Urgent Field Safety Notice

08th December 2016

Dear Customer,

Affected Product

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

Problem Description

Baxter Healthcare Corporation is issuing a Safety Alert 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. Baxter has identified a potential for increased likelihood of disconnection during post-market surveillance activities. The arterial and venous patient connectors are designed in compliance with the applicable International Standards ISO594 and ISO8638, allowing safe connection to vascular accesses. The post-market surveillance 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 is providing additional instructions on how to properly connect the devices.

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

In order to further enforce the above provided recommendations, Baxter is committed to update the Bloodlines Instruction For Use including the additional information for a proper screwing of the patient connectors.

Actions to be taken by the user

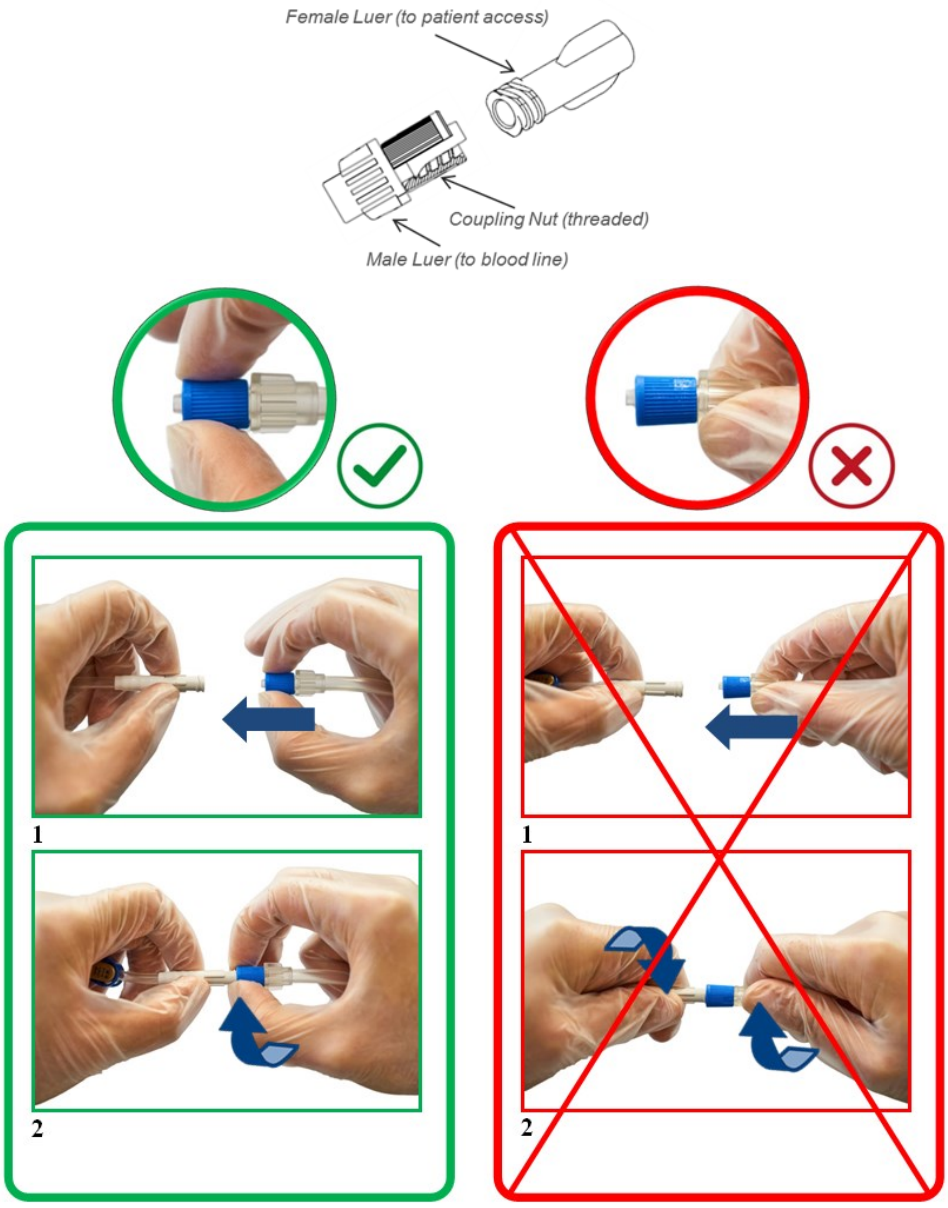
To ensure a secure connection between the female luer (to patient access) and the male luer (to bloodline), Baxter is providing additional instructions below on how to properly connect and to avoid a disconnection.

1. Insert the male luer cone in the female connector. Stop upon perception of

complete adherence between the two components.

2. Screw the male luer coupling nut on the female component until perception of the end stop.
3. After the connection is completed, check that the male luer coupling nut is firmly screwed.

During the whole connection procedure for both arterial and venous patient lines (red and blue coupling nuts), **hold and screw the male luer coupling nut only**. Do not apply the screwing torque to the male luer body.



Besides, Baxter is kindly asking that you take the following actions:

1. 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.

2. 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.

3. 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 action.

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

Sincerely,

_____

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply Form

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SAFETY ALERT DATED 08TH DECEMBER 2016

Product name: **Artiset HD SN HC**

Product code: 114533

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.

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***	_____/____/____

