Baxter

MOH LETTER

April 24th, 2019

IMPORTANT PRODUCT INFORMATION

Subject: Field Safety Notice – Prismaflex Sets Family and MARS Kits - Kinks in Access Bloodline

Product names: Prismaflex Sets, OXIRIS S, OXIRIS Set, Prismaflex MARS, Septex set, Prismaflex Adsorba

Product codes: 106697, 107140, 107142, 107144, 107636, 107640, 107642, 109990, 112016, 112017, 114877, 955503, 800540

Lot Numbers: Several lots

Dear Sir/Madam,

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.

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

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. Baxter is sending an Important Product Information letter to instruct healthcare providers that 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.

Our records indicate that customers have received this product in your market. For your information, please find attached the communication that is being sent to those customers.

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Should you have any questions, please contact Baxter.

Yours Sincerely,

Ági Zag

Ági Zag, 24 APR 2019

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