

## COMPANY ANNOUNCEMENT

# Nurse Assist, LLC Issues Recall of 0.9% Sodium Chloride Irrigation USP and Sterile Water for Irrigation USP Nationwide and to Canada

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

November 06, 2023

**FDA Publish Date:**

November 06, 2023

**Product Type:**

Medical Devices

**Reason for Announcement:**

Lack of sterility assurance

**Company Name:**

Nurse Assist, LLC

**Brand Name:**

Multiple brand names

**Product Description:**

0.9% Sodium Chloride Irrigation USP and Sterile Water for Irrigation USP

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## Company Announcement

**On November 6, 2023, Nurse Assist, LLC** initiated a voluntary recall of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP, due to the potential for a lack of sterility assurance, which could result in a nonsterile product. In populations most at risk, such as patients who are immunocompromised, there is a possibility that the use of the affected product could potentially result in severe or life-threatening adverse events.

To date, Nurse Assist, LLC has not received any reports of adverse events for these products.

The product was distributed in the United States and Canada. Recalled Product was distributed from November 1, 2021 to September 18, 2023.

Recalled products include the following products, these products may be packaged inside kits:

Product	Size
0.9% Sodium Chloride 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

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

Detailed product information is as follows:

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
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
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

Recalled products may be repackaged into medical device convenience kits.

The potential for a compromised sterile barrier was identified during routine product testing. Further investigations prompted a widening of product scope out of an abundance of caution.

Consumers who have these products should stop using them and contact their distributor or Nurse Assist, LLC for return authorization.

Nurse Assist, LLC is notifying its distributors and customers by electronic communication and letter and is arranging for replacement of all recalled products. Users are being requested to coordinate the return of product with Nurse Assist, LLC.

Consumers with questions may contact the company via telephone at 800-649-6800 Monday through Friday between the hours of 8am and 430pm (cst). Consumers may also contact the company via e-mail at [productremovalinfo@nurseassist.com](mailto:productremovalinfo@nurseassist.com) (<mailto:productremovalinfo@nurseassist.com>).

Nurse Assist, LLC has notified the FDA of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

## Company Contact Information

### Consumers:

Nurse Assist, LLC

☎ 800-649-6800

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Yes

No

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