Baxter

Urgent Field Safety Notice

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Prismaflex Sets
FA-2022-040
Correction

September 29th, 2022

Dear Sir/Madam,

Problem Description

Baxter Healthcare Corporation is issuing a Correction for the Prismaflex sets listed below. This field action is related to the Prismaflex set Instructions for Use (IFU) and not the filter set itself.

The current Prismaflex set IFU is a single booklet containing 27 translated languages, and the following products include a mistranslation in the Estonian (Eesti) IFU. The mistranslation indicates contradictory information related to the patient body weight restrictions. If the Estonian IFU is being used, this could result in incorrect therapy settings or use of product for patients that are outside the intended population.

Baxter will be updating the IFU to correct the translation error.

Affected Product

Product Code	Product Description	Lot Numbers	UDI Number
106696	Prismaflex M60 Set	All lots from 20K1004 and greater	07332414064549
106697	Prismaflex M100 Set	All lots from 20I0110 and greater	07332414064556
109990	Prismaflex M150 Set	All lots from 20I0107 and greater	07332414090005
109841	Prismaflex HF20 Set	All lots from 20D1605 and greater	07332414089443
107140	Prismaflex HF1000 Set	All lots from 20I0503 and greater	07332414069254
107142	Prismaflex HF1400 Set	All lots from 20I0108 and greater	07332414069315
107643	Prismaflex ST60 Set	All lots from 20J2005 and greater	07332414075682
107636	Prismaflex ST100 Set	All lots from 20I0804 and greater	07332414075613
107640	Prismaflex ST150 Set	All lots from 20I0203 and greater	07332414075651

Hazard Involved

The mistranslated IFU could result in use of the product for patients outside of the target population, which may lead to excessive therapy or blood loss in very low-weight patients. User recognition of the erroneous IFU may lead to a delay in initiation of therapy as further clarification is sought. There have been no reports of serious injury related to this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. The use of the Prismaflex HF20 set should be restricted to patients with a body weight greater than 8 kg (18lb).

   The use of the Prismaflex M60 and ST60 sets should be restricted to patients with a body weight greater than 11 kg (24lb).

   The use of the Prismaflex M100, ST100, M150, ST150, HF1000 and HF1400 sets should be restricted to patients with a body weight greater than 30 kg (66lb).

2. Customers who are not referring to the Estonian IFU should continue to follow the IFU instructions in their official language.

1. Please complete the enclosed Baxter Customer Reply Form and return it to QA_Dublin@baxter.com, even if you don't 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 authorities.**

3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

4. 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 Device Correction in accordance with your customary procedures.

5. If you purchased this product from a distributor, please return a copy of your reply form to the supplier according to their instruction.

Further information and support

For general questions regarding this communication, contact Baxter at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Reporting product quality complaints:

- Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:

- Email: vigilanceuk@baxter.com

The local Ministry of Health (MOH) has been notified of this action.

We apologise for any inconvenience this may cause you and your staff.

Sincerely,

Andrew Warburton

Business Unit Head, Acute Therapies

Baxter Healthcare Ltd

Baxter

Confirmation of receipt of communication - 29th September 2022

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Please complete and return one copy of this form per facility either by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Email and/or Telephone Number (including Area Code):	

Signature/Date: REQUIRED FIELD	_____

We have received the above-mentioned letter, performed the actions outlined in the letter, and have disseminated the information / documentation to our staff, other services/facilities and customers, as applicable.