

## Cardinal Health Issues Medical Device Recall for Nurse Assist Products Contained Within Kits/Trays

In direct response to the [Nurse Assist, LLC](#) voluntary product recall (which included products supplied to Cardinal Health used in Covidien and Cardinal Health™ brand kits and trays), Cardinal Health issued a medical device recall on December 5, 2023, for its 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. Under the Nurse Assist voluntary recall, this product is being recalled due to the potential for a lack of sterility assurance which could result in non-sterile 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. There have been no reports of patient harm. Our top priority is the safety of patients.

After reviewing the impact of the Nurse Assist recall, Cardinal Health has identified the below affected Covidien and Cardinal Health™ brand codes and lot numbers.

Customers who received the listed lots were given instructions to:

1. **QUARANTINE** affected kits/trays.
2. **ALERT** clinicians of the recalled component(s).
3. **AFFIX a 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. **NOTIFY** other departments, facilities or customers within the customer's hospital system, if they have transferred the affected kits/trays, and provide a copy of the notice and recall acknowledgement form to them.
5. **RETURN** their enclosed Acknowledgment Form confirming receipt of this action and the completion of over labeled product via fax to **614.652.9648**.

For additional questions related to this recall, please reach out [to: fieldcorrectiveaction@cardinalhealth.com](mailto:fieldcorrectiveaction@cardinalhealth.com) or call 800-292-9332.

***On December 21, 2023, Cardinal Health issued an additional notice to customers with an expanded list of impacted products. Please see complete list below.***

Product Code	Lot #	Product Description
2006	2231911964	2006 SIL U/M FOLEY TRAY 16FR
	2205328464	
	2206011264	
	2208815564	
	2214451164	
	2223543664	
	2216501264	
	2303011564	

	2309041764	
2016	2306612464	2016 ULTRAMER UMFT 16FR
6014	2211030964	6014 LTX CATH ECON F/T 16 FR
	2308700964	
	2309042564	
	2308900664	
	2216806564	
8887601220	2231221264	FOLY CATH TRAY W/PVP
	2210904664	
	2213048864	
	2209526564	
	2218615064	
	2218700664	
	2216504764	
	2224232664	
	2224940164	
	2226323864	
6146LL	2222830564	16FR SIL DRAIN BAG FOLEY TRAY
	2234606164	
	2300129064	
	2300129264	
	2206723564	
	2206723664	
	2213047764	
	2213741964	
	2214452664	
	2216503164	
	2211628464	
	2225100964	
	2305403264	
	2207404564	
7006LL	2223542964	6FR SIL URINE METER FOLEY TRAY
	2223543064	
	2231912364	
	2232102364	
	2206721364	
	2206721464	
	2210904064	
	2209525964	
	2213048664	
	2232601264	
	2216504164	
76030	2225619364	CATH PROCEDURE TRAY W/BZK....

	2308203664	
	2314320264	
	2317301364	
	2225619264	
	2223515364	
	2304507564	
	2307904164	
	2314219264	
	2321326564	
76010	2229812864	CATH PROCEDURE TRAY W/PVP
	2231228064	
	2231906364	
	2231906464	
	2231906564	
	2232203864	
	2225800564	
	2307903964	
	2315013764	
	2217912664	
	2319400664	
	2319812264	
76012	2219320964	10CC INSERTION TRAY WITH PVP
	2229812964	
	2231228364	
	2217912764	
	2301018064	
	2319400564	
6154	2233605364	6154 SIL MONOFLO TY PVI 18FR
	2206011164	
	2309042764	
6153	2206007764	6153 SIL MONOFLO TY PVI 16FR
	2222830664	
	2233605264	
	2300125764	
	2300125864	
	2300132664	
	2314302964	
	2205201164	
	2206007864	
	2213047864	
	2223545264	
	2304402364	
	2317731064	

