Evaluations & Guidance - Guidance

Transitioning from Getinge Cardiosave and Cardiohelp Systems: ECRI's Recommendations for Alternative Products

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EXECUTIVE SUMMARY

UPDATE: *On June 13, 2024, FDA issued a Class I recall for the Teleflex FiberOptix and UltraFlex intra-aortic balloon catheter kits. These catheter kits are used with the Teleflex AC3 Optimus intra-aortic balloon pump (IABP); this IABP is the only FDA-cleared alternative to the Getinge Cardiosave balloon pump. ECRI recommends that relevant healthcare providers, healthcare facilities, and distributors follow FDA's recommendations delineated in the June 13, 2024, recall notice. We also note that other intra-aortic balloon catheter kits that are compatible with the AC3 Optimus IABP may be available from Teleflex (e.g., RediGuard IAB catheter). Note that our article and recommendations below have not changed.*

This article expands on FDA's May 8, 2024, Letter to Health Care Providers, which recommended that facilities transition away from Getinge Cardiosave balloon pump and Cardiohelp extracorporeal cardiopulmonary support systems due to continuing safety and quality concerns. FDA's letter does not contain recommendations on alternative products. To help facilities select suitable options for adult patients, ECRI is providing recommendations and information on alternative devices.

Key points:

- Only one FDA-cleared alternative to the Cardiosave is available, sold by Teleflex; various alternatives to the Cardiohelp system are available. We provide general specifications and pricing for the Teleflex device and several Cardiohelp alternative products.
- Facilities with affected Getinge devices should follow the recommendations in FDA's letter. In addition, ECRI recommends the following:

- Assign device replacement planning to an appropriate facility committee, such as medical device, product evaluation, or value analysis.
- If necessary, assign supervision of Getinge Cardiosave and Cardiohelp system use to an appropriate facility committee, such as perfusion, patient safety, or risk management.
- For facilities with established adult ventricular assist device (VAD) programs, consider using a percutaneous VAD in suitable patients for short-term circulatory support instead of a balloon pump.

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In a May 2024 letter, FDA recommended that healthcare facilities transition away from Getinge Cardiosave and Cardiohelp circulatory support systems due to continuing safety and quality concerns. However, the letter does not contain recommendations on alternative products. To assist facilities in navigating the transition, ECRI is providing recommendations and information on alternative devices for adult patients.

FDA Letter about Concerns with Getinge IABP and ECMO Systems

On May 8, 2024, FDA published Safety and Quality Concerns with Getinge Cardiovascular Devices - Letter to Health Care Providers. In this letter, the agency describes its "concerns that Getinge/Maquet has not sufficiently addressed the problems and risks with these recalled devices"; these problems include, but are not limited to, unexpected shutdown of Cardiosave intra-aortic balloon pump (IABP) devices during use and sterility issues with the HLS Sets used with Cardiohelp extracorporeal membrane oxygenation (ECMO) systems. FDA has issued the following recommendations for healthcare facilities:

1. Plan for alternative capital equipment to transition away from the following Getinge devices:

    a) Getinge/Maquet/Datascope Cardiosave Hybrid and Rescue IABP devices

    b) Getinge cardiopulmonary bypass (CPB) devices including the Getinge/Maquet Cardiohelp system and HLS Sets

2. Use alternative devices if possible. If you don't have alternatives and continue to use these Getinge devices:

    a) Review the FDA's previous recommendations. Read any Urgent Medical Device Correction notices from Getinge and follow the recommendations.

b) Be aware of the recalls related to these devices. [To access ECRI's alerts related to the Getinge products, refer to the "Hazards" tab in the Technology Report that is referenced below.]

3. Report any issues or adverse events with Getinge devices to the FDA. For details on reporting, see Reporting Problems to the FDA. [ECRI encourages organizations to also submit reports to our problem reporting system.]

4. Report any supply chain issues to the deviceshortages@fda.hhs.gov mailbox.

Below we present recommendations for alternatives to the referenced Getinge products to help healthcare facilities choose suitable products for circulatory and cardiopulmonary support of adult patients.

