

December 6, 2023

URGENT: MEDICAL DEVICE RECALL

Nurse Assist Sterile 0.9% Normal Saline

2nd Notification: updated Actions to be taken

Customer Name
Street Address
City, State, Zip Code

Dear Device Distributor,

Purpose of this letter

The purpose of this letter is to advise you that Nurse Assist, LLC is voluntarily recalling their Sterile 0.9% Normal Saline indicated for moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions which is included in certain Busse products supplied to you.

Consequently, Busse Hospital Disposables has decided to extend the recall to any of our products containing the affected Nurse Assist Sterile 0.9% Normal Saline. It is crucial to emphasize that the recall does not compromise the integrity of the kit and other components in the kit by the affected Sterile 0.9% Normal Saline. To date, Busse has not received any reports of serious injuries or deaths resulting from the failure mode associated with this recall. We remain committed to ensuring the safety and well-being of our customers.

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 Nurse Assist notification 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.

Actions to be taken by the Customer/User:

Following our initial recall notification dated 11.21.2023, with instructions to segregate and refrain use of the affected product, we want to provide further clarity on the necessary actions to be taken regarding the affected Nurse Assist Sterile 0.9% Normal Saline products. Our Busse team has actively collaborated with Nurse Assist to gather additional information and has now determined the final course of action.

For the devices that have been shipped to your facility and identified as affected, they may now be destroyed. It is crucial to document the quantity of the destroyed product(s) and provide a

photograph of the items clearly displaying the lot number. Please use the attached destruction form and follow the instructions on the form to submit this information to Nurse Assist and a copy to Busse.

Additionally, for Busse, we request you complete and submit to Busse the attached Acknowledgement and Receipt Form regardless of whether you have product or not.

Affected Devices:

Catalog	Lot Number	Quantity (CS)	Busse SO	Customer PO

Type of Action by the Company:

- Busse Hospital Disposables has immediately identified product in stock affected by the recall and segregated it.
- Manufacture and sale of affected product has been placed on hold.
- Alternatives have been identified for customers in need of product. Please contact our dedicated customer service team at 800-645-6526 for alternative options.

OTHER INFORMATION:

- For questions, email NurseAssistRecall@busseinc.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.
- Nurse Assist Recall Notification is attached to this letter for your reference.
- Attachments:
 - Acknowledgement and Product Replacement Forms
 - Certificate of Destruction

Authorized by:

Muhamad Ansari
Director of Regulatory Affairs

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 12/06/2023 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.

Catalog	Lot	Busse SO	Customer PO	QTY Cases	QTY Each

Signature of Receipt _____

Name/Title	
Telephone	
Email address	



URGENT FIELD SAFETY NOTICE

Nurse Assist, LLC Sterile 0.9% Normal Saline, 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) and Sterile Water, USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes)

Field Safety Corrective Action

DATE: 11-8-2023

TO: Customers/Users of Nurse Assist, LLC Products

Problem Description

Sterile 0.9% Normal Saline, 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) and Sterile Water, USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes) cannot be verified as having the required sterility assurance level of (SAL) of 10^{-6} .

Affected Devices

Expiration dates range from November 1, 2023 to September 18, 2025 for all part numbers, with the exception of part number 1030A (USP STERILE WATER SYRINGE, UDI+B15010304N), which has an expiration date range from November 1, 2023 to September 18, 2028

Brand Name	Part Number	Description	UDI
NURSE ASSIST	6492775	100ML STERILE SALINE BOTTLE	B15064927754G
NURSE ASSIST	6492776	100ML STERILE WATER BOTTLE	B15064927764H
NURSE ASSIST	1010	10CC PREFILLED SYRINGES	+B15010104L
NURSE ASSIST	51638	10CC PREFILLED SYRINGES	+B150516384%
NURSE ASSIST	1210-BP	10ML IV FLUSH SYRINGE	+B1501210BP4G
NURSE ASSIST	6496723	30CC PREFILLED SYRINGE	B15064967234D
NURSE ASSIST	52333	30CC PREFILLED SYRINGES	+B150523334Z
NURSE ASSIST	1203-BP	3ML IV FLUSH SYRINGE	+B1501203BP4I
NURSE ASSIST	1205-BP	5ML IV FLUSH SYRINGE	+B1501205BP4K
NURSE ASSIST	6496722	SYRINGE PREFILLED 10 ML	B15064967224C
NURSE ASSIST	1030	USP STERILE WATER SYRINGE	+B15010304N
NURSE ASSIST	1030A	USP STERILE WATER SYRINGE	+B1501030A4X
STERICARE	6281	1000ML STERILE SALINE BOTTLE	(01)10850421008843
STERICARE	6291	1000ML STERILE WATER BOTTLE	(01)10850421008799
STERICARE	6240	100ML STERILE SALINE BOTTLE	(01)10850421008812
STERICARE	6250	100ML STERILE WATER BOTTLE	(01)10850421008768
STERICARE	6220	120ML STERILE SALINE FOIL LID CUP	(01)10850421008874
STERICARE	6210	120ML STERILE WATER FIOL LID CUP	(01)10850421008867
STERICARE	6507	210ML SALINE WOUND FLUSH	(01)10850421008744
STERICARE	6270	250ML STERILE SALINE BOTTLE	(01)10850421008829
STERICARE	6260	250ML STERILE WATER BOTTLE	(01)10850421008775
STERICARE	5280	500ML STERILE SALINE BOTTLE	850421008907
STERICARE	6280	500ML STERILE SALINE BOTTLE	(01)10850421008836
STERICARE	5290	500ML STERILE WATER BOTTLE	850421008914
STERICARE	6290	500ML STERILE WATER BOTTLE	(01)10850421008782



URGENT FIELD SAFETY NOTICE

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



URGENT FIELD SAFETY NOTICE

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

Transmission of this Field Safety Notice

Please forward this notice to the applicable personnel in your organization or any organization where the "Affected Devices" have been transferred.

Actions To Be Taken By Customers

1. Quarantine and do not use any "Affected Devices" that remain in your inventory.
2. Contact your distributor to arrange for the return and replacement of the devices.

Regulatory Reporting

This Field Safety Corrective Action is being reported to the relevant National Competent Authorities.

Nurse Assist, LLC Contact Person

Michelle Smith, Customer Service Coordinator

Email: msmith@nurseassist.com

Telephone: 800.649.6800 x120 (office)

Thank you very much for your cooperation in this important matter.



URGENT FIELD SAFETY NOTICE

Byron Walker
VP of Quality

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