Urgent Field Safety Notice

MiniCap Extended Life PD transfer
FA Number: FAV-2024-005
Manufacturer: Baxter Healthcare SA (CH-MF-000026124)
Type of Action: Safety Alert

October 2024

Baxter Healthcare Corporation is issuing a Safety Alert for the MiniCap Extended Life PD Transfer Sets listed below due to an increase in complaints related to the separation of the female connector from the main body of the transfer set. See Figure 1 below, which illustrates an example of a separation between the dark blue female connector and the light blue main body of the transfer set in which the silicone tubing has become visible. These separations may occur while connecting or disconnecting from PD therapy products. However, as the tubing remains attached to the dark blue female connector during a separation, the sterile fluid path is maintained, and there is no risk of microbial contamination that will result from the separation itself.

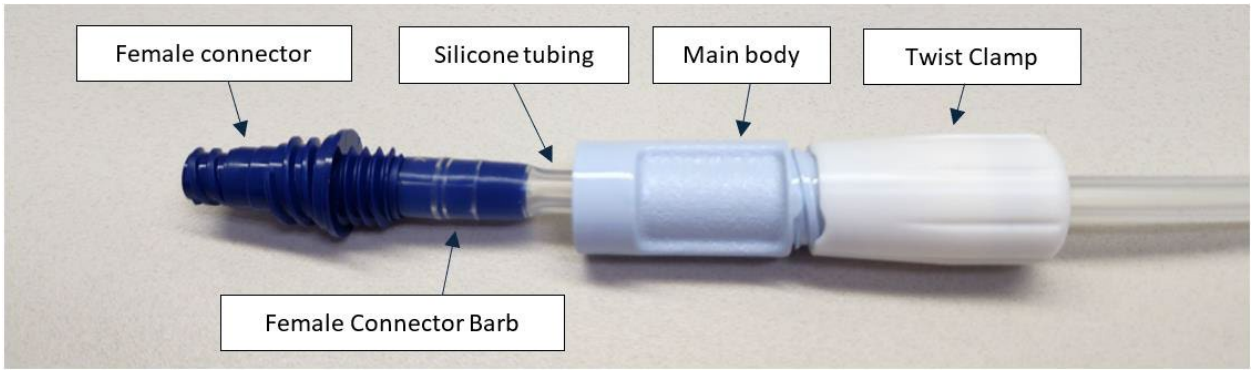

Figure 1. Example of a transfer set separation

Affected Product

Code	Description	Lot Number
5C4482	MINICAP EXTEND LIFE PD TRANSF	Lot H23J16074 and higher
R5C4482	MINICAP EXTEND LIFE PD TRANS	Lot H23K15033 and higher
R5C4482E	MINICAP EXTEND LIFE PD TRANSF	H23J18054, H24G10063
R5C4483	MINICAP EXTD LIFE TRANS SET W/	H23J30067
R5C4484	MINICAP EXTD LIFE TRANS SET W/	H23J23039

Hazard Involved

Separation of the female connector from the main body of the transfer set would not directly lead to a breach in sterility of the fluid path. However, Baxter has received reports of patients subsequently cutting the patient line and/or not following aseptic technique when trying to address the separation. This may increase the risk of peritonitis. Baxter has received 6 reports of peritonitis that are potentially related to this issue.

Actions to be Taken by Customers

1. **This is not a Recall; this is a Safety Alert communication.** If patients' transfer sets are still intact and have not experienced separation issues, please instruct them to continue to safely use the transfer sets while following aseptic technique.
2. If you have a patient who contacts your clinic experiencing separation of the transfer set, please replace their transfer set and contact Baxter.
3. Complete the enclosed customer reply form and return it to Baxter by either scanning and e-mailing it or sending it by post, 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.
4. 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.
5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. 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 Safety Alert in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter.

The local Ministry of Health (MOH) has been notified of this action.

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

Sincerely,

Baxter Healthcare Corporation

Enclosures: Baxter Customer Reply Form
Peritoneal Dialysis Patient Letter