

## IMPORTANT PRODUCT INFORMATION

April XX, 2019 (to be adapted locally)

Dear Healthcare Provider (to be adapted locally):

**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 Prismaflex Control Unit to alarm (to be adapted locally). 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.

(to be adapted locally)

| 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 |
| 107142       | Prismaflex HF1400 set      | All lots with expiration dates between 2020-03-01 – 2021-01-01 |
| 109990       | Prismaflex M150 set        | All lots with expiration dates between 2020-03-01 – 2021-03-01 |
| 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 |
| 107636       | Prismaflex ST100 set       | All lots with expiration dates between 2020-03-01 – 2021-02-01 |
| 955503       | OXIRIS S                   | All lots with expiration dates between 2020-03-01 – 2021-03-01 |
| 112016       | OXIRIS set                 | All lots with expiration dates between 2020-04-01 – 2021-02-01 |
| 112017       | Septex set                 | All lots with expiration dates between 2021-07-01 – 2022-01-01 |
| 114877       | Prismaflex HP-X set        | All lots with expiration dates between 2021-04-01 – 2022-03-01 |
| 107642       | Prismaflex Adsorba 150 kit | All lots with expiration dates between 2020-05-01 – 2021-01-01 |

**Affected Product**  
**(to be adapted locally)**

|        |                                          |                                                                   |
|--------|------------------------------------------|-------------------------------------------------------------------|
| 800540 | MARS Treatment Kit type<br>1116/1 X-MARS | All lots with expiration dates between<br>2020-11-30 – 2021-10-31 |
|--------|------------------------------------------|-------------------------------------------------------------------|

**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 [\(insert local contact information\)](#), or scanning and e-mailing it to [\(insert local contact information\)](#), **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.

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

Sincerely,

[Redacted Signature]

Baxter Healthcare Corporation **(to be adapted locally)**

Enclosure: Affected Product Table for specific lots impacted

**Confirmation of receipt of communication**

(IMPORTANT PRODUCT INFORMATION LETTER DATED XX (TO BE COMPLETED LOCALLY))

**Product Name:.... (to be completed locally)**

**Product code: .... (to be completed locally)**

**Batch numbers: .... (to be completed locally)**

Please complete and return one copy of this form per facility either by fax (Fax: \_\_\_\_\_) or by e-mail (\_\_\_\_\_) as confirmation that you have received this notification.  
A fax cover sheet is not required.  
*(Can be adapted locally)*

|                                                         |  |
|---------------------------------------------------------|--|
| Facility Name and Address:<br>(Please Print)            |  |
| Reply Confirmation Completed By:<br>(Please print name) |  |
| Title:<br>(Please print)                                |  |
| Email and/or Telephone Number<br>(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. *(to be adapted locally)*
  
- We have received the above-mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients. *(to be adapted locally)*

|                                                 |  |
|-------------------------------------------------|--|
| <b>Signature/Date:</b><br><b>REQUIRED FIELD</b> |  |
|-------------------------------------------------|--|

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