



STEVENS

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November 21, 2023

URGENT MEDICAL DEVICE RECALL NOTICE
NURSE ASSIST Sterile 0.9% Saline, USP and Sterile Water, USP

R2331
1st Attempt

Nurse Assist has advised The Stevens Company of a Type II recall for the following products sold by The Stevens Company:

Product Name	Stevens Catalog #	Manufacturer #	Expiry Date
WATER STERILE 120ml STERILE FOIL LID	372-6210	6210	Any product with an expiry date of: November 1, 2023 through September 18, 2025
SOLUTION SALINE 0.9% NACL 120ml STER IRRIGATION FOIL LID	372-6220 372-6220C	6220	
SOLUTION SALINE 0.9% NACL 100ml IRRSTER SCREW TOP BTL	372-6240	6240	
WATER STERILE 100ml IRRG w/SCREWTOP BOTTLE	372-6250	6250	
WATER STERILE 250ml IRRIGATION SUCTIONING SCREW TOP BOTTLE	372-6260 372-6260-X	6260	
SOLUTION SALINE 0.9% NACL 250ml STER IRRIGATION & SUCTIONING	372-6270 372-6270-X	6270	
SOLUTION SALINE 0.9% NACL 500ml STER IRRIG SCREW CAP BOTTLE	372-6280	6280	
SOLUTION SALINE 0.9% NACL 1000ml STER IRRIG SCREW CAP BOTTLE	372-6281	6281	
WATER STERILE 500ml IRRIG BOTTLESCREW CAP	372-6290	6290	
WATER STERILE 1000ml IRRIG BOTTLEBOTTLE SCREW CAP	372-6291	6291	
SOLUTION SALINE 0.9% NACL 7.1oz STER SPRAY WOUND FLUSH	372-6507	6507	

Reason for Recall

Nurse Assist is conducting a recall for select products expiring within the range of November 1, 2023 through September 18, 2025. Any product with an expiry date within this range is recalled.

Nurse Assist has determined that the sterility assurance level (SAL) cannot be verified to the required degree of 10⁻⁶.

Product with an affected expiration date is to be destroyed in the field and no return is required. Credit will be issued for recalled product destroyed.

Products with an unverified sterility may be contaminated which could result in infection. The Stevens Company has received no reports of adverse events because of this issue.

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Atlantic Canada	Québec	Ontario	Manitoba	Midwestern Canada	British Columbia
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Action Required (Due January 31, 2024)

1. Immediately review your inventory for product with an impacted expiry date.
2. Record the lot numbers and expiry dates of all recalled products on the Acknowledgment Form accompanying this notice.
3. Destroy recalled products.
4. Notify all affected users, facilities or customers of the contents of this notice.
5. Complete the attached Acknowledgment and return by email to qc@safecross.com or fax to 416-665-6897.

Even if you have no inventory of this product, please complete the Acknowledgment and check the appropriate box. Your response ensures that this recall is carried out effectively.

Thank you,
Steve Baker, CQIA
Regulatory Affairs & Quality Assurance Manager



STEVENS
www.stevens.ca

