Month XX, 2023

URGENT FIELD SAFETY NOTICE - MEDICAL DEVICE REMOVAL

Reference Number: 2242352-02/17/2023-002-R

Hemopro and Hemopro 2 Endoscopic Vessel Harvesting Systems

Product Code/REF Numbers/UDI Codes/Lot Numbers:	**Product Code/REF Number**	**Part Description**	**UDI Code**	**Distributed Affected Lot Number:**
	C-VH-3000-W	**VASOVIEW HEMOPRO, OUS**	**00607567700345**	**3000274687**
	C-VH-3500	**VASOVIEW HEMOPRO**	**00607567701250**	**3000280189**
				3000276183
	C-VH-4000	**VASOVIEW HEMOPRO 2**	**00607567700406**	**3000278401**
				3000271148
				3000268643
				3000263026
				3000274504
Manufacturing Dates:	September 16, 2022 – November 21, 2022			
Distribution Dates:	September 28, 2022 – December 15, 2022			

Dear Risk Manager,

Maquet Cardiovascular, LLC/Getinge is initiating a voluntary Medical Device Removal for the Hemopro, Product Code/REF Number VH-3500, and Hemopro 2, Product Code/REF Number VH-4000, Endoscopic Vessel Harvesting Systems for not having been sterilized to their minimum sterilization process specification.

> The VASOVIEW HEMOPRO and VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting Systems are designed for use in conjunction with the 7 mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and Harvesting Tool for cutting and sealing of vessel branches.

Identification of the issue:

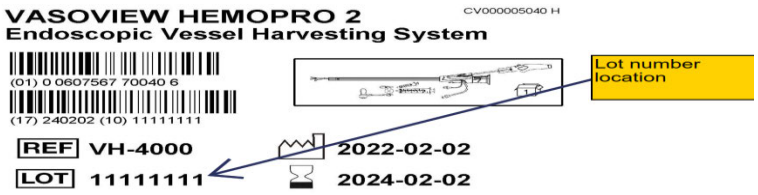
Maquet Cardiovascular, LLC/Getinge was notified by their sterilization provider (Steris) that for a period of roughly five months, some batches of product were not sterilized to their minimum sterilization specification.

The result of the lower sterilization treatment is a reduction of the product's Sterility Assurance Level from a theoretical probability of 1 in million chance of a nonsterile unit (1/1,000,000) to approximately 1 in 645,000 chance of a non sterile unit.

In summary the product has been sterilized but has received a lower level of sterilization treatment than specified, resulting in a reduced sterility assurance level of approximately 1 in 645,000 of a non sterile device.

Risk to Health:
If a non-sterile medical device is used inside a body cavity of a patient, that patient is at risk of developing a post-operative infection that could result in a serious or critical condition requiring additional medical management. The patient population most at risk for such a serious harm consists of patients who are critically ill, immunocompromised and the elderly.

Actions to be taken by the Customer:
Our records indicate that you have received the Hemopro lot(s) 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 with the product code/lot number(s) listed in this notice.

- Should you have any affected product lot(s) as listed in this notification, please stop using and remove the complete device from areas of use. If you have affected product, you are entitled to a credit. You will receive credit upon your acknowledgement that you have affected product for return.
- 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.
- For any affect product being returned, we are offering a full credit. Please contact your local GETINGE INSERT SSU CONTACT INFORMATION if you have product to return for credit.
- Whether you have affected product or not, please complete and sign the attached RESPONSE FORM (page 4) to acknowledge that you have received this notification by e-mailing a scanned copy to INSERT SSU EMAIL or by faxing the form to INSERT SSU FAX.

Type of Action by the Getinge:
Maquet Cardiovascular, LLC / Getinge has identified the cause of the issue and has already implemented corrective measures.
This voluntary recall only affects the products listed on page 1; no other products are affected by this voluntary recall.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Maquet Cardiovascular, LLC /Getinge representative or office. [INSERT SSU CONTACT INFO]

Sincerely,

_____

[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE – REMOVAL RESPONSE FORM

Reference Number: 2242352-02/17/2023-002-R

Hemopro and Hemopro 2

FAX BACK TO: INSERT SSU FAX#. EMAIL TO: INSERT SSU EMAIL

DISTRIBUTION DATES: September 28, 2022 – December 15, 2022

CUSTOMER INFO

I acknowledge that I have reviewed and understand this Urgent Medical Device Removal Letter for the affected Hemopro and Hemopro 2 Endoscopic Vessel Harvesting Systems at this facility.

I confirm that all users of the Hemopro and Hemopro 2 Endoscopic Vessel Harvesting Systems at this facility have been notified accordingly.

If you have any affected product for return, please indicate the information required in the table below. Please contact Getinge Customer Service to request return authorization, packaging and shipping instructions. Getinge Customer Service can be reached at (888) 880-2874 between the hours of 6:00 a.m. and 5:00 p.m. Pacific Standard Time.

Affected Lot Number:	Quantity Being Returned:	Getinge Returned RMA #:

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 Hemopro and / or Hemopro 2:
Circle one **YES** **NO**

We have sold/moved our Hemopro and / or Hemopro 2 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 FAX TO: INSERT SSU FAX or EMAIL TO: INSERT SSU EMAIL