PRODUCT DISRUPTION BRIEF

Intra-aortic balloon pump systems (IABP) (updated Oct 15)

Vizient adds Apex Medical Products to contract to provide alternative products in response to FDA recommendations for providers to transition away from certain Getinge Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump (IABP) and Class I recall for Teleflex/Arrow FiberOptix and UltraFlex Intra-Aortic Balloon (IAB) catheter kits.

Current conditions

Effective July 1, Vizient has added Apex Medical Products to contract for Intra-Aortic Balloon (IAB) catheter kits. Apex offers IAB catheters that are compatible with both Getinge & Teleflex pumps.

Teleflex/Arrow International

On June 3, the U.S. Food and Drug Administration (FDA) posted a Class I recall for Teleflex/Arrow International's FiberOptix and UltraFlex IAB catheter kits distributed between May 7, 2022 and April 8, 2024. The FDA findings show that a manufacturing error may cause the catheter's balloon to become overtwisted. The issue can sometimes be identified visually, but a device may still be impacted even if the issue cannot be detected visually. This issue may: prevent the balloon from fully inflating, cause blood to back up in the tubing, allow helium to leak, and lead to catheter damage or insertion difficulty during use. Use of this device may cause serious injury, including blood loss, tearing in the artery (perforation), unstable blood pressure (hemodynamic instability), prevention of blood flow to the heart (myocardial ischemia), or death.

- Teleflex/Arrow International reports 322 complaints.
- A total of 31 injuries and 3 deaths have been reported potentially related to this issue.

On April 29, Teleflex/Arrow International sent an Urgent Medical Device Notification letter to customers that included the recommended actions. Additional information is included in the FDA Class I recall notice.

Getinge/Maquet

Effective September 11, 2024, Getinge has reported stock levels of previously backordered balloon catheter kits have returned to a normal level.

On May 22, Getinge released a response to the FDA's May 8th letter. In response, Getinge is immediately pausing promotional activity of the Cardiosave until outstanding actions related to quality improvement are addressed and approved. Getinge will continue to supply and service balloon catheters. In regard to Cardiosave balloon pumps, Getinge is only providing Cardiosave as replacement on a 1:1 ration for existing IABP customers.

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/Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump (IABP) devices
- Getinge/Maquet Cardiohelp system and HLS Sets. For more information on ECLS/ECMO, see the 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.

Providers should review the FDA's previous recommendations. Read any Urgent Medical Device Correction notices from Getinge and follow the recommendations.

To learn more, please contact:
Corey Girard, Category Director,
corey.girard@vizientinc.com.

Mitigation strategy

Apex Medical Products, Inc offers IAB catheters that are compatible with both Getinge & Teleflex pumps. These products are covered under Vizient agreement MS7547. Providers should enroll in the contract through Vizient Catalog/Contract Price Activation.

- Cross-references to Apex products are available here.
- For additional information, contact Bryan Eckard, bryan@apexmedicalproducts.com, (215) 375-5765.

Teleflex is an alternative manufacturer of IAB pumps. On May 10, Teleflex issued a response to Getinge's letter.

- Cross-references to Teleflex products are available here.
- For additional information, contact Ashley Pugsley, Ashley.pugsley@teleflex.com, (469) 933-4346.

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 4 procedures, based on product utilization. This is not an exhaustive list of potentially impacted procedures.

- Drug-Eluting Coronary Stent Procedures
- CABG Procedures
- Peripheral Vascular Intervention Procedures
- Aortic Valve Replacement – Endovascular 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.