

**URGENT PRODUCT RECALL**

December 11, 2023

Dear Valued McKesson Customer:

Cardinal Health has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Product Recall regarding specific lots of their Kits and Trays containing Nurse Assist products. This notice has been issued because Nurse Assist, LLC products cannot be verified as having the required sterility assurance level of (SAL) of 10<sup>-6</sup>. 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. Affected product first shipped November 1, 2021.

This Urgent Product Recall 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 clinical inquiries, please contact Cardinal Health at **(888) 444-5440**.

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 below for a list of affected item(s) previously distributed by McKesson Medical-Surgical

MMS #	MMS Catalog #	Description	Affected Lot(s)		
10135	2101-	CATH TRAY, FOLEY LTX 16FR (20/CS)	2214422964	2214423064	
10358	5029	CATH TRAY, PREFIL SYR 10CC (20/CS)	2204637764	2208812864	2217922164
			2208812764		
10450	6153-	CATH TRAY, FOLEY SIL W/BG 16FR5CC (10/CS)	2205329464	2213742064	2216533964
			2205328764		
10451	6154-	CATH TRAY, FOLEY SIL W/BG 18FR(10/CS)	2217922664		
10466	6155-	CATH TRAY, FOLEY W/BG 16FR 5CC(10/CS)	2205319564	2205328664	2216802264
130512	5027	CATH TRAY, PREFIL SYR 30CC (20/CS)	2214434964	2227031164	2305904064
			2214435064	2301018164	2319902764
			2225305264		
132926	10142	SUCTION KIT, W/WATER 2GLV 14FR(24/CS)	2215804464	2222802464	2227022164
			2216520864	2223502364	2300121164
			2216804364	2224236664	2303107064
			2221306364	2224921364	2326115764
			2222116064	2226313264	2326115864
148371	6014	CATH TRAY, FOLEY LTX/SIL 16FR (10/CS)	2205318964	2215119764	
148372	6080-	CATH TRAY, FOLEY LTX/SIL 18FR (10/CS)	2214452564		
151399	3044-	CATH TRAY, FOLEY LTX 18FR (20/CS)	2208815964		
152814	6140-	CATH TRAY, FOLEY SIL 16FR (10/CS)	2205319164	2209519564	2218504964
161614	8887601220	CATH TRAY, W/O CATH/BG W/PVP TWL (20/CS)	2208901164	2216807564	
164319	10102	SUCTION KIT, W/WTR 10FR (24/CS) 373613	2216804264	2234017264	2302409564
			2219904964		

McKesson Medical-Surgical Inc.

MMS #	MMS Catalog #	Description	Affected Lot(s)		
165278	12153	SUCTION KIT, W/SALINE 2GLV 14FR (24/CS)	2200423964	2234028964	2234729564
			2203505264	2234029064	2302409864
			2204604164	2301204364	2302419564
			2219905464	2234029764	2308901764
			2220700264	2234729464	2324809964
			2221306564		
165513	12082	CATHETER KIT, SCTN NACL 2GLV 8FR (24/CS)	2201820964	2205203064	
165514	12102-	CATHETER KIT, SCTN NACL 2GLV 10FR (24/CS)	2200301264	2215804564	2210203464
			2201821064	2206715464	2303107164
165515	12182-	CATHETER KIT, SCTN NACL 2GLV 18FR (24/CS)	2221306664	2222135264	2306633164
166664	12142	CATHETER KIT, SCTN NACL 2GLV 14FR (24/CS)	2135114264	2219905364	2306633064
			2200423864	2220700164	2315904264
			2204604064	2221306464	2308902364
			2208105864	2222116164	2311517064
			2211605564	2223502664	2312110664
			2209404264	2232603864	2315904364
			2210203564	2303831264	2315904464
			2213010564	2234017364	2326115964
			2215804664	2302419664	2324810464
			2216804464	2303816964	2324809764
176802	8887600776	CATHETER TRAY, FOLEY 16FR (20/CS)	2217924364		
194111	47802	TRACH CARE KIT, W/PEROX & SALINE (24/CS)	2201103364	2216523964	2229112364
			2201103464	2217209464	2227725164
			2201804164	2219323864	2227725264
			2201804264	2217915264	2227022264
			2204627064	2219326264	2231226564
			2204627364	2219910964	2231914264
			2204801164	2221312264	2305711364
			2205309664	2221312164	2305711464
			2205309764	2222816164	2306201964
			2206020664	2222816364	2300121564
			2206020764	2223528364	2305706564
			2206731664	2223528464	2306622764
			2206731764	2224243164	2307909364
			2208117464	2224243264	2307305764
			2208117564	2224929764	2307305664
			2208828064	2224929864	2307909464
			2208828164	2225515664	2308600464
			2212326364	2226320664	2310101364
			2213014664	2225515764	2310101464
			2215107664	2226320764	2311517164
2215808564	2227034464	2310900364			
2222816264					

