

LMA-Fastrach™ Endotracheal Tube (ETT)

1 DESCRIPTION

The *LMA-Fastrach*™ Endotracheal Tube (ETT) is a non-sterile, reusable and autoclaveable device made of wire-reinforced silicone. Although it can be used conventionally as an endotracheal tube, the *LMA-Fastrach*™ ETT is designed to be used in conjunction with the *LMA-Fastrach*™, the intubating *LMA*™ airway.¹

The *LMA-Fastrach*™ ETT is a wire-reinforced, straight, cuffed tube with a Murphy eye. Every size of *LMA-Fastrach*™ ETT is designed to be compatible with every size of *LMA-Fastrach*™.

The *LMA-Fastrach*™ ETT has a unique molded tip for atraumatic passage through the vocal cords. The tip has been shown to increase ease of passage through the glottis for fiberoptic intubation compared to standard ETT levels.²

As a reference during intubation, the ETT has depth marks (in centimeters) that indicate the distance to the distal tip. The size of the pilot balloon with luer check valve and the placement of the inflation line facilitate passage through the *LMA-Fastrach*™.

The *LMA-Fastrach*™ ETT is 100% latex-free.

The cuff of the *LMA-Fastrach*™ ETT is characterized as being low volume, high pressure. However, studies have shown that the *LMA-Fastrach*™ ETT cuffs are lower pressure than the older red rubber endotracheal tubes that were associated with ischemic changes during long term use.³ At “just seal” or “minimal occlusion volumes”, mucosal pressures should remain within safe limits.

2 INDICATIONS

The *LMA-Fastrach*™ ETT is indicated for airway management by oral intubation of the trachea.

3 CONTRAINDICATIONS

The *LMA-Fastrach*™ ETT is contraindicated in procedures that involve the use of a laser beam or electro-surgical active electrode.

4 ADVERSE REACTIONS

Reported adverse events associated with the use of endotracheal tubes are numerous and diverse. Standard textbooks should be consulted for specific information.

5 CLEANING & STERILIZATION INSTRUCTIONS

With proper cleaning, sterilization, and handling, the *LMA-Fastrach*™ ETT can be used a maximum of 10 times. Proper cleaning and sterilization of the *LMA-Fastrach*™ ETT are essential to ensure continued safe usage up to 10 times.

Warning: The *LMA-Fastrach*™ ETT is delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

Caution: Careful handling is essential. The *LMA-Fastrach*™ ETT is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.

Remove the non-sterile *LMA-Fastrach*™ ETT from the protective package.

Caution: Do not use if the package has been previously opened or damaged.

• Cleaning

Thoroughly wash the *LMA-Fastrach*™ ETT in warm water using a dilute (8-10% v/v) sodium bicarbonate/water solution until all visible foreign matter is removed. Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with *LMA*™ products is Endozime® (Ruhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners, or quaternary ammonium compounds to clean or sterilize the *LMA-Fastrach*™ ETT. Such substances are absorbed by the materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device.

• Rinsing

Aseptically, rinse the tube thoroughly with a generous amount of water at room temperature ensuring that all traces of detergents are removed.

• Sterilization

Steam autoclaving is the only recommended method for sterilization. Ensure that the cuffed tube is totally deflated prior to sterilization. Note that any air left in the cuff will expand in the autoclave causing irreparable damage. Steam autoclave the tube following the recommendations of the institution or the autoclave manufacturer. Steam autoclave cycles typically used for porous items are generally acceptable for sterilization of the tube, provided the maximum autoclave temperature does not exceed 275°F (135°C). It is the responsibility of the user to validate the sterilization cycle and product sterility.

Minimum Exposure Time
Steam Sterilization 270-275°F

Autoclave Cycle	Wrapped	Unwrapped
Gravity Displacement	10-15min	10 min*
Prevacuum	3-4min	4 min*

*Mixed porous and non-porous items. Reference: AAMI Standards and Recommended Practices⁴

Let the tube cool to room temperature.

6 DIRECTIONS FOR USE WITH LARYNGOSCOPY

Warning: Always use aseptic technique. Intubation and extubation should be performed following currently accepted medical techniques. Expert clinical judgment should be used in choosing the suitable tube size for each patient.

