

# COUNTY OF EL DORADO

## HEALTH & HUMAN SERVICES

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## EMS Safety Bulletin 2014-02

**DATE:** 05/07/2014  
**TO:** All Personnel  
**FROM:** EDCEMSA  
**SUBJECT:** **Baxter Sodium Chloride Recall**

Please see the attached recall on bottles of 0.9% sodium chloride 1000mL bottles.

### MESSAGE CONFIRMATION:



NOT REQUIRED



REQUIRED



ACKNOWLEDGEMENT BY ALL PERSONNEL REQUIRED

**Urgent Product Recall**

Wednesday, April 30, 2014

Dear Valued Life-Assist Customer,

According to our records you have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have the following product with the affected lot number, given below in your inventory.

**Baxter 0.9% Sodium Chloride, 1000 mL Bottle**

Life-Assist, Inc. Product Code	Baxter Product Code	NDC	Lot #
SL7124	2F7124	0338-0048-04	G109272

Reason for Recall: This recall has been initiated, for lot G109272 of Baxter 0.9% Sodium Chloride, 1000 mL bottle, due to particulate matter found inside the container.

See the attached notification from the manufacturer for more information.

**If you find any product with the affected lot in your inventory, discontinue use immediately and contact Life-Assist Customer Service for a Return Authorization at 800-824-6016.**

We apologize for any inconvenience.

RECEIVED MAY 05 2014



# Urgent Product Recall

**Baxter**

April 21, 2014

Dear Director of Materials Management:

<b>Affected Product</b>	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
<b>Problem Description</b>	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.
<b>Hazard Involved</b>	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.
<b>Action to be taken if product was purchased directly from Baxter</b>	Baxter is requesting that you take the following actions: <ol style="list-style-type: none"><li>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).</li><li>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.</li><li>3. Complete the attached Customer Reply Form (Attachment 1), and return it to Baxter by either fax or scanned e-mail.</li><li>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.</li></ol>

FCA-2014-029

*Baxter is a registered trademark of Baxter International, Inc.*

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**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**

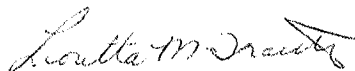
If you have questions regarding the content of this communication, please call The Center for One Baxter at 1-800-422-9837, Monday through Friday, during the hours of 8:00 am to 5:00 pm Central Time.

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](mailto:corporate_product_complaints_round_lake@baxter.com)
- Reporting to the FDA by completing and submitting the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Reporting to the FDA by Regular Mail or Fax: Download form from [www.fda.gov/MedWatch/getforms.htm](http://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 Inamoto  
Sr. Director, Global Quality  
Medical Products  
Baxter Healthcare

cc: Director of O.R. Nursing