

December 2024

URGENT MEDICAL DEVICE CORRECTION
Reference Number: 1170852
Vasoview Hemopro 2 Endoscopic Vessel Harvesting System
(VH-4000 and VH-4001)

Product Name	Vasoview Hemopro 2 Endoscopic Vessel Harvesting System		
Product Information	Model Number	UDI	Lot Numbers
	VH-4000	00607567700406	All unexpired lots
	VH-4001	00607567700451	All unexpired lots
Manufacturing Dates:	November 1, 2022, to Present		
Distribution Dates:	November 1, 2022, to Present		

Dear Healthcare Professional:

Purpose of the Letter

The purpose of this letter is to provide you with important safety information regarding the Vasoview Hemopro 2 Endoscopic Vessel Harvesting (EVH) System, referenced in the table above, due to complaints received for the following two (2) failure modes experienced during use:

1. A bent or detached heater wire
2. Silicone peeling or detaching from the Jaws of the Harvesting Tool

Maquet Cardiovascular, LLC (MCV), a subsidiary of Getinge, is not requesting any return of product from your facility.

The Vasoview Hemopro 2 EVH System is indicated for use in minimally invasive surgery allowing access for vessel harvesting and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. The device is indicated for cutting tissue and controlling bleeding through coagulation for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. The Harvesting Cannula has four lumens that house the Endoscope, C-Ring, distal lens washer tube and Vasoview Hemopro 2 Harvesting Tool. The Harvesting Tool is used for the cutting and cauterizing of vessel branches and has two curved Jaws. One of the Jaws contains the heating elements for branch cutting and cauterizing and for spot cautery as part of one planar heater: two cauterizing elements and a cutting element between them. Both Jaws have silicone insulation to protect the adjacent tissue.