Technology Report: Alternatives to Cardiosave IABP and Cardiohelp ECMO Systems

Multiple FDA-approved ECMO systems are available. However, Teleflex sells the only other FDA-cleared IABP. The following report from ECRI's Capital Guide program provides a feature comparison of some alternative ECMO systems, general specifications for the Teleflex IABP, and pricing for these alternative products.

Download the report:

Technology Report: Extracorporeal Pumps and IABP Systems

Additional Recommendations for Facilities That Use IABP and ECMO Systems

1. Determine whether your facility has any of the following:

   a) Getinge/Maquet/Datascope Cardiosave Hybrid IABP

   b) Getinge/Maquet/Datascope Cardiosave Rescue IABP

   c) Getinge/Maquet Cardiohelp system and HLS Sets

2. If your facility has any of these Getinge products, follow FDA's recommendations described above. In addition:

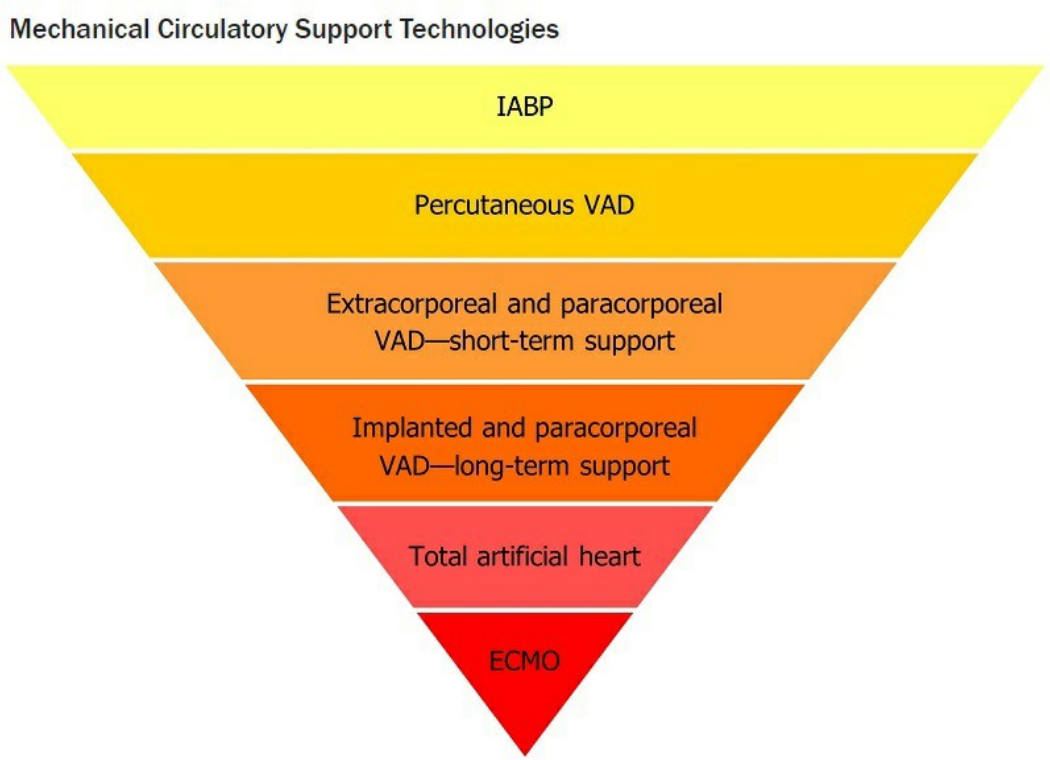
   a) Assign device replacement planning to an appropriate facility committee, such as medical device, product evaluation, or value analysis. Since there is only one other vendor of FDA-cleared IABPs, it may not be possible to replace the Getinge Cardiosave IABP in a timely manner. Getinge product replacement planning should be an urgent priority for this committee.

   b) If necessary, assign supervision of Getinge Cardiosave IABP and Cardiohelp cardiopulmonary support system transition to an appropriate facility committee, such as perfusion, patient safety, or risk management.

