

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

24th 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.

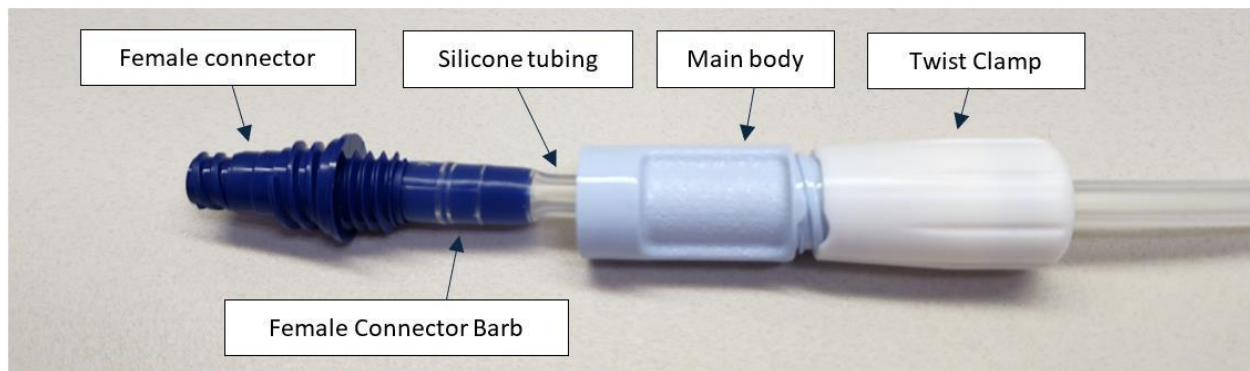


Figure 1. Example of a transfer set separation

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 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.
4. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. 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 Busuttill
RP/Regulatory Affairs Manager
Drugsales Ltd
Baxter Healthcare representative and distributor in Malta

Enclosures: Baxter Customer Reply Form