 повідомлення, пов'язані з нездатністю зарядити, що становить 0,386% скарг • 96 повідомлень, пов'язаних з нездатністю розгорнути, що становить 0,135% скарг • 30 повідомлень, пов'язаних з недостатнім гемостазом, що становить 0,042% скарг

Рекомендовані дії для пом'якшення наслідків

Компанія Getinge надає наступні інструкції, щоб уникнути/мінімізувати вищезгадані невдачі.

1. Неможливість завантаження ущільнення Heartstring Seal

a. Важливі нагадування:

i. Згідно з інструкцією з використання пристрою, ущільнювач HS III призначений для завантаження та видалення із завантажувального пристрою, а потім для перевірки та, за необхідності, для підтвердження успішного завантаження, і остаточного розблокування перед видаленням будь-якої адвентиції із запланованої області анастомозу та створенням аортотомії. Завантаження ущільнювача HS III та підтвердження успішного завантаження перед створенням аортотомії мінімізує ризик для пацієнтів, оскільки аорта залишається недоторканою до підтвердження успішного завантаження ущільнювача HS III.

ii. Якщо ущільнювач HS III не завантажується належним чином, пристрій слід замінити.

b. Як уникнути/мінімізувати виникнення цієї несправності

i. Перед використанням перегляньте інструкцію з використання пристрою Heartstring, особливо якщо Heartstring не використовується регулярно.

ii. Встановіть пломбу HS III, ретельно дотримуючись покрокових інструкцій із застосування пристрою (IFU).

iii. Відповідно до розділів 4.3-4.5 Інструкції, переконайтеся, що пломба HS III була належним чином встановлена в пристрій доставки, оглянувши завантажену пломбу HS III після того, як пломбу HS III було встановлено в пристрій доставки та вийнято з пристрою завантаження.

iv. Ущільнювач HS III, який не був належним чином перевірений після зняття із завантажувального пристрою, може вийти з ладу під час розгортання ущільнювача HS III та завдати шкоди пацієнту. (див. інформацію щодо невдалого розгортання).

v. Завершіть успішне завантаження ущільнювача HS III перед очищенням адвентиції поверхні аорти та створенням аортотомії.

c. Дії, які слід вжити, якщо ущільнювач HS III не завантажується.

i. Викиньте несправний ущільнювач HS III.

ii. Завжди майте під рукою другий ущільнювач HS III для заміни несправного пристрою. Зверніться до інструкції з експлуатації пристрою, щоб забезпечити успішне завантаження.

2. Неможливість розгортання ущільнювача Heartstring III в аортотомії

a. Важливі нагадування:

i. Переконайтеся, що ущільнювач HS III правильно завантажено в пристрій доставки, як описано у розділі вище.

ii. Після видалення завантаженого ущільнювача HS III із пристрою доставки перевірте завантажений ущільнювач HS III відповідно до розділів 4.3-4.5 Інструкції з використання, щоб підтвердити наступне:

1. Завантажений ущільнювач HS III не тріснув.

2. Частина ущільнювача HS III, яка не завантажена в трубку пристрою доставки, не розширюється ширше, ніж діаметр трубки пристрою доставки.

3. Кінці пружин натягу вирівняні таким чином, щоб вони контактували з обома проксимальними краями завантаженого ущільнювача HS III під час доставки ущільнювача в аортотомію.

b. Як уникнути/мінімізувати виникнення цієї помилки:

i. Після підтвердження успішного завантаження ущільнювача HS III та створення аортотомії, розгорніть завантажений ущільнювач HS III в аортотомію, ретельно дотримуючись кроків для розгортання ущільнювача HS III, описаних в інструкції з використання пристрою.

ii. Якщо ущільнювач HS III не розгортається належним чином, пристрій слід замінити.

c. Дії, які слід вжити, якщо ущільнювач HS III не розгортається успішно в аорті.

i. Закрийте аортотомію, щоб зупинити кровотечу, за допомогою вказівного пальця.

