



## Urgent Product Recall

December XX, 2014

Dear customer,

**Affected Product** Self-Righting Luer Slip Tip Cap, Yellow,  
Product Code: H93866100 Lot Number: 1001365  
UPN/GTIN CS Unit: 50085412478857, UPN/GTIN EA Unit: 00085412478852

These lots were distributed to Baxter customers between August 31, 2014 and September 9, 2014.

**Problem Description** Baxter Healthcare Corporation is voluntarily issuing a recall for the above mentioned lots of Luer caps due to the package seal integrity being compromised, affecting sterility assurance. The products were packaged in unapproved engineering study pouches; which may have punctures compromising the sterile barrier. The investigation is on-going and corrective actions will be implemented as soon as root cause(s) are identified.

**Hazard Involved** Caps for Luer and Luer Lock syringes which do not meet sterility assurance may potentially contaminate the sterile fluid path leading to blood stream infections. There have been no adverse events reported for this issue.

**Action to be taken if product was purchased directly from Baxter** 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 fax, scanned e-mail or post
3. 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. These lots were distributed to Baxter customers between August 31, 2014 and September 9, 2014. (May be adapted locally)



**Further information and support**      If you have questions regarding the content of this communication, please call Baxter at ...  
1.

The competent authorities have been notified of this action. Any adverse reactions or quality problems experienced with the use of these products should be reported using one of the following options: (To be adapted locally)

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

Sincerely,

Name

Title

Baxter Healthcare

Enclosure: Customer Reply Form (May be adapted locally)

## ENCLOSURE

**CUSTOMER REPLY FORM** related to Product Recall letter dated **XXXXXX** *(to be completed locally)*

**SELF-RIGHTING LUER LOCK TIP CAP**

**Product code:** \_\_\_\_\_ *(to be completed locally)*

**Batch/Serial Number:** \_\_\_\_\_ *(to be completed locally)*

Please complete and return one copy of this form per facility either by fax (Fax : \_\_\_\_\_) or by e-mail ( \_\_\_\_\_) as confirmation that you have received this notification. A fax cover sheet is not required. *(Can be adapted locally)*.

|   |  |
|---|--|
| 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: *(to be adapted locally)*

- 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><br><br>REQUIRED FIELD |  |
|--|--|

**TO BE COMPLETED BY BAXTER PERSONNEL** *(Below paragraph to be removed locally if needed)*

Number of product effectively received:

Justification (if discrepancy):