Urgent Field Safety Notice

Self-Righting Luer Slip Tip Cap
FA-2022-003
Device Correction

February 2022

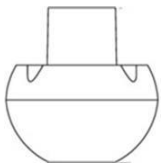
Dear Healthcare Provider:

Problem Description

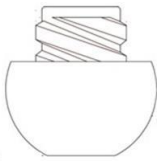
Baxter Healthcare Corporation has received one complaint of a customer getting self-righting Luer **lock** tip caps, yellow (product code H938690025) mislabeled as self-righting Luer **slip** tip caps, yellow (product code H93866100). The packaging contained the self-righting Luer lock tip caps, yellow, but the primary package and outer carton was incorrectly labeled as a self-righting Luer slip tip caps, yellow.

Both products are non-invasive medical devices intended to cover the tip of Luer slip and Luer lock dispensers (syringes) used in parenteral administration to prevent leaks and contamination. The Luer lock tip cap can be identified by threads, whereas the Luer slip tip cap does not have threads (see Figure 1).

Figure 1. Luer slip tip cap vs Luer lock tip cap



self-righting Luer **slip** tip cap



self-righting Luer **lock** tip cap

Affected Product

Product Code	Product Description	Lot Number
H93866100	Self-Righting Luer Slip Tip Cap (DISCPAC, 100 pack), Yellow	60268365
		60268609
		60268610

Hazard Involved

The mislabeled Luer lock tip cap has the potential to be observed prior to use. In the event that it is not observed and used as a Luer slip tip cap, it may lead to an improper fit on Luer lock dispensers, allowing the potential for contamination and/or a delay in therapy to get the correct cap or replace a dose where the cap has fallen off. The user can rotate the Luer lock tip cap onto the dispenser to prevent the loose cap. To date, there have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Please immediately check inventory to locate and segregate the affected product in your facility. If there are Luer lock tip caps co-mingled with Luer slip tip caps in the same DISCPAC container, please discard the DISCPAC container. Tip caps that are not co-mingled can continue to be used safely following good pharmacy practices.

2. Complete the enclosed customer reply form and return it to Baxter by either faxing it or 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. This step is required, per regulatory authorities.

3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

4. 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 in accordance with your customary procedures.

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

Further information and support

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

We thank you for your attention to this important product information.

Sincerely,

Baxter Healthcare Corporation