ii. Відкрийте другий ущільнювач HS III. Встановіть ущільнювач HS III відповідно до інструкції з використання пристрою. Введіть завантажений ущільнювач HS III в аортотомію та

дотримуйтесь інструкції з використання, щоб завершити анастомоз.

iii. Якщо встановлення другого ущільнювача HS III в аортотомію не вдалося або хірург на основі уподобань визначає, що ситуація не дозволяє використовувати замінний ущільнювач HS III, накладіть на аорту частковий оклюзійний затискач, ізолюючи аортотомію, та виконайте анастомоз традиційною хірургічною технікою.

3. Нездатність розгорнутого ущільнювача Heartstring III забезпечити належний гемостаз:

a. Як уникнути/мінімізувати виникнення цієї помилки:

i. Завжди завантажуйте та ретельно перевіряйте завантажений ущільнювач HS III, щоб переконатися в успішному завантаженні ущільнювача HS III у пристрій доставки, перш ніж очищати будь-яку адвентицію аорти та створювати аортотомію. (Див. важливі нагадування безпосередньо вище.)

ii. Не використовуйте систему проксимального ущільнювача Heartstring у пацієнтів з тонкостінною аортою.

iii. Під час виконання множинних анастомозів переконайтеся, що всі місця анастомозу знаходяться на відстані щонайменше 1,5 см одне від одного, щоб забезпечити гемостаз.

iv. Не замочуйте ущільнювач HS III у розчині перед розгортанням.

b. Дії, які слід вжити, якщо ущільнювач HS III не відкривається/не забезпечує належний гемостаз після розгортання ущільнювача.

i. Накрийте аортотомію вказівним пальцем та обережно відрегулюйте пружину натягу, щоб переконатися, що ущільнення HS III повністю розгорнуто.

ii. Якщо недостатній гемостаз не зникає:

1. Вийміть розгорнуте ущільнення HS III з аортотомії відповідно до інструкції з експлуатації пристрою.
2. Вставте друге ущільнення HS III та розгорніть завантажене ущільнення в аортотомію відповідно до інструкції з експлуатації пристрою та завершіть анастомоз.
3. Якщо друге ущільнення HS III не є успішним або хірург вважає, що ситуація не дозволяє використовувати заміну ущільнення HS III, накладіть частковий оклюзійний затискач на аорту, ізолюючи аортотомію, та виконайте анастомоз за традиційною хірургічною технікою.

<u>Дії клієнта</u>

Getinge просить вас виконати такі дії: 1. Будь ласка, переконайтеся, що це повідомлення переслано всім особам, яким потрібно повідомити у вашій організації або будь-якій організації, куди було передано відповідні пристрої.

<u>Додаткова Інформація</u>

Компанія Getinge передає цю інформацію відповідним регуляторним органам. Вибачте за будь-які незручності, які це може спричинити. Ми прагнемо безпеки пацієнтів і цінуємо вашу оперативну реакцію на це питання. Якщо у вас виникли будь-які запитання щодо цього повідомлення, зверніться до свого представника Getinge або до служби підтримки клієнтів Getinge за номером 1-888-880-2874 з понеділка по п'ятницю з 8:00 до 17:00 (за тихоокеанським часом).

З повагою,

Франциско Вісенті
Директор з якості та дотримання

нормативних вимог, тимчасово
виконуючий обов'язки Гетінге,
відділ серцево-судинної хірургії

United Arab Emirates (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.
2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.

- The loaded HS III Seal has been deployed into the aorta.
- Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

The following potential patient harms may occur:

- **Surgical procedure delay**: may occur as follows:
    - Additional operative time taken to attempt to make Seal adjustments to improve hemostasis by the delivered HS III Seal, remove the defective HS III Seal, open a new HS III Seal, load the replacement HS III Seal, and deliver the loaded HS III Seal into the created aortotomy (procedure delay without additional intervention)
    - Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)
- **Tissue damage**: Tissue damage may occur during manipulation of the affected HS III Seal, during Seal deployment of a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
- **Bleeding:** A small amount of blood loss around the deployed HS III Seal is normal and expected while performing the proximal anastomosis using a HS III Seal. Greater blood loss requiring additional intervention may occur when aortic tissue damage occurs, regardless of the cause.
- **Embolic event(s):** resulting from additional manipulation of the aorta secondary to addressing the HS III Seal failure to provide adequate hemostasis.

