

July 2025

Urgent Medical Device Correction Update
Vasoview Hemopro 2 Endoscopic Vessel Harvesting (EVH) System
Customer Letters 1170852 and 1044158

Dear Risk Manager,

The purpose of this letter is to update you on the actions Getinge has taken to address previously communicated issues related to the Vasoview Hemopro 2 Endoscopic Vessel Harvesting (EVH) System. As part of these efforts, Getinge has revised the Instructions for Use (IFU) for the Vasoview Hemopro 2 EVH System. The updated IFU is now included with all newly manufactured devices and can also be accessed via the QR code or link provided below.

The following 3 failure modes, previously communicated, are:

1. A bent or detached heater wire (Internal Reference: 1170852/FDA RES: 95908)
Link to recall database available on FDA website:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=211575>
2. Silicone peeling or detaching from the Jaws of the Harvesting Tool (Internal Reference: 1170852/FDA RES: 95908)
Link to recall database available on FDA website:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=211575>

The following statements have been added to the IFU to address the bent or detached heater wire and silicone peeling or detaching from the Jaws of the Harvesting Tool:

- While maintaining the angle of the Tool Adapter port, slowly insert the Harvesting Tool. Do not apply excessive force while inserting the Harvesting Tool.
- Carefully remove Hemopro 2 EVH System from its shipping package. Do not use if damaged or opened. Inspect entire device including Harvesting Tool Jaws to ensure no damage has occurred during transit or storage.
- Soak a soft, sterile fabric such as a gauze with normal saline.
- Moisten the Jaws with the wet gauze on conclusion.
- Place the device in a secure and sterile location on the sterile table to avoid damage while not in use.
- NOTE: Use a slow and steady approach during use of the Harvesting Tool. Rapid continuous activations of the tool may degrade the silicone over time or engage the safety shut down mechanism noted below.
- Take care when cleaning the Jaws. Damage may occur with improper cleaning.

3. Fluid ingress into the handle of the Harvesting Tool (Internal Reference: 1044158/FDA RES: 94700):
Link to recall database available on FDA website:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=208046>

The following Warnings and Precautions statements were added to the IFU: The Harvesting Tool Handle is designed with openings. Use caution during use of the Harvesting Tool to avoid fluid ingress into the handle. Fluid ingress can cause the Harvesting Tool to malfunction including unintended activation or deactivation.

You are receiving this communication for one of the following reasons:

- You were previously identified as a customer affected by this correction and have already received the enclosed letters.
- Our distribution records indicate you recently received affected product, and this is the first time receiving the enclosed letters.

Customer Actions

1. Please review the updated IFU and share with any current and prospective users of the VasoView Hemopro 2 Endoscopic Vessel Harvesting System within your hospital/facility.



<https://eifu.getinge.com/en-us/search/?q=C-VH-4000>

2. Getinge has created a training video, accessible via the QR code or link below, to guide users on the proper use of the device and reinforce essential precautions. Use the QR code to access the training.
 - Scanning the barcode will direct you to the landing page, where you'll find instructions on the next steps to access the 7-minute training video.



<https://visit.getinge.com/vasoview-hemopro-2-evh-supp-training>

3. 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: recallresponses.qrc@getinge.com
4. If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

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

Sincerely,



Sajjad Mansoor
Director, Quality & Regulatory Compliance

Enclosures:
Initial Customer Letter January 2025: 1170852
Initial Customer Letter May 2024: 1044158
Customer Response Form