PRODUCT DISRUPTION BRIEF

Medtronic NIM Standard and Contact EMG Endotracheal Tubes (updated July 11)

The FDA is alerting health care providers and facilities to stop using Medtronic NIM contact EMG reinforced endotracheal tubes and NIM (Standard) EMG reinforced endotracheal tubes due to issues with tube blockage.

Current conditions

The U.S. Food and Drug Administration (FDA) is alerting health care providers and facilities to stop using NIM contact EMG reinforced endotracheal tubes and NIM (Standard) EMG reinforced endotracheal tubes by Medtronic. These neural integrity monitor (NIM) electromyogram (EMG) endotracheal tubes are used during surgery to provide an airway for patient ventilation and to monitor EMG activity and the nerve integrity of the thyroarytenoid muscle of the larynx. The potential risks associated with the use of impacted devices include airway obstruction, unintended extubation, bronchospasm, hypoventilation, low oxygen saturation, hypoxia, respiratory distress, abnormal blood gas measurements, cyanosis, apnea, respiratory arrest, cardiac arrest, brain injury, and death. A list of affected products is available here.

Medtronic has issued an Urgent Medical Device Recall notice for removal of all NIM Standard and Contact EMG endotracheal tubes from inventory due to issues with tube blockage.

Medtronic said it received 77 complaints between March 31, 2020, and May 20, 2024. The risk of airway obstruction when using the affected devices could result in brain injury and death.

Medtronic sent a safety notice about the devices in 2022. The notice, which the FDA categorized as a Class I recall, described complaints about airway obstruction and advised users to avoid overinflation of the product's silicone cuff. At the time, Medtronic said three injuries and two deaths were associated with the issue between March 31, 2020, and March 31, 2022.

Mitigation strategy

Review the Urgent Medical Device Recall notice from Medtronic for removal from inventory of all NIM Contact EMG Reinforced Endotracheal Tubes and NIM (Standard) EMG Reinforced Endotracheal Tubes. This notice includes model numbers and Unique Device Identifier (UDI) information.

- Immediately identify, segregate, and quarantine affected products within your inventory or control. Do not use the affected devices. .Do not use NIM Contact EMG Reinforced Endotracheal Tubes and NIM (Standard) EMG Reinforced Endotracheal Tubes.
- Return affected products in your inventory to Medtronic. Please contact your Medtronic ENT rep if an alternative device is needed.
- Report any issues with these devices to the FDA.

Additional resources

Supply assurance webpage; Vizient Newsroom

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Affected products

Part no.	Description	UDI
8229306	ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	643169789524
8229306	ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	763000882389
8229306	ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	763000745813
8229307	ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	643169789531
8229307	ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	763000882396
8229307	ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	763000745820
8229308	ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	643169789548
8229308	ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	763000745837
8229308	ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	763000882402
8229506	ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	643169789555
8229506	ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	763000745844
8229506	ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	763000882419
8229507	ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	643169789562
8229507	ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	763000745851
8229507	ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	763000882426
8229508	ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	643169789579
8229508	ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	763000745868
8229508	ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	763000882433
8229306J	ENDOTRACH TUBE 8229306J NIM EMG 6MM	613994415455
8229307J	ENDOTRACH TUBE 8229307J NIM EMG 7MM	613994415462
8229308J	ENDOTRACH TUBE 8229308J NIM EMG 8MM	613994415431