Medtronic

Neuroscience
Ear, Nose & Throat (ENT)
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URGENT: MEDICAL DEVICE RECALL

NIM Contact™ EMG Reinforced Endotracheal Tubes and
NIM™ (Standard) EMG Reinforced Endotracheal Tubes

Model Numbers: 8229306, 8229307, 8229308, 8229506, 8229507, 8229508, 8229306J, 8229307J, 8229308J

July 2024

Dear Risk Manager/Customer,
The purpose of this letter is to advise you that Medtronic is conducting a recall to remove all lots of the NIM Contact™ EMG Reinforced Endotracheal Tubes and NIM™ (Standard) EMG Reinforced Endotracheal Tubes. Medtronic records indicate your facility may have at least one of the devices identified in the product scope table below.

The products listed in the Product Scope table below are no longer available for distribution or sale. Please follow the customer actions outlined in this communication.

Issue Description:
This recall is being initiated due to reports of issues with tube blockage, consistent with cuff herniation, in some cases due to overinflation of the Endotracheal Tube cuff.

Potential Health Hazards:
Between March 31, 2020, and May 20, 2024, Medtronic has received 77 complaints indicating potential health hazards of degraded or loss of functionality of the device with all models (see product scope table), which as reported resulted in 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.

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.

Previous Medtronic Safety Notice(s) Overview:
In April 2022, Medtronic issued a safety notice regarding the use of the NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube due to reports of events related to airway obstruction when using these devices. This notice also included information on the importance of carefully reviewing and adhering to the IFU, which included a warning on overinflation as well as provided additional mitigations in the event of airway obstruction.

In January 2024, upon the availability of the NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube labeling updates, Medtronic issued a follow up safety notice communicating additional new safety information provided in the IFU and reiterated the importance of carefully reviewing and adhering to the warnings, precautions and mitigations in adhering to the IFU. Additionally, training on the NIM Standard and Contact EMG Endotracheal tube was deployed through Medtronic Academy.

Product Scope:
Medtronic records indicate your facility may have at least one of the device lot numbers identified in the product scope table below.

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Brand Name	Model Number/Customer Facing Number (CFN)	UDI
ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	8229308	00643169789548
ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	8229308	00763000745837
ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	8229308	00763000882402
ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	8229307	00643169789531
ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	8229307	00763000882396
ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	8229307	00763000745820
ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	8229306	00643169789524
ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	8229306	00763000882389
ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	8229306	00763000745813
ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	8229507	00643169789562
ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	8229507	00763000745851
ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	8229507	00763000882426
ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	8229506	00643169789555
ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	8229506	00763000745844
ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	8229506	00763000882419
ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	8229508	00643169789579
ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	8229508	00763000745868
ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	8229508	00763000882433
ENDOTRACH TUBE 8229307J NIM EMG 7MM	8229307J	00613994415462
ENDOTRACH TUBE 8229306J NIM EMG 6MM	8229306J	00613994415455
ENDOTRACH TUBE 8229308J NIM EMG 8MM	8229308J	00613994415431

Customer Actions:

- Immediately identify, segregate, and quarantine affected products within your inventory or control. Do not use the affected devices.
  Note: The list of impacted products is included in the product scope table above. All lots numbers of NIM Standard and Contact EMG Endotracheal tubes are impacted.
- Return affected products in your inventory to Medtronic. Please contact your Medtronic ENT rep if an alternative device is needed.
  Note: Instructions on how to return any impacted products to Medtronic can be found on the Customer Confirmation Form. Your local Medtronic Representative can assist you with the initiation of the return.
- Complete and sign the Customer Confirmation form included with this letter and email it via email to neuro.quality@medtronic.com within 30 days of receipt even if you do not have the affected product.
  Please Note: Instructions on how to return that form to Medtronic can be found on the form itself.

Training on the NIM Standard and Contact EMG Endotracheal tube deployed with the January 2024 communication under Medtronic Academy is no longer required as part of this recall action. Medtronic will no longer ship NIM™ EMG (Standard) reinforced endotracheal tubes and NIM™ Contact EMG reinforced endotracheal tubes to customers. All existing orders will be canceled.

Additional Information:

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Contact your local Medtronic Representative or Medtronic Customer Quality at RS.JaxProductQuality@medtronic.com

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic ENT Representative.

FA1255_Phase 3_Removal
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FA1255_N

Medtronic

Sincerely,

Jason Busch
VP Quality ENT
Medtronic

Enclosure:
Customer Confirmation Form *(please complete and return upon receipt of this letter)*