

(SFDA Notification letter)

May 05th, 2020

Subject: Field Safety Notice – Safety Alert – Artiset Blood Tubing Sets (for Artis machines) – Tube Disconnections

Product Names: Artiset Tubing Set: Ultra HDF Post Line and Artiset HD DNL HC

Product Codes: 955037 and 955075

Lot numbers: Refer to Attachment A – Affected Product Table for a complete list

Dear NCMDR Team,

Baxter Healthcare Corporation is issuing a Safety Alert regarding ArtiSet Blood Tubing Sets (for Artis machines) due to reports of disconnection events. The issue has been isolated to a subset of lots, based on production dates. A disconnection event may result in external blood loss, air embolism, or delay in therapy. Baxter has received three reports of serious injury associated to this issue.

Currently the demand for this product has greatly exceeded supply and there are no alternative suppliers of this product. The product quality issue can be detected during set-up or priming of the device. Baxter is asking that customers perform product inspections to check the sets for disconnections prior to use to minimize the disruption of required hemodialysis treatments.

Following root cause investigation, Baxter has identified corrective actions to mitigate the occurrence of tube disconnection events on the Artis Blood Tubing sets.

Our records indicate that 02 customers (our distributors Farouk Maamoun Tamer and Company and Med-Surg Supplies) have received this product in Saudi Arabia.

Should you have any questions, please contact Alaa Alosaimi at +966 11 4343 718

Yours Sincerely,



Ziad Awadallah, CQA Manager Gulf, Baxter AG.

P.O. Box 246968 Riyadh 11312 Saudi Arabia

Phone : +966 11 4343 714/ Fax : +966 11 4343 777

E-mail : ziad_awadallah@baxter.com

Attachment A: Affected Lot Numbers

Product Code: 955037 Ultra HDF Post Line
Lot Number
1000226214

Product Code: 955075 Artiset HD DNL HC	
Lot Number	Lot Number
1000198920	1000224761
1000198921	1000224764
1000198926	1000224765
1000198929	1000224772
1000198932	1000224773
1000198933	1000225446
1000198934	1000226693
1000204793	1000229614
1000204794	1000229615
1000204800	1000229619
1000205909	1000229621
1000205910	1000229625
1000206890	1000231277
1000208210	
1000208214	
1000208217	
1000208236	
1000210332	
1000210337	
1000211706	
1000211714	
1000214635	
1000217374	
1000218863	
1000220508	
1000220509	
1000220510	
1000220524	
1000220526	
1000223055	
1000224760	