Baxter

Urgent Field Safety Notice

Self-Righting Luer Slip and Luer Lock Tip Caps

FA-2022-035

Recall

Month DD, YYYY (to be adapted locally)

Dear Sir/Madam (to be adapted locally)

Problem Description

Baxter Healthcare Corporation is issuing a Medical Device Recall for all non-expired lots of Self-Righting Luer Slip and Luer Lock Tip Caps listed below due to the potential of the packaging seal not maintaining a sterile barrier for the tip caps. The sterile tip caps are non-invasive medical devices intended to cover the tip of Luer slip and Luer lock dispensers used in parenteral administration to prevent leaks and contamination, and the packaging for these products is meant to maintain a sterile barrier until use. All lots within expiry for the affected product codes listed below are being recalled as the sterile barrier cannot be assured.

These product codes were distributed between 8/14/2019 and 6/17/2022 (to be adapted locally)

Figure 1. Image of a sealed DISCPAC. The sterile breach can occur anywhere along the yellow seal tape, on the edge of the DISCPAC.

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Affected Product
(to be adapted locally)

Product Code	Product Description	Lot Number	Expiry Date	UDI Number
H93866025	TIP CAPS, SELF-RIGHTING LUER SLIP, (DISCPAC, 25 Pack) YELLOW, STERILE	All lots within expiry	7/31/2022 – 1/31/2025	00085412478845
H93866100	TIP CAPS, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) YELLOW, STERILE	All lots within expiry	7/31/2022 – 5/31/2025	00085412478852
H93867025	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 25 Pack) ORANGE STERILE	All lots within expiry	1/31/2023 – 4/30/2025	00085412478869
H93867100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) ORANGE STERILE	All lots within expiry	12/31/2022 – 8/31/2024	00085412478890
H938671100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) WHITE STERILE	All lots within expiry	12/31/2023 – 11/30/2024	00085412479750
H938673100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) DARK BLUE STERILE	All lots within expiry	1/31/2023 – 3/31/2025	00085412479798
H938674100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) GREEN STERILE	All lots within expiry	7/31/2024 – 4/30/2025	00085412479811
H938676100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) PINK STERILE	All lots within expiry	11/30/2023 – 10/31/2024	00085412479859
H938677100	TIP CAP, SELF-RIGHTING LUER SLIP, (DISCPAC, 100 Pack) PURPLE STERILE	All lots within expiry	9/30/2022 – 4/30/2025	00085412479873
H938690025	TIP CAP, SELF-RIGHTING LUER LOCK, (DISCPAC, 25 Pack) YELLOW STERILE	All lots within expiry	7/31/2022 – 4/30/2025	00085412479941
H93869025	TIP CAP, SELF-RIGHTING LUER LOCK, (DISCPAC, 25 Pack) GREEN STERILE	All lots within expiry	7/31/2022 – 4/30/2025	00085412478937

H93869100	TIP CAP, SELF-RIGHTING LUER LOCK, (DISCPAC, 100 Pack) GREEN STERILE	All lots within expiry	1/31/2023 – 3/31/2025	00085412478944
H938693025	TIP CAP, SELF-RIGHTING LUER LOCK, (DISCPAC, 25 Pack) DARK BLUE STERILE	All lots within expiry	8/31/2022 – 12/31/2024	00085412479965

Hazard Involved

If the tip caps become contaminated, the integrity of the sterile fluid path is potentially compromised and there is a possibility of non-sterile medications/fluids being delivered to patients. This may lead to bacteremia and possibly sepsis. There have been no reports of any injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate, isolate/quarantine, and prepare for return any unused affected product from your facility. The product code and lot number can be found on the individual product package labeling and the shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at (insert local contact information) between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling. (to be adapted locally)

3. Complete the enclosed customer reply form and return it to Baxter by either faxing it to (insert local contact information) or 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. **This step is required, per regulatory authorities.**

4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions

5. If you distribute 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 Device Correction in accordance with your customary procedures.

Further information and support (to be adapted locally)	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)

CUSTOMER REPLY FORM related to Product Recall letter dated XXXXXX *(to be completed locally)*

Product Name: (to be adapted locally)
Product code: (to be adapted locally)
Batch Number: (to be adapted locally)

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *Print Name)*	
Title: *Print)*	
Email and/or Telephone Number (Including Area Code)	

Please check boxes as appropriate:

☐ We do not have any of the affected lots in our inventory.

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned

*You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	