

**IMPORTANT  
PRODUCT  
INFORMATION**

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, Connection Shield, Minicaps and Opticaps. (For product codes, see Attachment 1 - Table of Product Codes and Names).

Specifically for patients sensitive to iodine, Baxter wants to highlight that, the use of products which contain iodine (i.e., Povidone iodine) (Connection Shield, Minicaps and Opticaps) or for which iodine use is recommended (Transfer Sets and Titanium adapters) could result in adverse reactions.

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 put in contact with disinfectants or antiseptic agents that contain iodine, hydrogen peroxide, alcohol, or bleach.

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 (4<sup>th</sup>) quarter of 2015.

<b>Hazard Involved</b>	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.
<b>Action to be taken</b>	<ol style="list-style-type: none"><li>1. Identify peritoneal dialysis patients who are iodine sensitive.</li><li>2. Communicate this Important Product Information to the applicable patients using Connection Shield, Minicaps and Opticaps.</li><li>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.</li></ol>

4. Complete the enclosed customer reply form and return it to Baxter by either fax to 01604 704688 or scanned email to uk\_shs\_qad@baxter.com. Returning the customer reply form promptly will prevent you from receiving repeat notifications.
5. Forward this Important Product Information letter to your staff, home patients, 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 forwards this Important Product Information communication as appropriate.

We apologise for any inconvenience this may cause you, your staff and your patients. Should you have any clinical questions related to this please contact Surecall Baxter Medical Information on 01635 206345 or email surecall@baxter.com.

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:

- Call 01604 704 603
- Fax to: 01604 704688
- Email to: uk\_shs\_qad@baxter.com

Reporting adverse events with drugs:

- Call 01635 206 360
- Faxing to: 01635 206 281
- Email to: vigilanceuk@baxter.com

The MHRA has been notified of this action.

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

Sincerely,



Aftab Ibrahim  
Senior Product Manager- PD  
Baxter Healthcare Ltd.  
Newbury, Compton- RG20 7QW



## CUSTOMER REPLY FORM

IMPORTANT PRODUCT INFORMATION LETTER DATED FEB 2015

### BAXTER PERITONEAL DIALYSIS TRANSFER SETS, TITANIUM ADAPTERS, CONNECTION SHIELD, MINICAPS AND OPTICAPS PRODUCTS

**Product code:** Please refer to Attachment 1

**Batch Number:** All

Please complete and sign this form.

Email a scanned copy to **uk\_shs\_qad@baxter.com** or fax it to **01604 704688** 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>	
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.
- We have received the above mentioned letter and have disseminated this information to customers/Home Patients.
- We have received the above mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients.

<b>Signature/Date:</b> REQUIRED FIELD	<hr/>
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Attachment 1  
Products Codes and Names Table

<b>Product Code</b>	<b>Product Description</b>
R5C4325	UV-FLASH SOLUTION TRANSFER SET
R5C4326	UV-FLASH SOLUTION TRANSFER SET
R5C4482	MINICAP EXTEND LIFE PD TRANSF
R5C4483	MINICAP EXTD LIFE TRANS SET W/
R5C4484	MINICAP EXTD LIFE TRANS SET W/
SPC4129	LOCKING TITANIUM ADAPTER FOR PERITONEAL DIAL CATH
SPC4211	CON SHIELD I I W/SPONGE IMPERG W/POVIDONE -IODINE SOL
SPC4213	CONNECTION SHIELD I I K WITH POVIDONE -IODINE SOLN
SPC4466	MINI-CAP , W/PVP-I SOLUTION
SPC4486	OPTICAP