

**Urgent Field  
Safety Notice-  
RECALL**

Xx January 2016

Dear Sir/Madam,

**Affected  
Product**

<b>Product Code</b>	<b>Description</b>	<b>Lot #</b>	<b>Expiration Date</b>
UKF7114	Sterile Water for Irrigation, 1000mL	15J26BB1A	Sep 2018

**Problem  
Description**

Baxter Healthcare Ltd. is issuing a voluntary recall of the above mentioned product due to a complaint for a defect of the moulding and leaks in bottles of Sterile Water for irrigation (UKF7114, 15J26BB1A).

The analysis of the returned samples were conducted and the root cause has been concluded to be the concurrent occurrence of a number of atypical events, including a thinner bottle wall along the graduation panel challenged by an abnormal sterilization cycle. Sterility Assurance criteria was confirmed to have been met.

Actions have already been taken in order to mitigate any similar events and corrective actions are being implemented to prevent re-occurrence.

**Hazard  
Involved**

A leaking pour bottle may potentially lead to contamination of the solution with microbial agents. The solution is indicated as a topical irrigating solution for cleansing of body surfaces, wounds, and body cavities which by nature are contaminated surfaces. No injuries or adverse events have been reported for 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. 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/credit 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, contact your local Baxter Representative at 01 206 5500

Any suspected adverse reactions may be reported to Baxter Healthcare directly by calling 01-206-5500 or by email to [qa\\_dublin@baxter.com](mailto:qa_dublin@baxter.com).

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

The HPRA has been informed about this action.

Yours Sincerely,

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

Attachment 1: Customer Reply Form



**Quarantine product /  
Do not sell or distribute**

# ATTACHMENT 1

**CUSTOMER REPLY FORM related to Product Recall letter dated XX JANUARY 2016**

**STERILE WATER FOR IRRIGATION, 1000ML**

**Product code: UKF7114**

**Batch Number: 15J26BB1A**

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

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.

<b>Signature/Date:</b>	
REQUIRED FIELD	_____