Baxter

PRODUCT RECALL

August DD, YYYY *(to be adapted locally)*

Dear Director of Nursing *(to be adapted locally),*

Affected Product *(to be adapted locally)*

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 Corporation *(to be adapted locally)* 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 *(to be adapted locally)* 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. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Center for Service can be reached at *(insert local contact information)* between the hours of *(insert local information)*. Please have your ship-to account number ready when calling.
3. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to *(insert local contact information)* or scanning and e-mailing it to *(insert local contact information)* or sending it by post to *(insert local contact information)*, 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 *(to be adapted locally)*

For general questions regarding this communication, contact Baxter at *(insert local contact information)*, between the hours of *(insert local information)*.

Please note that your Ministry of Health has been informed.

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

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Medical Products *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Attachment 1: Customer Reply Form

Baxter

Quarantine product / Do not sell or distribute

(Customer communication)

CUSTOMER REPLY FORM related to Product Recall letter dated XXXXXX *(to be completed locally)*

PRODUCT NAME

Product code: _____(to be completed locally)

***Batch/Serial Number*: _____(to be completed locally)**

Please complete and return one copy of this form per facility either by fax (Fax :_____) or by e-mail (_____) as confirmation that you have received this notification. A fax cover sheet is not required. ***(Can be adapted locally)***.

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: *(to be adapted locally)*

☐ 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.

(Below paragraph to be removed locally if not applicable)

☐ I would like Baxter to contact my patients and will provide support as needed

☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

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	_____

(Customer communication)

TO BE COMPLETED BY BAXTER PERSONNEL *(Below paragraph to be removed locally if needed)*

Number of product effectively received:

Justification (if discrepancy):