1. Test the valve and cuff for integrity before intubation by inflating with air from a luer-tip syringe. Then deflate the cuff completely.

Warning: The *LMA-Fastrach*™ ETT cuff, pilot balloon, and valve should be tested by inflation and complete deflation prior to each use. Do not use if the cuff is damaged or cannot be made to inflate symmetrically, if the pilot balloon is showing any signs of deterioration or abnormalities, or if the inflation valve mechanism is displaying any signs of deficiency.

2. Check the airway tube for any signs of debris, kinking, or other damage.

Warning: Do not use the *LMA-Fastrach*™ ETT if the airway tube is damaged in any way. The *LMA-Fastrach*™ ETT should not be cut by the user.

3. Lubricate the distal end of the tube with a sterile water-soluble lubricating jelly.

Warning: Only use water-soluble lubricants with the *LMA-Fastrach™* ETT. Excessive amounts of lubricant on the inner surface of the tube could result in either a lubricant plug or a clear film that may partially or totally block the lumen and the airway.

4. Ensure the 15 mm connector is firmly attached into the *LMA-Fastrach™* ETT.
5. Intubate using currently accepted medical techniques. When using the *LMA-Fastrach™* ETT without the *LMA-Fastrach™*, a lubricated intubation stylet may need to be used due to the pliability of the silicone material.
6. Inflate the cuff with the minimum amount of gas mixture to provide an effective seal at the desired lung inflation pressure. Use of the Minimal Occluding Volume and Minimum Leak Techniques along with routine monitoring of intracuff pressure may reduce the occurrence of many of the adverse reactions associated with the use of cuffed endotracheal tubes.

Warning: Inflation of the cuff by “feel” or by using a measured amount of air is not recommended since resistance is an unreliable guide during inflation. In selecting the seal pressure, an intracuff pressure measuring device should be used in conjunction with the Minimal Occluding Volume or Minimum Leak techniques.

Warning: Do not overinflate the cuff. Overinflation can result in a rupture of the cuff with subsequent deflation or cuff distortion which may lead to airway blockage or tissue damage.

Warning: Diffusion of nitrous oxide, oxygen, or air may either increase or decrease cuff volume and pressure. To decrease such diffusion, inflating the cuff with the same gas mixture that will contact the cuff’s external surface is recommended.

7. Remove the luer-tip syringe from the valve.

Caution: If three-way stopcocks or other devices are used for extended periods of time, check valve integrity periodically. The resulting stress could damage the valve components allowing the cuff to deflate.

8. Check tube placement by confirming breath sounds and by monitoring end-tidal CO₂.
9. Establish the connection with the anesthesia or ventilator circuit.

Warning: Seat the connector firmly in both the *LMA-Fastrach™* ETT and the adapter on the ventilation equipment to prevent disconnection during use. Non-standard dimensions of some ventilators or anesthesia equipment connectors may make secure mating with the *LMA-Fastrach™* ETT 15 mm connector difficult.

10. The tube should be securely anchored and a bite block used to avoid unnecessary movement or damage.
11. Cuff pressure should be monitored. Any deviation from the selected seal pressure should be investigated and corrected immediately.

Warning: There are limited clinical data on how long an *LMA-Fastrach™* ETT can remain in place⁵ and clinical judgment must be used in each situation. In all situations, care should be taken to monitor and limit cuff inflation to a “just seal” pressure.

12. Before extubation or repositioning the *LMA-Fastrach™* ETT, completely deflate the cuff using a luer-tip syringe.

Warning: Movement of the *LMA-Fastrach™* ETT with the cuff inflated could result in patient injury or cuff damage.

13. When indicated, extubate using currently accepted medical techniques.

7 INSTRUCTIONS FOR USE OF THE *LMA-FASTRACH™* ENDOTRACHEAL TUBE WITH THE *LMA-FASTRACH™*

The *LMA-Fastrach™* is an *LMA™* airway designed to facilitate passage of endotracheal tubes while allowing ventilation during and between intubation attempts. Techniques for using the *LMA-Fastrach™* are described in the *LMA-Fastrach™* Instruction Manual.¹

• Preparation

Before using either the *LMA-Fastrach™* ETT or the *LMA-Fastrach™*, each must be sterilized according to the manufacturer’s instructions. Gently fit the connector into the *LMA-Fastrach™* ETT. The connector should be secure enough to allow adequate ventilation, but should not be so forcefully inserted to prevent its removal when the *LMA-Fastrach™* is withdrawn after intubation.

