



Michael R. Pence  
Governor

Jerome M. Adams, MD, MPH  
State Health Commissioner

**DATE:** February 19, 2016  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** *Laurie Kidwell*  
Laurie Kidwell, RRT Supervisor  
Food Protection Program  
**SUBJECT:** Baxter International Inc. – RECALL [Drug]

**AFFECTED PRODUCT:** 0.9% Sodium Chloride Irrigation, USP, 500 mL Plastic Pour Bottle solution

**SUMMARY:** Unclassified Recall; This product is being recalled due to a customer complaint prior to use for the presence of particulate matter, identified as an insect.

<u>Product Code</u>	<u>Product Description</u>	<u>Lot Number</u>	<u>Expiration Date</u>	<u>NDC</u>
2F7123	0.9 % Sodium Chloride Irrigation, USP, 500 mL Plastic Pour Bottle	G120162	11/30/2018	0338-0048-03

The lot being recalled was distributed to customers and distributors in the United States between November 12, 2015 and January 11, 2016.

**SUGGESTED ACTION:** For consumer inquiry only. Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at [onebaxter@baxter.com](mailto:onebaxter@baxter.com).

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### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

*Baxter Issues Voluntary Nationwide Recall of One Lot of 0.9% Sodium Chloride Solution for Irrigation Due to Presence of Particulate Matter*

For Immediate Release

February 17, 2016



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To promote and provide essential public health services.

Contact

## Consumers

Baxter International Inc.  
1-800-422-9837

### Announcement

Baxter International Inc. of Deerfield, Illinois, is voluntarily recalling one lot of 0.9% Sodium Chloride Irrigation, USP, 500 mL Plastic Pour Bottle solution to the hospital/user level. This product is being recalled due to a customer complaint prior to use for the presence of particulate matter, identified as an insect.

Sodium Chloride Irrigation solution with foreign material contamination potentially could result in a series of complications dependent in which anatomic location the irrigation is used, which could include inflammatory reaction, foreign body reaction, and infection which could be life-threatening.

To date, Baxter has not received any reports of adverse events related to this recall. 0.9% Sodium Chloride for Irrigation USP – 500 mL is an isotonic solution intended for irrigation. This solution can be used to rinse debris and residue from wounds and as a single use for rinsing/irrigation during surgical procedures. It may also be used to flush or rinse medical equipment such as catheters. The recall affects the following lot:

Product Code	Product Description	Lot Number	Expiration Date	NDC
2F7123	0.9 % Sodium Chloride Irrigation, USP, 500 mL Plastic Pour Bottle	G120162	11/30/2018	0338-0048-03

The lot being recalled was distributed to customers and distributors in the United States between November 12, 2015 and January 11, 2016.

Baxter is notifying its distributors and customers by letter that they should not use product from the recalled lot. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at [onebaxter@baxter.com](mailto:onebaxter@baxter.com). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

### About Baxter

Baxter International Inc. provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and

the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

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