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Customer Address

DEVICE CORRECTION

24-Feb-2010

Re: HomeChoice Automated PD System and HomeChoice PRO Automated PD System Product Codes: R5C8320

Dear Peritoneal Dialysis Clinician,

Baxter Healthcare is sending you this Device Correction letter to help reduce or eliminate overfill, also referred to as Increased Intra-Peritoneal Volume (IIPV), associated with HomeChoice/HomeChoice PRO cyclers. IIPV can result in serious injury or death from conditions including, but not limited to, hydrothorax, heart failure, pulmonary edema or pericardial effusion. Baxter has received complaints of IIPV, which resulted from patient use errors and/or prescription errors.

Description of IIPV

Overfilling or not draining enough fluid can result in excess fluid in the abdomen. While some patients may not have any symptoms, the most common symptoms of IIPV (overfill) include:

- Feeling full, bloated, or overfull
- Abdominal pain or discomfort
- Expanded or tense abdomen
- Vomiting or spitting-up
- Difficulties feeding
- Localized swelling around the PD catheter exit site, belly button, groin region, or genital area
- Leakage of fluid from the PD catheter exit site
- Difficulty breathing
- A child complaining of a "funny feeling" in the abdomen
- A child crying
- Unexpected increase in blood pressure

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Additional care should be taken to monitor patients who are not able to communicate IIPV symptoms to their caregiver during treatment, such as small children or infants.

How IIPV Occurs

IIPV is a condition that occurs when there is more fluid in the abdomen than was prescribed. This condition is sometimes called "overfill." Baxter has received reports of IIPV associated with patient use error or prescription error when using either the HomeChoice Automated PD System or HomeChoice PRO Automated PD System.

IIPV can occur if the prescription parameters are not programmed appropriately. It is important that clinicians consider these parameters when setting new patient prescriptions. It is also as important for clinicians to consider whether current patient prescriptions need to be revised. Baxter may contact you if, during the course of complaint investigations, we determine that patient prescriptions are potentially contributing to IIPV.

The following prescription parameters can influence the risk of IIPV:

- Fill Parameters such as Fill Volume, Day Fill Volume, Night Fill Volume, Last Fill Volume
- Drain Parameters such as I-Drain Alarm, Minimum Drain Volume %, Last Manual Drain, UF Target, Tidal Volume %, Total UF, Tidal Full Drains
- Low Fill Mode Only such as I-Drain Time, Minimum Drain Time, Negative UF Limit %

Actions to Take

Clinicians must carefully program patient fill volumes to prevent IIPV situations. Clinicians must also program drain alarms and ultrafiltration percentage to ensure patients are draining sufficiently. Insufficient draining could lead to an IIPV situation during their subsequent cycles or accumulation of ultrafiltration volume within the peritoneal cavity.

IF YOU SUSPECT YOUR PATIENT HAS IIPV, PLEASE TELL YOUR PATIENT OR PATIENT CAREGIVER TO DO THE FOLLOWING:

1.) Press ● immediately, then press ∇ and initiate a Manual Drain.
The Manual Drain procedure is located in the HomeChoice/HomeChoice PRO Patient at-home Guide, section 8.
2.) Once the fluid is completely drained from the abdomen, call your nephrologist.
3.) Call your nephrologist immediately if you have ANY complaints or symptoms of IIPV including those listed above.
4.) For assistance in performing the above steps, call your PD nurse or dialysis center or the local Baxter Technical Service line 09193 502 111.
5.) If you are unable to reach your dialysis center, nephrologist, or the Baxter Customer Service line, and the patient is experiencing symptoms of IIPV, call your local medical emergency number immediately or go to the nearest Emergency Room.

HomeChoice Labeling and Software Changes

Baxter is developing changes to the HomeChoice/HomeChoice PRO product labeling and software to reduce the potential incidence of IIPV due to patient use errors or prescription

errors. Baxter will notify you when these changes are available and arrange for your cyclers to be upgraded.

Attached to this letter is information on IIPV. This attachment contains Patient guidance and Clinician Guidance. Please read the attachment and use the information it contains when training or re-training your home patients. The attachment includes:

- A definition of IIPV, the related symptoms, and guidance on how to address IIPV should it occur.
- Warnings and cautions about IIPV.
- Programming instructions for the HomeChoice/HomeChoice PRO cyclers to improve clinicians' understanding of how programming the device relates to IIPV. New details have been added to specifically address Low-Fill Mode.
- Tables have been included with recommendations for the Initial drain (I-drain) alarm settings, recommendations for maximum Fill Volume based on patient's weight, and targets for Tidal Therapy ultrafiltration levels.

Adverse reaction reporting
Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Baxter by phone (089 31701 0) or by mail cqa_de@baxter.com.

If you have any questions about this issue, please contact our Technical Service (09193 502 111). We apologize for any inconvenience you may experience as a result of this notification.

The German MOH has been notified of this action.

Sincerely,

Baxter Deutschland GmbH

i. V.

[redacted]

Senior Manager CQA D-A-CH
Qualitätssicherung Deutschland

i. V.

[redacted]

Technical Service
Manager Deutschland

Attachment : Information on IIPV