• Lubrication

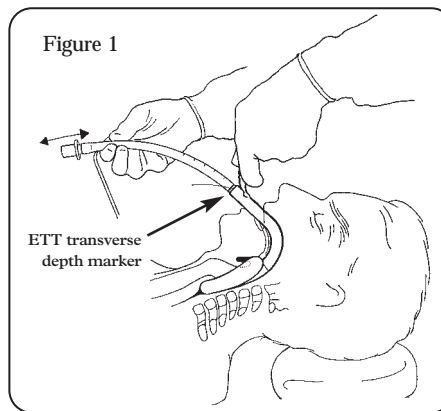
Lubrication must be carried out prior to use. Lubricate the fully deflated *LMA-Fastrach™* ETT with a sterile, water-soluble lubricant placed near the distal tip.

Holding the *LMA-Fastrach™* by its metal handle, insert the *LMA-Fastrach™* ETT through the *LMA-Fastrach™*. Using a twisting motion, move the *LMA-Fastrach™* ETT up and down inside the *LMA-Fastrach™* to uniformly distribute the lubricant.

When lubricant is adequately distributed, the *LMA-Fastrach™* ETT will spring back up in the *LMA-Fastrach™* when inserted into the point where the endotracheal tube transverse depth marker is flush with the connector end of the metal tube (See Figure 1). Now, remove the *LMA-Fastrach™* ETT from the *LMA-Fastrach™* maintaining aseptic technique.

• Intubation Through the *LMA-Fastrach™*

After insertion of the *LMA-Fastrach™* according to the manufacturer’s instructions¹, ensure adequate oxygenation and muscle relaxation before attempting intubation with the *LMA-Fastrach™* ETT. Always ensure that the correct size *LMA-Fastrach™* is being used and that the mask is properly positioned before attempting intubation.



Insert the *LMA-Fastrach™* ETT with the longitudinal black line on the tube facing the patient’s nose. Do not pass the ETT beyond the point where the transverse depth marker on the *LMA-Fastrach™* ETT is level with the outer rim of the *LMA-Fastrach™* airway tube, until satisfied that the *LMA-Fastrach™* ETT is moving easily with minimal friction through the metal airway tube.

The *LMA-Fastrach™* ETT is now passed with maximum caution through the *LMA-Fastrach™*, which should be steadied in position by holding its metal handle as shown in Figure 1. If the tube will not pass easily, do not use force under any circumstances. Conventional signs of correct intubation should be sought, e.g. evidence of expired CO₂.

Warning: Do not use force under any circumstances.

Assessment of mask position around the glottic aperture using a flexible fiberscope is recommended. See the *LMA-Fastrach™* Instruction Manual for details of the decisional algorithm (to verify correct size and placement) to be used when intubating through this device.¹

There are reports of pharyngeal edema and increased mucosal pressure attributed to the rigidity of the *LMA-Fastrach™* airway tube. Therefore, it is recommended that the *LMA-Fastrach™* be removed once intubation has been accomplished. If, however, a clinical decision is made to leave the *LMA-Fastrach™* in place after intubation, its cuff should be deflated to 20–30 cm H₂O intracuff pressure and care taken to avoid unnecessary movement of the *LMA-Fastrach™* airway tube or movement of the head or neck from the neutral position. There are currently no clinical data on how long the *LMA-Fastrach™* may be left in place.

• Removal of the *LMA-Fastrach™* After Intubation

Warning: Bronchial intubation, accidental extubation, esophageal intubation or other misplacement may occur if the *LMA-Fastrach™* removal procedure is not performed correctly. If accidental extubation or misplacement occurs, a correctly deflated *LMA-Fastrach™* should be reinserted without delay for patient ventilation and oxygenation.

After intubation but prior to removal of the *LMA-Fastrach™*, use the *LMA™* Stabilizer Rod with depth markings (or similar measuring device) to measure the distance from the lips or incisor teeth to the outer end of the *LMA-Fastrach™* ETT. This will facilitate verification of the correct location of the *LMA-Fastrach™* ETT by remeasuring this distance following removal of the *LMA-Fastrach™*.

