Arrow International Announces Worldwide Voluntary Recall of Intra Aortic Balloon Pump (IAB) Catheters

April 13, 2009

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Apr. 13, 2009-- Teleflex Medical announced today that the U.S. Food and Drug Administration (FDA) has classified the voluntary medical device recall initiated on February 2, 2009 by Arrow International's Cardiac Care Division involving volume connectors for its 30cc, 40cc and 50cc Intra Aortic Balloon Pump (IAB) Catheters as a Class 1 recall. FDA defines Class I recalls as, "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

This recall is being conducted because a fault in the connector of the pump tubing assembly may result in the volume setting on the pump defaulting to 2.5 cc or 5 cc, rather than the appropriate 30, 40, or 50 cc volume. In patients exhibiting moderate to severe myocardial ischemia or low perfusion states, prolonged exposure to the low default volume may fail to decrease ischemia and increase perfusion, leading to organ injury or infarct and may result in patient death. Prolonged exposure to a device which is inflated to less than 2/3 full could also result in thrombus formation on the IAB and possible subsequent systemic or cerebral thromboembolism.

Instructions contained in the operator's manual fully describe the necessary warnings and precautions that will identify the issue. The recall notice restates these instructions and references the sections in the owner's manual. If these instructions are followed, the issue for which the product was recalled can be discovered immediately, and the product can be removed and replaced.

Arrow International notified both domestic and foreign hospitals and distributors via an Urgent Medical Device recall letter dated February 2, 2009 that the company had become aware that the blue connector for the 40cc IAB was not properly recognized by the Arrow Intra-Aortic Balloon Pump (IABP) system. This recall involved the retrieval of unused product, issuance of mitigation instructions for patients and/or facilities in critical need, and the replacement of pump tubing assemblies.

At this time, there have been 25 complaints of this issue. There have been no reports of patient injury as a result of this issue. Approx. 423 lots are affected by this recall for a total 45,211 units.

PRODUCTS AFFECTED: 30/40/50 CC IAB Catheters:

PRODUCT CODES: IAB-04830-U, IAB-04840-U, IAB-05830-LWS,
IAB05830-U, IAB-05840-U, IAB-05840-LWS, IAB06830-U, IAB06840-U,
IAB-S730C, IAB-S840C, IAB-R950-U, IAK-02692, IAK-02693, and IAK-02691.

A list of products and lot numbers affected by this recall as well as the original recall notice can be found at Arrow's website:

http://www.arrowintl.com/iab_recall.asp

Consumers with questions may contact the company at 1-800-523-8446; 8am to 8pm, ET, Monday through Friday, for international calls 001-919-361-4062; 8am to 5pm, ET, Monday through Friday.

Any adverse reactions experienced with the use of this product, and/or quality problems can also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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