

Urgent Field Safety Notice

Prismaflex Sets
FA-2022-040
Correction

September 15, 2022 (to be adapted locally)

Dear Healthcare Provider: (to be adapted locally)

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.

The German and French IFU are not affected!

Affected Product

(to be adapted locally)

Product Code	Product Description	Lot Numbers	UDI Number
109841	Prismaflex HF20 Set	All lots from 20D1605 and greater	07332414089443
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.

Actions to be taken by Customers

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.
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.

**Further
information
and support**
(to be adapted
locally)

For general questions regarding this communication, contact Baxter at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)

Title (to be adapted locally)

Baxter Healthcare Corporation (to be adapted locally)