After ensuring the patient is stable and fully oxygenated, remove the connector from the *LMA-Fastrach™* ETT using the method shown in Figure 2a (not the method in 2b).

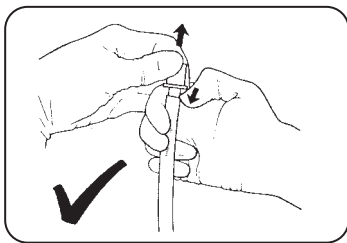


Figure 2a

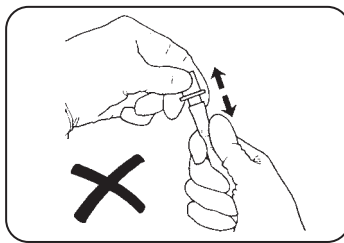


Figure 2b

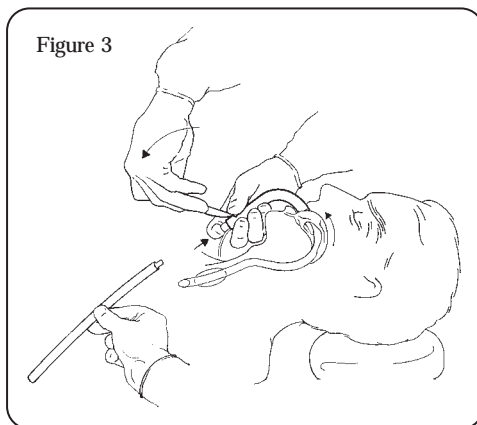


Figure 3

Deflate the cuff of the *LMA-Fastrach™* by withdrawing air through the blue pilot balloon. Do not deflate the flesh-tone pilot balloon of the *LMA-Fastrach™* ETT.

Keeping the *LMA-Fastrach™* ETT in place with one finger placed over the distal end of the tube, slide the *LMA-Fastrach™* outwards by gently tapping or swinging the metal handle caudally as shown in Figure 3.

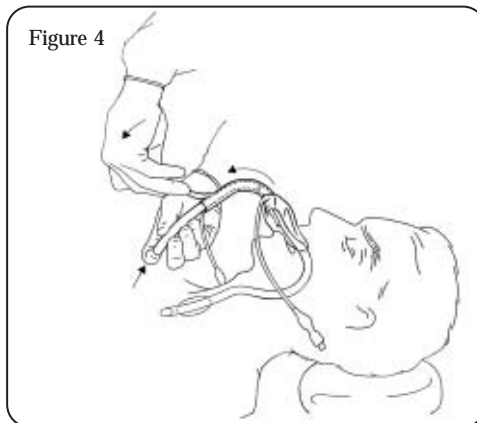


Figure 4

When the end of the *LMA-Fastrach™* ETT is flush with the rim of the metal airway tube of the *LMA-Fastrach™*, use the *LMA™* Stabilizer Rod to keep the ETT in place as the *LMA-Fastrach™* is rotated out of the oral cavity (Figure 4).

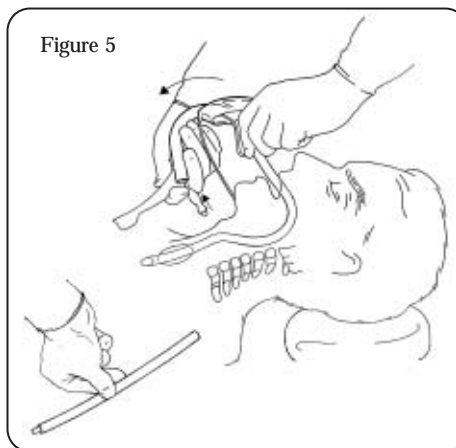


Figure 5

Once the mask portion is clear of the mouth, remove the Stabilizer Rod before grasping the *LMA-Fastrach™* ETT shaft at the level of the incisor teeth (Figure 5).

Failure to remove the Stabilizer Rod before fully removing the *LMA-Fastrach™* may result in accidental extubation or damage to the *LMA-Fastrach™* ETT pilot balloon or inflation line.

