Urgent Product Recall

Baxter

April 21, 2014

Dear Director of Materials Management:

Affected Product

Product Code: 2F7124
Lot Number: G109272
0.9% Sodium Chloride Irrigation, USP - Plastic Pour Bottle Container 1000mL
NDC 0338-0048-04
Manufacturing Date: September 19, 2013
Distributed to Baxter customers between September 24, 2013, and February 14, 2014

Problem Description

Baxter Healthcare Corporation is voluntarily issuing a recall for one lot of 0.9% Sodium Chloride Irrigation, USP - 1000 mL due to particulate matter found inside the container. One complaint has been received and is being investigated. Preventative actions are being implemented as potential root causes are identified.

Hazard Involved

If irrigation solution with particulate matter is used, it could result in the introduction of particulate matter at the application site. The particulate matter may be washed away during irrigation, or could lead to potential wound irritation, local infection or sepsis. There have been no adverse events reported for this issue.

Action to be taken if product was purchased directly from Baxter

Baxter is requesting 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 package or shipping carton).
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time. Please have your Baxter eight-digit ship-to account number ready when calling.
3. Complete the attached Customer Reply Form (Attachment 1), and return it to Baxter by either fax or scanned e-mail.
4. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please conduct a recall with your end-user customers in accordance with your customary procedures. Baxter distributed this product to customers between September 24, 2013, and February 14, 2014.

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Baxter Healthcare Corporation
25212 W IL Rte 120 / Round Lake, IL 60073
T 847-546-6311

Baxter

Action to be taken if product was purchased from a distributor or reseller

1. Locate and remove all affected product from your facility (the product code and lot number can be found on the individual product package or shipping carton).
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Center for Service can be reached at 888-229-0001, Monday through Friday, between the hours of 7:00 am and 6:00 pm Central Time. Please have your Baxter eight-digit ship-to account number ready when calling.
3. Follow your suppliers' reply and recall process. Please do not return the customer reply form to Baxter.

Further information and support

If you have questions regarding the content of this communication, please call The Center for One Baxter at 1-800-422-9837, Monday through Friday, during the hours of 8:00 am to 5:00 pm Central Time.

The United States Food and Drug Administration has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176, Monday through Friday, between the hours of 8:00 am and 5:30 pm, Central Time
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA by completing and submitting the report Online: www.fda.gov/medwatch/report.htm
- Reporting to the FDA by Regular Mail or Fax: Download form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Sincerely,

Loretta M. Inamoto

Loretta Inamoto
Sr. Director, Global Quality
Medical Products
Baxter Healthcare

cc: Director of O.R. Nursing

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