

PRODUCT DISRUPTION BRIEF

Coronary Artery Bypass Grafts (CABG) (updated August 23)

The FDA issues recommendations for healthcare providers on the use of oxygenators in extracorporeal circulation; Getinge issues urgent medical device removal for all Quadrox Oxygenators and certain Venous Hardshell Cardiotomy Reservoirs.

Current conditions

On May 18, 2023, Getinge/Maquet issued an [Urgent Medical Device Removal](#) notice to inform users to not use all Quadrox Oxygenators and certain Getinge/Maquet Venous Hardshell Cardiotomy Reservoirs due to potentially compromised packaging sterility that may result in the risk of infection/harm to the patient. For a list of impacted product codes, click [here](#).

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

- Lung Transplant
- Extracorporeal Circulation Auxiliary to Open Heart Procedures

Questions about Procedural Analytics? Contact askproceduralanalytics@vizientinc.com

Mitigation strategy

The U.S. Food and Drug Administration (FDA) has issued the following [recommendations](#) to healthcare providers:

- Review the [recall notice](#) from Getinge/Maquet.
 - Check your inventory to determine if you have any Quadrox Oxygenators or certain Venous Hardshell Cardiotomy Reservoirs.
 - **Do not use these devices unless they are already in use.**
- If the devices are already in use, then they may continue to be used. Monitor patients for the following signs and symptoms, and, if detected, treat the patient according to clinical protocols: inflammation, infection, sepsis, and ischemia.
- For new extracorporeal circulation procedures, use alternative device(s). Look for other manufacturers or suppliers of oxygenators to determine if alternatives are appropriate.
 - [FDA-cleared oxygenators for use in cardiopulmonary bypass \(CPB\) circuit](#)
 - [FDA-cleared oxygenators for use in extracorporeal membrane oxygenation \(ECMO\) circuit](#)
- Report any issues with oxygenators to the FDA.

Alternatives

Getinge is not a contracted supplier with Vizient for perfusion products and/or the products included in this urgent medical device removal. Alternatives are available from Medtronic (CE7526). Vizient is working with alternative suppliers to identify alternative products for those impacted and will continue to monitor the situation closely.

Additional resources

[Supply assurance webpage](#); [Vizient Newsroom](#)



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As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

Impacted product codes

ITEM	ITEM DESCRIPTION	UDI (Single device)
701050330	QUADROX-iD Pediatric- BEQ-HMOD30000-USA	4037691670164
701067820	HMO 70000-USA /QUADROX-i Adult	4058863019147
701067823	HMO 71000-USA /QUADROX-i Adult	4058863017341
701067829	BEQ-HMO 71000-USA /QUADROX-i Adult	4058863017372
701067840	HMOD 70000-USA/ QUADROX -iD Adult	4058863019000
701067859	BEQ-HMOD70000-USA/ QUADROX -iD	4058863019024
701067874	HMO 70100-USA-QUADROX-iR Adult without filter, with SOFTLINE Coating	Not Applicable
701067880	BEQ-HMO 71100-USA-QUADROX-iR Adult with filter, with BIOLINE Coating	4058863164052
701067886	HMO 71100-USA-QUADROX-iR Adult with filter, with SOFTLINE Coating	Not Applicable
701067891	HMO 50000-USA /QUADROX-i Small Adult	4058863019055
701067895	HMO 51000-USA /QUADROX-i Small Adult	4058863019185
701067905	BEQ-HMO 50000-USA / QUADROX -i Small	4058863019079
701067934	HMO 50100-USA-QUADROX-iR Small Adult without filter, with SOFTLINE Coating	Not Applicable
701067936	BEQ-HMO 51100-USA-QUADROX-iR Small Adult with filter, with BIOLINE Coating	Not Applicable
701067938	HMO 51100-USA-QUADROX-iR Small Adult with filter, with SOFTLINE Coating	Not Applicable
701070384	HMO 30000-USA /QUADROX-i Pediatric	4058863153681
701070388	HMO 31000-USA /QUADROX-i Pediatric	4058863154299
701070397	QUADROX-iD Pediatric- BEQ-HMOD30000-USA	4058863154435
701070412	HMO 10000-USA /QUADROX -i Neonatal	4058863154473
701070416	HMO 11000-USA /QUADROX -i Neonatal	4058863154558
701070441	VKMO 10000-USA /Venous Hardshell Cardiotomy Reservoir	4058863153889
701070445	VKMO 11000-USA /Venous Hardshell Cardiotomy Reservoir	4058863153889