NIM™ EMG Endotracheal Tube

Product Information and Instructions

REF	I.D. (mm)	O.D. (mm)	FR#
9450060	6.0	8.8	27
9450061	7.0	10.2	31
9450062	8.0	11.3	34

Rx Only

INTENDED USE AND DEVICE DESCRIPTION

The NIM™ EMG Endotracheal Tube is a flexible silicone elastomer endotracheal tube with an inflatable cuff. The tube is fitted with four stainless steel wire electrodes (two pairs) which are embedded in the silicone of the main shaft of the endotracheal tube and exposed only for a short distance, approximately 30.0 mm, slightly superior to the cuff, for contacting the vocal cords. The electrodes are designed to make contact with the patient's vocal cords to facilitate electromyographic (EMG) monitoring of the vocal cords during surgery of the neck when connected to a multi-channel EMG monitoring device. Both the tube and cuff are manufactured from silicone elastomer that allows the tube to conform readily to the shape of the patient's trachea with minimal trauma to tissues.

IMPORTANT

- It is strongly recommended that the clinician(s) have a thorough understanding of and experience with intraoperative EMG monitoring prior to using the NIM™ EMG Endotracheal Tube in a surgical procedure. This device is not intended to replace the surgeon's medical judgment or knowledge of neural anatomy and physiology. It is intended to provide the surgeon with an additional tool with which to make better-informed decisions regarding the surgical procedure.
- 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.

INDICATIONS FOR USE

The NIM™ EMG Endotracheal Tube is indicated for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor. The EMG tube is not intended for postoperative use.

CONTRAINDICATIONS

Not for use when paralyzing anesthetic agents are being used since they will significantly reduce, if not completely eliminate, EMG responses to direct or passive neural stimulation. Do not use local anesthetic gels or creams to lubricate the tube or apply topical anesthetic sprays on the vocal cords.

THE NIM™ HELPLINE

Should you need immediate help with a technical question or guidance through the appropriate protocol, call the NIM™ Help Line at 1-800-874-5797.

PACKAGE CONTENTS

1.....NIM™ EMG Endotracheal Tube with 2 sets (2 each) of paired stainless steel wire electrodes, 244 cm twisted-pair cables or protected pin connectors.
1.....Green Subdermal EMG Needle (12 mm) Electrodes with 244 cm cables and protected pin connectors.
1.....White/Red Subdermal EMG Needle (12 mm) Electrodes with 244 cm cables and protected pin connectors
1.....Standard Tracheal Tube Adapter for anesthesia gas connection.
1.....Instructions for Use.

WARNINGS

A warning identifies conditions or practices that may present danger to the patient and/or the user.

- Avoid insertion of a suction tube or stylet in a tube that has been distorted by biting or other forces. This may further damage the tube and block the airway.
- The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive neural stimulation. Do not use local anesthetics gels or creams to lubricate the tube or apply topical anesthetic sprays on the vocal cords.
- The cuff must not be over-inflated. Over-inflation may result in tracheal damage, cuff rupture with subsequent deflation, and cuff distortion leading to cuff herniation and tube blockage.
- Placement in the right main bronchus may result in inadequate oxygenation. Confirm the correct position of the tube after intubation.
- A disrupted air supply may result in inadequate oxygenation. Confirm, monitor, and maintain anesthesia gas delivery systems and connections at all times. Inspect tube patency by checking the inner diameter of tube after test inflation.
- Avoid direct electrosurgical sparks in the vicinity of all EMG Electrodes and the Stimulator Probe. Keep the EMG electrode leads away from electrosurgical generators, ancillary electrical cables and dispersive electrodes to reduce the risk of providing paths for high frequency currents that could induce burns to the patient.

- The tube is not combustion resistant. Flammable gases may ignite in the presence of an energy source. This device should not be used in surgical procedures that could expose flammable gases or the tube to thermal energy resulting from surgical lasers, cauteries, or other high temperature generating devices.
- The electrode leads of the NIM™ EMG Endotracheal Tube must be connected only to the EMG recording/monitoring equipment. Electrical shock resulting in patient injury may result if the leads are connected to other types of equipment or connections.
- Extubation of an inflated cuff may damage the larynx or vocal cords. Fully deflate the cuff prior to extubation. Exercise caution during extubation. If resistance is encountered during EMG tube removal, ensure that the cuff is fully deflated.
- Do not reuse the tube. Re-sterilization may be ineffective on the small electrode channels, leading to patient infection.
- Re-sterilization could damage or degrade the tube and/or electrode channels, which could create a hazard for patients by reducing EMG and increasing artifact.
- Do not rotate patient's head and neck during monitoring as misplacement of the EMG tube may occur resulting in false negative responses.
- False negative responses may result in patient injury. The lack of a measurable EMG response from a stimulus applied to intact and viable nerve tissue (a false negative response) can occur as a result of several factors. The surgeon, anesthesia provider and other OR personnel should be alert to these factors and avoid the following conditions which could result in false negative responses:
- Deep anesthesia which may suppress neuroelectrical activity of the recurrent laryngeal nerve.
- Neuromuscular fatigue from prolonged surgical procedures or repeated electrical stimuli.
- Misplacement of the EMG Endotracheal Tube. Maintain secure tube midline placement. Do not rotate patient's head and neck during monitoring as the tube's electrodes will rotate and cause a lead off connection. Do not orient left or right of patient's mouth, as this will also rotate the tube's electrodes causing misorientation or lead off connection.
- The use of local anesthetics, neuromuscular blockers or paralyzing agents.
- Connection to an inoperative EMG monitor.
- Using a tube size that is too small, causing insufficient contact between the electrodes and vocal cords.

