Baxter

IMPORTANT PRODUCT INFORMATION

Urgent Field Safety Notice

XX May 2019

Dear Healthcare Provider,

Problem Description

Baxter Healthcare Corporation has received customer reports of kinked access lines observed during treatment using Prismaflex sets. If the kink prevents blood flow, it causes the Prismaflex or Prismax Control Unit to alarm. The issue has been isolated to a subset of lots, based on production dates. The affected products are identified in the table below.

Baxter has implemented corrective actions to mitigate the occurrence of kinks in the access lines of newly manufactured Prismaflex sets.

Affected Product

Product Code	Product Description	Lot Numbers
106697	Prismaflex M100 set	All lots with expiration dates between 2020-03-01 – 2021-03-01
107140	Prismaflex HF1000 set	All lots with expiration dates between 2020-03-01 – 2021-02-01
107640	Prismaflex ST150 set	All lots with expiration dates between 2020-03-01 – 2021-02-01
107144	Prismaflex TPE2000 set	All lots with expiration dates between 2021-01-01 – 2022-02-01
955503	OXIRIS S	All lots with expiration dates between 2020-03-01 – 2021-03-01

Hazard Involved

A kinked access line has the potential to cause delay in therapy, blood circuit clotting as a result of reduced blood flow, or hemolysis. There have been no reports of serious injury associated with this issue and any are expected to be unlikely.

Actions to be Taken by Customers

1. Customers can continue to safely use the affected Prismaflex sets listed above. If a kink is observed before treatment, the Prismaflex set must be replaced as instructed by the Instructions For Use. If a kink is identified during treatment, therapy must be interrupted, extracorporeal blood in the circuit returned to the patient per normal procedure, and the set must be replaced to continue therapy.

2. **If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter** by faxing it to 01 206 5577, or scanning and e-mailing it to qa_dublin@baxter.com, **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.

3. 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 according to their instructions.

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 distribute this notification to customers.

Further information and support	For general questions regarding this communication, contact Baxter at qa_dublin@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:	**Reporting adverse events with drugs:**
• Call: 01 206 5500	• Call: 0044 1635 206 360
• Email: SHS_Complaints_Dublin@baxter.com	• Email: vigilanceuk@baxter.com

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

Yours Sincerely,

[redacted]

Marketing Manager, Acute Therapies, UK and Ireland
Baxter Healthcare Ltd.

Enclosure: Affected Product Table for specific lots impacted

Baxter

Confirmation of receipt of communication

(IMPORTANT PRODUCT INFORMATION LETTER DATED XX MAY 2019)

Product Code and Baxter Numbers as Detailed in the Letter.

Please complete and return one copy of this form per facility either by fax (Fax: 01 206 5577) or by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification. A fax cover sheet is not required.

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

☐ We have received the above-mentioned letter and have disseminated this information to our staff, other services and facilities.

☐ We have received the above-mentioned letter and have disseminated this information to customers/Home Patients. (If applicable)

Signature/Date: **REQUIRED FIELD**	_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.