Updated January 31, 2025

Getinge's Actions in Response to FDA's Letter to Health Care Providers Regarding Cardiosave, Cardiohelp and HLS Set Devices

Dear Valued Customer:

On May 8, 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), alerting health care providers about safety and quality concerns regarding Getinge's Cardiosave Intra-Aortic Balloon Pump (IABP), Cardiohelp System, and HLS Set Advanced. The safety and quality concerns are related to FDA's concern that Getinge has not sufficiently addressed outstanding problems and risks with the field actions affecting these devices.

The FDA is recommending that health care facilities transition away from use of these devices and seek alternatives if possible. For health care providers that do not have any alternative devices and continue to use Getinge's devices, FDA recommends that these facilities review previously communicated FDA recommendations and Urgent Medical Device notifications related to these products. The previous FSCA customer communications from Getinge can be found on the above link as well.

Getinge takes FDA's concerns very seriously, and in response, we have decided to take the following actions:

- Immediately pause promotional activities of the Cardiohelp System and Cardiosave IABP in the U.S. until outstanding actions related to quality improvements have been addressed and approved.
- Limit the sale of these hardware products to customers that are aware and understand the FDA's recommendation and choose to continue with these devices.
- As it has since February 2024, Getinge will limit the availability of Cardiosave only to existing Getinge IABP customers.
- Inform customers about the changes to the indications for use of the Cardiohelp System.

The company will continue to supply and service the installed base with intra-aortic balloon catheters and HLS sets.

In the May 8, 2024 letter to health care providers, FDA highlighted that it continues to work with Getinge to understand factors contributing to the device failures, as well as possible mitigation strategies. Getinge is working with FDA and other regulatory authorities to correct quality-related deficiencies. The company also has accelerated the development of the next generation of Cardiohelp and Cardiosave IABP hardware.

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

Best Regards,

Patricia Fitch

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President – North American Sales

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