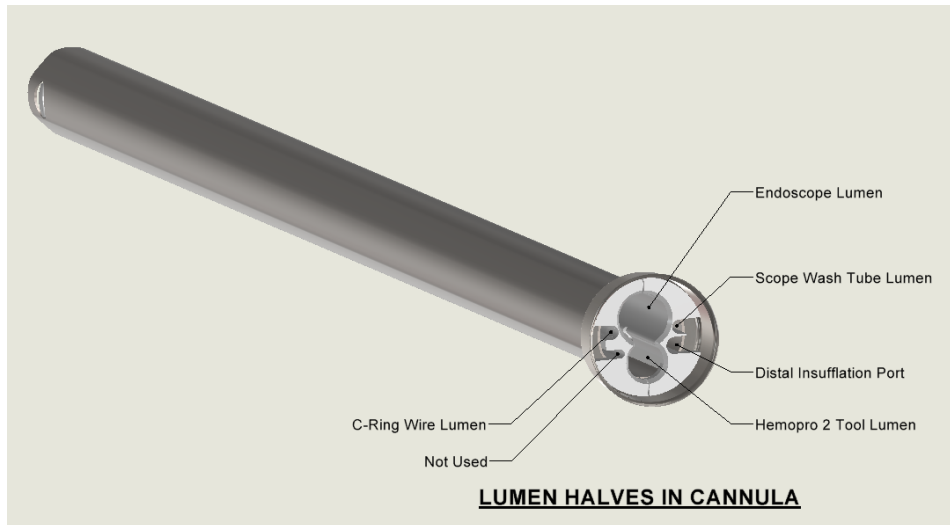


Figure 1: Harvesting Cannula

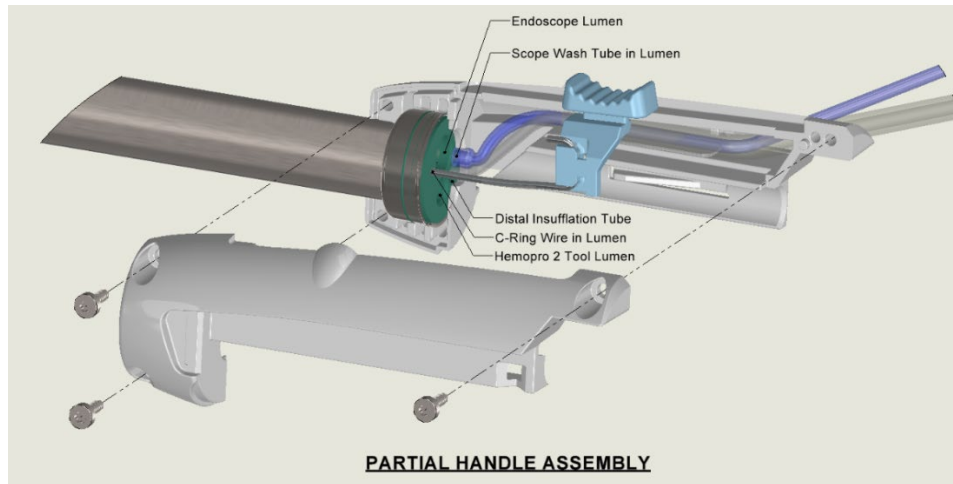


Figure 2: Handle Assembly of Harvesting Cannula

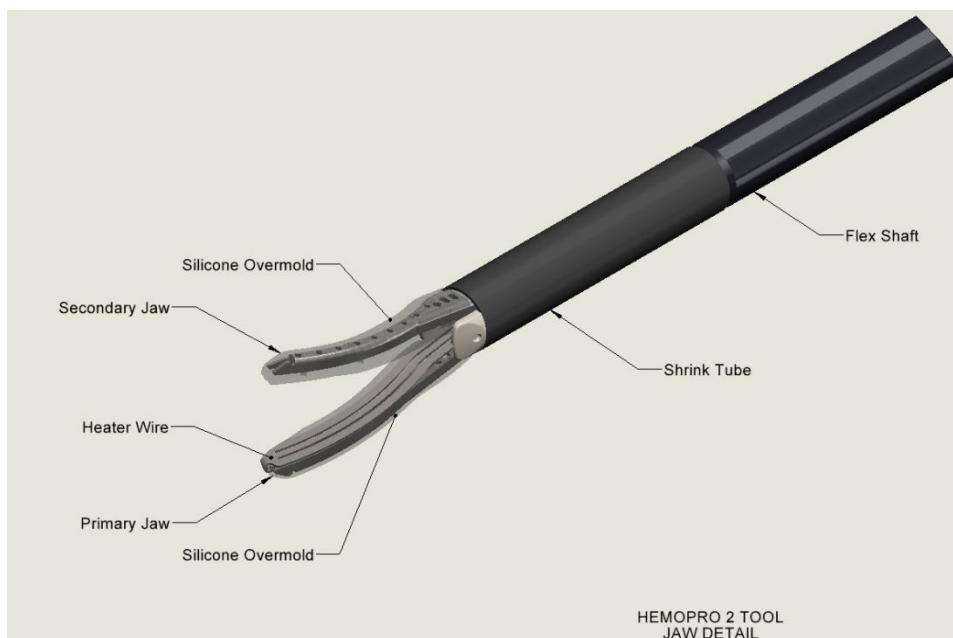


Figure 3: Harvesting Tool

Reason for Correction:

A detached heater wire is defined by disconnection of the heater wire tip from the silicone on the distal end of the harvesting tool jaw, with the proximal end of the heater wire remaining attached to the proximal end of the jaw. It is important to note the heater wire is still attached to the harvesting tool. A bent heater wire is defined by the heater wire bending away from the jaw with no detachment of the distal end. The heater wire can become bent or detached from external mechanical forces or during the initial phase of jaw degradation from user-activated over-delivery of energy. Thermal degradation refers to the process in which the jaw silicone material breaks down or loses its desirable properties due to exposure to high temperatures. This degradation occurs when the heat causes chemical bonds within the silicone polymer to weaken or break, leading to a reduction in the material's structural integrity and flexibility making it more brittle and prone to cracking or tearing.

MCV/Getinge has confirmed 254 complaints between August 1, 2022, and July 31, 2024, related to the bent or detached heater wire. There have been four (4) serious injuries related to this issue. Three (3) of the four (4) serious injuries required an additional incision during the procedure, and one (1) had a procedural delay due to a Pedicle Hematoma with minimal tearing. There were no reports of life-threatening or permanent injury.

