Month xx, 2022

URGENT FIELD SAFETY NOTICE MEDICAL DEVICE REMOVAL

Hemopro 2 with Vasoshield (VH-4001) and Vasoshield Syringe Packs (VH-5001)

Product Code/REF Number:	C-VH-4001, C-VH-5001
UDI Code:	VH-4001 00607567700901 VH-5001 00607567700468
Distributed Affected Lot Numbers	**Part Number: C-VH-4001** Lots: 25152107, 25152204, 25152293, 25152463, 25152771, 25153153, 25153273, 25153366, 25153585, 25153847, 25153960, 25154066, 25154880, 25155262, 25155326, 25155785, 25156245, 25156642, 25157016, 25157085, 25157244, 25157700, 25157898, 25158066, 25158152, 25158374, 25158822, 25158965, 25159100, 25159335, 25159572, 25159695, 25159791, 25160255, 25160398, 25160498, 25160712, 25160961, 25161193, 25161423, 25161672, 25162202, 25162407, 25162505, 25163168, 25163281, 25163367, 3000236928 **Part Number: C-VH-5001** Lots: 25147126, 25151632, 25152389, 25152964, 25163138, 25162077
Distributed Affected Device Component Lot Numbers	N/A
Manufacturing Dates:	July 6, 2020 to July 14, 2022
Distribution Dates:	**C-VH-4001** August 3, 2020 to September 1, 2022 **C-VH-5001** January 6, 2021 to June 1, 2022

Dear Hospital Contact,

Maquet Cardiovascular, LLC/Getinge is initiating a voluntary Medical Device Removal for the Hemopro 2 kits with Vasoshield, and Vasoshield Syringe multi-packs, due to the potential for ink on the Vasoshield syringe Maquet logo that may chip resulting in an unreasonable risk of harm to the patient.

Hemopro 2 with Vasoshield
The Hemopro 2 with Vasoshield, Product Code/REF Number C-VH-4001, is a single use device designed to be used in conjunction with a 7 mm Endoscope. The Hemopro 2 with Vasoshield is comprised of a Harvesting Cannula, a C-Ring, a distal lens washer tube, Vasoview Hemopro 2 Harvesting Tool for cutting and sealing of vessel branches, and one Vasoshield Syringe.

Syringe Multi Pack
The syringe multi-pack, Product Code/REF Number C-VH-5001 comes fully assembled and is comprised of five syringes each with a pressure relief valve that is controlled by a pressure setting ring. The device is used for the preparation and irrigation of blood vessels prior to use as a bypass graft.

Identification of the issue:
During the manufacture of Vasoshield Pressure Controlling Syringe (VH-5001) batch # 3000237368, it was discovered that the Syringe, Pressure Controlling, 50cc, part number RM7001114, showed signs of flaking of the ink that prints the MAQUET logo. That batch of syringe was also used in the manufacture of some finished good batches of C-VH-4001 (Hemopro 2 with Vasoshield).

There have not been any complaints reported for this issue.

Risk to Health:
Potential harms may include:
1) Foreign body reaction resulting from detached particulate (flecks of ink) displaced into the body cavity of the patient.
2) Coronary embolic event (myocardial infarction) resulting from detached particulate (flecks of ink) displaced into the vessel prep fluid and detached particulate becomes an embolic source resulting in an embolic event.
3) Peripheral embolic event (peripheral infarct) resulting from detached particulate (flecks of ink) displaced into the vessel prep fluid and detached particulate becomes an embolic source resulting in an embolic event.

Actions to be taken by the Customer:
Our records indicate that you have received affected product from lots affected by this recall. Please, note that Distributed Affected Lot Numbers appear on the device shelf boxes only.

Please examine your inventory immediately to determine if you have any of Hemopro 2 with Vasoshield and/or Vasoshield Syringe with the product code/lot numbers listed in this notice. LOT numbers can be found on the product label in the area circled in red. (LO*T number 11111111 is for reference only*)

Figure 1: Vasoshield Syringe-Multi Pack label

Figure 2: Hemopro 2 with Vasoshield Syringe label

1. Should you have any affected product lots as listed in this notification, please stop using and remove the complete device from areas of use. Distributed Affected Lot Number can be found on the device package.

2. Should you have un-used affected VH-4001 kits and/or VH-5001 (partial or full packs) you are eligible for credit.

3. Please forward this information to all current and potential Hemopro 2 with Vasoshield and Vasoshield Syringe 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. 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.

If you have affected products, you will receive credit at no cost to your facility.

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,

December XX, 2022

URGENT FIELD SAFETY NOTICE – REMOVAL RESPONSE FORM

Hemopro 2 with Vasoshield (VH-4001) and Vasoshield Syringe Packs (VH-5001)

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

DISTRIBUTION DATES: August 3, 2020 through September 1, 2022

Customer info

Please acknowledge that you have read and understand this URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE - Removal for the product lots listed on Page 1 affected by this recall. Please ensure that all users of the product at this facility have been notified accordingly, and complete the entire form where applicable whether or not you have product to return.

Facility Representative Information:	
Name	Title:
Department:	Phone:
Signature	Date:
Hospital Name (if different from above)	
Address, City and State (if different from above)	

I **DO NOT HAVE** ANY AFFECTED PRODUCT: ☐

I **HAVE AFFECTED** PRODUCT: ☐

If you have affected product lot(s) to return please complete the table below:

Enter part number and Lot number	**Quantity**	**RMA #**

Return the completed form by FAX TO: INSERT SSU FAX or EMAIL TO: INSERT SSU EMAIL