Baxter

PRODUCT RECALL

October, 2014

Dear Sir / Madam

Affected Product

Product Code	Description	Lot Number(s)
2C1724K	Intermate LV 250 – 24 Pack	14D012
2C1734K	Intermate SV 200 – 48 Pack	14A036, 14B011, 14C014, 14C045, and 14C051
2C1744K	Intermate LV 250 – 24 Pack	14A034 and 14B047

Problem Description

Baxter Healthcare Ltd is issuing a recall for the above affected lot numbers due to complaints for particulate matter in the fluid path. The root cause for the particulate matter was identified as misalignment of a component during manufacturing. This issue is being resolved. No adverse events have been reported to Baxter for the affected lots.

Hazard Involved

Although the Intermate devices contain an inline particulate filter, all particulate may not be captured and/or the filter may clog and result in delay in therapy. Intravenous administration of a solution containing sterile particulate matter may lead to adverse health consequences. The extent and severity of harm depends on many variables including the size, number, and composition of the foreign material, drug administered, and patient's underlying medical condition.

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).

Baxter Healthcare Ltd
Caxton Way / Thetford / Norfolk / IP24 3SE / Great Britain
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Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

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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 01604 704688 or scanning and emailing it to uk_shs_qad@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 organize return and replacement of the recalled products.

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

Should you have any clinical questions related to this please contact Surecall Baxter Medical Information on 01635 206345 or email surecall@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

- Call: 01604 704 603
- Fax: 01604 704688
- Email: uk_shs_qad@baxter.com

Reporting adverse events with drugs:

- Call: 01635 206 360,
- Fax: 01635 206 281,
- Email: vigilanceuk@baxter.com

The MHRA has been notified.

Sincerely,

Joanna Lorimer
Product Manager
Medical Products
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