January 6, 2015

Dear Peritoneal Dialysis Provider:

Baxter Healthcare Corporation is issuing this Important Product Information for MiniCaps in which the sponge was fully separated from the cap, partially protruding from the cap, or missing. Peritoneal dialysis (PD) patients who received potentially affected product directly from Baxter are also receiving a letter mailed directly to them (see enclosure).

<table>
<thead>
<tr>
<th>Affected Product</th>
<th>Product Code</th>
<th>Description</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>5C4466P</td>
<td>MiniCap with Povidone-Iodine Solution</td>
<td>All non-expired product</td>
<td></td>
</tr>
</tbody>
</table>

Problem Description
Baxter received complaints indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap, or missing. See figures below.

<table>
<thead>
<tr>
<th>Sponge is fully separated from the cap</th>
<th>Sponge is protruding from the cap</th>
<th>Missing sponge</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image of sponge fully separated from the cap" /></td>
<td><img src="image2.png" alt="Image of sponge protruding from the cap" /></td>
<td>Sponge is neither present inside the cap nor inside the pouch.</td>
</tr>
</tbody>
</table>

Hazard Involved
Use of MiniCaps with sponges fully separated or missing from the caps may compromise the ability of the MiniCap to provide a sterile barrier protection at the end of the transfer when the transfer set is not connected to the patient line of the automated peritoneal dialysis (APD) cassette or continuous ambulatory peritoneal dialysis (CAPD) twin bag set-ups. This may increase the risk of peritonitis.

Use of MiniCaps with sponges partially protruding from the caps may encourage non-aseptic techniques, such as inadvertently touching the sponge to reposition it inside the cap. This may increase the risk of peritonitis.
Action to be taken by customer/user

1. Upon opening the MiniCap pouch before each exchange, inspect the product to ensure there is no damage to the MiniCap and that the sponge is fully within the cap. Do not use the product if the sponge is protruding or missing from the cap, and obtain a new MiniCap.

2. To arrange for replacement product, contact Baxter Healthcare Center for Service at 888-229-0001, Monday through Friday, between the hours of 7:00 AM and 6:00PM Central Time.

3. Complete the enclosed customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com. Returning the customer reply form promptly will prevent you from receiving repeat notices.

4. If you are a dealer, wholesaler, or distributor/reseller that distributed any of the affected products to other facilities, please forward a copy of this communication to your end users in accordance with your customary procedures.

Further Information and support

- The patient’s notification (see enclosed) instructs them to contact their physician or PD nurse if they have any questions about their PD therapy.
- For clinical questions, contact Baxter’s Renal Clinical Helpline at 888-736-2543, option 2, Monday through Friday, between the hours of 8:00 AM and 5:00 PM Central Time.
- For general questions regarding this communication, contact The Center for One Baxter at 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 may cause you, your staff, and your peritoneal dialysis patients. Baxter Healthcare is currently investigating this issue and will take action accordingly. 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 using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176, Monday through Friday, between 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: Download the form from www.fda.gov/MedWatch/getforms.htm or call 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 800-332-0178.
We look forward to continuing to serve your dialysis needs and we thank you for your cooperation.

Sincerely,

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

Enclosures:  Customer Reply Form
Peritoneal Dialysis Patient Letter
January 12, 2015

Dear Peritoneal Dialysis Patient:

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Use of MiniCaps with sponges partially protruding from the caps may encourage non-aseptic techniques, such as inadvertently touching the sponge to reposition it inside the cap. This may increase the risk of peritonitis.
Action to be taken by customer/user

1. Upon opening the MiniCap pouch before each exchange, inspect the product to ensure there is no damage to the MiniCap and that the sponge is fully within the cap. Do not use the product if the sponge is protruding or missing from the cap, and obtain a new MiniCap.

2. To arrange for replacement product, contact Baxter Healthcare HomeCare Services at 800-284-4060, Monday through Friday, between the hours of 7:00 AM and 6:00 PM Central Time.

3. Complete the enclosed home patient reply form and return it to Baxter by faxing it to 224-270-5457, scanning and e-mailing it to fca@baxter.com or by mail in the enclosed, self-addressed, stamped envelope. Returning the home patient reply form promptly will prevent you from receiving repeat notices.

Further Information and support

- If you have any questions about your peritoneal dialysis (PD) therapy, please contact your physician and/or nurse.

- For general questions regarding this communication, contact The Center for One Baxter at 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 may cause you. Baxter Healthcare is currently investigating this issue and will take action accordingly. 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 using one of the following options:

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Rod Mell
Sr. Director, Global Quality
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Enclosure: Home Patient Reply Form