PRECAUTIONS

Precautions identify conditions or practices that could result in damage to the NIM™ EMG Tube Electrode:

- As with any endotracheal tube, the risk of damaging the tube is greater under extreme operating conditions (e.g., excessive bending, crushing by teeth or retractor, prolonged procedures, repeated manipulation, movement of the endotracheal tube, etc.). Therefore, a spare EMG Endotracheal Tube of the correct size should be kept readily available. The tube may be damaged by teeth during intubation.
- The cuff must not be over-inflated since it may cause cuff rupture with subsequent deflation or cuff distortion leading to cuff herniation and tube blockage.

EMG MONITORS

The NIM™ EMG Endotracheal Tube is designed for use with any multi-channel EMG monitoring equipment. The Medtronic Nerve Integrity Monitor is the recommended EMG monitor for use with the NIM™ EMG Endotracheal Tube. All references to connections and technical specifications for EMG monitors contained in these instructions are made with reference to the NIM™. Where an alternate multi-channel EMG monitoring device is used in conjunction with the NIM™ EMG Endotracheal Tube, the user is advised to consult the operator's manual for their EMG monitor. Medtronic recommends that the user of this device consult the NIM™ User's Guide for determining proper settings of the NIM™ and instructions for intraoperative EMG monitoring and motor nerve location/stimulation. A copy of the NIM™-Spine® User's Guide is supplied with each monitor unit. Replacement copies may be obtained by contacting Medtronic Customer Service Department at 1-800-933-2635 (U.S. only) or 1-800-876-3133.

INSTRUCTIONS FOR USE

Preparation

1. The proper size tube for the individual patient should be determined prior to intubation by the anesthesia provider and/or surgeon. A tube that is one size larger than standard selection is recommended whenever possible to improve electrode contact with vocal cords.
2. Before use, the cuff should be tested for cuff leakage with 15cc to 20cc of air. Thoroughly evacuate all air before intubation.
3. Lubricate cuff with an aqueous lubricant for intubation.

Warning: Do not use local anesthetic gels or creams to lubricate the tube.

4. Use a lubricated stylet for intubation.
5. Prior to insertion of the NIM™ EMG Endotracheal Tube, visually inspect the larynx endoscopically to assure that the tube can be inserted to allow adequate electrode contact with the patient's vocal cords.

Placement

1. The proper placement of the NIM™ EMG Endotracheal Tube is essential for accurately recording the EMG activity of the vocal cords. The electrodes are located on the anterolateral portion of the tube with a midpoint of approximately 10 cm above the caudal tip of the tube. The 3 cm electrode wire exposure is marked by the blue, radio opaque band for the reinforced products. For non-reinforced tubes, a red marking indicates the proximal aspect of the wire exposed area. This area of the tube must be in contact with the true vocal cords.
2. Intubate the patient per standard procedures for flexible reinforced endotracheal tubes with the following exception: use a non-paralyzing, aqueous lubricant on tube. **Note:** A bite block is recommended for use with the EMG Endotracheal Tube to prevent damage to the tube.
3. Do not rotate patient's head and neck during monitoring as misplacement of the EMG tube may occur resulting in false negative responses.

Warning: The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive neural stimulation. Do not use local anesthetics gels or creams to lubricate the tube or apply topical anesthetic sprays on the vocal cords.

4. Maintain Midline placement. Do not orient tube to the left or right of the patient's mouth as this will also rotate the tube's electrodes and cause a leadoff connection.
5. Red electrodes are positioned to the patient's right; blue electrodes to the left.
6. Visualize electrode contact with true vocal cords and secure. Use EMG monitor to verify electrode impedance measures less than 10Kohms and an imbalance less than 2Kohms on both channels. Reposition if necessary.
7. Confirm the depth of intubation via the standard procedures for such tubes. The NIM™ EMG Endotracheal Tube has depth markings on the anterior surface of the tube. Electrode depth and location should be checked against preoperative endoscopic inspection using these markings.

