Baxter

(MOH letter)

PRODUCT RECALL

10 January 2018

Subject: Field Safety Notice – Product Recall – MARS Treatment Kit - Inadequate Adhesive Connection for the MARS Tube Set

Product Name: MARS Kit Gambro, Type 1116/1 - X-MARS

Product Codes: 800540

Lot numbers: 22651, 22760

Dear Sir/Madam

Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lot numbers of MARS Treatment Kit listed above. The MARS method is used to remove protein-bound and/or water-soluble toxins from the blood. Baxter has received customer complaints regarding leakage in the albumin circuit. The leakage was caused by an inadequate adhesive connection of the tubing to the Hansen connector of the MARS Tube Set (manufactured by an external supplier), part of MARS Treatment Kit.

An undetected leaking albumin circuit could lead to excessive fluid removal from the patient during albumin dialysis. This could lead to hypovolemia. Delay or interruption of therapy may also occur if the issue is detected during priming. Baxter has not received any reports of adverse events or patient injury associated with this issue.

Baxter will ensure that the appropriate corrective and preventive actions are implemented at supplier of the MARS tube set and at Baxter level to avoid reoccurrence of this issue.

Baxter is asking its customers to locate and remove all affected products from their facilities.

Our records indicate that 1 customer have received this product in Croatia.
All received inventory is quarantined at Agmar wholesale, no distributrion was done to final users.

For your information, please find attached the communication that is being sent to Agmar.
Should you have any questions, please contact Monika Lichniak monika_lichniak@baxter.com

Yours Sincerely,

10 Jan. 2018

Monika Lichniak
FCA Coordinator CE