10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? AUSTRIA, BELGIUM, BULGARIA,CZECH REPUBLIC, GERMANY, DENMARK, ESTONIA, FINLAND, FRANCE, GREECE, HUNGARY, ICELAND, IRELAND, ITALY, LATVIA, LITHUANIA, LUXEMBOURG, MALTA, NETHERLANDS, NORWAY, POLAND, PORTUGAL, ROMANIA, SLOVAKIA, SLOVENIA, SPAIN, SWEDEN SWITZERLAND, TURKEY, UNITED KINGDOM. <u>Those countries may also report to their Competent Authority</u>: ALBANIA, AZERBAIJAN, BAHRAIN, BELARUS, BOSNIA AND HERZEGOVINA, CROATIA, EGYPT, GHANA, ISRAEL, JORDAN, KAZAKHSTAN, KENYA, KUWAIT, LEBANON, LIBYA, MACEDONIA, MONGOLIA, MONTENEGRO, MOROCCO, NIGERIA, OMAN, PAKISTAN, QATAR, RUSSIAN FEDERATION, SAUDI ARABIA, SERBIA, SOUTH AFRICA, SUDAN, SYRIAN ARAB REPUBLIC, TUNISIA, UKRAINE, UNITED ARAB EMIRATES.	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 19/09/2022	
Reference number assigned by the manufacturer FA-2022-040	
FSCA reference number assigned by NCA	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable)	
2. Information on submitter of the report	
Status of Submitters ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Other (identify the role)	
3. Manufacturer information	
Name Gambro Industries SAS	
Contact name Pascal Pollet	
Address 7 Avenue Lionel Terray	
Postcode 69883	City Meyzieu
Phone	Fax

+33 4 72 45 25 25	+33 4 72 45 25 25
E-mail complaints_europe@baxter.com	Country France
4. Authorized representative information	
Name N/A	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
5. National contact point information	
National contact point name	
Name of the contact person Nguyen Minh Trang	
Address 4 bis rue de la Redoute	
Postcode 78280	City
Phone	Fax
E-mail mv_france@baxter.com	Country France
6. Medical device information	
Class ☐ AIMD Active implants ☐ MDD Class III ☒ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I	 ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system GMDN	Nomenclature code 44601
Nomenclature text: Haemofilter	
Commercial name/brand name/make Prismaflex HF1000 set **Prismaflex HF1400 set** **Prismaflex HF20 set** **Prismaflex M100 set** **Prismaflex M150 set** **Prismaflex M60 set** **prismaflex ST100 set** **Prismaflex ST150 set** **Prismaflex ST60 set**	
Model number N/A	Catalogue number **106696 All lots from 20K1004 and greater** **106697 All lots from 20I0110 and greater** 107140 All lots from 20I0503 and greater **107142 All lots from 20I0108 and greater**

	107636 All lots from 20I0804 and greater **107640 All lots from 20I0203 and greater** **107643 All lots from 20J2005 and greater** **109841 All lots from 20D1605 and greater** **109990 All lots from 20I0107 and greater**
Serial number(s) N/A	lot/batch number(s) Please refer to the table above
Device Manufacturing date	Expiry date
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number 2797	

7. Description of FSCA

Background information and reason for the FSCA

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.

Description and justification of the action (corrective/preventive)

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

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.

Advice on actions to be taken by the distributor and the user

- 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).

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

- Acknowledge receipt of the Field Safety Notice (Using the Customer Reply Form)

- Forward a copy of this customer communication if products are distributed to other facilities or departments within the institution

- Distributors are asked to notify their customers of this communication in accordance with their procedures

Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Attached please find	FSN Status

☐ Field Safety Notice (FSN) in English ☒ FSN in national language ☐ Others (please specify):	☐Draft ☒ Final

Time schedule for the implementation of the different actions

Implementation date : **19/09/2022**
Local targeted closure date : **To be communicated once available**

These countries within the EEA and Switzerland and Turkey are affected by this FSCA
Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☒ EE	☒ ES
☒ FI	☒ FR	☒ UK	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☒ LT
☒ LU	☒ LV	☒ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI
☒ SK	☒ TR								

Candidate Countries:
☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
ALBANIA, AZERBAIJAN, BOSNIA AND HERZEGOVINA, BAHRAIN, BELARUS, CROATIA, EGYPT, GHANA, ISRAEL, JORDAN, KAZAKHSTAN, KENYA, KUWAIT, LEBANON, LIBYA, MOROCCO, MONTENEGRO, MACEDONIA, MONGOLIA, NIGERIA, OMAN, PAKISTAN, QATAR, SERBIA, RUSSIAN FEDERATION, SAUDI ARABIA, SUDAN, SYRIAN ARAB REPUBLIC, TUNISIA, UKRAINE, UNITED ARAB EMIRATES, SOUTH AFRICA.

8. Comments

I affirm that the information given above is correct to the best of my knowledge.

NGUYEN Minh Trang
19 SEP 2022

Signature

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person