

Product Recall

November 2, 2015

Dear Director of Materials Management:

| Affected Product | Product Code | Product Description | Lot Number(s) |
|------------------|--------------|-----------------------|---|
| | VMC9627 | Vented Paclitaxel Set | 14F14V705, 14G16V016, 14I05T696, 14L12T673, |

Problem Description Baxter Healthcare Corporation 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 result in potential skin contact which would result in potential skin irritation.

Actions to be taken

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product or shipping carton.
2. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by scanning and e-mailing to Baxter Sales Representative. Returning the Baxter Customer Reply Form promptly will prevent you from receiving repeat notices.
3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

We apologize for any inconvenience this may cause you and your staff. All the hospital pharmacy/ purchaser and distributor have been informed. The Health Sciences Authority has been notified of this product recall. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Please report to Angela Lim at angela_lim@baxter.com or call at +65 82000 434.
- Please report Product Complaints to Corynn Tan at chai_hwee_corynn_tan@baxter.com
- Please report Adverse Events to Singapore_patientsafety@baxter.com

Sincerely,

Corynn Tan
QA Manager
Baxter Healthcare (Asia) Pte Ltd

Enclosure: Baxter Customer Reply Form

CUSTOMER REPLY FORM**Medical Device Recall****November 2, 2015**

Please complete and return this form to the email ID listed below as confirmation that you have received this notification by **November 11, 2015 (Wednesday)**. A cover sheet is not required.

Attention: Corynn Tan
Email: chai_hwee_corynn_tan@baxter.com

| | |
|------------------------------|--|
| Facility Name and Address: | |
| Name: (Please Print Name) | |
| Title: (Please Print) | |
| Telephone Number: | |

| Product Code | Product Name | Lot Number | Quantity to be returned |
|--------------|-----------------------|------------|-------------------------|
| VMC9627 | Vented Paclitaxel Set | 14F14V705 | |
| | | 14G16V016 | |
| | | 14I05T696 | |
| | | 14L12T673 | |

Your signature below indicates understanding the contents of the attached letter; performing the actions as outlined in the letter, as needed; and dissemination of this information to staff and other services or facilities, as applicable.

| | |
|--|--|
| Signature/Date: REQUIRED FIELD | |
|--|--|

PLEASE ENSURE THE REPLY FORMS CONTAIN YOUR NAME, TITLE, SIGNATURE AND DATE IN THE ABOVE FIELDS.

RESPONDING TO THIS REQUEST WILL PREVENT THE RECEIPT OF UNNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.