February 2015

Dear Peritoneal Dialysis Provider,

Baxter Healthcare Corporation is issuing this Important Product Information for MiniCaps which have the sponge fully separated from the cap, partially protruding from the cap or missing from the cap.

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 from the cap. See pictures 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="Picture 1" /></td>
<td><img src="image2.png" alt="Picture 2" /></td>
<td><img src="image3.png" alt="Picture 3" /></td>
</tr>
</tbody>
</table>

Sponge is neither present inside the cap nor inside the pouch.

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 tip of the transfer set, when the patient is not performing a therapy. 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.

There have been no reported adverse events associated with these codes.
### 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 at 0800 820 860.

3. **Complete the enclosed customer reply form and return it to Baxter**.

4. **Please communicate to your patients concerning this problem**, to ensure their correct use of the product. The Baxter Clinical Coordinators are at your and your patients’ disposal for support on this topic.

5. **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

For general questions regarding this communication, contact Baxter Customer Service (0800 820 860) or Baxter Quality Assurance (044 908 52 17 or Switzerland_SHS_CQA@baxter.com).

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 actions accordingly.

Swissmedic has been notified of this action.

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

Sincerely,

Baxter AG