Baxter

URGENT FIELD SAFETY NOTICE

TPN MULTILAYER Bags
FA-2023-027
Recall

May 2023

Dear Sir/Madam,

Problem Description

In 2021, FA-2021-025 was initiated, related to falsified records to the sterilization process for Diffuplast product at their sterilization supplier. Baxter passed on Diffuplast's instructions to customers. Diffuplast's instruction was to "Continue to use the devices at risk, until an alternative product can be supplied."

As there is now alternative product available, in agreement with DKMA, the impacted lots will be recalled from the Danish market.

Affected Product

Product code	Product name	Lot
E1420OD	TPN BAG MULTILAYER 2000ML	L178FE
E1420OD	TPN BAG MULTILAYER 2000ML	L180FE
E1420OD	TPN BAG MULTILAYER 2000ML	L182FE

Hazard Involved

The product in scope had not been re-sterilized. The use of a non-sterilized product may result in a breach of the sterile fluid pathway potentially causing an infusion of contaminated fluid. Baxter has not received any reports of serious injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and remove all unused affected products 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.

3. 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.**

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 field safety notice 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