

**IMPORTANT
PRODUCT
INFORMATION**

March, 2013

Subject: Field Safety Notice - Baxter PD Transfer Sets

Dear PD Healthcare Professional

**Issue
Description**

Baxter would like to provide you with important information regarding changes that are being made to Instructions for Use (IFU) for Baxter PD Transfer Set product codes used for peritoneal dialysis (PD) therapy. Baxter is in the process of updating the IFUs for the Transfer Set codes listed in the table below to improve product labeling and ensure consistency of information across the Baxter Transfer Set product family.

Product Code	Product Description
R5C4325	CAPD Solution Transfer Set for use with UV-Flash Germicidal Exchange Device 1.2 M (48")
R5C4326	CAPD Solution Transfer Set (Short) for use with UV-Flash Germicidal Exchange Device
R5C4482	MINICAP Extended Life PD Transfer Set with Twist Clamp
R5C4483	MINICAP Extended Life PD Transfer Set with Twist Clamp (Extra Short)
R5C4484	MINICAP Extended Life Transfer Set with Twist Clamp – Extra Long

Key additions to the IFU include:

- This set is to be used with the Baxter Locking Titanium Adapter for Peritoneal Dialysis Catheter in disconnect applications and in cyclor applications where aseptic connections and disconnections are performed at the transfer set/cyclor set juncture. *(applies to all listed codes)*
- Wipe for a minimum of 1 minute around the connection between the titanium adapter and the Transfer Set or locking cap with a sterile gauze pad soaked in povidone-iodine. *(applies to all listed codes)*
- It is recommended that thyroid function be monitored in patients with small peritoneal dialysate fill volumes, typically infants and children. *(applies to all listed codes)*
- Based on *in vitro* testing, the UV-Flash Transfer Set should be replaced at intervals not longer than four months or more frequently as specified by a physician. *(applies to R5C4325 and R5C4326 only)*
- Based on *in vitro* testing, the Twist Clamp Transfer Set should be replaced at intervals not longer than six months or more frequently as specified by a physician. *(applies to R5C4482, R5C4483, and R5C4484 only)*
- Do not use if tip protectors are not in place. *(applies to all listed codes)*.
- This product does not contain *natural rubber latex*. *(applies to all listed codes)*

The following IFU information should be communicated to your patients:

- Ensure that the Transfer Set and catheter tubing are clean and dry, and to always maintain aseptic technique. Failure to do so may result in infection. *(applies to all listed codes)*
- This product does not contain natural rubber latex. *(applies to all listed codes)*

Additionally, at the request of Swiss Agency for Therapeutic Products (Swissmedic) Baxter would like to reinforce the importance of using appropriate chemical agents on Transfer Set connectors and not applying excessive force to operate the Transfer Set mechanism during Peritoneal Dialysis (PD) therapy. The function of the *MiniCap* Extended Life PD Transfer Set may be affected due to breakage of the twist clamp, the inner Transfer Set component. While the *MiniCap* PD Transfer Set is the primary closure mechanism of the system after therapy, the twist clamp ensures the closure of the fluid path during connection and disconnection to the PD disposable set. If a problem in functionality with this closure mechanism is not noted before an exchange, there may be potential for leakage and risk of contamination of the fluid path. The most likely causes of the breakage of twist clamp component are related to:

- direct exposure of the device to antiseptic solutions containing stress cracking agents such as hydrogen peroxide, alcohol, or antiseptic agents containing alcohol, and
- excessively turning the twist clamp sleeve in an open direction past the resistance occurring at the fully open position of the Transfer Set, called overtorquing of the twist clamp.

The information concerning the use of stress cracking agents is contained in the Instructions for Use (IFU) and states as follows: “Do not apply hydrogen peroxide, alcohol or antiseptic agents containing alcohol to the connectors.” However, as this device is placed by a Healthcare Professional, the patient, who is the final user of the device, may not have the access to the product labeling. Thus, Baxter is requesting PD Healthcare Professionals to deliver this important information to your patients and ask the patients to follow the guidelines provided below at each transfer set installation or exchange:

- The patient should avoid direct contact of the connectors with chemical antiseptic agents, such as hydrogen peroxide, alcohol, or antiseptic agents containing alcohol.
- The patient should ensure that the Transfer Set and Catheter tubing are clean and dry and to always maintain aseptic technique. Failure to do so may result in infection. The patients are to assure his/her hands are clean and dry before touching the Transfer Set.
- The patient should minimize the force used to turn the white twist clamp sleeve when opening the clamp. The twist clamp will rotate freely once it is passed the detent, creating an open fluid path. Additional rotation past the resistance occurring at the fully open position of the Transfer Set may damage the twist clamp and potentially cause leakage and risk of contamination of the fluid path.

Hazard Involved

Improper use of PD Transfer Sets could result in contamination leading to infection or peritonitis.

Action to be taken by customer/user

Baxter is requesting that you take the following actions:

1. Communicate applicable changes to the IFU and information related to product use to your patients.
2. Complete the attached Customer Reply Form (Attachment 1) and return it to Baxter using the contact details provided. Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications.
3. If you distribute the products listed in this communication to other facilities, or if you are a dealer, wholesaler, or distributor/reseller of the products, please forward this communication as appropriate.

Should you have any clinical questions related to this please contact Surecall Baxter Medical Information on 01635 206345 or email surecall@baxter.com.

The MHRA has been notified of this action.



We apologize for any inconvenience this may cause you and your staff. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

- Calling 01604 704 603
- Faxing to: 01604 704688
- Emailing to: uk_shs_qad@baxter.com

Reporting adverse events with PD solutions:

- Calling 01635 206 360,
- Faxing to: 01635 206 281,
- Emailing to: vigilanceuk@baxter.com
- Post to: Pharmacovigilance, Baxter Healthcare Ltd, Wallingford Road, Compton, Berkshire RG20 7QW

Sincerely,

Sharron Greateorex

Sharron Greateorex
Senior Product Manager
Renal Division
Baxter Healthcare

Attachment 1: Customer Reply Form



ATTACHMENT 1- CUSTOMER REPLY FORM
(IMPORTANT PRODUCT INFORMATION LETTER DATED MARCH 2013)

PRODUCT / DEVICE NAME: *Baxter PD Transfer Set*

Product code: *R5C4325, R5C4326, R5C4482, R5C4483, R5C4484*
Batch Number: *All Batches*

Please complete and return one copy of this form per facility either by fax (Fax :01604 704688) or by e-mail (uk_shs_qad@baxter.com) as confirmation that you have received this notification.
A fax cover sheet is not required.

Facility Name and Address: <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title: <i>(Please Print)</i>	
Telephone Number (Including Area Code):	

We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities, and have communicated applicable changes to the IFU and information related to product use to our patients.

Signature/Date: REQUIRED FIELD	<hr/>
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