



**PRODUCT
RECALL**

May DD, 2021

Urgent Field Safety Notice

Baxter Medication Delivery, Nutrition, and Renal Care Products – Third-Party Incomplete Sterilization Reports *(to be adapted locally)*

Dear Customer, *(to be adapted locally)*

**Problem
Description**

Baxter Healthcare *(to be adapted locally)* was informed by one of our third-party sterilization providers that certain lots of Medication Delivery, Nutrition, and Renal Care products, which are listed in Annex 1 of this notice may not have been properly sterilized, or adequate documentation of sterilization was not provided to Baxter. The risk to patients is that they may have an improperly sterilized product. After a thorough review, Baxter believes the risk to be low, however, to keep patients as safe as possible we are recalling the potentially impacted lots.

Baxter used this third-party provider to sterilize the affected product lots which have been distributed in *your country (to be adapted locally)*. Only products from the lots listed in Annex 1 are being removed from the market.

Note that other Baxter products or product lots, not listed in Annex 1, may also be in your or your patients' possession. These products are considered safe to use.

Baxter is kindly asking that you take the following actions:

**Action to be
taken by
Customers**

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Customers may continue to place orders for product lots that are not listed on Annex 1. Contact Baxter Healthcare Customer Service at XXX to order replacement product *(to be adapted locally)*.
3. Contact Baxter Healthcare Customer Service to arrange for return of the products and credit. Customer Service can be reached at *(to be adapted locally)* between the hours of *country (to be adapted locally)*. Please have your ship-to account number ready when calling.
4. Complete the enclosed Baxter Customer Reply Form and return it to Baxter using one of the following options:
 - scanning and e-mailing it to *(to be adapted locally)*.
 - faxing it to *(to be adapted locally)*.
 - sending it by post to *(to be adapted locally)*.



Please complete the Reply Form even if you do not 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 mandates.

5. 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 per their instructions.
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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 communication in accordance with your customary procedures.

The national regulatory authority *(to be adapted locally)* is informed about this product recall.

If you have additional questions, please contact your Baxter sales representative. *(to be adapted locally)*

Kind regards,

Baxter Healthcare
(to be adapted locally)

Enclosure: Annex 1: Affected Product Table
Baxter Customer Reply Form
Home Patient Customer Letter