Silicone peeling is defined as silicone that has peeled away from the Harvesting Tool Jaw but remains attached to the Jaw. Silicone detachment is defined as silicone that has peeled away from the Harvesting Tool Jaw(s) and detached from the Jaw assembly. Silicone peeling and detachment can occur when thermal loads on the device are not allowed to adequately cool down between actuations. This can happen when the device is actuated for long periods of time or in quick succession, such as in repeated tissue dissection or application of energy without tissue between the jaws.

MCV/Getinge has confirmed 126 complaints that are related to silicone peeling and/or detaching from the Jaws of the Harvesting Tool during use between November 1, 2022, and October 31, 2024. There have been three (3) serious injuries related to this issue. Two (2) of the three (3) serious injuries required an additional incision during the procedure, and one (1) resulted in a vessel burn. There were no reports of life-threatening or permanent injury.

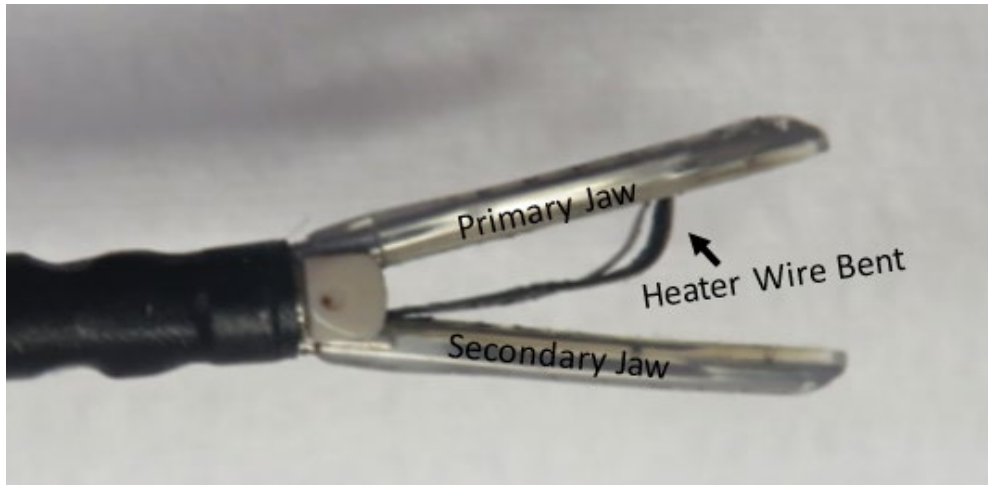


Figure 4: Example of a device experiencing a bent heater wire.

