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Urgent Field Safety Notice

Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube

Notification

February 2024

Medtronic Reference: FA1255

EU Manufacturer Single Registration Number (SRN): US-MF-000023264

Dear Anesthesia Care Providers / Users of these products,

The purpose of this letter is to advise you that Medtronic is issuing a follow up to the May 2022 safety notice regarding the use of the NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube since updates to the labeling were granted. This safety notice applies to all distributed products with the Model numbers listed in Table I.

Issue Description:

We have received reports of events related to airway obstruction while using NIM™ Standard Reinforced EMG Endotracheal Tube and NIM CONTACT™ Reinforced EMG Endotracheal Tube. NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube are silicone tubes with the main shaft reinforced by a wire coil to prevent collapse while maintaining flexibility. The cuffs are also silicone. An over-inflated cuff increases intra-cuff pressure which can cause the silicone cuff to extend, herniate, or distort over the end of the tube and/or the murphy-eye causing obstruction and loss of ventilation.

From 31-Mar-2020 to 17-January 2024, Medtronic has received a total of 70 reports globally for this issue. Medtronic has received report of 36 serious patient harms attributed to this issue.

In the event that an EMG Tube becomes blocked there is an anticipated cascade of events that have the potential to be realized: Airway Obstruction, Unintended Extubation, Bronchospasm, Hypoventilation, Oxygen Saturation Low, Hypoxia, Respiratory Distress, Abnormal Blood Gas Measurements, Cyanosis, Apnea, Respiratory Arrest, Cardiac Arrest, Brain Injury.

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It is important to carefully review and adhere to the Instructions for Use (IFU) M040175C001DOC1, Rev. C dated 2023-11, as some precautions, warnings and product labels have been added and/or changed. Additionally, we have provided recommendations below when airway obstruction is encountered for the affected products in Table I.

Recommended Actions when using NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube and airway obstruction is encountered:

If airway obstruction is encountered immediately deflate the cuff and attempt to recover ventilation. If ventilation cannot be re-established:

1. Extubate the EMG endotracheal tube from the patient.
2. Re-establish ventilation with Bag Valve Mask (BVM) or Laryngeal Mask Airway (LMA).
3. Re-intubate with a new non-silicone (PVC) endotracheal tube and establish airway or alternatively, if surgically needed, re-intubate with a new EMG endotracheal tube. If reintubating with a new EMG endotracheal tube, it is imperative to:
    i. use less than 5mL of air to inflate the cuff and verify intracuff pressure using a pressure monitoring device; or
    ii. use Minimal Occluding Volume or Minimum Leak techniques using a 5mL syringe.

Additional Discussion for Using a NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube:

Intubate the patient using standard of care and medical training and knowledge. Per clinical literature, a cuff pressure of under 25 cm H2O is recommended to provide an adequate seal and reduce the risk of complications: Holyszko A, Levin L, Feczko J, Krawczyk S, Tariman JD. How to Prevent Endotracheal Tube Cuff Overinflation: "5 for 25". AANA J. 2021 Apr;89(2):147-154. PMID: 33832575.

Additionally, as stated in the IFU, use care when manipulating the tube's position. Manipulation of an inflated tube can cause the inflated cuff to stretch over the tube opening causing obstruction. Any manipulation or repositioning of the tube and/or patient should be preceded by deflation of the cuff. Assess tube placement and patency to help ensure successful ventilation.

Product Scope:

Table I. Models in Scope

Brand Name	Model Number	UDI
ENDOTRACH TUBE 8229306 NIM EMG 6MM ROHS	8229306	00763000745813 00643169789524 00643169358690 00763000882389
ENDOTRACH TUBE 8229307 NIM EMG 7MM ROHS	8229307	00763000745820 00643169358713 00643169789531 00763000882396

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ENDOTRACH TUBE 8229308 NIM EMG 8MM ROHS	8229308	00763000745837 00643169358737 00643169789548
ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	8229506	00643169789555
ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	8229507	00643169789562 00763000745851
ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	8229508	00643169789579 00763000745868

Instructions For Use (IFU) Warnings and Precautions:

Per the Instructions For Use (IFU) Warning, an airway seal should be accomplished with using less than 5mL of air and verifying cuff pressure. Care should be taken to not over-inflate. Warnings and Precautions from the IFU have been restated below.

