



Medline Industries, LP. Issues a Voluntary Nationwide Recall of Various Lots of Tracheostomy Care and Cleaning Trays

NOTIFICATION DATE: 12/20/2023
LAST REVISED ON: 1/2/2024
SUPPLIER/CATEGORY: RESPIRATORY
THERAPY

SITUATION

- Medline Industries, LP. announced a voluntary nationwide recall of several lots and SKUs of Tracheostomy Care and Cleaning Trays. The Tracheostomy Care and Cleaning Trays include a tracheostomy brush as a component that may have sharp edges at the tip that can puncture tubing during use and/or cause user injury during handling. The bristles of the tracheostomy brush are detaching before and potentially during use. If bristles reach a patient's airway, they may cause unexplained increases in sputum or pulmonary secretions, signs of infection, or difficulty breathing.

BACKGROUND

- Medline Industries, LP. announced a voluntary nationwide recall on October 10th, 2023, of several lots and SKUs of Tracheostomy Care and Cleaning Trays.
- Tracheostomy Care Trays are medical devices intended to be used for the care and maintenance of a stoma site.
- These trays may be used in various healthcare environments including acute care settings, such as hospitals, and long-term care settings such as skilled nursing facilities.
- The tracheostomy brush component is used to clean tracheostomy tubing and cannulas.
- Tracheostomy cannulas should always be rinsed following brush cleaning.
- This component is packaged within Tracheostomy Care and Cleaning Trays, which contain multiple components packaged together.

ASSESSMENT

- The voluntary recall includes the following item numbers and lot numbers, distributed nationwide from March 21, 2022, through October 10, 2023. Affected product(s) can be identified by the lot number indicated on the medical device packaging.
- This has been distributed through One Recall.

PRODUCT ALERT NOTIFICATION



Advantus
Health Partners

Item Number	Item Description	UDI/GTIN Number	Lot Numbers
DYND40580	TRAY, TRACH,14FR SUCTION CATH, WHISTLE TIP	UDI: 10080196032761	6052203006, 6052203022, 6052204005, 6052204010, 6052205024, 6052206003, 6052206010, 6052206011, 6052206020, 6052206021, 6052207009, 6052207013, 6052207014, 6052207015, 6052208021, 6052208022, 6052209009, 6052209025, 6052209026, 6052212023, 6052301031, 6052303011, 6052303013, 6052303014, 6052304020, 6052305007, 6052305019, 6052306004, 6052306014, 6052306015, 6052305026, 6052306026, 6052306032, 6052307006, 6052307011, 6052307012

PRODUCT ALERT NOTIFICATION



Advantus
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DYND4061030	TRAY, TRACH, BASIC, PIPE CLEANERS	UDI: 10080196032877	6052209025, 6052209026, 6052210016, 6052210031, 6052210032, 6052211034, 6052212009, 6052212010, 6052212021, 6052212022, 6052212015, 6052301017, 6052306014, 6052306015, 6052306014, 6052306015, 6052307011, 6052307012, 6052307022, 6052307023, 6052307026, 6052308001, 6052308002, 6052308003, 6052308004, 6052309001, 6052309003, 6052309002	
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PRODUCT ALERT NOTIFICATION



Advantus
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CC3T4691A	BASIC TRACHEOSTOMY CARE KIT	UDI: 10080196503391	6052204005, 6052204010, 6052204011, 6052205021, 6052205022, 6052205023, 6052205024, 6052206021, 6052207009, 6052207013, 6052207014, 6052207015, 6052207030, 6052208009, 6052208010, 6052208021, 6052208022, 6052209026, 6052209038, 6052210008, 6052210015, 6052210016, 6052210032, 6052211021, 6052302012, 6052302013, 6052306004, 6052306014, 6052306015, 6052306017, 6052307012, 6052307022, 6052307023, 6052308001, 6052308002, 6052308003, 6052309002, 6052309001, 6052309003	
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PRODUCT ALERT NOTIFICATION



Advantus
Health Partners

CC4681A	TRACHEOSTOMY CARE KIT W/FORCEP	UDI: 10080196503407	6052203022, 6052205022, 6052205023, 6052205024, 6052205028, 6052206010, 6052206011, 6052206021, 6052207015, 6052208016, 6052208040, 6052209009, 6052209026, 6052209038, 6052210012, 6052210016, 6052301015, 6052301016, 6052301017, 6052302012, 6052302013, 6052302028, 6052302029, 6052304024, 6052305020, 6052306004, 6052306014, 6052306015, 6052307011, 6052307012, 6052309002, 6052309001, 6052309003	
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PRODUCT ALERT NOTIFICATION



Advantus
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CC3T3030A	MINI TRACHEOSTOMY CARE KIT	UDI: 10080196503384	6052204010, 6052204011, 6052205021, 6052205022, 6052205023, 6052205024, 6052205028, 6052206003, 6052206010, 6052206011, 6052210015, 6052210016, 6052210031, 6052210032, 6052212010, 6052212023, 6052301015, 6052301016, 6052301017, 6052301029, 6052302012, 6052302013, 6052303011, 6052303012, 6052303013, 6052303014, 6052304019, 6052304020, 6052305007, 6052305020, 6052306004, 6052306014, 6052306015, 6052307011, 6052307012, 6052307022, 6052307023, 6052308001, 6052308002, 6052308003, 6052309001	
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PRODUCT ALERT NOTIFICATION



Advantus
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DYND40622	TRAY, TRACH, MINI, NO GLOVES, NONSTERILE	UDI: 10080196032914	6052203006, 6052204005, 6052204010, 6052205023, 6052205028, 6052206003, 6052206010, 6052207009, 6052207030, 6052208009, 6052208021, 6052208040, 6052209027, 6052209025, 6052210008, 6052210031, 6052210032, 6052212009, 6052212021, 6052212023, 6052301016, 6052302013, 6052302028, 6052303012, 6052303014, 6052305018, 6052305019, 6052305020, 6052306004, 6052306014, 6052306015, 6052306017, 6052307022, 6052308001, 6052308002, 6052309002, 6052309001, 6052309003	
EDUC1025	NURSE KIT	GTIN: 40195327196647	GTIN: 40195327196647	
EDUC05038B	NURSING SKILLS KIT	GTIN: 40195327019878	22IDA181, 22FDB543, 22ADB550	

PRODUCT ALERT NOTIFICATION



Advantus
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EDUC05056A	NURSING TOTE KIT	GTIN: 40195327153695	22HDC201, 22HDA420
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RECOMMENDATIONS

- Medline Industries, LP. notified its distributors and consumers by First Class Mail and email on October 16, 2023
- Medline instructed consumers to destroy and dispose of any affected product per local and state regulations.
- No product is to be returned to Medline Industries, LP.
- Consumers with questions regarding this recall can contact Medline Industries, LP. by phone at 866-359-1704 or recalls@medline.com Monday through Friday between the hours of 8am and 5pm CST.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this medical device.
- 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. www.fda.gov/medwatch/report.htm Call FDA 1-800-FDA-0178