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URGENT: MEDICAL DEVICE SAFETY NOTICE

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

CFNs 8229306, 8229306J, 8229307, 8229307J, 8229308, 8229308J, 8229506, 8229507, 8229508

04 September 2023 | 17:29 SGT

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Anesthesia Care Providers / Users of these products:

The purpose of this letter is to advise you that Medtronic is issuing a safety notice regarding the use of the NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube. This safety notice applies to all distributed products with the Customer Facing Numbers (CFNs) listed in Table I.

Issue Description:

We have received reports of events related to airway obstruction while using NIM™ Standard Reinforced EMG Endotracheal Tube & 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 manufactured with silicone. Not following the Instructions for Use (IFU) and over-inflating the 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 potentially causing obstruction of the patient airway and loss of ventilation.

It is important to carefully review and adhere to the Instructions for Use (IFU). 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:

1. **Immediately deflate the cuff and attempt to ventilate.**
2. **If ventilation cannot be re-established:**

a. **Extubate the NIM™ Standard Reinforced EMG Endotracheal Tube or NIM CONTACT™ Reinforced EMG Endotracheal Tube from the patient**
b. **Re-establish ventilation with Bag Valve Mask (BVM) or Laryngeal Mask Airway (LMA).**
c. **Reintubate with a new non-silicone (PVC) Endotracheal Tube or, if surgically needed, re-intubate the patient with a new, larger NIM™ Standard Reinforced EMG Endotracheal Tube or NIM CONTACT™ Reinforced EMG Endotracheal Tube which will require less cuff inflation volume and pressure.**

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. 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 potentially causing obstruction to the patient's airway. Any manipulation or repositioning of the tube and/or patient should be preceded by deflation of the cuff. Then assess tube placement and non-occlusion to help ensure successful ventilation.

Product Scope:

Table I. Models utilizing IFU M726750C793, Rev. A

Brand	CFN
ENDOTRACH TUBE 8229306 NIM EMG 6MM ROHS	8229306
ENDOTRACH TUBE 8229306J NIM EMG 6MM ROHS	8229306J
ENDOTRACH TUBE 8229307 NIM EMG 7MM ROHS	8229307
ENDOTRACH TUBE 8229307J NIM EMG 7MM ROHS	8229307J
ENDOTRACH TUBE 8229308 NIM EMG 8MM ROHS	8229308
ENDOTRACH TUBE 8229308J NIM EMG 8MM ROHS	8229308J
ENDOTRACH TUBE 8229506 CONT EMG 6MM ROHS	8229506
ENDOTRACH TUBE 8229507 CONT EMG 7MM ROHS	8229507
ENDOTRACH TUBE 8229508 CONT EMG 8MM ROHS	8229508

Instructions For Use (IFU) Warnings:

Per the Instructions For Use (IFU) Warning, an airway seal should be accomplished without exceeding intracuff pressure of 25 cm H2O. Care should be taken to not over-inflate the cuff. Warnings from the IFU have been restated below.

To mitigate the potential for causing airway obstruction:

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

- From the "Warnings – EMG tubes" section, bullet 5: "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 7: "Inflation of the cuff by "feel" alone or by using a measured amount of air is not recommended since resistance is an unreliable guide during inflation. Intracuff pressure should be closely monitored with a pressure measuring device."

- From the "Warnings – EMG tubes" section, bullet 8: "Do not overinflate the cuff. Ordinarily, the cuff pressure should not exceed 25 cm H2O. Carroll and Greenvik recommend maintaining a seal pressure at or below 25 cm H2O (Carroll, R.G., and Greenvik, A.: "Proper Use of Large Diameter, Large Residual Cuffs." Critical Care Medicine Vol. 1, No. 3: 153-154, 1973). 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 9: "Minimal Occluding Volume or Minimum Leak techniques 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."

In addition to the above, the current Instructions For Use (IFU) for these devices are in the process of being updated to reinforce the warnings/precautions. A copy of the updated IFU will be mailed to each of you as soon as it becomes available and to any new customer after the initiation of this product safety notice.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please report adverse events to your local Medtronic field representative.

If you have any questions regarding this communication, please contact your Medtronic ENT Representative.

Sincerely,

Quality and Regulatory Affairs Director

Mainland and Island Southeast Asia

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URGENT: MEDICAL DEVICE SAFETY NOTICE
Customer Confirmation Form
Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube CFNs 8229306, 8229306J, 8229307, 8229307J, 8229308, 8229308J, 8229506, 8229507, 8229508

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

Reference #: FA1255

Affected Product(s)

Product Name	Model#/ CFN	Material/GTIN#	Lot Number(s)
ENDOTRACH TUBE 8229306J NIM EMG 6MM	8229306J	00643169358706	All Batches / Lots*
ENDOTRACH TUBE 8229307J NIM EMG 7MM	8229307J	00643169358720	
ENDOTRACH TUBE 8229308J NIM EMG 8MM	8229308J	00643169358744	
ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	8229306	00643169789524	
ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	8229307	00643169789531	
ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	8229308	00643169789548	
ENDOTRACH TUBE 8229506 CONTACT EMG 6MM	8229506	00643169789555	
ENDOTRACH TUBE 8229507 CONTACT EMG 7MM	8229507	00643169789562	
ENDOTRACH TUBE 8229508 CONTACT EMG 8MM	8229508	00643169789579	

**Note: All batches / lots are based on the shelf life of 4 years of the affected product.*

By signing this form, I confirm that I have read the Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube, dated 04 September 2023 | 17:29 SGT **, from Medtronic and taken appropriate action. Please note, this is a safety notice only. Product does not need to be returned as part of this action. Please complete and sign the form as indicated below and hand or scan and email back to your local Medtronic field representative. For questions, contact your local Medtronic field representative.**

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

Note: The addressee may continue to receive reminders of this notice until a response is received.