Month DD, YYYY

URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION

Reference Number: 2242352-05/21/2024-001-C
VasoView HemoPro Endoscopic Vessel Harvesting Systems
VH-4000 & VH-3000-W

Dear Hospital Contact,

Maquet Cardiovascular, LLC, a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for the VasoView HemoPro Endoscopic Vessel Harvesting System. If there is fluid ingress into the handle of the operating tool, the device may not provide cautery or may continue to provide cautery when not intended. These failures could result in a delay in therapy, surgical conversion from an Endoscopic procedure to an Open Vessel Harvesting procedure if a replacement device is unavailable, and bleeding / hemorrhage into tissue potentially leading to compartment syndrome in devices that do not provide cautery when intended. Additionally, if the device continues to provide cautery when not intended, there could be thermal injury / burn to the patient, user, and / or the vessel conduit that is being procured to serve as a bypass graft.

We are writing to notify you of the potential for these failures, which are not currently described in the products' Instructions for Use. No devices need to be returned.

Identification of the issue:

The VasoView HemoPro 2 & HemoPro Endoscopic Vessel Harvesting (EVH) Systems (VH-4000 and VH-3000-W) are indicated for use in minimally invasive surgery allowing access for vessel harvesting and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. Both the HemoPro 2 & HemoPro systems are designed for use in conjunction with the Getinge 7mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and VasoView HemoPro Harvesting Tool for cutting and cauterizing of vessel branches. The Harvesting Tool can be inserted, removed, rotated, extended, and retracted from the main Harvesting Cannula through the Tool Adapter Port.

The HemoPro 2 and HemoPro Harvesting Tools are powered by direct current (DC). The Harvesting Tool has two curved Jaws. One of the Jaws contains the heating elements for branch cutting and cauterizing and spot cautery. Both jaws have insulation protecting the adjacent tissue. The Vasoview HemoPro Harvesting Tool has two curved Jaws. One jaw contains the heating elements for branch cutting and sealing; the second jaw is longer and has a serrated inner edge The Harvesting Tool, and more specifically, the distal end of the Harvesting Tool, possesses the jaws which are used for cutting and sealing vessel branches during the vessel harvesting procedure.

Maquet Cardiovascular, LLC received seven (7) complaints for the VH-3000, VH-3500 and VH-4000 devices between 13-June-2016 and 20-March-2024 reporting that the harvesting tool was not able to provide cautery or continued to provide cautery when not intended during use. No adverse events have been reported to date in association with this issue.
These failures have occurred when fluids are introduced into the handle of the harvesting tool and interfere with the function of the electrical and mechanical components of the tool. These potential fluid ingress failures are not identified in the affected products' Instructions for Use.

Risk To Health:

If the Harvesting Tool is not functioning as intended, either not delivering energy or intermittently delivering energy to the Jaws when activated, or appearing to be activated or being activated when not intended, there is a potential risk to patients or users resulting from:

1. Procedural delays
2. Bleeding that results in:
    a. control with the Harvesting Tool or manual pressure,
    b. the diagnosis of compartment syndrome,
    c. Burn injury to the patient, the user, and/or the conduit.

Each of these potential harms, if experienced by the patient, can add increased morbidity and may prolong the patient's hospital stay and post-operative recovery, with the patients that are elderly, obese, diabetic, and immunocompromised patients; as well as patients with peripheral vascular disease, very thin and/or emaciated patients, and any patient with low or an absence of subcutaneous fat. being at greatest risk of harm.

Actions to be taken by the customer:

Our records indicate that you have received the VasoView HemoPro Endoscopic Harvesting Systems that are affected by this notification.

1. Users should be made aware of the following additional safety information about the products:

   The Vasoview Hemopro and Hemopro 2 Endoscopic Vessel Harvesting Tool handle is designed to have openings. Use caution during use to avoid fluid ingress into the Harvesting Tool handle. Fluid ingress can cause the Harvesting Tool to malfunction including unintended device activation or deactivation.

