



As announced on November 6, 2023

URGENT: MEDICAL DEVICE RECALL

0.9% Normal Sterile Saline for Irrigation USP, Sterile Water for Irrigation USP, and Sterile Saline Spray Cans

Dear Device Customer/Distributor,

Purpose of this letter:

The purpose of this letter is to advise you that Nurse Assist, LLC is voluntarily recalling the following products indicated for moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation. It is important that we coordinate this action with you. Key action items for you and for us are described below.

- 0.9% Normal Sterile Saline for Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 3.1oz spray can, 7.1oz spray can, 3mL syringes, 5mL syringes, and 10mL syringes)
- Sterile Water for Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes)

Affected Devices:

Brand Name	Part Number	Description	UDI	Expiration Dates
NURSE ASSIST	6492775	100ML STERILE SALINE BOTTLE	B15064927754G	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	6492776	100ML STERILE WATER BOTTLE	B15064927764H	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1010	10CC PREFILLED SYRINGES	+B15010104L	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	51638	10CC PREFILLED SYRINGES	+B150516384%	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1210-BP	10ML IV FLUSH SYRINGE	+B1501210BP4G	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	6496723	30CC PREFILLED SYRINGE	B15064967234D	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	52333	30CC PREFILLED SYRINGES	+B150523334Z	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1203-BP	3ML IV FLUSH SYRINGE	+B1501203BP4I	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1205-BP	5ML IV FLUSH SYRINGE	+B1501205BP4K	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	6496722	SYRINGE PREFILLED 10 ML	B15064967224C	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1030	USP STERILE WATER SYRINGE	+B15010304N	Nov 6, 2023 to Sep 18, 2025
NURSE ASSIST	1030A	USP STERILE WATER SYRINGE	+B1501030A4X	Nov 1, 2023 to Sep 18, 2028
STERICARE	6281	1000ML STERILE SALINE BOTTLE	(01)10850421008843	Nov 6, 2023 to Sep 18, 2025
STERICARE	6291	1000ML STERILE WATER BOTTLE	(01)10850421008799	Nov 6, 2023 to Sep 18, 2025
STERICARE	6240	100ML STERILE SALINE BOTTLE	(01)10850421008812	Nov 6, 2023 to Sep 18, 2025
STERICARE	6250	100ML STERILE WATER BOTTLE	(01)10850421008768	Nov 6, 2023 to Sep 18, 2025
STERICARE	6220	120ML STERILE SALINE FOIL LID CUP	(01)10850421008874	Nov 6, 2023 to Sep 18, 2025
STERICARE	6210	120ML STERILE WATER FOIL LID CUP	(01)10850421008867	Nov 6, 2023 to Sep 18, 2025
STERICARE	6507	210ML SALINE WOUND FLUSH	(01)10850421008744	Nov 6, 2023 to Sep 18, 2025

