Baxter

Follow-up Communication

Urgent Field Safety Notice

02nd August 2017

Dear Customer,

Affected Product

Product Code	Product Description	Lot Number
114533	Artiset HD SN HC	Lot 1634 and onwards

Problem Description

On December 08th, 2016, Baxter Healthcare Corporation issued an Urgent Field Safety Notice communication to inform customers of the potential for disconnection of the ArtiSet bloodline (luer of arterial and/or venous patient connector) from the patient access site (needle/catheter) during treatment. The reports of disconnection of the ArtiSet bloodline from the patient access site were caused by the healthcare provider improperly connecting the two devices. To address this issue, Baxter provided additional instructions on how to properly connect the devices. Refer to the enclosed Urgent Field Safety Notice dated December 08, 2016 for those instructions.

Hazard Involved

Disconnection of the bloodline from the patient access site due to an improper connection of the patient access line could result in serious adverse health consequences such as air embolism and/or blood loss. Baxter received sporadic events reporting an inappropriate connection between the bloodline and the patient access site, resulting in external blood loss for the patient.

Actions taken by Baxter to avoid reoccurrence of the issue

With the aim of increasing effectiveness of the corrective action, a decision was taken by Baxter to reintroduce the original patient connector design implemented in ArtiSet bloodlines, before the introduction of the patient connector design involved in this Field Action. Bloodlines with the original patient connector design will be reintroduced starting with lot number 1724. Baxter will not be updating the Bloodlines Instruction for Use as the connectors affected by this field action (lots listed above through lot 1723) are no longer being produced.

For your reference, the patient connector involved in the FA and the original patient connector (which will be reintroduced on ArtiSet bloodlines) can be distinguished based on some visual differences explained below.

Patient connector involved in this field action (lots listed above through lot 1723)

Original patient connector

- Coupling nut (blue end piece): the original connector is slightly transparent with a different shape and is movable in axial direction.
- Wings of the body (clear piece): no wings are present on the original connector.

Actions to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Clinicians may continue to safely use the Bloodsets with the old connectors by closely following the enclosed instructions for use.

2. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to qa_dublin@baxter.com or sending it by post to Quality Department, Baxter Healthcare Ltd., Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin 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.

3. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

4. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

Further information and support

For general questions regarding this communication, contact your local Baxter Representative.

The Health Products Regulatory Authority (HPRA) has been informed about this follow-up communication.

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

Sincerely,

Niamh Farrelly
CQA Team Leader, Quality
Baxter Healthcare Ltd.,
Unit 7 Deansgrange Business Park,
Blackrock,
Co. Dublin.

Attachment 1: Baxter Customer Reply Form
Attachment 2: Customer Communication dated December 08th, 2016

Baxter

Attachment 1: Customer Reply Form

URGENT FIELD SAFETY NOTICE (FOLLOW-UP COMMUNICATION) DATED *01ST AUGUST 2017*

Product name: **Artiset HD SN HC**

Product codes: 114533

Please complete and return one copy of this form per facility either by fax (01 206 5547) or by e-mail (qa_dublin@baxter.com) as confirmation that you have received this notification. A fax cover sheet is not required.

Customer Confirmation

We confirm that that we have have received the above mentioned letter, understood its content, and have disseminated this information to our staff, other services and facilities.

We confirm that we have received the above mentioned letter, understood its content and have disseminated this information to our Customers

Facility Name and Address: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name and Title)*	Print Name:_____ Title: _____
Email and/or Telephone Number (Including Area Code):	
Signature/Date: ***REQUIRED FIELD***	_____/____/____