

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health.

Arrow International Inc. Recalls Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits Due to Sheath Separation Issue

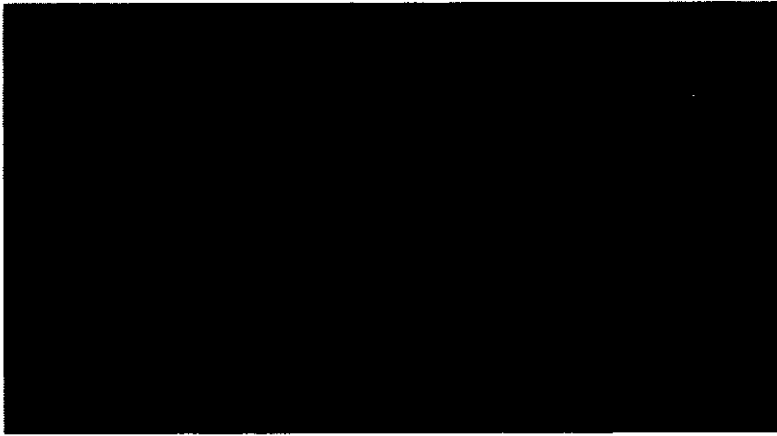
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits
- Device Models: FiberOptix Ultra 8 IAB: 8Fr 30cc – K021462; Ultra 8 IAB: 8Fr 30cc – K000729; FiberOptix Ultra 8 IAB: 8Fr 40cc – K021462; Ultra 8 IAB: 8Fr 40cc – K000729; UltraFlex IAB: 7.5Fr 30cc – K000729; UltraFlex IAB: 7.5Fr 35cc – K000729; UltraFlex IAB: 7.5Fr 40cc – K000729; RediGuard IAB: 7Fr 30cc – K981660; Percutaneous Insertion Tray – K000729; Percutaneous Insertion Tray – K981660
- Manufacturing Dates: December 1, 2013 to December 1, 2015
- Distribution Dates: January 1, 2014 to February 1, 2016
- Devices Recalled in the U.S.: 13,405 units distributed nationwide

Device Use

The Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits are designed to provide cardiac assist therapy for patients with failing hearts and/or insufficient blood flow through the coronary arteries who are not responding to medical therapy. The IAB is inserted through the femoral artery into the aorta using an elongated Teflon cover (sheath) used to dilate the incision of the artery. The Intra-Aortic Balloon Catheter provides mechanical circulatory support by inflating and deflating the balloon to the patient's heartbeat.



Intra-Aortic Balloon Catheter Kit

Reason for Recall

Arrow International Inc. is recalling the Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits because the sheath body may separate from the sheath hub during the insertion procedure. This may cause significant bleeding if not addressed promptly and an interruption of the inflating-deflating balloon therapy.

The FDA has received 13 medical device reports of serious adverse health consequences, including one death related to this device malfunction.

Who May be Affected

- Health care professionals using the catheter and insertion kits
- All patients undergoing procedures involving these catheters and insertion kits

What to Do

On February 11, 2016, Arrow International Inc. sent an Urgent: Medical Device Recall letter, which instructed consignees to:

- Review the list of affected products and lots
- Immediately quarantine unused products from their inventory
- Communicate the recall to any customer who received the affected products using the customer letter and the recall acknowledgment form template provided by the company
- Return affected products along with the recall acknowledgment form to the company
- Contact the company at 1-866-246-6990; 8am to 8pm, Eastern Time, Monday through Friday or at recalls@teleflex.com with any questions related to the recall
- Report adverse events or quality problems experienced with use of the product to the FDA through:
 - [MedWatch Online](#)
 - Phone: 800-FDA-1088

Date Recall Initiated:

February 10, 2016

Additional Resources

- [FDA MedWatch Safety Alert for This Recall](#)

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[2016 Medical Device Recalls](#) [2015 Medical Device Recalls](#) [2014 Medical Device Recalls](#)