

URGENT FIELD SAFETY NOTICE

November 9, 2023

Dear Valued McKesson Customer:

Nurse Assist, LLC has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Field Safety Notice regarding specific lots of 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). This notice has been issued because product cannot be verified as having the required sterility assurance level of (SAL) of 10⁻⁶. Affected product first shipped November 1, 2021.

This Urgent Field Safety Notice is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Nurse Assist at **(800) 649-6800**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
560285	37-6210	WATER, IRR SOL FOIL-LID CUP STR 120ML (48/CS)	Expiration Date range from November 1, 2023 to September 18, 2025
560286	37-6220	SALINE, IRR SOL FOIL-LID CUP STR 120ML (48/CS)	
560284	37-6240	SALINE, IRR SOL STR 100ML (48/CS)	
560283	37-6250	WATER, IRR SOL STR 100ML (48/CS)	
520119	37-6260	WATER, IRR SOL STR 250ML (24/CS)	
520118	37-6270	SALINE, IRR SOL STR 250ML (24/CS)	
733255	37-6280	SALINE, IRR SOL 0.9% 500ML (18/CS)	
1086157	37-6281	SALINE, IRR SOL 0.9% 1000ML (6/CS)	
733254	37-6290	WATER, IRR SOL STR 500ML (18/CS)	
1086158	37-6291	WATER, IRR SOL STR 1000ML (6/CS)	
1103071	37-6503	CLEANSER, WOUND SALINE FLUSH 3.0OZ (1EA/CS 12EA/CS)	
636352	37-6507	CLEANSER, WND SALINE FLUSH 7.1OZ (12/CS)	
216197	6220	SALINE, IRR SOL STR 120ML (48/CS)	

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and expiration date(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Field Safety Notice from Nurse Assist, LLC has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days. **Please note:** Credit will only be issued for the affected expiration date(s) of the product(s) listed above and entered on the reply form. **Please place a new order for replacement product if there is an immediate need.**
- 4.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.
- 5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this Urgent Field Safety Notice.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
 Field Safety Notice Reply Form: RC-2023-241
 Nurse Assist – Sodium Chloride Irrigation & Sterile Water for Irrigation

November 9, 2023

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

I acknowledge that I DO HAVE product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			560285	37-6210	WATER, IRR SOL FOIL-LID CUP STR 120ML (48/CS)
			560286	37-6220	SALINE, IRR SOL FOIL-LID CUP STR 120ML (48/CS)
			560284	37-6240	SALINE, IRR SOL STR 100ML (48/CS)
			560283	37-6250	WATER, IRR SOL STR 100ML (48/CS)
			520119	37-6260	WATER, IRR SOL STR 250ML (24/CS)
			520118	37-6270	SALINE, IRR SOL STR 250ML (24/CS)
			733255	37-6280	SALINE, IRR SOL 0.9% 500ML (18/CS)
			1086157	37-6281	SALINE, IRR SOL 0.9% 1000ML (6/CS)
			733254	37-6290	WATER, IRR SOL STR 500ML (18/CS)
			1086158	37-6291	WATER, IRR SOL STR 1000ML (6/CS)
			1103071	37-6503	CLEANSER, WOUND SALINE FLUSH 3.0OZ (12EA/CS)
			636352	37-6507	CLEANSER, WND SALINE FLUSH 7.1OZ (12/CS)
			216197	6220	SALINE, IRR SOL STR 120ML (48/CS)

*Discard Affected lot numbers only

*** The affected expiration date(s) are listed on the McKesson customer letter. Please dispose of affected product in accordance with your institution's policies and procedures.**

Credit will only be issued for product(s) listed above with affected lots.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.



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 WOULD 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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