IMPORTANT PRODUCT INFORMATION

January XX, 2015

Dear Peritoneal Dialysis Provider:

Baxter Healthcare 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).

Affected Product

Product Code	Description	Expiration Date
SPC4466	MiniCap with Povidone-Iodine Solution	All non-expired product

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.

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.

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. 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.

We apologize for any inconvenience this may cause you. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative or e-mail to Lily Yip at lily_yip@baxter.com

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to Corynn Tan at chai_hwee_corynn_tan@baxter.com.
- Please report Adverse Events to singapore_patientsafety@baxter.com

The Health Sciences Authority has been notified of this action.

We sincerely apologize for any inconvenience this communication causes and thank you for your continued support.

Sincerely,

Corynn Tan
QA Manager

Enclosures: Peritoneal Dialysis Patient Letter

IMPORTANT PRODUCT INFORMATION

January XX, 2015

Dear Peritoneal Dialysis Patient:

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Affected Product

Product Code	Description	Expiration Date
SPC4466	MiniCap with Povidone-Iodine Solution	All non-expired product

Problem Description

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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.

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Action to be taken by customer/user

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Sincerely,

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Enclosures: Peritoneal Dialysis Patient Letter

