



**PRODUCT  
RECALL**

August **DD**, 2021

**Urgent Field Safety Notice**

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

Dear Customer,

**Problem Description** Baxter Healthcare used Steril Milano, a third-party contract supplier of sterilization services, between May and July 2020 to sterilize 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 sterilization.

Although an internal Baxter analysis determined that sterility of these product lots was not impacted by the documentation issue, out of an abundance of caution, and in collaboration with the notified body BSI, Baxter is recalling all lots of product sterilized by Steril Milano in your country.

<b>Affected Product</b>	<b>Product Code</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>Expiration Date</b>
	106696	PRISMAFLEX M60 SET	20B2329M	31-Jan-2022
	106697	PRISMAFLEX M100 SET	20B2323M	31-Jan-2022
	106697	PRISMAFLEX M100 SET	20B2328M	31-Jan-2022
	107144	PRISMAFLEX TPE2000 SET	20B2325M	31-Jan-2023

**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 remove all affected product from your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Contact Baxter Customer Service to arrange for return of the products and credit. Please have your ship-to account number ready when calling.
3. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by either scanning and e-mailing it, faxing it or sending it



by post. 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.

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 per 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 communication in accordance with your customary procedures.

The national regulatory authority in your country is informed about this product recall.

If you have additional questions, please contact your Baxter sales representative.

Kind regards,



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Enclosure: Baxter Customer Reply Form