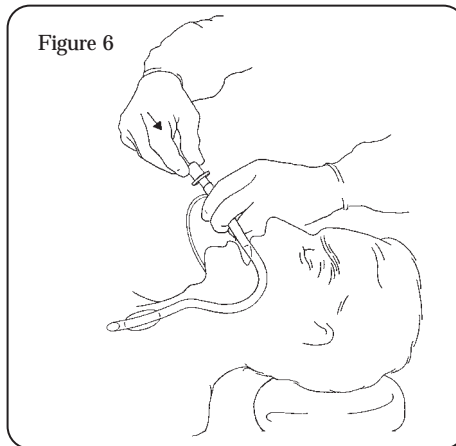


Figure 6

Warning: After intubation has been accomplished, if the *LMA-Fastrach™* Stabilizer Rod is not removed from the metal airway tube before completely removing the *LMA-Fastrach™*, the *LMA-Fastrach™* ETT may be accidentally pulled out or the pilot balloon or inflation line tubing may be damaged.

Firmly replace the 15mm connector on the *LMA-Fastrach™* ETT (Figure 6).

Use the *LMA™* Stabilizer Rod to confirm that the *LMA-Fastrach™* ETT lies at the correct depth. Seek evidence of effective ventilation and secure the ETT in place with a bite block.

8 USE WITH MAGNETIC RESONANCE IMAGING

The following is a summary of the testing performed to determine *LMA-Fastrach™* ETT compatibility with magnetic resonance imaging (MRI). Full details are found in the Appendix. Prior to using the ETT with MRI, compare the equipment and test conditions described with those planned for use in the actual clinical environment.

The *LMA-Fastrach™* ETT is MR safe when using a shielded MRI system with static magnetic fields of 1.5 Tesla or less, gradient magnetic fields of 20 Tesla/second or less, and a maximum whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 30 minutes of imaging.

Warning: The effects of performing MRI procedures using MR systems with static magnetic fields greater than 1.5 Tesla and other conditions have not been tested.

The *LMA-Fastrach™* ETT does not pose a safety risk to the patient or other personnel and its performance is not degraded by exposure to the MR environment. The *LMA-Fastrach™* ETT exhibits magnetic field interactions with respect to translational force and torque under the MR conditions noted (maximum spatial gradient, 450 gauss/cm). However, when the tube is properly positioned and secured with tape there is no direct risk to the patient with respect to movement or dislodgment. MR imaging quality may be compromised depending on the pulse sequence that is used, and if the area of interest is in the same area or relatively close to the position of the *LMA-Fastrach™* ETT.

¹ *LMA-Fastrach™* Instruction Manual, The Laryngeal Mask Company Limited / LMA North America, Inc.

² Greer JR, Smith SP, Strang T. A comparison of tracheal tube tip designs on the passage of an endotracheal tube during oral fiberoptic intubation. *Anesthesiology* 2001;94:729-31.

³ Wiesel S, Warm T. Fastrach uses a low-volume, high-pressure cuff for the endotracheal tube system. *Anesthesiology* 1999;91:592-3. Reply by Young.

⁴ ANSI/AAMI ST46-1993 and ST37-1996. In *AAMI Standards and Recommended Practices*. Association for the Advancement of Medical Instrumentation. Arlington, Virginia 2001.

⁵ Young PJ, Burchett K, Harvey I, Blunt MC. The prevention of pulmonary aspiration with control of tracheal wall pressure using a silicone cuff. *Anaesth Intensive Care* 2000;28:660-665.

APPENDIX

LMA-Fastrach™ ETT Use in MRI Environment

Safety information for the use of magnetic resonance imaging (MRI) procedure (i.e., imaging, angiography, functional imaging, spectroscopy, etc.) in patients pertains to shielded MR systems with static magnetic fields of 1.5 Tesla or less, gradient magnetic fields of 20 Tesla/second or less, and a maximum whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 30 minutes of imaging. The effects of performing MRI procedures using MR systems and conditions above these levels have not been determined.

The *LMA-Fastrach™* ETT has been determined to be MR safe. That is, the *LMA-Fastrach™* ETT when placed in a patient undergoing an MRI procedure and properly secured will not present an additional risk to the patient, but may affect image quality depending on the pulse sequence that is used and the imaging area of interest.

