January 7, 2015

Dear Peritoneal Dialysis Healthcare Provider:

Baxter Healthcare Corporation is committed to maintaining the highest standards of quality and safety for our products for the patients we serve. Baxter is sending this communication to provide you with important product information to the instructions for use (IFU) for Baxter peritoneal dialysis transfer sets, titanium adapters, disconnect caps and clamshell product codes. See enclosed for product codes, descriptions.

Specifically, Baxter is adding contraindication statements to address iodine allergy for Baxter’s peritoneal dialysis products which contain iodine (i.e., povidone iodine) or for which iodine use is recommended. The changes in the contraindication statements are not the result of a change in any of the products, but are a further enhancement of existing Baxter labeling. Baxter has not received any reports of complaints associated with these products for allergic or adverse reactions to iodine. Furthermore, this action is intended to ensure labeling consistency across the peritoneal dialysis portfolio. These contraindication statements are targeted to be added to product labeling (listed on the enclosed Table of Product Codes) by the fourth (4th) quarter of 2015.

The following contraindication statements are being incorporated into the IFU for Baxter peritoneal dialysis products that contain iodine or have iodine-use statements:

- Disconnect Caps and Clamshells:
  Do not use this product if there is a known history of allergic reaction to iodine. Contact your clinician for further instruction.

- Transfer Sets and Titanium Adapters:
  Do not use povidone-iodine to connect the Transfer Set to the Baxter Titanium Adapter if there is a known history of allergic reaction to iodine. Use other disinfectants or antiseptic agents that do not contain iodine, hydrogen peroxide, alcohol, or bleach.

**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 an adverse reaction if it enters the peritoneal cavity.
Action to be taken if product was purchased directly from Baxter

1. Identify peritoneal dialysis patients who are iodine sensitive.

2. Communicate the changes in the IFU 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 Baxter’s Renal Division Clinical Helpline at 1-888-736-2543, option 2, Monday through Friday, between the hours of 8:00 AM and 5:00 PM Central Time.

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 forwards this Important Product Information communication as appropriate.

If product was purchased from a distributor or reseller

1. Identify PD patients who are iodine sensitive.

2. Communicate the changes in the IFU 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 PD transfer set/adapter installation or exchange. For clinical questions, contact Baxter’s Renal Division Clinical Helpline at 1-888-736-2543, option 2, Monday through Friday, between the hours of 8:00 AM and 5:00 PM Central Time.

4. Forward this Important Product Information letter to other departments or facilities in accordance with your procedures.

5. Follow your supplier’s reply process. Please do not return the customer reply form to Baxter.

Further Information and support

For general questions regarding this Important Product Information letter, please contact The Center for One Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 AM and 5:00 PM Central Time.
We apologize for any inconvenience this communication may cause you, your staff, and your PD patients.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these peritoneal dialysis products may be reported via one of the following options:

• Calling Baxter Product Surveillance at 1-800-437-5176, Monday through Friday, between the hours of 8:00 AM and 5:30 PM, Central Time.
• Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
• Reporting to the FDA by completing and submitting the report online at: www.fda.gov/medwatch/report.htm.
• Reporting to the FDA by regular mail or fax to the FDA: Download the form from www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return it to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

Sincerely,

Rod Mell
Sr. Director, Global Quality
Medical Products
Baxter Healthcare

Enclosures
<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Description</th>
<th>Target Date for Updated Instructions for Use</th>
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<tbody>
<tr>
<td>5C4449</td>
<td>MINICAP Extended Life PD Transfer Set (EASY-LOCK)</td>
<td>Q4, 2015</td>
</tr>
<tr>
<td>5C4482</td>
<td>MINICAP Extended Life PD Transfer Set with Twist Clamp</td>
<td>Q4, 2015</td>
</tr>
<tr>
<td>5C4483</td>
<td>MINICAP Extended Life PD Transfer Set with Twist Clamp (Extra Short)</td>
<td>Q4, 2015</td>
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<tr>
<td>5C4129</td>
<td>Locking Titanium Adapter for Peritoneal Dialysis Catheter</td>
<td>Q4, 2015</td>
</tr>
<tr>
<td>5C4212P</td>
<td>EASY-LOCK, Disconnect Cap with Povidone Iodine Solution</td>
<td>Q4, 2015</td>
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<tr>
<td>5C4213P</td>
<td>Connection Shield II-K, with Povidone Iodine Solution</td>
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<tr>
<td>5C4215P</td>
<td>Connection Shield III, with Povidone Iodine Solution</td>
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<tr>
<td>5C4456</td>
<td>Flexicap Disconnect Cap</td>
<td>Q4, 2015</td>
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<tr>
<td>5C4466P</td>
<td>MINICAP Disconnect with Povidone Iodine Solution</td>
<td>Q4, 2015</td>
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