Urgent Field Safety Notice

MiniCap Extended Life PD transfer
FA Number: FAV-2024-007
Manufacturer: Baxter Healthcare SA (CH-MF-000026124)
Type of Action: Correction

22nd October 2024

Dear Sir/Madam,

Baxter Healthcare Corporation (Baxter) is issuing a Correction for the MiniCap Extended Life PD transfer sets listed below, which are manufactured with peroxide-cured silicone tubing as a fluid pathway component. These transfer sets are used during Peritoneal Dialysis therapy to transfer peritoneal dialysis solution to the patient catheter from the source solution bag.

Baxter is aware of several recalls by other manufacturers related to the potential risk of exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs) when using certain peritoneal dialysis and hemodialysis devices. The source of the NDL PCBAs and/or NDL PCBs in those recalls was due to the manufacturing process of the silicone tubing, which used a chlorinated peroxide initiator.

Baxter is in the process of evaluating whether these same risks are present with the MiniCap Extended Life PD transfer sets. At this time Baxter does not have data to definitively conclude whether there is a safety risk. Therefore, Baxter is informing you of the potential patient safety risk while our evaluation is in process.

While this evaluation is ongoing, Baxter is also in the process of transitioning certain product codes of the MiniCap Extended Life PD transfer sets from peroxide-cured silicone tubing to platinum-cured silicone tubing. Available information indicates that NDL PCBAs and NDL PCBs are not detected in medical devices with this modified version of silicone tubing. Please note that the exact timing of this transition will vary by geographic region, and that Baxter will continue to make the existing peroxide-cured silicone tubing configuration of the transfer sets available in your country until this transition occurs, as there is currently no definitive data to demonstrate that a patient safety risk exists. The purpose of this letter is to inform you of this current status, and to let you know that as additional data becomes available, Baxter will provide you with further communication if any mitigation measures are necessary for Transfer Sets with the peroxide cured silicone tubing components.

Affected Product

Product Code	Product Description	Lot Numbers
5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots within expiry
R5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	
R5C4482E	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	
R5C4483	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	
R5C4484	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	

Hazard Involved

Polychlorinated biphenyls are persistent organic pollutants that have a negative impact on the ecosystem and all living beings and continue to represent a serious risk to human health. The risks include neuropsychological, neurobehavioral deficits, dementia, immune system dysfunctions, cardiovascular diseases, cancer and harmful effects on the reproductive system. Baxter is in the process of evaluating whether these risks are present with the MiniCap Extended Life PD transfer sets. At this time Baxter does not have data to definitively conclude whether there is a safety risk. To date, Baxter has not received any complaints related to this issue.

Actions to be Taken by Customers

While Baxter's ongoing evaluation into this potential issue continues, we are recommending the following actions:

1. **Healthcare providers should continue to provide dialysis treatments to their patients, as peritoneal dialysis systems are critical to patient care.** Until Baxter has further information available, we recommend the continued use of the peroxide-cured silicone tubing sets to ensure patient compliance with the prescribed therapy.

2. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to device.safety@drugsalesltd.com, 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.

3. If you purchased this product from a distributor, please note that responding via the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.

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

5. 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 notification in accordance with your customary procedures.

6. Please notify your home patients of this Field Safety Notice, as appropriate.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Drugsales Ltd on device.safety@drugsalesltd.com or on 21417070/1/2

The local Malta Medicines Authority has been notified of this action.

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

Sincerely,

Adrian Busuttil
RP/Regulatory Affairs Manager
Drugsales Ltd
Baxter Healthcare representative and distributor in Malta

Enclosures: Baxter Customer Reply Form