2. **Please forward this information to all current and potential VasoView HemoPro Endoscopic Vessel Harvesting System users within your hospital / facility** and **post a copy of the Notice on Page 5** in all inventory locations within your facility where the devices are stored.

3. Your facility can continue use of the devices. **No devices need to be returned.**

4. Whether you have affected product or not, please complete and sign the attached MEDICAL DEVICE Correction - RESPONSE FORM (page 6) to acknowledge that you have received this notification. Return the completed form to [INSERT LOCAL SSU EMAIL HERE] or by faxing the form to [INSERT LOCAL SSU FAX NUMBER HERE].
5.
6. **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**

Actions to be taken by Getinge:

Getinge will notify each facility using the VasoView HemoPro VH-4000 and VH-3000-W Endoscopic Harvesting System regarding these fluid ingress failures and potential risks to users and patients if this situation were to occur. Getinge is currently investigating this issue further to determine root cause and will notify customers in the event additional action needs to be taken to correct this issue. Additionally, the current VasoView HemoPro VH-4000 and VH-3000-W Instructions for Use (IFU) will be updated to include the additional safety information related to fluid ingress.

This voluntary Notification only affects the products listed on page 1; no other products are affected

by this voluntary Notification.

We apologize for any inconvenience this Urgent Medical Device – Correction may cause. If you have any questions, please contact your Maquet/Getinge representative or call the Maquet/ Getinge Customer Support [INSERT SSU CONTACT INFO].

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

Sincerely,

Marc De Carlo

URGENT: MEDICAL DEVICE – CORRECTION

VASOVIEW HEMOPRO

Endoscopic Vessel Harvesting System

Product Codes: VH-4000 and VH-3000-W

Lots: ALL

PLEASE POST THIS LABEL NEAR ALL PRODUCT INVENTORY

INADEQUATE INSTRUCTIONS FOR USE

Maquet/Getinge is initiating a voluntary Medical Device Notification for the Vasoview Hemopro Endoscopic Vessel Harvesting Systems to provide additional safety information.

READ PRIOR TO USE OF DEVICE

The Vasoview Hemopro and Hemopro 2 Endoscopic Vessel Harvesting Tool handle is designed to have openings. Use caution during use to avoid fluid ingress into the Harvesting Tool handle. Fluid ingress can cause the Harvesting Tool to malfunction including unintended device activation or deactivation.

MMDDYYY

URGENT: MEDICAL DEVICE - CORRECTION RESPONSE FORM

Reference Number: 2242352-05/21/2024-001-C

VasoView HemoPro Endoscopic Vessel Harvesting System

VH-4000 and VH-3000-W

[INSERT LOCAL SSU EMAIL HERE] or by faxing the form to [INSERT LOCAL SSU FAX NUMBER HERE]

DISTRIBUTION DATES:
VH-4000: March 27, 2022 to present
VH-3000-W: March 27, 2023 to present

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

I acknowledge that I have read and understand this Medical Device Correction Letter for the affected **VasoView HemoPro Endoscopic Vessel Harvesting Systems** at this facility. I confirm that all users of the above-mentioned products at this facility have been notified accordingly.

Please provide the required information and signature below.

Facility Representative Information:
Signature:_____Date:_____
Name:_____Phone:_____
E-Mail Address:_____
Title:_____Department:_____
Hospital Name:_____
Address, City and State:_____
We have scrapped/discarded our affected product:
Circle one **YES** **NO**
We have sold/moved our affected product to another facility:
Circle one **YES** **NO**
If you answered YES above: please provide new facility information below.
New Facility Name: _____
New Facility Address: _____
New Facility Contact Name:_____
New Facility Phone #: _____

Return the completed form by EMAIL to [Insert Local SSU email Here] or by FAX to [Insert Local SSU Fax Here].