

DEC 26 2025

REPLY INSTRUCTION SHEET*Urgent Drug Recall*

Sterile Water for Irrigation,
250ml Plastic Pour Bottle - Particulate Matter in Fluid Path
December 22, 2025

ACCOUNT NUMBER: 34219389
ATTENTION: DIRECTOR OF NURSING
PEDIATRIC HOME RESPIRATORY SVCS LLC
2800 CLEVELAND AVE N
SAINT PAUL, MN 55113-1126

1ST

Baxter Field Action Portal – Acknowledgement Instructions:

1. Review and perform the actions outlined in the customer letter.
2. **Acknowledge receipt of this customer letter** by navigating to the Baxter Field Action Portal at <https://BaxterFieldActionCustomerPortal.onprocess.com/> or by using the QR code below. Please use Google Chrome as your internet browser; other browsers will not work.



3. Log in using the following Customer Account Number (**34219389**).
4. Click on the Field Action number associated with this customer letter (**FA-2025-050**).
5. Populate all of the required fields.
6. Click Submit to complete acknowledgment.
7. Submitted customer acknowledgements can be printed or accessed at a later time by logging in to the portal and clicking the View Reply Receipt button on the Customer Dashboard screen.

URGENT DRUG RECALL

December 22, 2025

Dear Directors of Nursing and Pharmacy:

Baxter Healthcare Corporation is issuing a voluntary product recall for one lot of 250-mL plastic pour bottles of sterile water for irrigation (refer to Figure 1 for product label). In some cases, plastic particles from the bottle rim were observed floating in the solution while pouring. The affected lot number was distributed from 6/14/2024 to 9/15/2025. This recall is being conducted to the hospital/user level.

Affected Product

Product Code	Product Description	Lot Number	Expiry Date	NDC
2F7112	Sterile Water for Irrigation	G171359	05/31/2027	0338-0004-02

Hazard Involved

The plastic pour bottle may contain particulate matter. If the particulate matter is noticed before use, there may be a delay or interruption of irrigation therapy. Should this delay or interruption occur, no harm is expected while another bottle of irrigation solution is retrieved for use. In the unlikely event that the fluid with particulate matter would go unnoticed and be used during irrigation, the particulate matter would likely be washed away during the irrigation process. Particulate matter that remains in the site of irrigation may lead to more serious adverse health consequences such as granuloma formation and/or it could serve as a nidus for infection. To date, Baxter has not received any reports of patient injury related to this issue.

Actions to be Taken by Customers

1. Please inspect any unopened sterile water for irrigation you may have. If the product code and lot number on the label match those listed in the table above, contact Baxter Healthcare Center for Service to arrange for a return and replacement OR credit at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.
2. If you received this communication directly from Baxter, acknowledge receipt by following the instructions on the enclosed reply instruction sheet, even if you have no remaining inventory. Acknowledging receipt of this notification will prevent you from receiving repeated notices. If you do not complete the acknowledgement, you will receive a phone call from Accenture LLP on behalf of Baxter to confirm your receipt of this notification.
3. If you purchased this product from a distributor or wholesaler, please contact your supplier to arrange for the return and replacement of the affected product. Please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
4. Please forward a copy of this communication to the head of clinical department, healthcare professionals, compounding center manager, facility risk manager/patient safety manager, and any others within your institution that use the affected product.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) and you have affected product please do not further distribute it. Please conduct a user-level recall of the affected product that you distributed to customers and check the associated box on the customer portal.

Further Information and Support

For general questions regarding this communication, please contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

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

- Contacting Baxter Product Surveillance at the Baxter product feedback portal at <https://productfeedback.baxter.com>, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
 - **Online:** By completing and submitting the report at www.accessdata.fda.gov/scripts/medwatch
 - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

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

Sincerely,

Craig Plunkard
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Instruction Sheet

2F7112 250 mL
NDC 0338-0004-02

Baxter
Not for Injection For Irrigation Only

Sterile Water for Irrigation, USP

Prepared by distillation. No antimicrobial agent or other substance has been added. pH 5.5 (5.0 to 7.0). Osmolarity 0 mOsmol/L (calc.). Sterile, nonpyrogenic. Pour Bottle. **Warning:** This solution is not isotonic and is hemolytic. **Dosage and Administration:** As directed by a physician. **Cautions:** Warm in oven to not more than 50°C for a maximum of 60 days. Discard after 60 days of warming. Do not use unless solution is clear and seal is intact. Discard unused portion. Rx only. **Recommended storage:** Room temperature (25°C). Avoid excessive heat.

PL 325 plastic
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA 07-09-64-068

Bar Code Position Only*

303380004027

07-09-64-068

Figure 1. Sterile Water for Irrigation Product Label