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 HA 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.
2. Complete and return the enclosed response form Getinge by e-mailing a copy to recallresponses.qrc@getinge.com.

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,

Sajjad Mansoor
Director, Quality & Regulatory Compliance
Getinge, Cardiovascular Surgery