

15<sup>th</sup> January 2016

Dear Sir/Madam

**Urgent Field  
Safety Notice-  
RECALL**

**Affected  
Product**

<b>Product Codes</b>	<b>Description</b>	<b>Lot Numbers</b>
EMC4015N VMC4005	Uromatic Tur Admin. Set	See attachment 2

**Problem  
Description**

Baxter is issuing a recall for the above listed lot numbers of the Uromatic Tur Administration Set due to customer complaints received related to the disconnection of the spike from the tubing of the set.

The issue is limited to the lot numbers listed in the Attachment 2.

**Hazard  
Involved**

The most likely hazard resulting from this issue is delay/interruption of therapy. However, disconnections also have the potential to lead to microbial contamination of the fluid path and hence contamination of the surgical field. Baxter has not received any reports of adverse event or patient injury related to 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 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 Baxter 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.



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

The HPRA has been informed about this action.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'I. Gavigan', is positioned below the closing text.

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

**Attachments:**

- Attachment 1 : Customer Reply Form
- Attachment 2 : List of impacted products



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

**ATTACHMENT 1**

**CUSTOMER REPLY FORM related to Product Recall letter dated 15<sup>th</sup> January 2016  
UROMATIC TUR ADMIN. SET**

**Product code: EMC4015N**

**Batch Numbers: 14G01V291M, 14G08V296M, 14G09V297M, 14I01V842M,  
14K03V521, 15D01V259, 15F23V968, 15F17V943**

**Product code: VMC4005**

**Batch Numbers: 14F30V935M, 14H01V616M, 15A31V202**

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 ( <i>Please Print</i> ):	
Title ( <i>Please print</i> ):	
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>	
<b>REQUIRED FIELD</b>	_____



ATTACHMENT 2

**LIST OF IMPACTED PRODUCTS**

<b>Product Codes</b>	<b>Product Name</b>	<b>Lot Numbers</b>	<b>Expiration Date</b>
EMC4015N	Uromatic Tur Admin. Set	14G01V291M	Jun-19
EMC4015N	Uromatic Tur Admin. Set	14G08V296M	Jun-19
EMC4015N	Uromatic Tur Admin. Set	14G09V297M	Jun-19
EMC4015N	Uromatic Tur Admin. Set	14I01V842M	Aug-19
EMC4015N	Uromatic Tur Admin. Set	14K03V521	Oct-19
EMC4015N	Uromatic Tur Admin. Set	15D01V259	Mar-20
EMC4015N	Uromatic Tur Admin. Set	15F23V968	May-20
EMC4015N	Uromatic Tur Admin. Set	15F17V943	May-20
VMC4005	Uromatic Tur Admin. Set	14F30V935M	May-19
VMC4005	Uromatic Tur Admin. Set	14H01V616M	Jul-19
VMC4005	Uromatic Tur Admin. Set	15A31V202	Dec-19