U.S. Food and Drug Administration

Medical Devices

Fresenius Medical Care North America, CombiSet True Flow Series Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for Use with the Blood Volume Monitor

Recall Class: Class I

Date Recall Initiated: November 11, 2010

Product: CombiSet True Flow Series Hemodialysis Blood Tubing Set with Priming Set and Transducer Protectors for Use with the Blood Volume Monitor

This recall affects ONLY Part Number 03-2695-9 and ONLY Part Number 03-2795-7. To locate the specific lot numbers, see the Firm Press Release under Useful Links below.

These products were manufactured between June 11, 2010 and October 17, 2010. Part Number 03-2695-9 was distributed between August 2010 and November 2010. Part Number 03-2795-7 was distributed between August 2009 and November 2010.

Use: The CombiSet Hemodialysis Blood Tubing Set is blood tubing used during hemodialysis. It is intended for single use only The CombiSet Hemodialysis Blood Tubing Set may be used with conventional and high flux negative pressure hemodialyzer equipment.

Recalling Firm:

Fresenius Medical Care Holdings, Inc.
920 Winter Street
Waltham, Massachusetts 02451-1521

Reason for Recall:

The hemodialysis blood tubing sets may develop kinking of the arterial line. Kinking can cause the destruction of red blood cells which may result in serious injury and/or death.

Public Contact: Clinic Managers, Unit Administrators, and/or distributors with questions may contact the Fresenius Medical Care Customer Service Team at 1-800-323-5188 (within the U.S.).

FDA District: New England

FDA Comments:

On November 19, 2010, the company sent their customers an "Urgent Recall" letter by certified mail with return receipt. Customers were instructed to check their stock immediately to determine if they had any of the affected lots. If they did, **customers were instructed to IMMEDIATELY discontinue using the affected lots and place the products in a secure and separate area for return to the company.** Customers were instructed to contact the company for instructions on how to return the recalled products.

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 MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Useful Links:

- Firm Press Release [1] [2]
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program [3]

Links on this page:

1. http://www.fmcna.com/idc/idcplg?IdcService=GET_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Web&dDocName=PDF_300037691
2. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
3. http://www.fda.gov/Safety/MedWatch/default.htm