

**Urgent Field  
Safety Notice  
RECALL**

06<sup>th</sup> November 2015

Dear Customer,

**Affected Product**

Product Code	Description	Lot Number(s)
VMC9627	Vented Paclitaxel Set	14A08V008, 14F14V705, 14G16V016, 14I05T696, 14K19T380, 14L12T673, 15A12T126, 15B17T404

**Problem Description**

Baxter Healthcare Ltd is voluntarily issuing a recall for the above referenced lots due to complaints received for leaks at the spike's air vent subassembly. Baxter has investigated this issue and corrective actions have been taken.

**Hazard Involved**

A leak in a Paclitaxel set may result in a breach in sterility of the fluid path with subsequent contamination of the solution. If not detected during priming or initial set up, this may lead to serious adverse health consequences.

A leak in a Paclitaxel set may also result in potential skin contact which would result in potential skin irritation.

At this time, Baxter has received no reports of adverse events associated with this issue.

**Actions to be taken by customer/user**

- Locate and remove all products with code number and batch numbers as listed in this communication from their facility. If you distribute these products to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they also locate and remove the affected products (the product code can be found on the individual product package and shipping carton).
- If you are a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, please notify your customers of this action so that they can locate and remove all affected products.
- Acknowledge your receipt of this recall notification by completing the attached Customer Reply Form and return to Baxter by either faxing it to 01 206 5577 or scanning and emailing it to [QA\\_Dublin@baxter.com](mailto:QA_Dublin@baxter.com). Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications. Once your reply form is received you will be contacted by Baxter to organise return and replacement of the recalled products.

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

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,



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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**

## CUSTOMER REPLY FORM related to Product Recall letter dated 05<sup>th</sup> November 2015

### VENTED PACLITAXEL SET

**Product code: VMC9627** Batch Number: 14A08V008, 14F14V705, 14G16V016,  
14I05T696, 14K19T380, 14L12T673, 15A12T126, 15B17T404

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 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.

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

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	_____