PRODUCT RECALL

August 1, 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 Saudi Arabia.

Affected Product

Product Code	Product Description	Lot Number	Expiration Date
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 Healthcare Customer Service to arrange for return of the products and credit. Customer Service can be reached at mohamed_alsohagy@baxter.com between the hours of 8:00 AM to 5:00 PM. Please have your ship-to account number ready when calling.

3. Complete the enclosed Baxter Customer Reply Form and return it to Baxter using one of the following option:
    - scanning and e-mailing it to Ahmed_Albalaasi@Baxter.com

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 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 SFDA is informed about this product recall.

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

Kind regards,

Ahmed Albalaasi

Digitally signed by: Ahmed Albalaasi
DN: CN = Ahmed Albalaasi OU = EU, Saudi Arabia, Users, Riyadh
Date: 2021.08.01 15:04:35 +03'00'

Baxter Healthcare

Enclosure: Baxter Customer Reply Form