

November 15, 2024

Getinge's Response to FDA's Letter to Health Care Providers Regarding Vasoview Hemopro Devices

Dear Valued Customer:

On November 15, 2024, the U.S. Food and Drug Administration (FDA) published a letter to health care providers on its website, available at Safety Notifications ([getinge.com](https://www.getinge.com)), alerting health care providers and facilities about safety concerns with the use of Getinge/Maquet Vasoview Hemopro Endoscopic Vessel Harvesting (EVH) Systems, and a supply concern for EVH devices.

Previously, on September 20, 2024, Getinge/Maquet issued an Urgent Medical Device Removal notice to inform users to not use Vasoview Hemopro 1.5 (VH-3500) and Vasoview Hemopro 1 (VH-3000-W), which is marketed only outside of the United States.

The FDA has issued this letter to help ensure that health care providers and facilities are aware of the recall notice for Vasoview Hemopro 1.5 devices, the ongoing evaluation of potential safety concerns with Vasoview Hemopro 2 devices, and supply concern for EVH devices. FDA has also recommended the use of alternative products.

Getinge takes FDA's concerns very seriously and will continue to work with the FDA on the reports of silicone detachment impacting the jaws of Vasoview Hemopro 2 EVH System.

Please note the following:

- The Vasoview Hemopro 2 EVH System employs enhanced design features to minimize the failure modes observed in Vasoview Hemopro 1.5 EVH System.
- We have significantly increased our production capacity and will be out of back order by the end of December 2024.
- Vasoview Hemopro 2 EVH System remains available for sale globally.
- Vasoview Hemopro 2 EVH System meets our current safety and performance standards.
- We are working on enhancements to product training materials to reinforce safe and effective use of the Vasoview Hemopro 2 EVH System.

In the interim, please do not hesitate to contact your sales representative with any questions. We will share further information in response to questions we receive as quickly as we can.

Sincerely,

Patricia Fitch

Patricia Fitch

President, North America