Baxter

Field Safety Notice - Recall

13th October 2014

Dear Customer

Affected Product

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

Problem Description

Baxter Healthcare 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 your 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 01 206 5577 or scanning and emailing it to **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.

We apologise 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.

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The HPRA has been notified.

Sincerely,

Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph. 00353 1 2065500

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CUSTOMER REPLY FORM related to Product Recall letter dated 13th October 2014

PRODUCT NAME: INFUSOR Patient Control Module 0.5ml
Product code: 2C1079K
Batch/Serial Number*:* 14A056, 14B059, and 14C030

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 *(Please Print)*:	
Title *(Please print)*:	
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.

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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.

Signature/Date: REQUIRED FIELD	_____