

Urgent Field Safety Notice



28th January 2015

Affected Product MiniCap with Povidone-Iodine Solution
Product Code: SPC4466
Lot Numbers: All non-expired lot numbers

Dear Customer,

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. Peritoneal dialysis (PD) patients who received potentially affected product directly from Baxter, are also receiving a letter mailed directly to them (see enclosure).

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.

Sponge is fully separated from the cap	Sponge is protruding from the cap	Missing sponge
		Sponge is neither present inside the cap nor inside the pouch.
picture 1	picture 2	picture 3

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 this code.

**Action to be
taken by
customer/user**

- 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.
- If replacement product is needed, contact Baxter Healthcare on 01 206 5500, Monday through Friday, between the hours of 9:00 am and 5:30pm.
- Please ensure that your patients are made aware of this issue.
- Complete the enclosed customer reply form and return it to Baxter by faxing it to 01 206 5577 or scanning and e-mailing it to qa_dublin@baxter.com. Returning the customer reply form promptly will prevent you from receiving repeat notices.

**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.
- If you have any questions regarding this communication, please contact your local Baxter Representative or call 01 206 5500.

We apologise 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.

The Health Products Regulatory Agency (HPRA) has been notified of this action.

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

Sincerely,



Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph. 00353 1 2065500

Customer Reply Form**PRODUCT NAME: MiniCap with Povidone-Iodine Solution****Product code: SPC4466****Batch Number: All non-expired lot numbers**

Please complete and return one copy of this form per facility either by fax (Fax :01 206 5577) or by e-mail (qa_dublin@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>	
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.

Signature/Date: REQUIRED FIELD	<hr/>
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