

Recall of Certain Saline and Sterile Water Medical Products Associated with Nurse Assist: FDA Safety Communication

Español (<https://www.fda.gov/medical-devices/safety-communications/no-utilice-determinadas-marcas-de-productos-medicos-de-suero-salino-y-agua-esteril-de-nurse-assist>)

Update: March 12, 2024

Additional Related Recalls of Saline and Sterile Water Medical Products Associated with Nurse Assist

In direct response to the [Nurse Assist, LLC](https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nurse-assist-llc-issues-recall-09-sodium-chloride-irrigation-usp-and-sterile-water-irrigation-usp#:~:text=for%20Irrigation%20USP-Company%20Announcement,result%20in%20a%20nonsterile%20product) (<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nurse-assist-llc-issues-recall-09-sodium-chloride-irrigation-usp-and-sterile-water-irrigation-usp#:~:text=for%20Irrigation%20USP-Company%20Announcement,result%20in%20a%20nonsterile%20product>), recall on November 6, 2023, distributors of Nurse Assist water-based medical products and manufacturers of kits and trays that contain Nurse Assist recalled products are initiating voluntary recalls.

The list of additional recalls and affected products are described [below](#).

The FDA is receiving reports of adverse events associated with use of Nurse Assist products and is further evaluating this information.

Date Issued: November 6, 2023

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.

On November 6, 2023, Nurse Assist, LLC announced a [recall](/safety/recalls-market-withdrawals-safety-alerts/nurse-assist-llc-issues-recall-09-sodium-chloride-irrigation-usp-and-sterile-water-irrigation-usp) of the following water-based medical products because the products may not be sterile:

- 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 Vyair. The recalled products may be available as individual units or may be included as part of a kit.

Recommendations for Consumers, Health Care Providers, and Facilities

- 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](/safety/recalls-market-withdrawals-safety-alerts/nurse-assist-llc-issues-recall-09-sodium-chloride-irrigation-usp-and-sterile-water-irrigation-usp) 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 (<mailto: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.

Device Description

Water-based medical products include sterile saline (0.9% sodium chloride) and sterile water medical products used for irrigation or flushing of wounds or medical tubing (such as [intravenous \(IV\)](https://medlineplus.gov/ency/article/002383.htm)) catheters and urinary catheters). Water-based products may also be used for other medical purposes.

Products May Not Be Sterile

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.

Patients who are elderly, critically ill, have weak immune systems (including newborn infants, pregnant women, and cancer patients) or have chronic diseases are particularly at risk of infection. However, other patients could also develop infections after they are exposed to contaminated water-based medical products.

To date, the FDA is not aware of reports of adverse events associated with the use of these recalled products.

FDA Actions

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.

Affected Products

Product information provided by the company, including [Unique Device Identifier \(UDI\)](#), is in the table below.

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)

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

Brand Name	Part Number	Description	UDI
STERICARE	6210	120ML STERILE WATER FIOI 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
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)20885632398978
HALYARD OWENS MINOR	SS005	0.9% USP SODIUM CHLORIDE INJECTION	(01)208856323989761
HALYARD OWENS MINOR	SS010	0.9% USP SODIUM CHLORIDE INJECTION	(01)208856323989754
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)20885632398946
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
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	RDJ30296	100ML STERILE SALINE BOTTLE	(01)40884389338248
MEDLINE	54380	100ML STERILE WATER BOTTLE	Customer Kitted
MEDLINE	RDJ30295	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
VVAIRE	4873C	CUP STERILE SALINE FOIL LID 120 ML	Discontinued

Unique Device Identifier (UDI)

The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. For more information on UDI, please visit [Unique Device Identification System \(UDI Systems\) \(/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system\)](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system).

