

SAFETY ALERT

4th November 2024,

Dear Healthcare Providers and Wholesale/Distributors,

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. The affected lots were listed below.

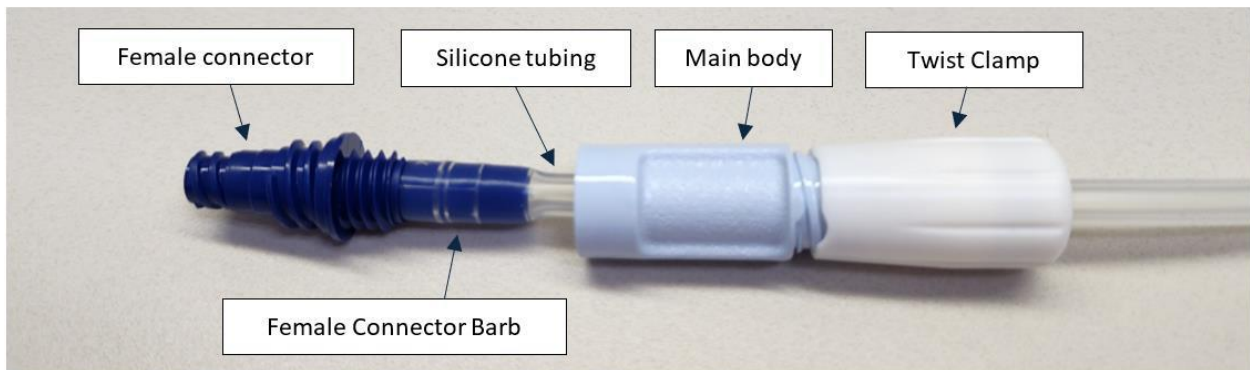


Figure 1. Example of a transfer set separation

Affected Product

Product Code	Product Description	Lot Numbers	UDI Number
5C4483	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short)	H23J10051	0085412007748
		H23J23062	
		H23K20066	
		H24F12046	
		H24F17045	

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. **If you received this communication directly from Baxter, please acknowledge receipt of this letter by completing the Customer Reply Form (Enclosed).** Acknowledging receipt of this notification will prevent you from receiving repeat notices.
4. If you purchased this product from a distributor, please note that responding via the customer reply form 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 and **acknowledge receipt of this letter by completing the Customer Reply Form (Enclosed).**

Further Information and Support

For general questions regarding this communication, please contact Baxter Renal office Malaysia which can be reached at +603-76616990 between the hours of 9.00 am and 5.30 pm, Monday through Friday. Customers should contact their local Baxter sales representative for account- specific issues.

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported via contacting Baxter Product Surveillance by navigating to the Baxter – Product Feedback Portal at <https://productfeedback.baxter.com>

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

Sincerely,



*Electronically signed by:
Wensze Sharon Ding
Reason: I am the author
of this document
Date: Nov 4, 2024 19:53
GMT+8*

Sharon Ding
QA/RA Manager/Pharmacist
Vantive Sdn Bhd (Baxter Renal company)
B-21-3, Level 21, The Ascent Paradigm,
No 1, Jalan SS7/26A, Kelana Jaya,
47301, Petaling Jaya, Selangor

Enclosures: Customer Reply Form