Baxter

Urgent Field Safety Notice RECALL

21st August 2015

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

Problem Description

Baxter Healthcare Corporation is issuing a voluntary recall for all lots with expiry date between 01 Aug 2015 and 29 July 2017 of Actifuse ABX 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 the 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 01 206 5577 or 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.
3. Baxter will contact you to organise return and replacement of the recalled products.

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, please contact your local Baxter Representative.

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

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

Yours Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
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Blackrock
Co. Dublin
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Attachment 1: Customer Reply Form