Baxter

Urgent Field Safety Notice

MiniCap Extended Life PD Transfer Sets
FA-2021-058
Device Correction

January DD, 2022 (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

Problem Description

Baxter Healthcare Corporation is issuing a Device Correction for the MiniCap Extended Life PD transfer sets listed below. The following products may cause damage (for example, leaking or cracking), if they come into direct contact with the transfer set:

- Cleaning products such as hand sanitizer, or those containing, but not limited to, hydrogen peroxide, bleach, alcohol or antiseptic agents
- Solvents intended to remove adhesive residue, such as those containing acetone, toluene, xylene, or cyclohexanone

Baxter will be updating the Instructions for Use (IFU) to include a warning against the use of these cleaning products and solvents.

Affected Product (to be adapted locally)

Product Code	Description	Lot #
5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set (6”) with Twist Clamp)	All lots within expiry
R5C4482	MINICAP EXTEND LIFE PD TRANSFER SET	
R5C4483	MINICAP EXTD LIFE TRANSFER SET	
R5C4484	MINICAP EXTD LIFE TRANSFER SET	
R5C4482E	MINICAP EXTEND LIFE PD TRANSFER SET	

Hazard Involved

A damaged or leaking transfer set could result in microbial contamination of the sterile fluid path. This may predispose patients to peritonitis. Baxter has received 13 reports of peritonitis possibly related to this issue. Additional hazards that may result include delay in therapy and exposure to bodily fluids.

Actions to be taken by Customers

1. If you are using one of the above-mentioned cleaning products or solvents, please discontinue use of this product or solvent immediately. Please ensure all home patients are aware of proper cleaning practices. Clinicians who are not using any of the above-mentioned cleaning products or solvents may continue to use Baxter transfer sets.

2. If you have patients who have used the cleaning products or solvents listed above and have identified damage to their transfer set, please replace their transfer set and contact Baxter.

3. Baxter will be updating the Instructions for Use (IFU) for all Luer transfer sets to instruct patients not to allow cleaning products or solvents to come into contact with the transfer set.

4. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter** by either faxing it to (insert local contact information) or scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

5. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions

6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

7. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Device Correction in accordance with your customary procedures.

Further information and support (to be adapted locally)	For general questions regarding this communication, contact Baxter at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

We apologize for any inconvenience this may cause you and your staff.

Sincerely,
Name (to be adapted locally)
Title (to be adapted locally)
Baxter Healthcare Corporation (to be adapted locally)

Baxter

Confirmation of receipt of communication

(DEVICE CORRECTION LETTER DATED XX (TO BE COMPLETED LOCALLY)

MINICAP EXTENDED LIFE PD TRANSFER SETS

Product code : *…. (to be completed locally)*

Serial numbers : *…. (to be completed locally)*

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification.
A fax cover sheet is not required.
(Can be adapted locally)

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Email and/or Telephone Number (including Area Code):	

Signature/Date: REQUIRED FIELD	

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.