STERICARE	6270	250ML STERILE SALINE BOTTLE	(01)10850421008829	Nov 6, 2023 to Sep 18, 2025
STERICARE	6260	250ML STERILE WATER BOTTLE	(01)10850421008775	Nov 6, 2023 to Sep 18, 2025
STERICARE	5280	500ML STERILE SALINE BOTTLE	850421008907	Nov 6, 2023 to Sep 18, 2025
STERICARE	6280	500ML STERILE SALINE BOTTLE	(01)10850421008836	Nov 6, 2023 to Sep 18, 2025
STERICARE	5290	500ML STERILE WATER BOTTLE	850421008914	Nov 6, 2023 to Sep 18, 2025
STERICARE	6290	500ML STERILE WATER BOTTLE	(01)10850421008782	Nov 6, 2023 to Sep 18, 2025
STERICARE	6503	90ML USP SALINE WOULD FLUSH	(01)10850421008751	Nov 6, 2023 to Sep 18, 2025
CARDINAL	1020	100ML STERILE SALINE BOTTLE	(01)50192253044490	Nov 6, 2023 to Sep 18, 2025
CARDINAL	1022	100ML STERILE SALINE BOTTLE	(01)50192253044506	Nov 6, 2023 to Sep 18, 2025
CARDINAL	PT00103427	100ML STERILE SALINE BOTTLE	(01)50192253044506	Nov 6, 2023 to Sep 18, 2025
CARDINAL	1024	100ML STERILE WATER BOTTLE	(01)50192253044513	Nov 6, 2023 to Sep 18, 2025
CARDINAL	10000	100ML STERILE WATER BOTTLE	(01)50192253044520	Nov 6, 2023 to Sep 18, 2025
CARDINAL	PT00103419	100ML STERILE WATER BOTTLE	(01)50192253044513	Nov 6, 2023 to Sep 18, 2025
COVIDIEN	210SAL	STERILE WOUND SOLUTION	(01)10884521139756	Nov 6, 2023 to Sep 18, 2025
COVIDIEN	90SAL	STERILE WOUND SOLUTION	(01)20884521140940	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	SS003	0.9% USP SODIUM CHLORIDE INJECTION	(01)20885632389778	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	SS005	0.9% USP SODIUM CHLORIDE INJECTION	(01)20885632389761	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	SS010	0.9% USP SODIUM CHLORIDE INJECTION	(01)20885632389754	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49154	1000ML STERILE SALINE BOTTLE	(01)20885632395939	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49150	1000ML STERILE WATER BOTTLE	(01)20885632395892	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49155	100ML STERILE SALINE BOTTLE	(01)20885632395946	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49151	100ML STERILE WATER BOTTLE	(01)20885632395908	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	SS010SFR	10ML SYRINGE STERILE	(01)20885632389846	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49152	250ML STERILE SALINE BOTTLE	(01)20885632395915	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49148	250ML STERILE WATER BOTTLE	(01)20885632395878	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49153	500ML STERILE SALINE BOTTLE	(01)20885632395922	Nov 6, 2023 to Sep 18, 2025
HAYLARD OWENS MINOR	49149	500ML STERILE WATER BOTTLE	(01)20885632395885	Nov 6, 2023 to Sep 18, 2025
IDEXX	98-09444-01	BOTTLE STERILE WATER 10 PACK	No UDI	Nov 6, 2023 to Sep 18, 2025
MAC MEDICAL	9210	10ML FILL SYRINGE LABEL	20850020865042	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6281	1000ML STERILE SALINE BOTTLE	612479228399	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6291	1000ML STERILE WATER BOTTLE	612479228405	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6240	100ML STERILE SALINE BOTTLE	612479168565	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6250	100ML STERILE WATER BOTTLE	612479168572	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6220	120ML STERILE SALINE CUP	612479168558	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6210	120ML STERILE WATER CUP	612479168541	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6507	210ML SALINE WOUND FLUSH	612479133761	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6270	250ML STERILE SALINE BOTTLE	612479168596	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6260	250ML STERILE WATER BOTTLE	612479168589	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6280	500ML STERILE SALINE BOTTLE	612479180307	Nov 6, 2023 to Sep 18, 2025
MCKESSON	37-6290	500ML STERILE WATER BOTTLE	612479180314	Nov 6, 2023 to Sep 18, 2025

MCKESSON	37-6503	88.7ML SALINE WOUND FLUSH STERILE	612479228429	Nov 6, 2023 to Sep 18, 2025
MEDICHOICE OWENS MINOR	SWF071	CAN STERILE SALINE SPRY MEDI 7.1 OZ	(01)50885632127043	Nov 6, 2023 to Sep 18, 2025
MEDLINE	DYND1000MLS	1000ML STERILE SALINE BOTTLE	(01)208882776699466	Nov 6, 2023 to Sep 18, 2025
MEDLINE	52011	100ML STERILE SALINE BOTTLE	Customer Kitted	Nov 6, 2023 to Sep 18, 2025
MEDLINE	RDI30296	100ML STERILE SALINE BOTTLE	(01)40884389338248	Nov 6, 2023 to Sep 18, 2025
MEDLINE	54380	100ML STERILE WATER BOTTLE	Customer Kitted	Nov 6, 2023 to Sep 18, 2025
MEDLINE	RDI30295	100ML STERILE WATER BOTTLE	(01)40884389338231	Nov 6, 2023 to Sep 18, 2025
MEDLINE	EMZ10091240	10ML IV FLUSH STERILE FIELD	(01)20363807109166	Nov 6, 2023 to Sep 18, 2025
MEDLINE	DYND40540	110ML STERILE SALINE CUP	(01)40884389334233	Nov 6, 2023 to Sep 18, 2025
MEDLINE	DYND40570	110ML STERILE WATER CUP	(01)40884389334226	Nov 6, 2023 to Sep 18, 2025
MEDLINE	PCS1650	250ML STERILE SALINE BOTTLE	(01)40884389338262	Nov 6, 2023 to Sep 18, 2025
MEDLINE	PCS1550	250ML STERILE WATER BOTTLE	(01)40080196427056	Nov 6, 2023 to Sep 18, 2025
MEDLINE	DYND500MLS	500ML STERILE SALINE BOTTLE	(01)40884389118406	Nov 6, 2023 to Sep 18, 2025
MEDLINE	DYND500MLW	500ML STERILE WATER BOTTLE	(01)40884389118390	Nov 6, 2023 to Sep 18, 2025
MEDLINE	CURSALINE7	CAN SALINE STERILE SPRAY CURAD	40080196297970	Nov 6, 2023 to Sep 18, 2025
SOL	PFF001	0.9% SODIUM CHLORIDE IV FLUSH SYRINGE	(01)20810062438895	Nov 6, 2023 to Sep 18, 2025
TRUDELL	T167007	CUP STERILE SALINE FOIL LID 120 ML	No UDI	Nov 6, 2023 to Sep 18, 2025
TRUDELL	T167005	CUP STERILE WATER FOIL LID 120 ML	No UDI	Nov 6, 2023 to Sep 18, 2025
VYAIR	4873C	CUP STERILE SALINE FOIL LID 120 ML	Discontinued	Nov 6, 2023 to Sep 18, 2025

Reason for the Voluntary Recall:

Nurse Assist has identified product in distribution for which the required sterility assurance level (SAL) of 10⁻⁶ cannot be guaranteed.

