Month DD, YYYY

URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION

Reference Number: 2242352-06/07/2024-001-R
VasoView HemoPro Endoscopic Vessel Harvesting Systems
VH-4000, VH-4001, & VH-3500

Product Name	**VasoView HemoPro Endoscopic Vessel Harvesting System**
Product Code	**VH-4000 / VH-4001 / VH-3500**
UDI-DI	**VH-4000: 00607567700406** **VH-4001: 00607567700451** **VH-3500: 00607567700345**
Distributed Affected Lot Number:	**3000371260, 3000378288, 3000362934** **3000371798, 3000378554, 3000377320** **3000372477, 3000378950, 3000380847** **3000376542, 3000380314**
Manufacturing Dates for All::	**VH-4000: 01-Jan-2024 thru 30-April-2024** **VH-4001: 01-Jan-2024 thru 30-April-2024** **VH-3500: 01-Jan-2024 thru 30-April-2024**
Distribution Dates for All:	**VH-4000 / VH-4001** **05-Mar-2024 thru 19-April-2024** **VH-3500** **25-Mar-2024 thru 28-Mar-2024**

Dear Health Care Professional,

Maquet Cardiovascular, LLC (MCV), a subsidiary of Getinge, is initiating a voluntary Medical Device Removal for the VasoView HemoPro 2 & HemoPro Endoscopic Vessel Harvesting (EVH) Systems due to the potential that Stainless Steel wire component in the C-Ring Assembly has an insufficient bend radius.

The VasoView HemoPro 2 & HemoPro EVH Systems (VH-4000, VH-4001, & VH-3500), are indicated for use in minimally invasive surgery allowing access for vessel harvesting and are primarily indicated for patients undergoing endoscopic surgery for arterial bypass. Both the HemoPro 2 & HemoPro systems contain a Harvesting Cannula with 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 C-Ring is designed to retract the main vessel and protect the vessel from thermal injury from the Harvesting Tool during tissue harvesting.

Identification of the issue:

MCV/Getinge received twenty-seven (27) complaints for the VH-3500 and VH-4000 devices between 22-March-2024 and 30-April-2024 reporting that the C-Ring wire is straightened and the distance between the C-Ring and Harvesting Tool is closer than normal. MCV/Getinge has identified and corrected the manufacturing deviation responsible for the defect in affected devices. No adverse

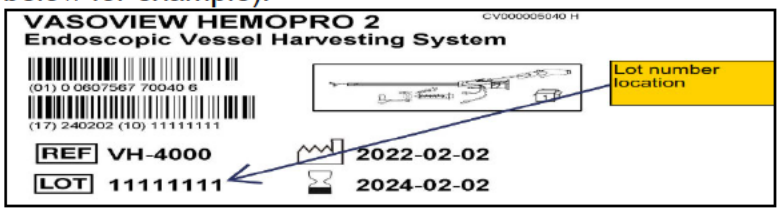
events have been reported to date in association with this issue.

Risk To Health:
If the C-Ring component is defective, it may result in the following risks to patients:

1. Complications (including infection, pain, scarring, and a longer recovery) secondary to a required reoperation to remove a retained device part/piece of the C-Ring that has detached inside the endoscopic tunnel
2. Complications secondary to a required conversion of the EVH procedure to an Open Vessel Harvest (OVH) procedure
3. Burn/thermal injury to the main vessel/conduit
4. Adverse reaction in the event a retained part/piece of the C-Ring in the endoscopic tunnel goes unnoticed
5. Complications secondary to the need for additional incision(s) to remove a retained part/piece that has detached inside the endoscopic tunnel
6. Delay of therapy to retrieve a retained part/piece that has detached inside the endoscopic tunnel
7. Delay of therapy to set up a replacement device

Actions to be taken by the customer:
Our records indicate that you have received VasoView HemoPro or HemoPro 2 EVH Systems from lot(s) that are affected by this recall.

Please, note that Distributed Affected Lot Number(s) appear on the device shelf boxes only (see below for example).



Please examine your inventory immediately to determine if you have any of the HemoPro devices with the product code/lot number(s) listed in this notice.

- Prior to use, always refer to Instructions for Use, Section "Warning and Precautions", specifically:
  - HemoPro 2
    - **Always advance the C-Ring and Harvesting Tool under endoscopic visualization. Ensure adequate visualization of the HEMOPRO 2 Jaws and the surgical site prior to application of electrosurgical energy. If visualization of the surgical site is impaired, do not initiate or continue activation of energy to the HEMOPRO 2 Jaws to avoid thermal injury to tissue.**
  - HemoPro:
    - **Always advance the C-Ring and Harvesting Tool under endoscopic visualization. CAUTION: Take care to avoid engaging the components of the C-Ring assembly with the VASOVIEW HEMOPRO jaws. Doing so may damage**

portions of the C-Ring assembly causing the components to separate from the assembly and fall into the body.

- Should you have any affected product as listed in this notification, do not use the product and remove it from areas of use. You will receive credit upon the return of any affected devices.
- Please forward this information to all current and potential HemoPro and HemoPro 2 users within your hospital / facility.
- If you are a distributor who has shipped any affected product(s) to customers, please forward this document to their attention for appropriate action.
- Please contact Getinge Customer Service at [INSERT SSU CONTACT INFORMATION]. a return material authorization (RMA) and shipping instructions to return any affected product. Pack the product to be returned with the appropriate return documents and, using the shipping instructions provided, arrange for pickup with the designated delivery service provider.
- Whether you have affected product or not, please complete and sign the attached MEDICAL DEVICE REMOVAL RESPONSE FORM (see page 4) to acknowledge that you have received this notification. Return the completed form [INSERT LOCAL SSU EMAIL HERE] or by faxing the form to [INSERT LOCAL SSU FAX NUMBER HERE].

Actions to be taken by Getinge:
MCV/Getinge has identified the cause of the issue and has already implemented corrective measures.

This voluntary removal only affects the products listed on page 1; no other products are affected by this voluntary removal.

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

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

Sincerely,

[Month DD, YYYY]

URGENT: MEDICAL DEVICE REMOVAL RESPONSE FORM

Reference Number: 2242352-06/07/2024-001-R
VasoView HemoPro Endoscopic Vessel Harvesting System
VH-4000, VH-4001, & VH-3500
[INSERT LOCAL SSU EMAIL HERE] or by faxing the form to [INSERT LOCAL SSU FAX NUMBER HERE]

DISTRIBUTION DATES:
VH-4000 / VH-4001: 05-Mar-2024 thru 19-April-2024
VH-3500: 25-Mar-2024 thru 28-Mar-2024

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

I acknowledge that I have read and understand this Medical Device Removal 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].