Baxter

Urgent Field Safety Notice

ARTISET TUBING SET
FA-2020-020

30th April 2020

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). 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

Product Code	Product Description	Lot Number
955075	ARTISET 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 01 206 5500**.** 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 scanning and emailing to qa_dublin@baxter.com, 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.

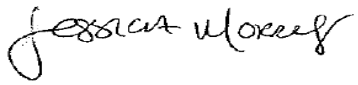
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

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.**

Further information and support

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Baxter Dublin Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Yours sincerely,



Jessica Morris
QA Specialist / Responsible Person

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