3. For facilities with established adult VAD programs, consider using a percutaneous VAD instead of an IABP in patients who meet your facility's criteria for short-term circulatory support. ECRI provides a feature comparison of various VADs in the Device Comparison Guide report Circulatory Assist Units, Cardiac, Ventricular. (Device Comparison Guide is available to members of ECRI's Device Evaluation Plus and Capital Guide programs.)

Background: Summary of Current Mechanical Circulatory Support Technologies

For adult patients in need of circulatory support, several mechanical circulatory support technologies are available. The figure shows current options for adult patients, ranging from the least invasive modality (IABPs) to the most invasive (ECMO).



In more detail, these options include:

- IABP—A mechanical counterpulsation device that inflates and deflates a balloon catheter placed within a patient's aorta to reduce the heart's workload.
- Percutaneous VAD—A micropump that is inserted into the patient's left ventricle via aortic catheterization and can provide short-term circulatory support.
- Other VAD types are extracorporeal, paracorporeal, and intracorporeal/implanted.
  - For extracorporeal VAD systems, the pump and the VAD controller are external to the body with inflow/outflow connections to the heart. These devices are indicated for short-term circulatory support.
  - Similarly, paracorporeal VAD systems also have the pump and VAD controller external to the body, but the VAD rests on the patient's skin or clothes.
  - Implanted VADs are implanted in the heart with transcutaneous connections to an external, wearable VAD controller. These devices are generally intended for long-term circulatory support.
- Total artificial hearts are intended to replace a patient's native heart, providing left and right heart circulatory support.
- An ECMO system includes a controller, extracorporeal VAD, heater unit, gas supply, gas blender, and cannula for inflow/outflow connections to the heart and lungs for veno-arterial ECMO, or across the lungs for veno-

venous ECMO. ECMO is intended for short-term cardiopulmonary support.

Additional ECRI Resources

The following resources are accessible to members of selected ECRI services.

Capital Guide Technology Report:

- Technology Report: Extracorporeal Pumps and IABP Systems

Alerts:

- Abbott—Thoretec CentriMag Acute Circulatory Support Systems: Pump Motor Can Spontaneously Become Hot Enough to Damage Blood
- FDA Recommends Transitioning Away from Use of Getinge/Maquet Cardiosave Hybrid IABPs, Cardiosave Rescue IABPs, Cardiohelp Systems, and HLS Sets

Device Comparison Guide reports:

- Circulatory Assist Units, Cardiac, Ventricular
- Heart-Lung Bypass Units; Pumps, Extracorporeal Perfusion; Oxygenators, Extracorporeal Membrane

Clinical Evidence Assessment reports:

- Impella Heart Pumps (Abiomed, Inc.) for Treating Cardiogenic Shock
- Intra-aortic Balloon Pumps for Treating Cardiogenic Shock
- Long-term Left Ventricular Assist Device Placement for Treating End-stage Heart Failure
- Nautilus Smart ECMO Module (Medtronic plc.) for Temporary Cardiopulmonary Support

RELATED RESOURCES

Therapeutic Cardiology Technologies: The Essentials

TOPICS AND METADATA

Topics

Equipment and Facility Planning
Hazard and Recall Management
Procurement Trends
Quality Assurance/Risk Management
Physician Preference Items
Technology Management
Technology Selection
Inventory Management

Caresetting

Hospital Inpatient
Trauma Center

Clinical Specialty

Cardiothoracic Surgery
Cardiovascular Medicine
Critical Care
Nursing
Transplantation

Roles

Biomedical/Clinical Engineer
Clinical Practitioner
Materials Manager/Procurement Manager
Nurse
Patient Safety Officer
Quality Assurance Manager
Regulator/Policy Maker
Risk Manager

Information Type

Guidance

UMDNS

Circulatory Assist Units, Cardiac, Intra-Aortic Balloon [10-846]
Catheters, Vascular, Intra-Aortic Balloon [10-725]
Heart-Lung Bypass Units [11-969]
Pumps, Extracorporeal Perfusion [13-203]
Circulatory Assist Units, Cardiac [10-840]

CITATION

ECRI. Transitioning from Getinge Cardiosave and Cardiohelp systems: ECRI's recommendations for alternative products. *Device Evaluation*. Updated June 17, 2024.