

**Important  
Product  
Information**

August 3, 2009

**Subject: INFUSOR**

**Product Codes: 2C1008KP, 2C1009KP - Multiple Lots Affected**

Dear Director of Nursing and Director of Pharmacy:

Baxter Healthcare Malaysia is providing this notification to inform you of reported incidents of leakage on the INFUSOR at the connection of the blue winged cap and the distal male Luer. This notification affects only the product code numbers and lot numbers listed in Table #1 (attached).

Baxter has not received any reports of adverse events associated with this issue.

Investigation of these reports indicates the incidence of leakage has only occurred after pumps are filled, primed, re-capped (using the blue winged Luer cap) and stored for a period of time, typically overnight. In addition, the reported instances of leakage were contained within the storage pouch provided and observed prior to patient use.

Please ensure the blue winged Luer cap is tightly secured after filling and priming to mitigate such an occurrence of leakage. As always, continue to follow normal clinical practices to reduce contact with leaking medication. Should medication come in contact with skin, follow your facility's protocol regarding such an exposure. Baxter recommends that, for any medication pre-dispensed, the pump be stored in the sealed pouch provided.

If you notice a leak, place the pump in a plastic bag, quarantine the device and call Baxter's Product Product Specialist for further instructions.

Please return the attached reply form via FAX to 03-2283 1784. The prompt return of the attached reply form prevents the receipt of repeat notices.

If you distribute the products listed on this notification to other facilities, or if you are a distributor of the product outlined above, please forward this communication as appropriate.

We apologize for any inconvenience this may cause you and your staff. If you have clinical/technical questions, please call Baxter's Clinical Team at 03-2267 6000.

Sincerely,



NG YU SEEN  
Assistant Manager, Regulatory Affairs

**CUSTOMER REPLY FORM****Important Product Information Notification  
August 03, 2009****Infusor****Product Codes: 2C1008KP, 2C1009KP - Multiple Lots Affected - See Table #1**

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

**FAX#: 03-2283 1784**

Facility Name and Address:

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

**Required Fields:**

|  |  |
|--|--|
| Reply Completed By:<br><b>(Signature/Date)</b> |  |
| Name <b>(Please Print)</b> :                   |  |
| Title <b>(Please Print)</b> :                  |  |
| Telephone Number <b>(Inc. Area Code)</b> :     |  |

**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 REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.**

**Table #1 – Affected Product Codes and Lot#s**

| <b>Product Description</b> | <b>Product Code</b> | <b>Batch #</b> |
|----------------------------|---------------------|----------------|
| Infusor LV2                | 2C1008KP            | 09B044         |
|                            |                     | 09D018         |
|                            |                     | 09E019         |
| Infusor LV5                | 2C1009KP            | 09A052         |
|                            |                     | 09B048         |