Urgent Field Safety Notice

ARTISET HD DNL HC
FA-2019-055
Recall

PRODUCT RECALL

xx October 2019

Dear Healthcare Provider:

You are receiving this information as you have received some product affected by this issue:

Problem Description

Baxter Healthcare Ltd. is issuing a voluntary product recall for the ArtiSet Blood Tubing Sets listed below due to the potential for an occlusion of the blood circuit pathway just after the pump segment.

Affected Product

Product Code	Product Description	Lot Number
955075	ARTISET HD DNL HC	1000218861

Hazard Involved

Occlusion of the blood tubing set may result in delay in therapy or minor blood loss; however, serious adverse health consequences are not expected. There have been no reports of serious injury associated with this issue.

Actions to be taken by Customers

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

2. Since only certain lots are impacted by this Recall, you can continue to order other unaffected lots of the ArtiSet Blood Tubing Sets.

3. **If you purchased this product directly from Baxter, complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to** 01 206 5577 or 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, contact your supplier for return and credit. Please note 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 conduct a consumer-level recall of the affected product that you distributed to customers.

Further information and support

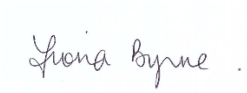
For general questions regarding this communication, contact Baxter at qa_dublin@baxter.com

Reporting product quality complaints:
- Call: 01 206 5500
- Email: SHS_Complaints_Dublin@baxter.com

Reporting adverse events with drugs:
- Call: 0044 1635 206 360
- Email: vigilanceuk@baxter.com

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

Sincerely,



Fiona Byrne
Head of Renal Care Ireland
Baxter Healthcare Ltd.

Enclosure: Baxter Customer Reply Form

Baxter

Quarantine product / Do not sell or distribute

CUSTOMER REPLY FORM related to Product Recall letter dated XXXXXX

PRODUCT NAME: *ArtiSet HD DNL HC*

Product codes*: 955075*

Batch/Serial Number*: 1000218861*

Please complete and return one copy of this form per facility either by fax 01 206 5577 or 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:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate:

☐ We do not have 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
955075	1000218861	

*You may attach an additional sheet if required.

☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

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	_____