Baxter

PRODUCT RECALL

October XX, 2014 (to be adapted locally)

Dear Director of Materials Management: (to be adapted locally)

Affected Product (to be adapted locally)

Product Code	Description	Lot Number(s)
2C1079K	INFUSOR Patient Control Module 0.5ml	14A056, 14B059, and 14C030

Problem Description

Baxter Healthcare Corporation (to be adapted locally) is issuing a recall for the above affected lot numbers of the INFUSOR Patient Control Module 0.5ml (PCM) due to complaints for partially detached back-plates on the underside of the device. A partial detachment of the PCM back-plate may cause an incomplete shut-off of the PCM watch tubing resulting in continuous flow of medication from the PCM to the patient. Baxter is investigating the root cause of this issue.

Hazard Involved

Continuous flow of pain medication to the patient may result in sedation, respiratory depression, or respiratory failure resulting in the need for medical intervention. These conditions could lead to serious injury or death.

Actions to be taken by customer/user

1. Locate and remove all products with code numbers 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 codes can be found on the individual product package and shipping carton).
2. 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.
3. Acknowledge your receipt of this recall notification by completing the attached Customer Reply Form and return to Baxter by either faxing it to XX (to be adapted locally) or scanning and emailing it to (to be adapted locally). Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications (to be adapted locally). Once your reply form is received you will be contacted by Baxter to organize return and replacement of the recalled products.

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We apologize for any inconvenience this may cause you and your staff. Any adverse reactions or quality problems experienced with the use of this product must be reported through your local Baxter Sales Representative.(to be adapted locally)

The local MOH (to be adapted locally) has been notified.

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Medical Products (to be adapted locally)
Baxter Healthcare (to be adapted locally)