Baxter

Product Recall

ARTISET HD DNL HC
FA-2022-009
Recall for lot # 21K03V497

23rd March 2022

Dear Sir/Madam,

Problem Description

Baxter Healthcare Corporation is issuing a voluntary product recall for one lot of Artiset Blood Tubing Sets listed below due to reports of tubing disconnection events.

Affected Product

Product Code	Description	Lot #
955549	ARTISET HD DNL HC	21K03V497

Hazard Involved

A disconnection event may result in blood loss, air embolism, or delay in therapy.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and remove all affected product lots from your facility. The product code and lot number can be found on the individual product or shipping carton.

2. **Complete the enclosed customer reply form and return it to Baxter by e-mailing it to qa_dublin@baxter.com, even if you don't have any inventory**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. **This step is required, per regulatory authorities.**

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

Further information and support	For general questions regarding this communication or any product issue you are experiencing, contact Baxter Customer Services at shs_customer_services_dublin@baxter.com or phone 01 206 5500.

Reporting product quality complaints:

- Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:

- Email: vigilanceuk@baxter.com

The local Ministry of Health (MOH) has been notified of this action.

We apologise for any inconvenience this may cause you and your staff.

Sincerely,

Lucia Cardone
Senior Product Manager HD | Renal Care
Baxter Healthcare Ltd

CUSTOMER REPLY FORM related to Product Recall letter FA-2022-009 dated 23rd March 2022.

Product Name: ARTISET HD DNL HC
Product code: 955549
Lot Number: 21K03V497

Please complete and return one copy of this form per facility by e-mail (**qa_dublin@baxter.com**) as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *Print Name)*	
Title: *(Print)*	
Email and/or Telephone Number (Including Area Code):	

Please check boxes as appropriate:

☐ We do not have any of the affected lot in our inventory.

☐ We do have the affected lot in our inventory and products have been quarantined.

Please list the quantity of the specific lot to be returned below*:

Product Code	Lot number	Quantity in units to be returned
955549	21K03V497	

*You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	