PRODUCT DISRUPTION BRIEF

Extracorporeal membrane oxygenation (ECMO)

(reviewed August 21)

The FDA recommends providers to transition away from certain Getinge Cardiohelp system and HLS Sets devices due to continued safety and quality concerns.

Current condition

On May 22, Getinge released a response to the U.S. Food and Drug Administration (FDA)'s May 8th letter. In response, Getinge is immediately pausing promotional activity of the Cardiohelp until outstanding actions related to quality improvement are addressed and approved. When product supply is available, customers will be able to purchase Cardiohelp in case no other options are available.

On May 8, the U.S. Food and Drug Administration (FDA) alerted providers of continued safety and quality concerns with the following Getinge/Maquet cardiovascular medical devices:

- Getinge/Maquet Cardiohelp system and HLS Sets.
- Getinge/Maquet/Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump (IABP) devices; see disruption brief here.

The FDA recommends that health care facilities transition away from use of these devices and seek alternatives, if possible, based on our continued concerns that Getinge/Maquet has not sufficiently addressed the problems and risks with these recalled devices.

Mitigation strategy

The FDA provided the following recommendations:

- Plan for alternative capital equipment to transition away from these Getinge cardiovascular devices: Getinge Cardiopulmonary bypass (CPB) devices including the Getinge/Maquet Cardiohelp system and HLS Sets
- Use alternative devices, if possible. If you don't have alternatives and continue to use these devices:
  - Review the FDA's previous recommendations. Read any Urgent Medical Device Correction notices from Getinge and follow the recommendations.
  - Be aware of the recalls related to these devices.
  - Report any issues or adverse events with Getinge devices to the FDA. For details on reporting, see Reporting Problems to the FDA.
- Report any supply chain issues to the deviceshortages@fda.hhs.gov mailbox.

Fresenius, Abbott, Spectrum & Nautilus/Medtronic are alternative manufacturers of ECMO devices in the United States.

- Vizient is working to identify cross-referencing for the affected product and will update this brief when available.
- For additional information from Fresenius, contact Frank Kelsey, Franklin.kelsey@freseniusmedicalcare.com , (317) 864-3160.
- For additional information from Spectrum, contact Wade Berger, Wade.Berger@spectrummedical.com, 803-558-0004
- For additional information from Nautilus/Medtronic, contact Jon Linden, jon.linden@medtronic.com

To learn more, please contact:
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Potentially impacted procedures

As a result of this disruption, there may be potential impact to the following procedures. Based on Vizient's Procedural Analytics, these are the top 10 procedures, based on product utilization. This is not an exhaustive list of potentially impacted procedures.

- Extracorporeal Circulation Auxiliary to Open Heart Procedures
- Heart Transplant
- Mitral Valve Procedures, Other
- Aortic Valve Replacement, Open
- Lung Transplant
- Thoracic Aorta Procedures
- Implantable VAD Insertion
- Mitral Valve Replacement, Open
- CABG
- Other Heart Surgery Procedures

Questions about Procedural Analytics? Contact askproceduralanalytics@vizientinc.com

Additional resources

Supply assurance webpage, FDA Medical Device Recalls

Want to receive weekly Supply Assurance updates?
Update your preferences through our Subscription Manager by selecting Supply Assurance Weekly Digest.

Questions? Contact novaplus@vizientinc.com, pharmacyquestions@vizientinc.com, disasterresponse@vizientinc.com.