Related Additional Recalls (Updated 3/12/2024):

Recalling Firm	Description	Additional Information
Cardinal Health	Covidien and Cardinal Health brand urology and operating room-specific kits and trays that contain 0.9% sodium chloride irrigation USP and sterile water for irrigation USP supplied by Nurse Assist	Cardinal Health Issues Medical Device Recall for Nurse Assist Products Contained Within Kits/Trays (/safety/recalls-market-withdrawals-safety-alerts/cardinal-health-issues-medical-device-recall-nurse-assist-products-contained-within-kitstrays-0) Affected Covidien and Cardinal Health brand codes and lot numbers (/media/175947/download?attachment)
Busse Hospital Disposables	Medical device kits and trays, such as, tracheostomy care trays, tracheostomy care sets, and dressing change trays, containing 1 Nurse Assist part 6240, Stericare 100ML Sterile Saline Bottle.	Busse Hospital Disposables Issues Nationwide Recall of Kits/Trays Containing Sterile Water Based Products Under Recall by Nurse Assist (/safety/recalls-market-withdrawals-safety-alerts/busse-hospital-disposables-issues-nationwide-recall-kitstrays-containing-sterile-water-based)
ROI CPS LLC	Regard Operative Lap P&S Surgical trays or kits which contain irrigation solution component recalled by Nurse Assist.	ROI CPS, LLC Recalls Regard Operative Lap P&S Surgical Kit Due to Possible Lack of Sterility FDA (/medical-devices/medical-device-recalls/roi-cps-llc-recalls-regard-operative-lap-ps-surgical-kit-due-possible-lack-sterility); Affected Products UDI and lot numbers (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=204649)
Windstone Medical Packaging dba Aligned Medical Solutions	Convenience kits, such as low extremity packs, ocular packs, and closure kits which contain the recalled Nurse Assist Sterile Saline, brand Name - Medline Medical part # DYND40540 110ML Sterile Saline Cup or Nurse Assist Sterile Saline Brand Name - McKesson Medical part # 560284 100ML Sterile Saline Bottle.	Windstone Medical Packaging dba Aligned Medical Solutions Issues Nationwide Recall of Nurse Assist Sterile Saline Placed Into the Following Kits: AMS10833 Local Lower Extremity Pack I, AMS12947 In House Ocular Pack, AMS12947A In House Ocular Pack and AMS13043 Closure Kit (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/windstone-medical-packaging-dba-aligned-medical-solutions-issues-nationwide-recall-nurse-assist) Windstone Medical Packaging, Inc. Recalls Local Lower Extremity Pack, In House Ocular Pack and Closure Kit Containing Sterile Water Based Products Under Recall by Nurse Assist (/medical-devices/medical-device-recalls/windstone-medical-packaging-inc-recalls-local-lower-extremity-pack-house-ocular-pack-and-closure-kit)
Maquet Cardiovascular, LLC	Express chest drains, models 4000-100N and 4050-100N, disposable systems prepackaged with 30 mL syringe filled with water-based products recalled by Nurse Assist.	Maquet Cardiovascular, LLC Recalls Atrium Express Dry Suction Dry Seal Chest Drain Containing Sterile Water Based Products Under Recall by Nurse Assist (/medical-devices/medical-device-recalls/maquet-cardiovascular-llc-recalls-atrium-express-dry-suction-dry-seal-chest-drain-containing-sterile)
Avanos Medical, Inc	MIC* Gastric - Jejunal Feeding Tube Kits. These kits include Nurse Assist supplied syringes, pre-filled with sterile water, essential for inflating the retention balloon of the feeding tube.	Avanos Medical, Inc. Announces Voluntary Recall in Response to Nurse Assist, LLC Sterile Water Medical Products Recall (/safety/recalls-market-withdrawals-safety-alerts/avanos-medical-inc-announces-voluntary-recall-response-nurse-assist-llc-sterile-water-medical)

Reporting Problems to the FDA

If you think you had a problem with these recalled products, or any medical device, the FDA encourages you to [report the problem through the MedWatch Voluntary Reporting Form \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](#).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities\)](#) should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>) or call 800-638-2041 or 301-796-7100.

Was this helpful?