Class I Medical Device Recall: Cook Inc., Single, Double, Triple and Five-Lumen Central Venous Catheter Trays AND Single and Double Lumen PICC Peripheral Inserted Central Veno...

U.S. Food & Drug Administration

Date Recall Initiated: October 4, 2010

Products: Single, Double, Triple and Five-Lumen Central Venous Catheter Trays AND Single and Double Lumen PICC Peripheral Inserted Central Venous Catheter Trays

See under **Additional Links** below for specific product information.

See also related Excelsior Medical Class I recall notice **[1].**

These products were manufactured from December 4, 2008 through May 1, 2009 and distributed from January 1, 2009 through September 30, 2010.

Use: These catheters are used by physicians to monitor a patient's pressure in a vein, for blood sampling, and administration of drugs and fluids.

Recalling Firm:
Cook, Inc.
750 Daniels Way
Bloomington, Indiana 47404-9120

Reason for Recall:

These kits and trays contain 0.9% Sodium Chloride Injection USP 5 mL fill in 6 mL flush syringes that have been recalled by Excelsior Medical. Leaks in the plunger luer were detected during a routine syringe leak test. The potential exists for leakage and possible loss of sterility. This may cause serious adverse health consequences and/or death.

Public Contact:

Customers with questions may contact Cook Customer Relations Department at 1-800-457-4500 or by FAX at 1-800-544-8335, Eastern Time.

FDA District: Detroit

FDA Comments:

On October 4, 2010, Cook Inc. sent Urgent Device Recall letters to their customers. The company asked their customers to examine their inventory and notify Cook about returning these recalled products. The letter included a response form.

Class 1 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 the FDA's Safety Information and MedWatch Adverse Event Reporting Program [2] either online, by regular mail or by FAX.

Additional Links:

- Cook Central Venous Catheter Tray, Double Lumen Polyurethane [3]
- Cook Central Venous Catheter Tray, Triple Lumen Polyurethane [4]
- Related Recalls for Miscellaneous Central Venous Catheter Trays AND Double Lumen PICC Peripheral Inserted Central Venous Catheter Trays [5]

SOURCE [6]

Source URL (retrieved on *07/10/2014 - 7:30am*):
http://www.mdtmag.com/news/2011/03/class-i-medical-device-recall-cook-inc-single-double-triple-and-five-lumen-central-venous-catheter-trays-and-single-and-double-lumen-picc-peripheral-inserted-central-veno?qt-video_of_the_day=0&qt-most_popular=0

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm231053.htm
[2] http://www.fda.gov/Safety/MedWatch/default.htm
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=97100
[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=97105
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=91&event_id=57663&productdescriptiontxt=&centerclassificationtypetext=&recallnumber=&postdatefrom=&postdateto=&productshortreasontxt=&firmlegalnam=&pagenum=10&sortcolumn=cdd
[6] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm245588.htm