Teleflex Incorporated Announces Worldwide Recall of ARROW International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits

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Teleflex Incorporated announces worldwide recall of ARROW International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits. The Arrow IAB is inserted in the aorta and provides mechanical circulatory support for cardiac patients, by inflating and deflating at different phases of the cardiac cycle to increase cardiac output and decrease the work of the heart.
For detailed information pertaining to this Recalls, Market Withdrawals and Safety Alerts message, please click the link at the beginning of this bulletin.

03/11/2016

Arrow International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits by Teleflex Incorporated : Class I Recall - Sheath Body may become Separated from Sheath Hub

AUDIENCE: Cardiology, Risk Manager
ISSUE: Teleflex Incorporated (NYSE: TFX) announces worldwide recall of Arrow International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits. On 9-Feb-2016, Teleflex Incorporated initiated a worldwide recall of 47,140 units distributed to hospitals, clinics, and medical centers throughout the United States and globally. The Arrow International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits are being recalled because the sheath body may become separated from the sheath hub. If the separation occurs, the patient may bleed from the sheath. If bleeding is not promptly addressed, significant blood loss or exsanguination may occur. Interruption or loss of intra-aortic balloon pump treatment may also occur. At the time of the recall, there were 13 adverse events reported; including 6 serious injuries and 1 death.
A list of affected product codes and full list of affected lot numbers can be found in the Recall Notice and appendix.
BACKGROUND: The Arrow IAB is inserted in the aorta and provides mechanical circulatory support for cardiac patients, by inflating and deflating at different phases of the cardiac cycle to increase cardiac output and decrease the work of the heart.
RECOMMENDATION: Teleflex notified domestic distributors and customers via an Urgent Medical Device recall letter dated February 11, 2016. Consumers who have affected product should immediately discontinue use and return all affected product to Teleflex.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- **Complete and submit the report Online: www.fda.gov/MedWatch/report**

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address

on the pre-addressed form, or submit by fax to 1-800-FDA-0178
Read the MedWatch safety alert, including a link to the Recall Notice, at http:// www.fda.gov/Safety /MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ ucm490454.htm

Amikacin Sulfate Injection USP, 1 gram/4mL (250 mg/mL) Vials by Teva: Recall - Glass Particulate Matter

AUDIENCE: Pharmacy, Infectious Disease

ISSUE: Teva Pharmaceuticals announced a voluntary recall of one lot of amikacin sulfate injection USP, 1 gram/4mL (250 mg/mL) vials due to the potential presence of particulate matter identified as glass in one vial. The recalled lot # is 4750915, Expiration Date 9/2017.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.

BACKGROUND: Amikacin sulfate injection USP is used in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, and has also been shown to be effective in staphylococcal infections and may be considered as initial therapy under certain conditions in the treatment of known or suspected staphylococcal disease.

Amikacin sulfate injection is packaged in pharmacy bulk packages, containing ten 1 gram/4 mL (250 mg/mL) vials per shelf pack. Amikacin sulfate injection 250 mg/mL, 4 mL vials were distributed nationwide through wholesalers, retailers and pharmacies.

RECOMMENDATION: Teva is arranging for impacted product to be returned to Inmar. Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all retail and medical facility accounts. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

FDA MedWatch - Human and Animal Sterile Drug Products by I.V. Specialty: FDA Alert - Lack of Sterility Assurance –(note AUSTIN TXcompany)

03/09/2016

Human and Animal Sterile Drug Products by I.V. Specialty: FDA Alert - Lack of Sterility Assurance

AUDIENCE: Pharmacy, Nursing, Veterinary Medicine, Infectious Disease

ISSUE: The U.S. Food and Drug Administration (FDA) is alerting health care professionals and patients not to use drug products intended to be sterile that are produced and distributed by I.V. Specialty Ltd., Austin, Texas, due to lack of sterility assurance. On March 7, 2016, FDA recommended that I.V. Specialty cease sterile production until appropriate corrective actions are implemented, and recall all non-expired drug products intended to be sterile. The company has neither ceased sterile production nor initiated a recall. Therefore, FDA is alerting health care professionals and patients to dispose of and not use drug products intended to be sterile that were produced and distributed by I.V. Specialty.

BACKGROUND: During FDA's recent inspection of I.V. Specialty, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about I.V. Specialty's ability to assure the sterility of the drug products it produces. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.

RECOMMENDATION: Health care professionals and consumers should immediately check their medical supplies, quarantine any drug products labeled as sterile from I.V. Specialty, and not administer them to patients. Health care professionals should make alternative arrangements to obtain any medications they administer to patients from reliable sources that adhere to proper quality standards. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Fluconazole Injection, USP, (in 0.9 Percent Sodium Chloride) 200mg per 100ml: Recall - Elevated Impurity

03/07/2016

AUDIENCE: Infectious Disease, Pharmacy, Nursing

ISSUE: Sagent has initiated a voluntary recall of one lot of Fluconazole Injection, USP, 200mg per 100mL to the user level due to the discovery of an out of specification impurity result detected during routine quality testing of stability samples at the 18-month interval. This impurity has been identified as Metronidazole. An elevated impurity has the potential to decrease effectiveness of the product in patients. Patients on the product and on concomitant medication of Metronidazole may receive an increased dose of Metronidazole.

BACKGROUND: The lot number being recalled is Lot 40608 which was distributed to hospitals, wholesalers and distributors nationwide from November 2014 through December 2014. Fluconazole Injection, USP, 200mg per 100mL is indicated, for the treatment of Oropharyngeal and esophageal candidiasis, cryptococcal meningitis, and is supplied in 100mL and 200mL flexible container bags.

RECOMMENDATION: Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com

Medical Device Safety and Recalls: Dräger Evita V500 and Babylog VN500 Ventilators - Recall Expanded to Include Optional PS500 Batteries with New Power Supply Firmware

03/03/2016

Dräger Medical has expanded its December 2015 recall to include the PS500 Optional Power Supply units that were updated with new software as part of the December recall. The new software installed failed to correct the issue depleting the battery and Dräger Medical will now replace all affected PS500 power supply units.

The ongoing PS500 power supply issue could cause the ventilator to shut down unexpectedly. If the ventilator shuts down, a patient may not receive necessary oxygen. This could cause patient injury or death.