Class I Medical Device Recall: Arrow International, Inc. (subsidiary of Teleflex, Inc.), Multi-Lumen Venous Catheterization Set with Blue FlexTip ARROWg+ard Catheter

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: May 3, 2012

Product: Multi-Lumen Venous Catheterization Set with Blue FlexTip ARROWg+ard Catheter

See part numbers and lot numbers here: [1]

The product was manufactured from June 28, 2010 through March 4, 2012 and distributed from December 9, 2010 through February 29, 2012.

Use: The multiple-lumen catheter is inserted in a large vein to administer drug therapy

Recalling Firm:
Arrow International, Inc. (subsidiary of Teleflex, Inc.)
2400 Bernville Road
Reading, Pennsylvania 19605

Reason for Recall: The device’s labeling erroneously states that the product "contains no medication," however, the device contains chlorhexidine and silver sulfadiazine. Additionally, the product’s label is missing the appropriate chlorhexidine contraindication.

If a patient with a known or unknown allergy/sensitivity to chlorhexidine or silver sulfadiazine/sulfa drug is exposed to this product, there is the potential for an allergic reaction such as a delayed rash, hives or potentially an immediate Type 1, IgE mediated anaphylaxis (loss of blood pressure, bronchospasm and vascular collapse).

This product may cause serious adverse health consequences, including death, if used in a patient who is allergic to either chlorhexidine or silver sulfadiazine.

Public Contact: Health care professionals and consumers may contact Arrow International, Inc. at 1-610-378-0131.

FDA District: Philadelphia District Office

FDA Comments:

On May 3, 2012, the firm sent its distributors an Urgent Field Correction Action letter. In the letter, the firm asked their distributors to quarantine any affected inventory and relay the information to their Arrow sales representatives. The Arrow sales representative will place a new label on each kit within their inventory.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2] either online, by regular mail or by FAX.

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http://www.mdtmag.com/news/2012/07/class-i-medical-device-recall-arrow-international-inc-subsidiary-teleflex-inc-multi-lumen-venous-catheterization-set-blue-flextip-arrowgard-catheter?qt-recent_content=0

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=109437
[2] http://www.fda.gov/Safety/MedWatch/default.htm