Warning: Placement of the tube in the right main bronchus may result in patient injury.

8. Inflate the endotracheal tube cuff with a minimum volume of air or nitrous oxide to create an airtight seal and ensure against slippage of the tube in situ. Air or nitrous oxide is injected with a syringe through the cuff inflation valve.

MONITOR SETUP

1. The proper connection of the NIM™ EMG Endotracheal Tube to the NIM™ system is essential for accurately recording the EMG activity of the vocal cords. Connect the electrodes of the NIM™ EMG Endotracheal Tube to the EMG monitor. Each recording channel is color-coded: red twisted wires identify the right pair of electrodes and blue twisted wires identify the left pair of electrodes.

Important: Be sure to note which recording channel of the EMG Monitor is assigned to each pair of electrodes before the case begins.

2. Insert the green recording ground electrode into one shoulder and the red/white electrode into the opposite shoulder. The red/white electrode is the monopolar stimulator return (anode, +) electrode. Insert the connectors into the corresponding locations on the NIM™ Patient Interface.
3. Separate the Stimulator leads [both the red/white wire (anode, +) and probe wire (cathode, -)] from the red and blue twisted paired wires to reduce the possibility of feedback into the input channels during stimulator probe use. Locate and secure the EMG Electrode inputs (red and blue twisted pair wires) to the patient.

PATIENT MONITORING

1. After positioning of the NIM™ EMG Endotracheal Tube is achieved and confirmed, the baseline activity of the monitoring set-up should be noted on the screen of the NIM™. Baseline electrical activity may vary from patient to patient and during the course of an individual procedure.
2. Extubate the patient by pulling on the tube, not the harness.

Warning: Extubation of inflated cuff may damage larynx or vocal cords. Fully deflate cuff prior to extubation. Exercise caution during extubation.

IMPORTANT MONITORING TIPS

This section identifies conditions or practices which require attention for most desirable monitoring results.

- It is better to have a pair of recording electrodes that have high impedance values, but relatively balanced, than to have one electrode with very low impedance and the other with very high impedance.
- Suggested electrode impedance values for the NIM™ EMG Endotracheal Tube are less than 10 Kohms. Impedance imbalance values of less than 2.0 Kohms are recommended between the positive and negative electrodes of a channel. Although monitoring can proceed, one is likely to experience problems with electrical and bioelectric artifact and extensive background "noise" with large recording electrode imbalance values.
- Check electrode impedance and imbalance values regularly throughout the case. Should impedance or imbalance levels change suddenly during the case and proper electrode to vocal cord contact has been compromised, it is likely that the tube has rotated enough to dislodge an electrode away from the vocal cord. Tube position and orientation should be confirmed and/or modified until electrode impedance/ imbalance values improve to an acceptable level.
- A baseline EMG value which significantly increases in a short period of time (a few seconds to a minute) can be indicative of an ensuing "train" of activity from the muscle being monitored due to motor nerve irritation, or an impending electrode impedance imbalance situation. Pressing STATUS CHECK on the NIM™ will confirm electrode condition.

STERILITY

Warning: The NIM™ EMG Endotracheal Tube is provided STERILE and is intended for single patient use only. **DO NOT RE-STERILIZE BY ANY MEANS.** Re-sterilization could damage the tube and/or electrode channels, which could create a hazard for patients. Medtronic assumes no liability for tubes that have been re-sterilized by the healthcare facility.

LIMITED WARRANTY

A. This LIMITED WARRANTY provides assurance for the customer who purchases a NIM™ EMG Endotracheal Tube (hereinafter the "Product") that should the Product fail to function to Medtronic Sofamor Danek's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment), Medtronic Sofamor Danek will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Sofamor Danek or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
   1. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
   2. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
   3. Medtronic Sofamor Danek must be notified in writing within thirty (30) days following discovery of a defect.
   4. The Product must be returned to Medtronic Sofamor Danek within thirty (30) days of Medtronic Sofamor Danek receiving notice as provided for in (3) above.
   5. Upon examination of the Product by Medtronic Sofamor Danek, Medtronic Sofamor Danek shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Sofamor Danek or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Sofamor Danek be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

CAUTION
Applicable law may restrict the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

RETURNS AND/OR REPAIRS
Medtronic Sofamor Danek Customer Service
Phone: 800-933-2635
Fax: 800-468-9705
Monday - Friday 7:00 a.m. - 7:00 p.m. CST

Note: When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase, and nature of inquiry available.

SYMBOLS

REF	Catalog number
LOT	Lot number
	Attention, See Instructions For Use
	Use by date
	Do not reuse
STERILE EO	Sterilized by ethylene oxide. Do not use if package is opened or damaged.
Rx Only	Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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