

May xx, 2021

FA-2021-027

Subject: urgent product recall - Access Sets, Reconstitution Devices and Nutrition Devices, Acute Set for Children CAPD, PD 3L Empty Bag System II and Apheresis Filter *(to be adapted locally)*

Dear Customer

Description of the issue Baxter was informed about a series of deviations and the manipulation of documentation which occurred at the provider of sterilization services Steril Milano SRL. These deviations concern the parameters and processes defined for ethylene oxide sterilization.

Baxter Healthcare SA has used the sterilization services of Steril Milano SRL for the sterilization of the batches of product listed in Annex 1 and distributed in *country (to be adapted locally)*.

Potential safety risks The deviations to which the impacted devices were exposed, have the potential to compromise the effectiveness of the sterilisation process and subsequent device functionality. However, based on our robust internal evaluation, we concluded that there is no additional risk to the patients who were treated with the impacted products. Nevertheless, due to the reported deviations in the sterilization cycles, Baxter is recalling the products listed in Annex 1 from the *country (to be adapted locally)* market as a precautionary measure.

Action to be taken by the user Baxter is kindly asking that you take the following actions:

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.

Contact Baxter Healthcare Customer Service to arrange for return of the products and credit. The 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.

2. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by one of the following options *(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.

3. 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.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. 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 competent authority *(to be adapted locally)* is informed about this product recall.

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

Kind regards,

Baxter Healthcare
(to be adapted locally)



**Quarantine product /
Do not sell or distribute**

(Customer communication)

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

Product Name: (to be completed locally)

Product code: (to be completed locally)

Lot numbers: (to be completed 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:	
Reply Confirmation Completed By (Please Print):	
Title (Please print):	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate: (to be adapted locally)

- ☐ 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.

(Below paragraph to be removed locally if not applicable)

- ☐ I would like Baxter to contact my patients and will provide support as needed
- ☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

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	<hr/>
--	-------



(Customer communication)

TO BE COMPLETED BY BAXTER PERSONNEL [*\(Below paragraph to be removed locally if needed\)*](#)

Number of product effectively received:

Justification (if discrepancy):