September 20, 2024

URGENT MEDICAL DEVICE – REMOVAL

FSCA 2242352-09/20/2024-002-R

VasoView HemoPro Endoscopic Vessel Harvesting Systems VH-3000-W & VH-3500

Product Name	**VasoView HemoPro Endoscopic Vessel Harvesting System**	
Product Code	**VH-3000-W / VH-3500**	
UDI-DI	**VH-3000-W**	**00607567700413**
	VH-3500	**00607567701250**
Distributed Affected Lot Number:	**See the attached listing (Page 4) for all applicable lot numbers.**	
Manufacturing Dates for All:	**September 08, 2023, to July 26, 2024**	
Distribution Dates for All:	**September 25, 2023, to July 19, 2024**	

Dear Risk Manager,

Maquet Cardiovascular, LLC (MCV), a subsidiary of Getinge, is initiating a voluntary Medical Device Removal for all affected products within its shelf life of the VasoView HemoPro Endoscopic Vessel Harvesting (EVH) Systems due to complaints received of silicone detaching from the Harvesting Tool component of the device during use, resulting in debris being introduced to affected patients.

The VasoView HemoPro EVH Systems (product codes VH-3000-W (outside the U.S.) and 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. The Harvesting Cannula has four lumens that house the Endoscope, C-Ring, distal lens washer tube, and VasoView HemoPro Harvesting Tool. The Harvesting Tool is used for cutting and cauterizing vessel branches and has two curved Jaws. One of the Jaws contains the heating elements for branch cutting and cauterizing. Both Jaws have silicone insulation to protect the adjacent tissue.

Identification of the issue:

MCV/Getinge received 18 complaints for the VH-3500 devices between 01-Apr-2024 and 31-July-2024 related to silicone detaching from the Jaws of the Harvesting Tool during use. There were 17 reports of serious injury due to silicone debris being introduced to the patients including 3 instances where this debris was unable to be removed. MCV/Getinge has determined that this issue potentially impacts all manufactured lots of the VH-3000-W and VH-3500 devices and is, therefore, removing all affected product within its shelf life from the field.

Risk To Health:

Detachment of silicone from the Hemopro Harvesting Tool Jaws can render the device Harvesting Tool non-functional, requiring replacement. If silicone detaches into the endoscopic tunnel while the device is in use, detached material must be removed from the patient. This hazardous situation can lead to an EVH procedural delay and/or conversion of the EVH procedure to a more invasive open vessel harvest (OVH) procedure. Conversion to an OVH procedure may increase a patient's risk of pain, bleeding, delayed wound healing, infection, a longer hospitalization, and potentially a longer recovery due to the increased number or length of incision required by the procedure.

Additionally, there is a risk that the detached silicone may be too small to be removed endoscopically or could go unnoticed by the surgical team and be retained within the endoscopic tunnel, and potentially lead to future complications and harm to the patient. Future complications could include such harms as delayed onset of pain, infection, localized allergic/adverse reaction, and/or readmission to a medical facility for additional medical and/or surgical intervention to treat complications and/or retrieve retained material.

Actions to be taken by the customer:

Our records indicate that you have received one or more of the VasoView HemoPro EVH Systems that are affected by this notification.

1. **Please forward this information to all current and potential VasoView HemoPro Endoscopic Vessel Harvesting System users within your hospital/facility.**

2. **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**

3. Please examine your inventory immediately to determine if you have any of the VasoView HemoPro EVH Systems with the product codes and lot numbers listed in this notice and remove these from use.

4. Return any unused/unexpired affected product to MCV/Getinge. Please contact MCV/Getinge Customer Service at 1-888-880-2874 between the hours of 6:00 am and 5:00 pm PST (Pacific Standard Time) to request a return authorization

number (RMA) and shipping instructions. If you have an affected product, you are entitled to a credit. You will receive credit upon your acknowledgment that you have affected the product for return.

5. Whether or not you have affected the product, please complete, and sign the attached MEDICAL DEVICE REMOVAL - RESPONSE FORM (page 5) to acknowledge that you have received this notification. Return the completed form to MCV/Getinge by emailing a scanned copy to Hemopro-peeling-detached-silicone2024.act@getinge.com or by faxing the form to +1 (866) 594 8101.

Actions to be taken by Getinge:

MCV/Getinge is continuing to investigate this issue to determine and implement the appropriate actions to prevent the recurrence of this failure. MCV/Getinge will notify customers in the event additional action is needed to address this issue.

Getinge will facilitate the removal of affected products from your facility and provide credit for your return of these products. This voluntary removal only affects the products listed on page 1; no other products are affected by this voluntary medical device removal.

Adverse reactions or quality problems experienced with the use of this product can be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178 (1-800-332-0178)

We apologize for any inconvenience this medical device removal may cause. If you have any questions, please contact your MCV/Getinge representative or call the MCV/Getinge Customer Support at 1-888-880-2874, Monday through Friday, between the hours of 6:00 am and 5:00 pm PST.
This notification is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Sajjad A Mansoor

Director, Quality and Regulatory Compliance

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VasoView HemoPro Endoscopic Vessel Harvesting System

Listing of Affected Batches

VH-3000-W

3000365379	3000382334	3000392749

VH-3500

3000333967	3000354228	3000364520	3000376542	3000384902	3000400713
3000339701	3000355224	3000365391	3000376883	3000385174	3000401094
3000340534	3000355369	3000366446	3000377320	3000385849	3000401623
3000341133	3000355798	3000366831	3000377699	3000386206	3000402378
3000341675	3000356048	3000367160	3000378079	3000386871	3000403161
3000342250	3000357837	3000367439	3000378654	3000387986	3000403837
3000342251	3000360574	3000367542	3000379282	3000387987	3000404029
3000343264	3000360576	3000367852	3000379691	3000388401	3000404374
3000343266	3000360775	3000368165	3000380264	3000388676	3000404720
3000344887	3000361036	3000368658	3000380475	3000389329	3000411951
3000345068	3000361423	3000369005	3000380671	3000392530	
3000346640	3000361707	3000369122	3000381049	3000392531	
3000351187	3000362064	3000369645	3000381287	3000393159	
3000351376	3000362258	3000370069	3000381620	3000393427	
3000351407	3000362671	3000370290	3000382054	3000393838	
3000351619	3000362933	3000372257	3000382868	3000394234	
3000351747	3000363162	3000375534	3000383367	3000395128	
3000351860	3000363947	3000375776	3000383779	3000398856	
3000352770	3000364082	3000376132	3000384088	3000399341	
3000354226	3000364309	3000376388	3000384382	3000399911	