MRI procedures must only be performed according to the following guidelines:

Static Magnetic Field: A patient with the *LMA-Fastrach™* ETT may safely undergo an MRI procedure using a shielded MR system with a static magnetic field of 1.5 Tesla or less. The *LMA-Fastrach™* ETT exhibits magnetic field interactions with respect to translational force and torque during exposure to a shielded 1.5 Tesla MR system (maximum spatial gradient, 450 gauss/cm). However, when the *LMA-Fastrach™* ETT is properly positioned and adhesive tape or other similar dressing is used to retain this device in place, there is no additional risk to the patient with regard to movement or dislodgment using a shielded MR system with static magnetic field of 1.5 Tesla or less. Thus, special care is required to ensure that the *LMA-Fastrach™* ETT is maintained in place during exposure to the 1.5 Tesla MR environment.

Gradient Magnetic Fields: Pulse sequences (e.g., echo planar imaging technique or other rapid imaging pulse sequence), specialized gradient coils or other techniques or procedures that exceed gradient magnetic fields of 20 Tesla/sec must not be used for MRI procedures in a patient with the *LMA-Fastrach™* ETT. Use of unconventional or non-standard MRI techniques have not been assessed and, therefore, must be avoided.

Radiofrequency (RF) Fields of MR Systems: MRI safety tests conducted using a whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 30 minutes indicated that there is less than a 0.4°C temperature increase for the *LMA-Fastrach™* ETT. Therefore, MRI procedures must not exceed exposures to RF fields greater than a whole body averaged SAR of 1.1 W/kg for 30 minutes of imaging in a patient with the *LMA-Fastrach™* ETT.

MRI Artifacts: Artifacts for the *LMA-Fastrach™* ETT products have been characterized using a 1.5 Tesla MR system and a fast multiplanar, spoiled gradient echo and T1-weighted spin echo pulse sequences. Based on this information, MR image quality may be compromised if the area of interest is in same area or relatively close to the position of the *LMA-Fastrach™* ETT.

Artifact size is dependent on the type of pulse sequence used for imaging (e.g., larger for fast multiplanar spoiled gradient recalled echo pulse sequences and smaller for spin echo and fast spin echo pulse sequences) the direction of the frequency encoding direction (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view. Positional errors and artifacts on MR images will be smaller for MR systems with lower static magnetic field strengths using the same imaging parameters. The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of the *LMA-Fastrach™* ETT compared to the use of other imaging techniques.

Summary of MRI Artifact Information for the *LMA-Fastrach™* ETT

Signal Void Size	1,492	3,631	2,218	6,917
Static Magnetic Field (T)	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	FMPSPGR	FMPSPGR
TR (msec)	300	300	50	50
TE (msec)	20	20	2.6	2.6
Flip Angle	N/A	N/A	30°	30°
Bandwidth	16 kHz	16 kHz	16 kHz	16 kHz
Field of View	24 cm	24 cm	24 cm	24 cm
Matrix Size	256 x 128	256 x 128	256 x 128	256 x 128
Section Thickness	10 mm	10 mm	10 mm	10 mm
Maximum Readout Gradient Strength	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m
Orientation of Device To Field	Parallel	Perpendicular	Parallel	Perpendicular
Phantom Filler	Gel	Gel	Gel	Gel

(T1-SE, T1-weighted spin echo; FMPSPGR, fast multiplanar spoiled gradient recalled echo in the steady state; N/A, not applicable; values for artifact size indicated in mm²; Note that the T1 and T2 values for the gel used for the phantom filler are similar to the values of skeletal muscle or organ tissue.)

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.

The Laryngeal Mask Company Limited recommends that the *LMA-Fastrach™* Endotracheal Tube be used a maximum of 10 times. Use beyond this recommendation may affect the product's performance. This device is warranted against faulty materials or manufacturing defects for ten (10) uses or a period of one (1) year from date of invoice, whichever comes first, provided that the *LMA-Fastrach™* Endotracheal Tube is used in accordance with the procedures set forth in this instruction sheet. *The LMA-Fastrach™* Endotracheal Tube must accompany any request for evaluation of a manufacturing defect. Warranty applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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