Class I Medical Device Recall: Baxter Healthcare Corporation, Buretrol Solution Sets

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: September 07, 2012

Products Affected	Product Codes	Lot Numbers
Interlink System Buretrol Solution Set with 150 mL Burette	2C7519	All
Interlink System Buretrol Solution Set with 150 mL Burette –Non-DEHP	2H7519	All
Clearlink System Buretrol Solution Set with 150 mL Burette	2C8819	All
Clearlink System Buretrol Solution Set with 150 mL Burette – Non-DEHP	2H8819	All

Range of manufacturing and distribution dates : Products were manufactured from April 30, 2003 through July 26, 2012 and were distributed from May 1, 2003 through August 16, 2012.

Use: Baxter Healthcare Corp. Buretrol Solution Sets are **non-reusable, disposable devices** used for the administration of fluids from a container into the patient's blood vessels (vascular system) through a device that allows frequent access to patients' veins (a vascular access device).

Recalling Firm:
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Reason for Recall : Baxter Healthcare Corp. (Baxter) has initiated a voluntary recall of its Buretrol Solution Sets because the ball-valve feature may not function as expected. Baxter has determined that the ball-valve component is allowing air to flow past the valve and enter the tubing once the pre-measured amount of fluids is completely administered to the patient. If the air is not removed, the air present in the tubing may enter the patient's vascular system potentially causing air in the bloodstream (an air embolism). This product may cause serious adverse health consequences, including death.

Public Contact : Customers with questions can call Center for One Baxter at 1-800-422-9837, Monday through Friday from 7:00 am to 4:30 pm CT.

FDA District: Chicago District Office

FDA Comments: On September 7, 2012, Baxter Healthcare sent an Urgent Product Recall letter to affected customers informing them of the problem with the ball-valve feature. Customers were asked to do the following:

- **STOP using affected Buretrol Solution Sets**,
- Contact Baxter for instructions on how to return the affected product,
- Complete the attached customer reply form confirming their receipt of the letter, and
- Fax the customer reply form to Baxter at the number provided.

Any questions regarding the communication were directed to Medical Information Services at Baxter at 1-800-933-0303.

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 [1] either online, by regular mail or by FAX.

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Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm