**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

Month DD, YYYY (to be adapted locally)

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** (to be adapted)

|  |  |  |
| --- | --- | --- |
| **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 either 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.
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. (to be adapted locally)

**Further Information and Support**

For general questions regarding this communication or any product issue you are experiencing, 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)

Enclosures: Baxter Customer Reply Form

Peritoneal Dialysis Patient Letter