



## PRODUCT RECALL

02 Aug 2021

### Urgent Field Safety Notice

#### **Prismaflex Sets – Third-Party Sterilization Report Falsification**

Dear Customer,

#### **Problem Description**

Baxter Healthcare Ltd used Steril Milano, a third-party contract supplier of sterilisation services, between May and July 2020 to sterilise the lots of Prismaflex Sets listed below due to product processing capacity issues during the Covid-19 pandemic. Baxter was notified that Steril Milano provided inaccurate and/or false documentation related to its sterilization processes. These deviations are related to the parameters and processes defined for Ethylene Oxide sterilisation.

Although an internal Baxter analysis determined that sterility of these product lots was not impacted by the documentation issue, as a precaution, and in collaboration with the notified body BSI, Baxter is recalling all lots of product sterilised by Steril Milano in the United Kingdom.

#### **Affected Product**

<b>Product Code</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>Expiration Date</b>
106697	PRISMAFLEX M100 SET	20B2323M	31-Jan-2022

#### **Hazard Involved**

No adverse health consequences are expected to result from this issue. Nevertheless, Baxter is recalling the products listed above as a precautionary measure. There have been no reports of serious injury associated with this issue.

#### **Action to be taken by Customers**

Baxter is kindly asking that you take the following actions:

1. Locate and quarantine all affected product in your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Complete the enclosed Baxter Customer Reply Form and return it to Baxter using one of the following options:
  - scanning and e-mailing it to [uk\\_shs\\_fca@baxter.com](mailto:uk_shs_fca@baxter.com)
  - faxing it to 01635 206034

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.

3. If you purchased this product from a distributor, please return their reply form as 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 regulatory authority has been informed about this product recall.

If you have additional questions, please contact Baxter at [uk\\_shs\\_fca@baxter.com](mailto:uk_shs_fca@baxter.com).

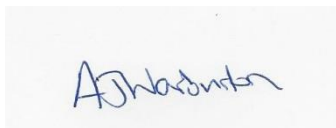
Reporting product quality complaints:  
drugs:

- Call: 01604 704 603
- Fax: 01604 704 688
- Email: [uk\\_shs\\_qa\\_complaints@baxter.com](mailto:uk_shs_qa_complaints@baxter.com)

Reporting adverse events with

- Call: 01635 206 360
- Fax: 01635 206 281
- Email: [vigilanceuk@baxter.com](mailto:vigilanceuk@baxter.com)

Kind regards,



Andrew Warburton  
Business Unit Head UKI, Acute Therapies  
Baxter Healthcare Ltd

Enclosure: Baxter Customer Reply Form



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

**CUSTOMER REPLY FORM related to Product Recall letter dated 02 Aug 2021**

**Product Name: 106697**

**Product code: PRISMAFLEX M100 SET**

**Lot numbers: 20B2323M**

Please complete and return one copy of this form per facility either by fax (Fax: 01635 206034) or by e-mail (uk\_shs\_fca@baxter.com) as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By ( <i>Please Print</i> ):	
Title ( <i>Please print</i> ):	
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
106697	20B2323M	

**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.**

<b>Signature/Date:</b> REQUIRED FIELD	
--	--