Arrow International Announces Worldwide Voluntary Recall for the 5800 Series Intra-Aortic Balloon Catheters (IAB) with Super Arrow-Flex(R) Sheath Introducers

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LIMERICK, Pa., Dec 21, 2010 (BUSINESS WIRE) --

Arrow International has announced a worldwide voluntary recall of its 5800 Series IABs with Super Arrow-Flex Sheath Introducer. This recall is being conducted because of an increase of "stuck in sheath" reports involving the use of the Super Arrow-Flex Sheath with 5800 Series IAB products. When the IAB becomes stuck in sheath, the user is unable to move the IAB catheter forward or backward, potentially causing a delay in critical therapy. Excessive manipulation of the IAB due to it becoming stuck in sheath during insertion may also result in excessive bleeding or arterial damage, significant vasospasm, prolonged tissue ischemia, tissue/vascular ischemia, injury, infarct, or death.

The U.S. Food and Drug Administration ("FDA") has classified this action as a Class I 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."

Healthcare facilities should immediately discontinue use of the device and return all unused 5800 Series IABs with Super Arrow-Flex Sheath Introducers to Arrow, in accordance with the instructions provided in Arrow's recall notification. The affected product codes are:

IAB-05830-U	IAB-05840-U
IAB-05830-LWS	IAB-05840-LWS
IAK-05845	

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/iabRecall.

This field action affects product shipped between January 1, 2009 and December 17, 2010. All affected healthcare facilities are being notified, and Arrow is in the process of working with them to retrieve all remaining devices. The FDA has been apprised of this action.

This field action supersedes Arrow's Field Safety Alert issued on October 8, 2010.

Consumers with questions or adverse reactions may contact the company at 1-866-396-2111; 8am to 7pm, ET, Monday through Friday, for international calls 1-919-361-3964; 8am to 5pm, ET, Monday through Friday.

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.

About Arrow International

Arrow International is a subsidiary of Teleflex Incorporated (NYSE:TFX), a global provider of medical technology products that assist healthcare providers in their efforts to improve patient outcomes, reduce infections and support patient and provider safety. Teleflex, which employs approximately 12,800 people worldwide, also has niche businesses that serve segments of the aerospace and commercial markets with specialty engineered products. Additional information about Teleflex can be obtained from the company's website at www.teleflex.com.

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