Baxter

August 2015

PRODUCT RECALL

Dear Customer,

Affected Product

Product Code	Product Name	Lot Number
506005078047	Actifuse ABX, 1-2 mm, 2.5 mL, ROW	ALL
506005078048	Actifuse ABX, 1-2 mm, 5.0 mL, ROW	ALL
506005078049	Actifuse ABX, 1-2 mm, 10.0 mL, ROW	ALL
506005078057	Actifuse ABX, 1-2 mm, 20.0 mL, ROW	ALL
506005078059	Actifuse ABX, 1-2 mm, 1.5 mL, ROW	ALL
506005078069	Actifuse MIS System, 1-2 mm, 7.5 mL, ROW	ALL
506005078071	Actifuse MIS System Refill, 1-2 mm, 7.5 mL, ROW	ALL
506005078079	Inductigraft, 1-2 mm, 1.5 mL, ROW	ALL
506005078080	Inductigraft, 1-2 mm, 2.5 mL, ROW	ALL
506005078081	Inductigraft, 1-2 mm, 5.0 mL, ROW	ALL
506005078082	Inductigraft, 1-2 mm, 10.0 mL, ROW	ALL
506005078083	Inductigraft, 1-2 mm, 20.0 mL, ROW	ALL

Problem Description

Baxter Healthcare Ltd. is issuing a voluntary recall for all lots with expiry date between 01 Aug 2015 and 29 July 2017 of Actifuse ABX, Actifuse MIS System, and Inductigraft products due to the possibility that the products may have endotoxin levels above specification criteria.

This recall is not compelled by a confirmed safety signal, but rather an out-of-limit endotoxin test result for a stability batch. The limit pertains to products that may come in contact with the cerebrospinal fluid. Baxter has identified root cause and is implementing corrective actions.

Hazard Involved

In surgical procedures where there is device contact with the cerebrospinal fluid through a dural opening (iatrogenic injury), the use of a medical device with increased endotoxin levels may augment the typical inflammatory reaction to surgery and contribute to adverse health consequences. Baxter has not received product-related adverse event reports that can be linked to cerebrospinal fluid exposure to increased levels of endotoxins.

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. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01635 206034 or scanning and e-mailing it to UK_SHS_FCA@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.

3. Once your reply form is received you will be contacted by Baxter to organize return and credit of the recalled products.

4. An alternative product is available; please contact your local Baxter representative for additional details and ordering.

5. 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.

We apologise for any inconvenience that this issue may cause.

Should you have any clinical questions related to this please contact Baxter Medical Information on 01635 206345 or email MedInfo_UKI@baxter.com. For general queries, please contact the CQA department on 01604 704603 or email uk_shs_fca@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

- Call: 01604 704 603
- Fax: 01604 704688
- Email: uk_shs_qad@baxter.com

Reporting adverse events with drugs:

- Call: 01635 206 360
- Fax: 01635 206 281
- Email: vigilanceuk@baxter.com

The MHRA has been notified.

Yours Sincerely,

Charlie Campion
Marketing Manager
Baxter Healthcare Ltd
Compton, Newbury

Attachment 1: Customer Reply Form

Quarantine product / Do not sell or distribute

Baxter

CUSTOMER REPLY FORM related to Product Recall letter dated Aug 2015

Actifuse ABX, Actifuse MIS System, and Inductigraft

Product code: As mentioned in the above letter

Please complete and return one copy of this form per facility either by fax (**Fax: 01635 206034**) or by **e-mail (UK_SHS_FCA@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 Telephone Number:	

Please check boxes as appropriate:

☐ We do not have any of the affected lots in our inventory.

☐ We have now discarded 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/discarded 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	_____