	2211628564	
8887600784	2215827464	FOLY TRAY SLCON 5CC 18FR
3044	2319902464	3044 FOLEY CATH TRAY 18FR
	2305206864	
2101	2232802564	2101 FOLEY CATH TRAY 16FR
	2224939064	
	2305206564	
5029	2221408764	5029 ADD-A-CATH 10CC
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	2231225064	
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	2305100864	
	2317730764	
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	2205318664	
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	2206006364	
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	2300131064	
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8887600776	2301032164	FOLY TRAY SLCON 5CC 16FR
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	2305232064	
3718	2303815264	3718 18FR KENGUARD FOLEY TRAY
	2307202164	
	2209534664	
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	2219402664	
	2220726564	
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3716	2203930364	3716 16FR KENGUARD FOLEY TRAY
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	2222114064	
	2222114164	
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PP16ULD	2209514764	PRM BAG 16FR LATEX CATH SECURE
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7946	2222832064	7946 16FR ECONOMY FOLEY TRAY
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P4P14ULD	2210901864	400 UM 14FR LATEX CATH SECURE
	2308700464	
P4P16XTSD	2204636464	400 UM 16FR TSC CATH SECURE
	2304400764	
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P4P18XTSD	2213739364	400 UM 18FR TSC CATH SECURE
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P4P14TSD	2319101064	400 UM TSC CATH SECURE
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P4P18TS	2219401064	P400 PREM U/M 18FR TMP SNS
P4P16XTS	2217920264	P400 PREM U/M 16FR SL TMP SNS
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7020LL	2303824064	ADD-A-U/M FOLEY TRAY W/LUER LO
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	2232613764	
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PP16XSD	2301030964	PREC PRM 16FR SILVER FLY TY
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6144ICLL	2208800564	14FR SILVER DRAIN BAG FOLEY TR
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6175	2307111964	6175 ADD-A-FOLEY PVI
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6148LL	2210903364	18FR SIL DRAIN BAG FOLEY TRAY
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6140	2206723264	6140 SIL FOLEY TRAY 16FR
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	2213301264	
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2018	2223543764	2018 ULTRAMER UMFT 18FR
6155	2318417664	6155 LTX MONOFLO TY PVI 16FR
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	2312208864	
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	2313100664	
	2210903464	
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8949	2206903964	8949 100% SILI FOLEY TY 16FR
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	2231220164	
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	2213043064	
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	2313614864	
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7006ICLL	2223120264	16FR SILVER URINE METER FOLEY
68820	2217401764	IRRIG TRAY SALINE PISTON SYR
	2305706564	
76020	2301018164	CATH PROCEDURE TRAY W/BZK....
5027	2225801364	5027 CURITY ADD-A-CATH 30CC
12182	2303816964	SAFVAC 18FR 2 L GL SALINE TRAY
12082	2201820964	SAF VAC 8FR 2 L GL SALINE TRAY
	2205203064	
12102	2200301264	SAFVAC 10FR 2 L GL SALINE TRAY
	2201821064	
	2215804564	
	2206715464	
	2210203464	
	2303107164	
12142	2227022264	SAFVAC 14FR 2 L GL SALINE TRAY
	2302419564	
	2311517164	
10142	2324809764	SAF VAC 14FR 2 L GL WATER TRAY
10102	2226313264	SAF VAC 10FR 2L GL WATER TRAY
12191	2324810164	SAFVAC 14FR DRP 2 L GL WWATER TOWEL
1814	2210206164	LATEX BOAT 14FR 5CC
	2211627364	
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2004LL	2210902464	14FR SIL U/M FOLEY TRAY
	2211627464	
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	2222828564	
	2223543564	
	2232518064	
2020	2211627664	ADD-A-FOLEY U/M F/T
	2223543864	
2116IC	2303822664	16FR FOLEY INSERTION TY
3515	2210219864	KENGUARD ADDFOLEY 10CCSYR
	2212322764	
	2213741264	
	2300203164	
	2303814264	
	2309042464	
	2314901764	
3531	2220726364	KENGUARD ADD A FOLEY 30CC

407716	2213046864	TRAY CLSD FLY 16FR SIL
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8887606161	2300203564	FOLY LIT SLCON 5CC 16FR
6070	2214452464	SIL MONOFLO TRAY 14FR
	2233606964	
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6146ICLL	2206728064	16FR SILVER BAG FOLEY
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	2308005164	
	2310901764	
6148ICLL	2219330364	18FR SILVER DRN BG FL
	2223545164	
	2308701164	
6156	2217403164	MONOFLO TRAY 18FR LATEX
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	2314306864	
	2318417764	
6162	2212323264	ULTRAMER FOLEY TY 14FR
	2307111864	
6164LL	2216503264	14FR ULTRMR(LTX) DRN BG
6165C	2313611764	16FR 5CC LTX COUDE MONO
6165LL	2216503364	16FR ULTRMR LTX DRN BG
	2222830964	
	2234606064	
	2305207264	
6166LL	2208804164	18FR ULTRMR(LTX) DRN BG
	2219403264	
6176LL	2210903664	ADD-A-FOLEY TRAY W/LL
	2213742164	
	2213747764	
	2216503464	
	2303012364	
	2308005664	
	2310813464	
	2317731264	
	2318417864	
6210	2214453164	SIL FOLEY TRAY 18 FR
6255	2206014664	ECON ADD-A-FOLEY
	2213742464	

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6946	2219403864	16FR ULTRAMER TY W/AR CHM
	2303009364	
6947LF	2211629164	100% SIL FLY TY 14FR LF
	2309043164	
6948	2306613264	ULTRAMER TY W/AR CHM
7008LL	2216807164	18FR SIL U/M FOLEY TRAY
	2217801764	
	2232612864	
701672	2212324064	NEDLELESS 16FR ULTY UM
7016C	2212323964	16FR COUDE UM FOLEY TRAY
	2232613064	
7016LL	2211629564	16FR ULTRAMER U/M FOLEY
	2223546264	
7018LL	2214456264	18FR ULTRAMER U/M FOLEY
7100	2211629664	CURITY ADD-A-CATH TRAY
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8122	2211629864	URINE METER FOLEY TRAY
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8256	2212324364	NDLELSS ADD-FOLEY W/AR CH
8944	2213743264	14FR FLY TY 5CC ULTR CATH
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	2322322464	
8948	2213049064	NDLELSS 18FR ULTR W/AR CH
	2312301864	
8950	2208818264	100% SIL FOLEY TY 18FR NS
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	2209524364	
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P4P18CSDK2	2232517864	100% SILICONE 400 ML U/M
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P4P18TSD	2210902064	400 UM 18FR TSC
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P4P18XCSDK	2206726464	P400 UM TRAY WITH 18 FR SILVER-HYDROGEL
	2208815264	
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PP14ULD	2309040764	PRM BAG 14FR LATEX
PP14XSD	2301206264	PREC PRM 14FR SILVER
PP16CSD	2208814364	PRECISION PRM 16FR SIL
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	2309040964	
	2321617164	
PP18CSD	2301206164	PRECISION PRM 18FR SIL
	2318417064	
PP18XSD	2309041064	PREC PRM 18FR SILVER
PPAD	2212321364	PREC PRM ADD A FOLEY 10CC

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