Baxter

Urgent Field Safety Notice RECALL

26th June 2015

Dear Customer

Affected Product

Product Code	Description	Lot #	Expiration Date
VMC9609	Flo Gard 6201 Compatible Blood Set	14L17V882	November 2019

Problem Description

Baxter Healthcare is issuing a voluntary recall ofthe above affected lot number of Flo Gard 6201 Compatible Bloodset due to complaints received for the spike of the set detaching from the main body.
The root cause was determined to be due to lack of solvent application on this manually assembled junction on some of the units.

Baxter has started internal investigations that confirmed that only this lot was impacted. Appropriate corrective and preventive actions will be put in place to avoid reoccurrence of such issue in the future.

Hazard Involved

A disconnection may lead to a breach in the sterility of the fluid path with subsequent contamination. This may predispose patients to blood stream infections. A disconnection may also lead to blood loss and delay in treatment, and may also expose healthcare staff to a risk of infection. At this time, there have been no reports of adverse events received.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and remove all products with code number and batch number as listed in this communication from yourfacility. If you distribute these products to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they also locate and remove the affected products (the product code can be found on the individual product package and shipping carton).

2. If you are a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, please notify your customers of this action so that they can locate and remove all affected products.

3. Acknowledge your receipt of this recall notification by completing the attached Customer Reply Form and return to Baxter by either faxing it to 01 206 5577 or scanning and emailing it to QA_Dublin@baxter.com. Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications Baxter will contact you to organise return and replacement of the recalled products.

We apologise for any inconvenience this may cause you and your staff. Any adverse reactions or quality problems experienced with the use of this product must be reported through your local Baxter Representative.

Please note that the Health Products Regulatory Authority (HPRA) has been notified.

Yours Sincerely,

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

Baxter

CUSTOMER REPLY FORM related to Product Recall letter dated 26th June 2015

Flo Gard 6201 Compatible Blood Set Baxter

Product code: VMC9609
Batch Number: 14L17V882

Please complete and return one copy of this form per facility either by fax (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 any of the affected lots 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
VMC9609	14L17V882	

Please quarantine all affected product and prevent from use until it is collected by Baxter

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	_____