MMS #	MMS Catalog #	Description	Affected Lot(s)		
197085	8887600784	CATH TRAY, FOLEY 18FR (20/CS)	2215120764		
204162	68820-	IRR TRAY, PISTON SYR 100ML SALINE (20/CS)	2200426764	2213015364	2232203764
			2201121964	2213709164	2312920864
			2212328164	2215108864	2313507064
207022	2016	URINE METER TRAY, FOLEY 16FR (10/CS)	2205334564	2215118364	
210331	10122	SUCTION KIT, W/WTR 12FR (24/CS) 373614	2219310964	2303816764	2328306664
			2300121064		
221336	76000	CATH PROCEDURE TRAY, W/O CATH 30CC (20/CS)	2209408264	2215809864	2305228964
			2210207964	2217211464	2305706764
			2211007564	2217912564	2312920964
			2213709364	2220901064	2321910264
			2214416164	2303825364	2308203564
			2211609964	2304507464	2313507264
			2215109364	2305228764	2314219064
			2216525364		
221337	76010-	CATH PROCEDURE TRAY, W/O CATH 10CC (20/CS)	2132716964	2134110464	2211610064
			2132717064	2134110564	2212328664
			2133422864	2208109064	2209408364
			2133422964	2211007664	2210208064
223222	2006	URINE METER TRAY, FOLEY 16FR (10/CS)	2215118264		
292264	8946	CATHETER TRAY, ULTRAMER 16FR (10/CS)	2209526664		
299196	76020	CATH PROCEDURE TRAY, W/O CATH 30CC (20/CS)	2209408564	2222808464	2224800564
			2210208264	2220707664	2307904064
			2211007864	2220726364	2315710664
			2211610264	2223515264	2316409064
			2215109464		
315112	8949-	CATHETER TRAY, FOLEY 16FR (10/CS)	2205320964	2209526764	
321278	6256	CATH TRAY, W/O CATH (10/CS)	2209525764		
329055	3716	CATH TRAY, FOLEY W/DRN BG 16FR(10/CS)	2200120364	2204635764	2208812264
			2200120464	2204635864	2209101864
			2200429564	2205317964	2212301864
			2200429664	2205318064	2212301964
			2203930464	2206024964	2216806264
			2203930564	2206025064	2217921864
329057	3532-	CATH TRAY, FOLEY SYR 30CC (10/CS)	2213741364	2306612564	2314901664
405030	12191	SUCTION KIT, CATH W/WATER 14FR(24/CS)	2219311064	2220700364	2222116264
			2219905564	2221306764	
478608	76030	INSERTION TRAY, CATH W/10CC PFSYR (20/CS)	2134208364	2215109564	2210208364
			2208109364	2209408664	
498197	3718	FOLEY TRAY, KENGUARD 18FR (10/CS)	2201131264	2209525464	2217921964
			2203933064	2210232964	

MMS #	MMS Catalog #	Description	Affected Lot(s)		
548899	6146LL-	CATHETER TRAY, FOLEYSIL MONO16F LUER LCK (10/CS)	2203933464	2210210364	2212323064
			2209525664	2210210464	2215116164
550207	6144ICLL-	CATH TRAY, FOLEY SLVR W/BAG 14FR (10/CS)	2216802364		
550216	7006LL	CATH TRAY, FOLEY SIL 16FR (10/CS)	2207805664	2212323864	2215826764
			2208817564		
550223	6144LL	CATHETER TRAY, FOLEY SIL MONO 14FR (10/CS)	2214435164	2217922564	
550224	6148LL	CATHETER TRAY, SIL MONO 18F (10/CS)	2212900264	2212900364	
703937	6175	CATHETER TRAY, CURITY W/MONO FLO DRN BAG (10/CS)	2205319864	2205328564	
733605	P4P16SD	URINE METER TRAY, FOL CATH SECURE 16FR (10/CS)	2201116464	2204633964	2212500164
			2134203264	2204634064	2214422064
			2134203364	2205315364	2214422164
			2200118864	2207402764	2217917064
			2200118964	2210218564	2217917164
			2200428164	2208814664	2218625764
			2203928464	2212321664	2201116564
770124	PP16SD	CATHETER, FOLEY W/CATH SECURE & DRN BAG 16FR (10)	2134217964	2201132664	2208814464
			2200119064	2204633564	2215823864
			2200428064	2204633664	
852741	PP18ULD	CATHETER TRAY, URETH 18FR STRTTIP LTX W/2000ML BG	2215117764		
852742	PP16ULD	CATHETER TRAY, URETH COUDE 16FR W/2000ML DRAIN BAG	2208814564	2215823964	
861121	PP16XSD	CATHETER, FOLEY DOVER SILVER 16FR (10/CS)	2217919764		
863277	PP14SD	CATHETER, FOLEY W/DRAIN BAG 14FR SILICONE TRAY (10/CS)	2200119164	2201132564	2215117664
			2200427964		
863281	PP18SD	CATHETER, FOLEY W/DRAIN BAG 18FR SILICONE TRAY (10)	2203931364		
1037888	76012	INSERTION TRAY, CATH UNIV W/PVP 10CC (20/CS)	2132134964	2211007764	2209408464
			2208109164	2210208164	

