



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

BLAST FAX 10-08

TO: Hospital Administrators
Nursing Home Administrators
Home Health Agencies
Outpatient Dialysis Units

FROM: Barbara Cass, R.N.
Public Health Services Manager
Facility Licensing and Investigations Section
410 Capitol Avenue
Hartford, Connecticut, 06134

DATE: March 5, 2010

SUBJECT: RECALL - Automated peritoneal dialysis (PD) systems

Please be advised that the FDA has issued a recall associated with HomeChoice and HomeChoice Pro peritoneal dialysis cyclers. Please see recall notice below.

If you have any questions or concerns please contact Cheryl Theriault, Supervising Nurse Consultant at (860) 509-7400.

Baxter HomeChoice and HomeChoice PRO

Company, Product(s): Baxter Healthcare Corporation HomeChoice and HomeChoice PRO Automated Peritoneal Dialysis Systems

Recall Class: Class I

Date Recall Initiated: January 8, 2010

Product Names:

Baxter Healthcare Corporation, HomeChoice and HomeChoice PRO Automated Peritoneal Dialysis Systems. These systems have been distributed since 1994.

Model	Product Code	Lot Number	Manufacturing Date
HomeChoice	5C4471	All	All
HomeChoice	5C4471R	All	All
HomeChoice	5C4474	All	All
HomeChoice	5C4474R	All	All



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HomeChoice	T5C4441	All	All
HomeChoice	T5C4441R	All	All
HomeChoice	5C4474D	All	All
HomeChoice	5C4474DR	All	All
HomeChoice PRO	5C8310	All	All
HomeChoice PRO	5C8310R	All	All
HomeChoice PRO	R5C8320	All	All
HomeChoice PRO	R5C8320R	All	All
HomeChoice PRO	T5C8300	All	All
HomeChoice PRO	T5C8300R	All	All

Use: Automated peritoneal dialysis (PD) systems are prescription medical devices used to treat pediatric and adult patients with kidney failure.

In PD, a soft tube called a catheter is used to fill the abdomen with a cleansing liquid called dialysis solution. The walls of the abdominal cavity are lined with a membrane called the peritoneum, which allows waste products and extra fluid to pass from the blood into the dialysis solution. These wastes and fluid then leave the body when the dialysis solution is drained. Several fill – drain cycles are typically needed during a treatment. Automated PD systems, like the HomeChoice systems, can be programmed to deliver and remove several cycles of doctor-prescribed amounts of dialysis solution.

HomeChoice systems are used in conjunction with Baxter’s single use disposable tubing sets and bags of dialysis solutions.

The HomeChoice PRO model also has a small electronic data card, called a PRO card, which stores information from the nurse or doctor and automatically sets up the system for the patient.

Recalling Firm:

Baxter Healthcare Corporation
One Baxter Way
Deerfield, IL 60015

Reason for Recall: Baxter is conducting a recall of the HomeChoice and HomeChoice PRO because of reports of serious injuries and at least one death associated with increased Intraperitoneal Volume (IIPV), also known as overflow of the abdominal cavity. IIPV can cause serious breathing and heart problems that can result in serious injury or death.

Public Contact: If you need assistance with your HomeChoice or HomeChoice PRO, call the Baxter Customer Service line, available 24 hours and day, 7 days a week at 1-800-553-6898.

FDA District: Chicago

FDA Comments:

Although Baxter is not removing the HomeChoice and HomeChoice PRO from the market, clinicians should weigh the risks and benefits to continued use of these devices by their patients versus other forms of dialysis therapy. Clinicians should also review the prescription settings for patients who continue to use these devices.

IIPV may result in serious injury or death from conditions including but not limited to: abdominal wall and/or diaphragmatic hernias, hydrothorax, heart failure, acute hypertension, pulmonary edema, decreased pulmonary function, pericardial effusion, and peritonitis.

Children and non-verbal patients may be at increased risk because of their smaller size or inability to communicate. Increased monitoring of these patients is recommended.

Other vulnerable populations include critically ill patients and patients with pulmonary and hemodynamic instability.

Patients and caregivers should watch for the potential signs of IIPV. **If patients or caregivers notice any of the signs of IIPV, stop the device, initiate manual drain, and contact your doctor immediately.** Please refer to the [Baxter press release](#)^{1,□²} for a list of signs and symptoms of IIPV and more specific instructions for what to do if symptoms appear.

Any adverse reactions experienced with the use of this product or quality problems should be reported to the Baxter Renal Division at 1-888-736-2543, prompt 3 (Corporate Product Surveillance), and the FDA's MedWatch Program by phone at 1-800-FDA-1088.

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.

Useful Links:

- [Baxter Press Release](#)^{3□⁴}
- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)⁵