



Recall of Certain Saline and Sterile Water Medical Products Associated with Nurse Assist

NOTIFICATION DATE: 01/17/2024
LAST REVISED ON: 01/22/2024
SUPPLIER/CATEGORY: IV THERAPY PRODUCTS

SITUATION

- Nurse Assist LLC recall distributors of Nurse Assist water-based medical products and manufacturers of kits and trays that contain Nurse Assist recalled products.
- 0.9% Sodium Chloride Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000 mL 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, 1000 mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes).
- These products were sold under the following brands: Nurse Assist, Cardinal, Covidien, Halyard Owens Minor, Idexx, Mac Medical, McKesson, Medichoice Owens Minor, Medline, Sol, SteriCare, Trudell, and Vyaire. The recalled products may be available as individual units or may be included as part of a kit.

BACKGROUND

- Water-based medical products that are nonsterile and potentially contaminated with bacteria could cause serious or life-threatening infections, including bloodstream, urinary tract, open wound/soft tissue, and respiratory infections.
- The FDA will continue to work with Nurse Assist, LLC to help ensure that the public is notified to stop using the recalled products. The FDA is monitoring reports of problems with water-based medical products manufactured by Nurse Assist, LLC. The FDA will continue to keep the public informed if new or additional information becomes available.

PRODUCT ALERT NOTIFICATION



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ASSESSMENT

- The affected product information is listed below.
- The U.S. Food and Drug Administration (FDA) is warning consumers, health care providers, and health care facilities not to use recalled saline (0.9% sodium chloride) and sterile water medical products manufactured by Nurse Assist, LLC, and sold under various brands.

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 FIOLETT 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	8.50421E+11
STERICARE	6280	500ML STERILE SALINE BOTTLE	(01)10850421008836
STERICARE	5290	500ML STERILE WATER BOTTLE	8.50421E+11
STERICARE	6290	500ML STERILE WATER BOTTLE	(01)10850421008782
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

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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	2.085E+13
MCKESSON	37-6281	1000ML STERILE SALINE BOTTLE	6.12479E+11
MCKESSON	37-6291	1000ML STERILE WATER BOTTLE	6.12479E+11
MCKESSON	37-6240	100ML STERILE SALINE BOTTLE	6.12479E+11
MCKESSON	37-6250	100ML STERILE WATER BOTTLE	6.12479E+11
MCKESSON	37-6220	120ML STERILE SALINE CUP	6.12479E+11
MCKESSON	37-6210	120ML STERILE WATER CUP	6.12479E+11
MCKESSON	37-6507	210ML SALINE WOUND FLUSH	6.12479E+11
MCKESSON	37-6270	250ML STERILE SALINE BOTTLE	6.12479E+11
MCKESSON	37-6260	250ML STERILE WATER BOTTLE	6.12479E+11
MCKESSON	37-6280	500ML STERILE SALINE BOTTLE	6.12479E+11
MCKESSON	37-6290	500ML STERILE WATER BOTTLE	6.12479E+11
MCKESSON	37-6503	88.7ML SALINE WOUND FLUSH STERILE	6.12479E+11
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

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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	4.00802E+13
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
VYAIRE	4873C	CUP STERILE SALINE FOIL LID 120 ML	Discontinued

The recalled products have these expiration dates:

- November 1, 2023 - September 18, 2025 (all products, except for 1030A)
- November 1, 2023 - September 18, 2028 (part number 1030A)

RECOMMENDATIONS

- Circulate the notice to all who need to be aware.
- Check your supply of saline (0.9% sodium chloride) and sterile water medical products (bottles, spray cans, cups, and prefilled syringes) to find out if you have any of the [recalled](#) products at home or in your health care facility's inventory.
- Do not use these recalled products and follow the recommendations in the company's [recall](#) announcement.
- Be aware that these recalled products may be available as individual units or may be included as part of a kit.
- If you have questions about this recall, contact Nurse Assist, LLC by phone at 800-649-6800 Monday through Friday between the hours of 8:00 am and 4:30 pm (CST) or by e-mail at productremovalinfo@nurseassist.com.
- Report any problems with saline and sterile water medical products by Nurse Assist, LLC to the FDA. See [Reporting Problems to the FDA](#) below.
- DICE@FDA.HHS.GOV or call 800-638-2041 or 301-796-7100.