To Mitigate the Potential for Causing Airway Obstruction:

Read and follow the product IFU. For convenience and expedience, the following information is provided from the IFU:

- From the 'Warnings – EMG tubes' section, bullet 4: 'Do not attempt to manipulate an EMG tube with an inflated cuff after insertion. Manipulating a tube with an inflated cuff may cause partial airway blockage at the tip and/or Murphy Eye, cuff herniation, tip deflection, and/or injury of the larynx or vocal cords. Ensure that the cuff is fully deflated before any manipulation and confirm that the airway is free of any potential occlusion after repositioning.
- From the 'Warnings – EMG tubes' section, bullet 6: 'Inflation of the cuff by "feel" alone is not recommended since resistance is an unreliable guide during inflation. Use less than 5mL of air to inflate and verify intracuff pressure using a pressure monitoring device.'
- From the 'Warnings – EMG tubes' section, bullet 7: 'Do not overinflate the cuff. Overinflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.'
- From the 'Warnings-EMG tubes' section, bullet 8: 'Minimal Occluding Volume or Minimum Leak techniques, using a 5mL syringe, should be used in conjunction with an intracuff pressure measuring device in selecting the sealing pressure. Cuff pressure should continue to be monitored thereafter, and any deviation from the selected seal pressure should be investigated and corrected immediately.'
- From the 'Precautions' section, bullet 3: 'It is strongly recommended that the surgeon consult with the attending licensed medical practitioner who will be administering anesthesia prior to the use of EMG monitoring to review EMG monitoring techniques, goals and the effects of the administration of anesthesia on neuromuscular activity.'
- From the 'Precautions' section, bullet 5: 'Proper sizing, oral intubation and extubation should be in accordance with accepted medical techniques and expert clinical judgment. A tube that is one size larger than standard selection is recommended whenever possible to improve electrode contact with vocal cords. The proper size tube for the patient should be determined prior to

intubation by the anesthesia provider and/or surgeon.'

- From the 'Precautions' section, bullet 10: 'The use of Nitrous Oxide as an anesthetic agent should be avoided as this gas can diffuse into the EMG ET Tube (silicone) cuff resulting in significant increase in cuff pressures which may increase cuff herniation. If Nitrous Oxide must be used, it should only be used with continuous pressure monitoring and careful attention to keep the cuff pressure under 25cm of H2O pressure.'
- From the 'Precautions' section, bullet 11: 'If the patient is moved or inadvertently moves during the procedure, confirm the EMG ET Tube is intubated as intended.'

The Instructions for Use (IFU) for these devices has been updated with the safety information above. New product shipments will include the updated IFU.

- Link to IFU: https://www.medtronic.com/content/dam/emanuals/st/M040175C001DOC1C.pdf

Complete Training Under Medtronic Academy:

New training material is being deployed and traced via Medtronic Academy to reinforce the safe usage of the EMG Tubes. Please note, this training is important to complete prior to using the device.

- Link to Training - https://www.medtronicacademy.com/en-xd/content/nim-standard-reinforced-emg-endotracheal-tube-nim-contact-reinforced-emg-endotracheal-tube-safety-training
- QR Code to Training:

We apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.
Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred or distributed.
The Competent Authority of your country has been notified of this action.

If you have any questions regarding this communication, please contact your Medtronic Representative Directly or via Tel No. 01511 1400.
Sincerely,

Keith Taverner: Principal Regulatory Affairs Specialist UK & Ireland
Customer Acknowledgement Form Below

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FA1255 Phase II Customer Acknowledgement Form - Response is required

EMG Tube Airway Blockage Issue

IFU Update and Account Training

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tubes by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed these products as required.

_____	_____	_____
Name: (print)	Signature:	Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative Directly.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:

rs.regulatoryuk-ire@medtronic.com