



The Florida ESRD Network

Baxter HomeChoice and Home Choice PRO Automated Peritoneal Dialysis Systems: Class I Recall

3/10/2010

Baxter is Deploying Revised Labeling, Training and Upcoming Software Revisions to Further Assist Clinicians and Patients

DEERFIELD, Ill., March 2, 2010 – Baxter Healthcare Corporation announced today that the U.S. Food and Drug Administration (FDA) has classified Baxter's recent Urgent Product Recall regarding Increased Intraperitoneal Volume (IIPV), or overfill of the abdominal cavity, associated with HomeChoice and HomeChoice Pro peritoneal dialysis cyclers as a Class I recall. This action has been classified as a Class I recall because of the risk of serious injury or patient death that could be associated with the use of this device. Over the last two years, Baxter has received serious injury reports and at least one patient death report associated with this issue.

About IIPV

IIPV may result in serious injury or death from conditions such as: abdominal wall and/or diaphragmatic hernias, hydrothorax, heart failure, acute hypertension, pulmonary edema, decreased pulmonary function and pericardial effusion. **Children and non-verbal patients may be at increased risk because of their smaller size and/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.**

HomeChoice systems are intended for automatic control of dialysis solutions exchange in the treatment of adult and pediatric renal failure patients undergoing peritoneal dialysis. The recall notice does not require the physical return of HomeChoice units and patients may continue using them. **Affected model numbers include: 5C4471, 5C4471R, 5C8310, 5C8310R, 5C4474, 5C4474R, R5C8320, R5C8320R, T5C4441, T5C4441R, T5C8300, T5C8300R, 5C4474D and 5C4474DR.** It is important that clinicians review the prescription settings for devices to help reduce prescription errors and weigh the risks and benefits of continued use of this device by their patients.

Baxter sent recall notices to clinicians and patients informing them of this action and identifying steps that are intended to reduce the harm associated with IIPV. These January 2010 letters contain more detailed information about device usage and are available at www.baxter.com. Customers or patients with questions regarding this notice may contact Baxter 24 hours a day, seven days a week at 1-800-553-6898. Any adverse reactions experienced with the use of this product, and/or quality problems, should be reported to Baxter's Renal business at 1-888-736-2543, prompt 3, and the FDA's MedWatch Program at 1-800-FDA-1088 or www.fda.gov/MedWatch/report.htm. View the Baxter press release at http://www.baxter.com/press_room/press_releases/2010/03_02_10_homechoice.html.

The Florida ESRD Network (Network 7) is providing this fax blast as a Technical assistance activity for the Florida renal community.

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