**McKesson Customer Instructions:**

- 1.) Examine your inventory for any product matching the affected items and lot numbers listed above.
- 2.) A copy of the Urgent Component Recall from Cardinal Health has been included for reference.
- 3.) If you have product affected by this notice, please affix a Recall Warning Label to the product packaging. Upon opening the kit for use, dispose of affected Nurse Assist component. Adhesive labels can be requested from Cardinal Health via phone at 888-444-5440. **Please note:** all other components in the kits are not affected by this recall and may be used.
- 4.) If you have further distributed any of the items referenced in this notification, provide your accounts with a copy of this Urgent Product Recall.

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](mailto:MMSRecalls@McKesson.com) or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

**McKesson Medical-Surgical Inc.**

# URGENT: KIT/TRAY COMPONENT RECALL

Cardinal Health 200, LLC  
3651 Birchwood Drive  
Waukegan, IL 60085  
[cardinalhealth.com](http://cardinalhealth.com)



**CardinalHealth**

December 05, 2023

## Various Kits/Trays Containing Nurse Assist Products

### **Please reference Attachment 1 — Impacted Products**

File #: Event-2023-05906 and Event-2023-05907

Dear Valued Customer or Distributor:

Cardinal Health was recently informed that Nurse Assist, LLC initiated an Urgent Field Safety Notice regarding several products that cannot be verified as having the required sterility assurance level of (SAL) of  $10^{-6}$ . 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. Please see enclosed Nurse Assist, LLC Urgent Field Safety Notice.

Cardinal Health has completed its investigation regarding this recall and determined that you may have received trays/kits containing the affected Nurse Assist component(s). ~~Please reference Attachment 1 — Impacted Products in identifying impacted product along with the corresponding lot numbers that are affected by this action.~~

If you locate affected product within your facility, please do the following:

1. **QUARANTINE** affected kits/trays.
2. **ALERT** your clinicians of this action.
3. **AFFIX** the enclosed WARNING LABEL to the front of each kit/tray so that it is clearly visible to clinicians, instructing them to remove and **discard** the recalled component(s).
4. **NOTE** if you have transferred the affected kits/trays to other departments or facilities within your system, please provide a copy of this notice ~~and recall acknowledgement form to them.~~
5. **DISTRIBUTOR** if you have further distributed affected kits/trays, please notify your customers of this recall.
6. **RETURN** ~~a copy of the enclosed Acknowledgment Form confirming your receipt of this action and the completion of over-labeled product via email [GMB-FieldCorrectiveAction@cardinalhealth.com](mailto:GMB-FieldCorrectiveAction@cardinalhealth.com) or fax to 614.652.9648.~~

Additional labels will be sent to your facility upon request.

**CONTACT** the appropriate Customer Service group with questions related to this notification. Monday – Friday between 8:00am - 5pm EST:

- Hospital – 800-965-5227
- Federal Government – 800-444-1166
- Distributor – 800-635-6021
- All Other Customers – 888-444-5440

For field action concerns, please contact the field action team at:

[GMB-FieldCorrectiveAction@cardinalhealth.com](mailto:GMB-FieldCorrectiveAction@cardinalhealth.com) or call 800-292-9332.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, require additional labels or desire special assistance relating to this recall, please feel free to contact Cardinal Health at 800.292.9332.

Sincerely,

A handwritten signature in black ink that reads "Catherine Redmond".

Catherine Redmond  
Director, Quality Management





## 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<sup>-6</sup>.

### 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](mailto: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

Nurse Assist, LLC  
4409 Haltom Road  
Haltom City, TX 76117  
Telephone: 800.649.6800 x 215 (office) or 817-879-4421 (mobile)  
Email: [bwalker@nurseassist.com](mailto:bwalker@nurseassist.com)



