Baxter

IMPORTANT PRODUCT INFORMATION

3 October 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. The affected lots were distributed beginning in June 2018 in Singapore.

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

Affected Product (Singapore)

Product Code	Product Description	Lot Numbers
106697	Prismaflex M100 set	All lots with expiration dates between 2020-03-01 – 2021-03-01
107144	Prismaflex TPE2000 set	All lots with expiration dates between 2021-01-01 – 2022-02-01
112016	OXIRIS set	All lots with expiration dates between 2020-04-01 – 2021-02-01
800540	MARS Treatment Kit type 1116/1 X-MARS	All lots with expiration dates between 2020-11-30 – 2021-10-31

Do note: There are other identifiers and/or lots affected globally but not supply in Singapore. Kindly verify with Baxter if in doubt.

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. Kindly complete the enclosed Baxter Customer Reply Form and return it to Baxter by e-mailing it to Baxter Representative. Returning the customer reply

form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

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

The Health Sciences Authority (HSA) has been notified of this action. If you have questions regarding this communication or if you have any other questions, please call your Baxter Sales Representative.

Please kindly report any quality problems or any adverse events associated with the product to the following personnel:

- Please report Product Complaints to singapore_productcomplaint@baxter.com
- Please report Adverse Events to singapore_patientsafety@baxter.com

We sincerely apologize for any inconvenience this communication causes and thank you for your continued support. This field action will take additional measures to further ensure patient safety.

Sincerely,

Corynn Tan
Senior Manager, QA

cc: Chairman Medical Board and relevant Head of Departments
Enclosure: Customer Reply Form

CUSTOMER REPLY FORM

October 3, 2019

FA-2019-019

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Please complete and sign this form.
Email a scanned copy to [redacted] as a confirmation that you have received this notification. A cover sheet is not required.

Please complete this reply form even if there is no remaining inventory at your facility. Ensure that all fields below are completed. Responding to this request will prevent unnecessary repeat notifications for this issue.

Please note that ***BAXTER CANNOT PROCESS UNSIGNED FORMS.***

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____

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