Risk to Health:

According to the U.S. Centers for Disease Control and Prevention (CDC), the effects of specific bioburden on people “vary widely, ranging from no symptoms at all to serious infections”. Possible contaminants pose little medical risk to healthy people and use on intact skin, but people who have certain health problems like weak immune systems, who are otherwise susceptible to infection or chronic lung diseases may be more susceptible. Some of the risks include blood stream infections, urinary tract infections or respiratory infections and in the worst-case scenario sepsis and death.

How to recognize that the device may fail:

It is not possible to recognize this potential device failure.

Devices that have been shipped to your facility:

Please see Attachment.

Urgent Actions Items for Customers/Distributors:

- “Devices that have been shipped to your facility” should be immediately taken out of use and quarantined.
- A Returned Goods Authorization will be provided by Nurse Assist, LLC to facilitate the return of the product. This may involve products already in the distribution chain.

- Immediately notify your customers by sending the attached recall notification to all customers who have received “Devices that have been shipped to your facility”. This notice instructs customers to return any affected devices to their distributor.
- Please follow up with customers to ensure they received the recall notification and are taking appropriate action.
- Please make every effort to retrieve any of these unused products from your customers and complete and return the attached MEDICAL DEVICE RECALL RETURN RESPONSE FORM. Forms should be emailed or faxed to RQA, Inc. (a third-party recall provider) at nurseassist@rqa-inc.com or faxed to 844-329-2772.
- Please provide a “Customer Shipment Report” that lists all devices shipped to customers. The report should include the Shipment Date, Customer Name and Address, Part Number, Lot Number, and Quantity. This information is important to determine removal effectiveness.
- Please complete Attachments of Acknowledgement and Product Replacement Forms (separate sheets) and return to RQA, Inc.
- We have reported this recall to the applicable regulatory agencies. If your company repacked these medical devices into convenience kits, please contact your local FDA recall coordinator to evaluate the need for a new recall.

Nurse Assist, LLC Actions:

- Provide Initial FSCA Report to regulatory authorities. Expected by November 17, 2023.
- Address any concerns regulatory authorities may have. Issue Follow-Up Reports as needed.
- Monitor progress of device removal. Follow-up with distributors and customers as needed.
- Provide Final FSCA Report to regulatory authorities.
- Nurse Assist has determined the root cause to be prolonged exposure of the bottled product to the induction sealing process, causing the lift and peel tab adhesive to degrade.
- Nurse Assist has implemented a 100% visual verification of the induction sealing process, along with sampling after the induction sealing process for vacuum leak testing of the sterile barrier.

OTHER INFORMATION:

- For questions, email: productremovalinfo@nurseassist.com.
- Adverse reactions or quality problems experienced with the use of this product should be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Authorized by:

Name: Byron Walker

Signature:

Title: VP Quality

Consumers with questions may contact the company via telephone at 800-649-6800 between the hours of 8am and 430pm (CST). Consumers may also contact the company via e-mail at productremovalinfo@nurseassist.com.

MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form
Response is Required

Customer Information:

0.9% Sodium Chloride Irrigation and Sterile Water, USP

Lot/Serial numbers:

I have read and understand the recall instructions provided in the 11/16/2023 letter. Yes ____
No ____

Any adverse events associated with recalled product? Yes ____ No ____

If yes, please explain:

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Part Number	Lot Number	Quantity in inventory	Quantity shipped to customers	Quantity destroyed	Quantity returned

Return Response Box:

Please provide any additional information, if applicable. Adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax

Distributors:

- I have checked my stock and have quarantined inventory consisting of _____ units
_____ cases
- I have identified and notified my customers that were shipped or may have been shipped this product by **(specify date and method of notification)**;

Questions: (when applicable)

Preferred Methodology:

Please specify your preferred methodology below for handling the recall. RQA, Inc. (a third-party recall provider) can authorize destruction of the product or pick-up.

- Destruction (Customers with 10 or less cases to complete and return a Certificate of Destruction provided by RQA, Inc. Destruction should not occur until authorization has been provided by RQA, Inc.)
- Freight Pick-Up (Customer has a minimum of one pallet to return)
- FedEx Pick-Up (Customer to receive FedEx air bills to return 10 cases or less)

Signature of Receipt _____

Location Name/Full Address

Name/Title

Telephone

Email address

PLEASE FAX OR EMAIL COMPLETED RESPONSE FORM TO:

FAX: 844-329-2772 / ATTN: Nurse Assist

[EMAIL](mailto:nurseassist@rqa-inc.com): nurseassist@rqa-inc.com

For any questions, please contact RQA, Inc. directly at (888) 322-4925.