

# Arrow International Inc. Recalls Arrow AutoCAT®2 and AC3 Optimus® IABP Series Due to Possible Breakdown of Motor Connector Wires

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## Recalled Product

- Arrow AutoCAT®2 and AC3 Optimus® Intra-Aortic Balloon Pump Series
- Model, Product Names, Product Codes, and Serial Numbers: See List of Affected Devices
- Manufacturing Dates: 08/01/2014 to 01/2020
- Distribution Dates: March 15, 2018 to May 1, 2020
- Devices Recalled in the U.S.: 2123
- Date Initiated by Firm: May 20, 2020

## Device Use

The Arrow AutoCAT®2 and AC3 Optimus® are Intra-Aortic Balloon Pumps (IABP) are cardiac assist devices used with patients undergoing cardiac and non-cardiac surgery, and to treat patients with acute coronary syndrome or complications from heart failure.

## Reason for Recall

Arrow International is recalling the Arrow AutoCAT®2 Intra-Aortic Balloon Pump and AC3 Optimus® Intra-Aortic Balloon Pump Series because both devices have a part within called the MForce motor driver that may break, char, and discolor the motor connector wires. This may lead to pump alarms for "System Error 3" and "High Baseline" presented on the screen of the IABP. Furthermore, the IABP may suddenly stop, even without an alarm. This may cause serious patient harm including serious organ damage and death.

Arrow International has received 30 complaints in total about these devices. There were no injuries or deaths reported as a result of any of the complaints.

## Who May Be Affected

- Health care providers using affected Arrow AutoCAT®2 and AC3 Optimus® IABP Series devices

- Patients undergoing procedures using the affected device

## What to Do

On May 20, 2020, Arrow International Inc. sent an Urgent Medical Device Correction letter to all affected customers. The notice instructed customers to:

- Immediately check the inventory for Arrow® AutoCAT®2 and Arrow® AC3 Optimus® IABPs, whether stored or in use, and determine if there is an IABP with a model number listed below.
  - If the IABP mentioned in the Urgent Medical Device Correction letter displays a "System Error 3" or "High Baseline" alarm, now or at any point in the future until the company's Long-Term Corrective Actions specified in the letter occur, immediately quarantine the device and contact Teleflex.
- Ensure that a backup IABP is available as instructed within the Operator Manual.
  - If no such replacement IABP is immediately available, it is recommended that the risks and benefits of using the IABP be assessed by the medical team treating the patient and that alternative circulatory support devices be considered.
- Use a backup IABP or alternative therapy in the event an IABP displays a "System Error 3" or "High Baseline" alarm, at the discretion of the attending physician.
- Closely monitor IABP units should be during delivery of IABP therapy.
- Use of IABP for ground or air transport between medical facilities is not recommended.
- If pump shutdown is experienced, take note of the time of day and call knowledgeable maintenance personnel as stated in the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump / Arrow® AC3 Optimus® Intra-Aortic Balloon Pump Operator Manuals.
  - Pump shutdown requires immediate staff action. If pumping cannot be restored within 15-30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends there be a back-up IABP system available.
- Keep a copy of the Urgent Medical Device Correction letter from Arrow International with each IABP at all times until the complete implementation of the company's Long-Term Corrective Actions specified in the letter.
- Quarantine the device for inspection, if "System Error 3" and "High Baseline" alarms are experienced at a later time, taking into consideration the use of available alternative therapies, and adhering to the instructions specified under the heading "ACTIONS TO BE TAKEN BY FACILITIES" in the Urgent Medical Device Correction letter.

Arrow International Inc. will send a subsequent notification letter to affected customers with updated instructions for ground or air transport use. Instructions will replace a uniform "Not Recommended for Transport" statement with a risk benefit analysis, use of a backup device, and recommendation to use a newer manufactured device.

## Contact Information

Customers who have questions about this recall can contact Teleflex at 1-855-419-8507 or [recalls@teleflex.com](mailto:recalls@teleflex.com) (<mailto:recalls@teleflex.com>) to receive support for inspection and servicing of the impacted device.

## Lists of Affected Devices

These Class 1 Device Recall pages list the serial number ranges for recalled products.

- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE, Product Code IAP-0500 - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181531>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT 2, Product Code IAP-0400 - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181529>)
- Arrow AC3 Optimus Intra-Aortic Balloon Pump AC3 Optimus IABP NA/EMEA, Product Code IAP-0700 - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181537>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AEROAUTOCAT 2 WAVE, Product Code IAP-0535 - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181536>)
- Arrow AC3 Optimus Intra-Aortic Balloon Pump AC3 Optimus IABP NA/AJLA, Product Code IAP-0701 - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181538>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE JAPANESE, Product Code IAP-0500J - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181534>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE ITALIAN, Product Code IAP-0500I - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181533>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE SPANISH, Product Code IAP-0500E - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181532>)

- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 SPANISH, Product Code IAP-0400E - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181530>)
- Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE DUTCH, Product Code IAP-0500NL - Recall Database Entry  
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181535>)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.

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