Between June 1, 2023, and July 22, 2025, Getinge received the following complaints:

- 274 reports related to failure to load, representing a complaint rate of 0.386%
- 96 reports related to failure to deploy, representing a complaint rate of 0.135%
- 30 reports related to inadequate hemostasis, representing a complaint rate of 0.042%

<u>Recommended Mitigations and Actions</u>

Getinge is providing the following instructions to avoid/minimize the failures discussed above.

1. **Failure of the Heartstring Seal to Load**
    a. Important reminders:
        i. Per the device IFU, the HS III Seal is intended to be loaded and removed from the Loading Device, then inspected and adjusted if necessary to confirm successful loading and finally unlocked prior to clearing any adventitia from the planned anastomotic area and creating the aortotomy. Loading the HS III Seal and confirming successful loading <u>prior</u> to creating the aortotomy minimizes risk to patients because the aorta remains untouched until confirming successful loading of the HS III Seal.
        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU <u>prior</u> to use, especially if Heartstring is not used on a routine basis.

ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).

iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.

iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).

v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.

c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.

ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

2. Failure of the Heartstring III Seal to Deploy into the aortotomy

a. Important reminders:

i. Ensure the HS III Seal has been properly loaded into the Delivery Device as described in the section above.

ii. After removing the loaded HS III Seal from the Loading Device, inspect the loaded HS III Seal, according to IFU Sections 4.3-4.5, to confirm the following:

1. The loaded HS III Seal is not cracked.
2. The portion of the HS III Seal that is not loaded into the Delivery Device Tube does not flare wider than the Delivery Device Tube diameter.
3. The Tension Spring ends are aligned such that they will contact both proximal edges of the loaded HS III Seal during Seal delivery into the aortotomy.

b. How to avoid/minimize the occurrence of this failure:

i. After confirmation of successful HS III Seal loading and creation of the aortotomy, deploy the loaded HS III Seal into the aortotomy by carefully following the steps for HS III Seal deployment documented in the device IFU.

ii. If the HS III Seal fails to deploy as intended, the device should be replaced.

c. Action to be taken if the HS III Seal fails to successfully deploy into the aorta.

i. Occlude the aortotomy to control bleeding using an index finger.

ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.

iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:

i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)

ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.

iii. When performing multiple anastomosis, ensure all anastomotic sites are at least

1.5 cm apart to ensure hemostasis.

iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
    i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
    ii. If lack of adequate hemostasis persists:
        1. Remove the deployed HS III Seal from the aortotomy per device IFU.
        2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
        3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

Customer Actions

Getinge requests that you take the following actions:

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.

Additional Information

Getinge is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service.

Sincerely,

Francisco Vicenty
Director Quality & Regulatory Compliance, Interim
Getinge, Cardiovascular Surgery

GETINGE

United Kingdom (en)

August 2025

Field Safety Notice
Heartstring III Proximal Seal System
Reference Number: 1336551

Model Number	UDI	Model Name	Serial/Lot Numbers
HS-3045 HSK-3038 HSK-3043	00607567700307 00607567700314 00607567700321	Heartstring III Proximal Seal System	All Unexpired Lots
Distribution Dates:		July 1, 2024 - Present	
Manufacturing Dates:		March 7, 2024 - Present	

Dear Risk Manager,

The purpose of this letter is to advise you that Maquet Cardiovascular, a subsidiary of Getinge, is issuing an Urgent Medical Device Correction for the Heartstring III Proximal Seal System (HS III Seal). Our records indicate that you have received one or more of the affected devices that are affected by this notification.

