Medtronic (Schweiz) AG
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Urgent Field Safety Notice

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

Recall

July 2024

Medtronic Reference: FA1255
EU Manufacturer Single Registration Number (SRN): US-MF-0000023264

Dear Health Care Professional / Risk Manager,

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 May 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 February 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.

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

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 lot numbers of NIM Standard and Contact EMG Endotracheal tubes are impacted.

- Return affected products in your inventory to Medtronic. Please contact your Medtronic Representative if an alternative device is needed.

Note: Instructions on how to return any impacted products to Medtronic can be found on the Customer Acknowledgement Form. Your local Medtronic Representative can assist you with the initiation of the return.

- Complete and return the Customer Acknowledgement form included with this letter 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 February 2024 communication under Medtronic Academy is no longer required as part of this recall action.

Additional Information:

Medtronic has notified the Competent authority of your country of this action.

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 Representative.

Sincerely,
Medtronic (Schweiz) AG

Enclosures:

- Customer Acknowledgement Form

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Please email this form back to Medtronic (even if you do not have affected inventory):

rs.dusregulatory@medtronic.com

Urgent Field Safety Notice - Recall

FA1255 Phase III: EMG Tube Airway Blockage Issue

Customer Contact Details			
Company name:		Account number (optional):	
Address:	City:		Country:
• I confirm that I have read and understood the Urgent Field Safety Notice. • I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred. • I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: ☐ No affected products are located at our facility. ☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.			
Name (print):	**Job title**:	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot # / Serial #**	**Quantity** *(please count units inside of the box)*
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:

Contact Person at Point of Collection:		
Pick-up address / Department *(please provide location details. E.g.: collection/accessible area):*		
City:		Post code:
Pick-up phone number:	Pick-up email:	
When the product will be ready for pick-up? *(Please allow 2 days for handling your request):*		
Opening hours of the pick-up location:		Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 kg:

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.