Baxter

PRODUCT RECALL

29th April 2019

Dear Sir/Madam

Affected Product

Product Code	Description	Lot #
EMC0062M	EXTENSION SET 76CM W/LUERLOCKADAPTOR	14F19V680N 14I16T737N 14J01T126N 14K24T469N 15F14T705N 15J31T031N 15K28T389N 16A11T042N 16B24T355N
EMC9190	CATHETER EXTENSION SET WITH CLEARLINK - MALE LUER LOCK ADAPTER	17J18T018

Problem Description

Baxter Healthcare Corporation is issuing a voluntary product recall for the Extension Sets listed below due to a potential sterility breach between the luer and the cap. This issue was identified during routine product testing. Only sets which were assembled using caps manufactured during a defined period, failed the testing. The affected lots were distributed between 24 July2014 and 04 April2018.

Hazard Involved

A breach in the cap-to-luer interface may result in delay or interruption of therapy, under delivery, unintended drug exposure, air embolism and blood stream infection. There have been no reports of adverse events associated with this issue.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Contact Baxter Healthcare Customer Services to arrange for return and credit. Baxter Customer Services can be reached at 01-206 5500 between the hours of 9am-5:30pm. Please have your ship-to account number, product code, lot number and quantity of the product to be returned ready when calling.

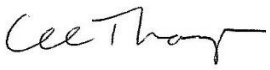
3. Complete the enclosed Customer Reply Form, and return it to Baxter by either faxing it to 01 206 5577 or by scanning and e-mailing it to qa_dublin@baxter.com , even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you are a dealer, wholesaler, or distributor/reseller that distributed affected product to other facilities, please conduct a recall with your end-user customers in accordance with your customary procedures.

Further information and support	For general questions regarding this communication, contact Baxter at qa_dublin@baxter.com.

We apologise for any inconvenience this may cause you and your staff. The HPRA have been notified.

Yours faithfully,



Lee Thompson
Product Executive, Fluid Systems
Baxter Healthcare Ltd.
0044 (0)1635 206012

Attachment 1: Customer Reply Form

Baxter

Quarantine product / Do not sell or distribute

CUSTOMER REPLY FORM
related to Product Recall letter dated 29th April 2019

PRODUCT NAME: CLEAR LINK EXTENSION SETS

Product codes: EMC0062M, EMC9190

Batch Numbers: 14F19V680N, 14I16T737N, 14J01T126N, 14K24T469N, 15F14T705N, 15J31T031N, 15K28T389N, 16A11T042N, 16B24T355N

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

Please complete and return one copy of this form per facility either by fax Fax: 01 2065577 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 lots in our inventory and products have been quarantined.

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

Product Code	Lot number	Quantity in units to be returned

*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	_____