Issue Description

Three primary failure modes have been identified.

1. **Failure of the Heartstring Seal to Load**: This failure applies to any malfunction of the device that occurs during the four-step loading process using the Heartstring Loading Device, the visual inspection of a successfully loaded HS III Seal, and unlocking the Delivery Device upon successful completion of the HS III Seal loading steps.
2. **Failure of the Heartstring Seal to Deploy into the aortotomy**: This failure applies to any malfunction of the HS III Seal and/or Delivery Device from the time the Delivery Device is successfully unlocked to once complete delivery of the HS III Seal into the aortotomy and all contents of the Proximal Seal (the Tether, Tension Spring, Seal Stem, Anchor Tab) have exited the Delivery Device.
3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** This failure applies to any malfunction of a successfully deployed HS III Seal that does not adequately control bleeding at the anastomotic to allow the surgeon to perform suturing of the anastomosis, despite gentle adjustment of the Tension Spring after Seal deployment and/or the use of a blower mister, suction, or saline syringe to clear the anastomotic site. This failure includes customer identification of a defective or damaged HS III Seal following successful deployment of the HS III Seal into the aorta that results/or may result in inadequate hemostasis that prevents the surgeon to complete the anastomosis without removing the defective HS III Seal.

Root cause investigation is ongoing at this time.

Risks to Health

1. **Failure to Load:** When used in accordance with the device Instructions for Use (IFU), a HS III Seal that fails

to load does not pose a direct risk to the patient. However, this failure may lead to a delay in the surgical procedure. This delay can range from a few minutes to retrieve and load a new Seal, to a potential conversion from using the HS III Seal to perform the proximal anastomosis to employing an aortic clamp to complete the procedure.

2. **Failure to Deploy:** When the loaded HS III Seal fails to deploy from the Delivery Device, the following procedural steps have already been performed and may contribute to the potential risk of patient harm. If the loaded HS III Seal fails to deploy from the Delivery Device, several procedural steps will have already been completed which may increase the potential risk of patient harm.
   - The aortotomy has been created.
   - The distal end of the Delivery Device Tube has been inserted through the aortotomy.
   - The Plunger of the Delivery Device has been depressed, or an attempt has been made to depress it.
   - The loaded HS III Seal has not successfully deployed from the distal end of the Delivery Device Tube.
   - When the Delivery Device is removed from the aortotomy the HS III Seal will not be deployed and bleeding from the aortotomy will need to be controlled by placing a finger over the aortotomy.

   The following potential patient harms may occur:

   - **Surgical procedure delay**: to remove the non-deployed HS III Seal, open a new HS III Proximal Seal, load the Seal into the Delivery Device, and deliver the loaded HS III Seal into the created aortotomy (delay without additional intervention) vs. the decision to use an aortic clamp to complete the anastomosis because the loaded Seal failed to deploy (delay with an additional intervention)
   - **Tissue damage**: may occur as a result of deploying a loaded HS III Seal that is flared at the tip. A flared tip will have a diameter that is larger than the distal Delivery Device Tube. Deploying a loaded Seal that has a flared tip can cause aortotomy tissue damage and if greater force is used to deploy the affected Seal there is a potential risk of backwalling the aorta during insertion. Tissue damage may also occur during removal of the Delivery Device from the aortotomy, deploying a second loaded HS III Seal into the same aortotomy, and/or needing to convert to use of an aortic clamp to complete the aortotomy.
   - **Bleeding:** minimal blood loss may occur when removing the Delivery Device from the aortotomy, controlling the bleeding from the aortotomy manually, and delivering a replacement HS III Seal. Greater blood loss, requiring additional intervention, may occur if tissue damage occurs.
   - **Embolic event** resulting from additional manipulation of the aorta to address the HS III Seal loading failure.

