State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Medline Industries, LP - Northfield Recalls Medline Sub-G Endotracheal Tube With Subglottic Suctioning

Recall Date	Product Description	Recalling Firm	Recall Reason
5/28/2024	**Medline Sub-G Endotracheal Tube With Subglottic Suctioning** (1) REF DYNJ18860, Polyurethane Cuff 6.0 mm ID; (2) REF DYNJ18865, Polyurethane Cuff 6.5 mm ID; (3) REF DYNJ18870, Polyurethane Cuff 7.0 mm ID; (4) REF DYNJ18875, Polyurethane Cuff 7.5 mm ID; (5) REF DYNJ18880, Polyurethane Cuff 8.0 mm ID; and (6) REF DYNJ18885, Polyurethane Cuff 8.5 mm ID	**MEDLINE INDUSTRIES, LP - NORTHFIELD** Northfield, Illinois	Complaints have been received that the device inflation tube detached and/or tore from the main tube, resulting in potential moisture buildup, loss of pressure, or inability to inflate. There were also reports the suction pump is difficult to connect or detaches during use.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Medline Sub-G Endotracheal Tube with Subglottic Suctioning** UDI-DI numbers for the individual tubes: (1) DYNJ18860 - UDI-DI 20888277652672; (2) DYNJ18865 - UDI-DI 20888277652689; (3) DYNJ18870 - UDI-DI 20888277652696; (4) DYNJ18875 - UDI-DI 20888277652702; (5) DYNJ18880 - UDI-DI 20888277652719; (6) DYNJ18885 - UDI-DI 20888277657318. Kit code information: (1) Kit ACC010502	168,632 Tubes and 13,092 Kits Nationwide	May 2024 and prior.

	- Kit UDI-DI: 10193489846171; Case UDI-DI: 40193489846172; lot numbers: 23FDC233, 23FDB211, 23EDC153, 23EDB775, 23DDB280, 23CDB943, 23CDA556, 22LDA029, 22IDA550, 22HDA813, 22FDC033, 22CDC284, 21JDC054, 21IDB345, 21HDB405, and 21DDB305; (2) Kit ACC010527 - Kit UDI-DI: 10193489884333; Case UDI-DI: 40193489884334; lot numbers: 23JDA443, 23IDA363, 23IDA232, 23HDC331, 23HDA117, 23GDB600, 23FDC372, 23FDB913, 23FDA966, 23FDA310, 23EDC371, 23EDC154, 23EDC094, 23EDB732, 23EDA387, 23CDB838, 23CDA557, 23BDC008, 23BDA945, 23ADB791, 22LDA005, 22JDB800, 22HDB976, 22HDA451, 22GDB041, 21LDB937, 21LDB416, 21JDB262, 21IDB491, 21IDA193, 21GDB207, and 21FDC754; (3) Kit ACC10540 - Kit UDI-DI: 10193489977547; Case UDI-DI 40193489977548; lot number: 23ADB410; (4) Kit ACC10540A - Kit UDI-DI 10195327330088; Case UDI-DI 40195327330089; lot numbers: 23HDA588, 23GDB107, and 23BDA684; (5) Kit ACC010717 - Kit UDI-DI 10195327458997; Case UDI-DI 40195327458998; lot numbers: 24ADA577, 23LDA731, and 23IDA629; (6) Kit DYNDJ1132 - Kit UDI-DI 10195327454821; Case UDI-DI 40195327454822; lot numbers: 23LDA733, 23LDA617, 23JDC021, and 23HDA569; (7) Kit DYNDJ1133 - Kit UDI-DI 10195327428532; Case UDI-DI 40195327428533; lot numbers: 24BMB124, 23LMB682, 23HMF259, and 23HMD765; (8) Kit DYNJ909501 - Kit UDI-DI 10195327384852; Case UDI-DI		

	40195327384853; lot number: 23GBI504; (9) Kit DYNJ909501A - Kit UDI-DI 10195327549817; Case UDI-DI 40195327549818; lot numbers: 24BBD129, 24ABK281, and 23KBR773; (10) Kit DYNJAA269 - Kit UDI-DI 10195327209049; Case UDI-DI 40195327209040; lot numbers: 24BBE224, 24ABM718, 24ABD835, 23LBB055, 23JBP694, 23JBQ783, 23IBU821, 23IBF348, 23HBP188, 23CBX318, 23CBX319, 23BBR494, 23ABI514,22LBI988, 22KBH009, and 22JBH478.		

For additional information, please visit the FDA website.

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