Baxter

Urgent Field Safety Notice

27th February 2015

Dear Peritoneal Dialysis Healthcare Provider,

Baxter is sending this communication to provide you with an Important Product Information related to the use of Baxter peritoneal dialysis Transfer sets, Titanium adapters, Disconnect caps and Clamshell product codes (see Attachment 1 - Table of Product Codes and Names).

Specifically, Baxter wants to highlight that, for patients sensitive to iodine, the use of products which contain iodine (i.e., povidone iodine) (Disconnect Caps and Clamshells) or for which iodine use is recommended (Transfer Sets and Titanium adapters) could result in adverse reactions.

All peritoneal dialysis (PD) patients are also receiving a letter mailed directly to them (see enclosure).

Consequently, in case of a known patient's history of allergic reaction to iodine:

- Products containing iodine should not be used
- Products for which iodine use is recommended should not be used with disinfectants or antiseptic agents that contain iodine

Note: As already outlined in the instructions for use for these products, disinfectants or antiseptic agents that contain hydrogen peroxide, alcohol or bleach are also unsuitable for use with these devices as these agents may affect the function of the device over its expected lifetime.

Baxter has not received any report of complaint or adverse event associated with these products for allergy to iodine. However, in order to further enhance existing Baxter labeling and ensure labelling consistency across the peritoneal dialysis portfolio, two new contraindications statements will be added in the Instruction for Use to address iodine allergy for Baxter's peritoneal dialysis products which contain iodine or for which iodine use is recommended. These contraindication statements are targeted to be added to product labeling by the fourth (4th) quarter of 2015.

Hazard Involved

For patients sensitive to iodine, the use of products which contain iodine or for which iodine use is recommended could result in a contact allergy or local/systemic reactions if it enters the peritoneal cavity.

Action to be taken

1. Identify peritoneal dialysis patients who are iodine sensitive.
2. Communicate this Important Product Information to the applicable patients using disconnect caps and clamshells.
3. Ensure povidone iodine is not used on iodine-sensitive patients while following the IFU for each peritoneal dialysis transfer set/adapter installation or exchange. For clinical questions, contact your local Baxter

representative.

4. Complete the enclosed customer reply form and return it to Baxter by either fax or scanned email. Returning the customer reply form promptly will prevent you from receiving repeat notifications.
5. Forward this Important Product Information letter to other departments or facilities in accordance with your procedures.
6. If you are a dealer, wholesaler, or distributor/reseller of the Peritoneal Dialysis (PD) products in this Important Product Information communication, please forward this Important Product Information communication as appropriate.

Further Information and support

- For clinical questions, contact your local Baxter Representative.
- Please report any suspected adverse reactions to the HPRA via their website at www.hpra.ie
- Any suspected adverse reactions observed during use may also be reported to Baxter Healthcare directly by calling 01-206-5500 or by email on qa_dublin@baxter.com.

The Health Products Regulatory Authority (HPRA) has been notified of this action

We apologise for any inconvenience this communication may cause you, your staff, and your PD patients.

We thank you for your cooperation and look forward to continuing to serve your dialysis needs.

Sincerely,

Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
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Baxter

CUSTOMER REPLY FORM

IMPORTANT PRODUCT INFORMATION LETTER DATED 27TH FEBRUARY 2015

BAXTER PERITONEAL DIALYSIS TRANSFER SETS, TITANIUM ADAPTERS, DISCONNECT CAPS AND CLAMSHELL PRODUCTS

Product code: *See Attachment #1*

Batch Number*: All*

Please complete and return one copy of this form per facility either by fax (Fax :01 206 5577) or by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification.
A fax cover sheet is not required.

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	

☐ We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.

Signature/Date: REQUIRED FIELD	_____