3. **Failure of the deployed Heartstring Seal to provide adequate hemostasis:** When a deployed HS III Seal fails to provide adequate hemostasis for the surgeon to complete the proximal anastomosis, several steps of the HS III Seal System use have already been completed and may increase the potential risk of patient harm. The following procedural steps will have taken place.
   - The aortotomy has been created.
   - The loaded HS III Seal has been deployed into the aorta.
   - Bleeding from the aorta is deemed by the surgeon too great to perform the anastomosis.

   The following potential patient harms may occur:

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- Surgeon deems it most appropriate to use an aortic clamp to complete the anastomosis because the deployed HS III Seal failed to provide adequate hemostasis to complete the anastomosis and a replacement HS III Seal is not available or surgeon preference determines the situation does not allow for use of a replacement HS III Seal and an aortic clamp is use to complete the proximal anastomosis per traditional surgical technique. (procedure delay with an additional intervention)

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        ii. If the HS III Seal fails to load as intended, the device should be replaced.
    b. How to avoid/minimize occurrence of this failure
        i. Review the Heartstring device IFU prior to use, especially if Heartstring is not used on a routine basis.
        ii. Load the HS III Seal by carefully following the device step-by-step Instructions for Use (IFU).
        iii. Per Section 4.3-4.5 of the IFU, confirm the HS III Seal has been properly loaded into the Delivery Device by inspecting the loaded HS III Seal once the HS III Seal has been loaded into the Delivery Device and has been removed from the Loading Device.
        iv. A HS III Seal that is not properly inspected after removal from the Loading Device may fail during HS III Seal Deployment and cause patient harm. (see information relating to Failure to Deploy).
        v. Complete successful loading of the HS III Seal prior to cleaning the aortic surface adventitia and creating the aortotomy.
    c. Action to be taken if the HS III Seal fails to load.

i. Discard the failed HS III Seal.
ii. Always have a second HS III Seal available to replace a failed device. Refer to the device IFU to ensure successful loading.

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b. How to avoid/minimize the occurrence of this failure:
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   ii. Open a second HS III Seal. Load the HS III Seal per the device IFU. Deliver the loaded HS III Seal into the aortotomy and follow the IFU to complete the anastomosis.
   iii. If delivery of the second HS III Seal into the aortotomy is not successful, or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the anastomosis per traditional surgical technique.

3. Failure of the deployed Heartstring III Seal to provide adequate hemostasis:

a. How to avoid/minimize occurrence of this failure mode:
   i. Always load and carefully inspect the loaded HS III Seal to confirm successful loading of the HS III Seal into the Delivery Device prior to clearing any aorta adventitia and creating the aortotomy. (See important reminders directly above.)
   ii. Do not use the Heartstring Proximal Seal System in patients with a thin-walled aorta.
   iii. When performing multiple anastomosis, ensure all anastomotic sites are at least 1.5 cm apart to ensure hemostasis.
   iv. Do not soak the HS III Seal in solution prior to deployment.

b. Action to be taken if the HS III Seal does not open/provide adequate hemostasis post Seal deployment.
   i. Cover the aortotomy with an index finger and gently adjust the Tension Spring to ensure the HS III Seal has been fully deployed.
   ii. If lack of adequate hemostasis persists:
      1. Remove the deployed HS III Seal from the aortotomy per device IFU.
      2. Load a second HS III Seal and deploy the loaded Seal into the aortotomy per device IFU and complete the anastomosis.
      3. If the second HS III Seal is not successful or surgeon preference determines the situation does not allow for use of a replacement HS III Seal, place a partial occlusion clamp on the aorta, isolating the aortotomy, and perform the

anastomosis per traditional surgical technique.

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We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Getinge representative or Getinge Customer Service at 01773 814 730.

Sincerely,

Sian Rogers
QRC Director UK & Ireland

Getinge Ltd
Unit 3, Indurent Park
Andressey Way
Chaddesden
Derby
DE21 6YH
UK

Phone: +44 (0) 1773 814 730
Email: fsca.uki@getinge.com