



Ref: MCR-26-42

September 14, 2026

Health Product Risk Communication
Baxter's Sterile Water for Irrigation and 0.9% Sodium Chloride for Irrigation

Dear Valued Medline Canada Customer,

This letter is to inform you that Baxter Corporation is issuing a **Health Product Risk Communication (HPRC)** letter for all lots of Baxter's Sterile Water for Irrigation and 0.9% Sodium Chloride for Irrigation in Plastic Pour Bottles (**Table 1** – Affected Products and Affected Lots) that may exhibit “scuffing” on the inner rim of the bottle (see photos below). This scuffing has the potential to result in intrinsic particulate matter which may enter the product solution at the time of use.



Baxter's investigation confirmed that the intrinsic material is polypropylene (i.e. the material that comprises the bottle and cap closure) generated during the manufacturing process and is not a result of external or foreign contamination. Baxter is currently in the process of implementing mitigations and corrective actions to address this issue.

The product may continue to be used under the conditions described in the “Hazard Involved” and Action 1 of the “Table 2: Actions to be taken”, sections below.

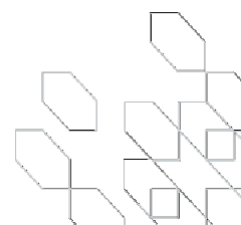


**Table 1 – Affected Products and Affected Lots**

Medline Product Code	DIN	Product Name	Package Size	Lot Number / Expiration Dates of Products
533-JF7113	00799998	Sterile Water for Irrigation, USP	500 mL	All lots within expiry through December 2029
533-JF7114			1000 mL	
533-JF7123	00786160	0.9% Sodium Chloride Irrigation, USP	500 mL	
533-JF7124			1000 mL	

Hazard Involved:

The scuffing on the inner rim of the bottle has the potential to result in particulate matter in the product solution. If this particulate matter is noticed by the user and the user discards that unit, a delay in therapy initiation or interruption of therapy may result as the user obtains an alternative product/unit. Should this delay or interruption occur, no harm is expected while another bottle of irrigation solution is retrieved for use.

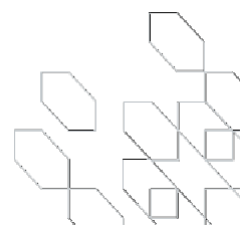
If this particulate matter is not noticed and the plastic pour bottle is used, the patient may be exposed to the particulate matter. In wound management, this could lead to localized tissue effects such as inflammation, foreign body reaction, or infection. If the plastic pour bottle is used during a highly vascular procedure, there is a potential risk of systemic complications, such as thrombosis, pulmonary embolism, or systemic embolization. Such serious complications are considered a theoretical, worst-case scenario rather than a reasonably expected clinical outcome. Accordingly, caution should be exercised when the product is used in vascular procedures, where particulate matter may have the potential to enter the circulation.

To date, there have been no reports of adverse events associated with this issue.

Corrective Actions and Timeline:

Baxter is in the process of implementing mitigating actions and long-term corrective actions to address this issue.

Baxter expects to implement mitigating actions by the end of September 2026, with post-mitigation product anticipated to reach the Canadian market in December 2026.





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Table 2: Actions to be taken

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| <ol style="list-style-type: none">1. Baxter recommends reinforcing routine visual inspection prior to preparation and use in accordance with the product labeling. In addition, users should:<ul style="list-style-type: none">• Visually examine the inner rim of the bottle after opening for evidence of scuffing.• If scuffing is observed, visually inspect for particulate matter in solution.• If visible particulate matter is observed in the solution, discontinue use and obtain an alternative. |
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