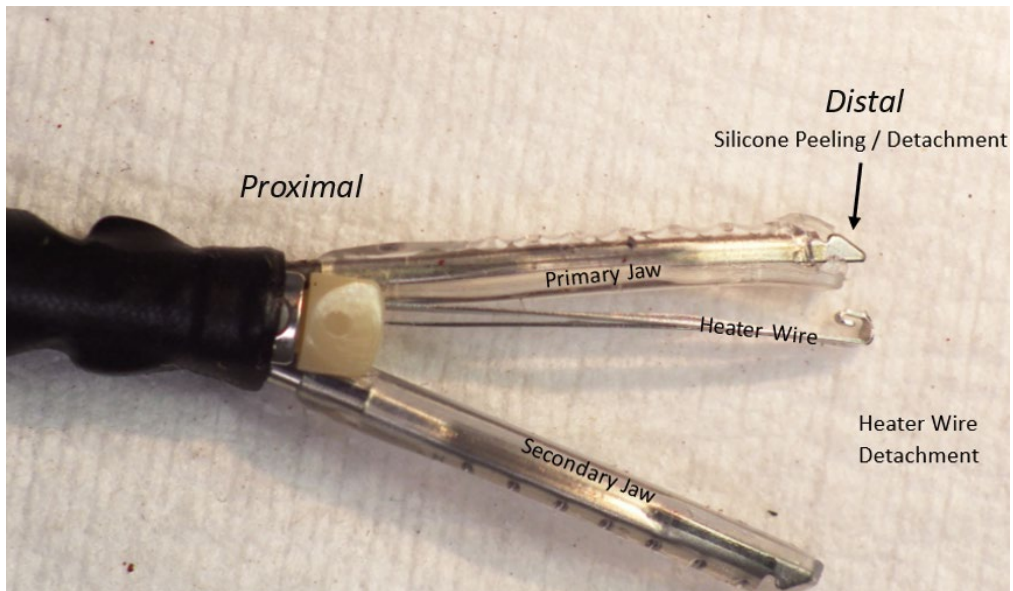


Figure 5: Example of a device experiencing both Heater Wire Detachment and Silicone Peeling/Detachment.

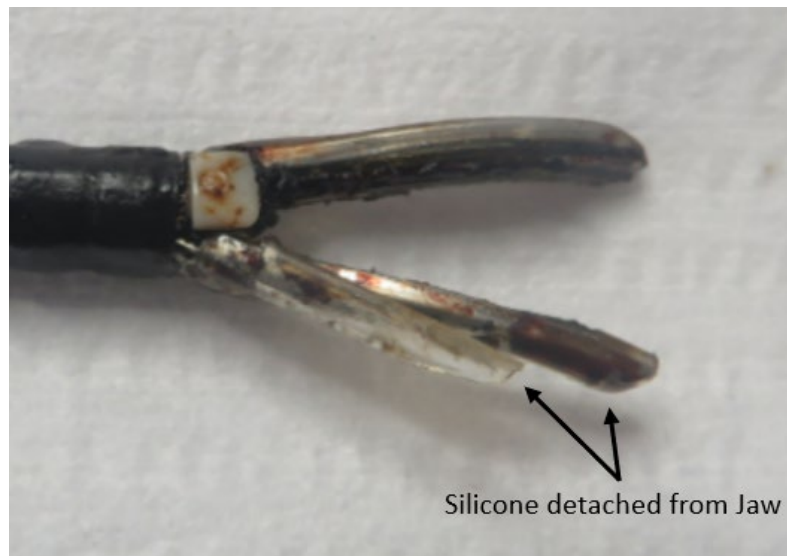


Figure 6: Example of a device experiencing silicone detachment.

Risk To Health:

Peeling or detachment of silicone from the Hemopro 2 Harvesting Tool Jaws can result in the Harvesting Tool not functioning as designed and intended. If the Hemopro 2 Harvesting Tool Jaw Heater Wire becomes compromised, bent, or detached from the Jaw during use (as referenced in Figure 5), there is risk of creating hazardous situations that may result in patient harm. The following patient harms, listed in the order of most to least likely to occur, may result if either of the device failures occurs during use of the Vasoview Hemopro 2 EVH System:

- Procedure delay to troubleshoot the device issue/failure, to retrieve detached silicone, and/or to locate, open, and set up new EVH device.
- Additional intervention(s) to retrieve the detached material from the patient; to complete the vessel harvest; to address bleeding and tissue, vessel, and/or conduit injury; and/or, to harvest additional necessary conduit to complete the bypass surgery as planned.
- Bleeding secondary to incomplete cauterization, trauma or damage to vascular anatomy.
- Burn to vessel, conduit, and/or tissue secondary to exposure to damaged Harvesting Tool Jaw material.
- Retained detached silicone within the patient body cavity.

If the detached silicone goes unnoticed or is not removed from the patient, future complications could occur, which may include such patient harm as delayed onset of pain, infection, localized allergic/adverse reaction, and/or readmission to a medical facility for additional medical and/or surgical intervention to treat complications and/or attempt to retrieve retained material.

Patients who have been treated with an affected device should continue to be managed according to your standard patient management protocols.

Actions to be taken by the customer:

1. Review the IFU information provided in [Appendix A](#), specifically note the following warnings to minimize over-delivery of energy:
 - When inserting or retracting the Harvesting Tool through the Harvesting Cannula, close the Jaws and ensure the Jaw tips are oriented upwards (concave side up) to prevent damage to the Jaws.”
 - “Application of energy without tissue between the Jaws of the Harvesting Tool should be kept to minimum in order to maximize Harvesting Tool performance.”
 - “When separation of the branch tissue is noticed, open the Jaws and stop application of energy by pushing the Activation Toggle into the forward most position and retract the Harvesting Tool slightly.”
“NOTE: Once material has been transected, stop application of energy.”

