Urgent Field Safety Notice

ARTISET TUBING SET AND CARTRIGDE
FA-2020-020
Safety Alert

April XX, 2020 **(to be adapted locally)**

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation has received customer complaints of various disconnection events with Artiset blood tubing sets (for Artis dialysis machines) and Cartridge sets (for Phoenix/Innova dialysis machines) **(to be adapted locally)**. The issue has been isolated to a subset of lots, based on production dates. Please see the product codes and lot numbers potentially affected by this issue listed below.

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.

Baxter has implemented corrective actions to mitigate the occurrence of disconnections in newly manufactured sets.

Affected product table (to be adapted locally)

Product Code	Product Description	Lot Number
113898	EVOSET AFB K INFUSION	Refer to Attachment A
114510	CARTRIDGE WITH HEMOSCAN	Refer to Attachment A
114533	ARTISET HD SN HC	Refer to Attachment A
114598	CARTRIDGE EXTENDED PATIENT LINES	Refer to Attachment A
114599	CARTRIDGE EXT/ PATIENT LINES + INFUSION	Refer to Attachment A
114611	CARTRIDGE STANDARD	Refer to Attachment A
114613	CARTRIDGE LOW WEIGHT LOW VOLUME	Refer to Attachment A
114614	CARTRIDGE SINGLE NEEDLE	Refer to Attachment A
115283	ULTRA HDF LINE	Refer to Attachment A

955037	ULTRA HDF POST LINE	Refer to Attachment A
955075	ARTISET HD DNL HC	Refer to Attachment A
955077	ARTISET PREPOST	Refer to Attachment A
955526	PHYSIOSET HD DNL HC	Refer to Attachment A

Hazard Involved

A disconnection event may result in blood loss, air embolism, or delay in therapy. Baxter has received three reports of serious injury related to blood loss as a result of disconnection events.

Actions to be taken by Customers

1. Prior to use, thoroughly inspect each connection of the set to check for any detachments in the tubing. Operators may continue to safely use affected sets if no detachments are observed. Additionally, per the Instructions for Use (IFU), users should observe carefully for leaks during priming and use and examine the tubing carefully to be certain that all connections are secure, all lines are unobstructed and that there are no kinks or leaks in the tubing.

2. If you find sets with tubing disconnections, please contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at **(insert local contact information).** Please have your ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

3. **If you purchased this product directly from Baxter, a customer reply form is included in your mailing. Please complete the enclosed Baxter customer reply form and return it to Baxter by faxing it (to be adapted locally), 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.

4. 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.

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

6. 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 and **check the associated box on the reply form (to be adapted locally)**.

Further information and support For general questions regarding this communication, contact Baxter at **(insert local contact information),** between the hours of **(insert local information).**

We apologize for any inconvenience this may cause you, your team, and our patients.

Sincerely,

Name **(to be adapted locally)**
Title **(to be adapted locally)**
Medical Products **(to be adapted locally)**
Baxter Healthcare Corporation **(to be adapted locally)**

Enclosure: Baxter Customer Reply Form
Attachment A - Affected Product Table