2. Consider the following to mitigate the risks:
 - Inspect the device prior to use for any signs of damage including silicone peeling away from the jaws.
 - Check the outer surface of the device for rough surfaces, sharp edges, or unusual protrusions that may be a hazard.
 - Monitor the device during use for silicone peeling away from the jaws.
 - Inspect the device after use for missing or damaged parts.
 - If, at any time of use, the user notices missing or damaged parts or peeling of silicone, device use should be terminated, and any fragmented components should be located and removed from the patient.
 - Monitor patients for complications if you suspect fragment(s) of the device may have been retained. Future complications could include delayed onset of pain, infection, and/or localized allergic/adverse reaction.
3. Please forward this information to all current and potential Vasoview Hemopro 2 Endoscopic Vessel Harvesting System users within your hospital/facility.
4. If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.
5. Please complete and sign the attached MEDICAL DEVICE CORRECTION RESPONSE FORM to acknowledge that you have received this notification. Return the completed form to MCV/Getinge by e-mailing a scanned copy to:
hemopro-peeling-detached-silicone2024.act@getinge.com
OR by faxing the form to 1-866-594-8101.

Actions to be taken by Getinge:

MCV/Getinge is continuing to investigate these issues to determine and implement appropriate actions. Training to reinforce precautions and appropriate use of the device is expected to be deployed and communicated to all customers by end of January 2025. We are committed to resolving the current supply chain constraints by end of December 2024.

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

1. **Online:** www.accessdata.fda.gov/scripts/medwatch/.
2. **Regular Mail:** Download form at 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.
3. **Fax:** 1-800-FDA-0178 (1-800-332-0178).

We apologize for any inconvenience this may cause. If you have any questions, please contact your MCV/Getinge representative or call the MCV/Getinge Customer Support at 1-888-880-2874 Monday through Friday, between the hours of 8 AM and 6 PM (Eastern Time Zone).

This notification is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,



Sajjad A Mansoor

Director, Quality and Regulatory Compliance

Enclosures:

- Appendix A: Instructions for Use
- Urgent Medical Device Correction Response Form

Appendix A: Instructions for Use

MCV/Getinge has included information directly from the instructions for use (IFU) for your review.

“PREPARATION FOR INSERTION INTO THE HARVESTING SPACE”

- “Ensure the HEMOPRO 2 Jaws are closed prior to insertion through the VASOVIEW Harvesting Cannula.”

“Hold the Harvesting Cannula with Tool Adapter Port on top. Hold the VASOVIEW HEMOPRO 2 Harvesting Tool shaft approximately 6 (or 15 cm) from the tips, with the Jaws concave side up and the Jaw tips oriented upwards before inserting through the Tool Adapter Port.”
- “If desired, Surgilube (or another water-soluble lubricant) may be used on the Harvesting Tool. Insert the Harvesting Tool through the Tool Adapter Port of the Harvesting Cannula, but do not advance the tip of the Harvesting Tool beyond the end of the Harvesting Cannula.”
- “Pre-test the VASOVIEW HEMOPRO 2 Harvesting Tool to verify complete electrical activity and Power Supply setting of 3.”

Important use “WARNINGS AND PRECAUTIONS”

- “When inserting or retracting the Harvesting Tool through the Harvesting Cannula, close the Jaws and ensure the Jaw tips are oriented upwards (concave side up) to prevent damage to the Jaws.”
- “Application of energy without tissue between the Jaws of the Harvesting Tool should be kept to minimum in order to maximize Harvesting Tool performance.”
- “When separation of the branch tissue is noticed, open the Jaws and stop application of energy by pushing the Activation Toggle into the forward most position and retract the Harvesting Tool slightly.”
“NOTE: Once material has been transected, stop application of energy.”
- “Check the outer surface of the device for rough surfaces, sharp edges, or unusual protrusions that may be a hazard.”