EN - English

INSTRUCTIONS FOR USE – LMA® Fastrach™ ETT

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

WARNING: LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod accessory are supplied 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 sterilisation.

WARNING: Read all Instructions for Use warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

GENERAL INFORMATION:

Unless otherwise stated, the reference to "LMA® Fastrach™ stated on this Instructions For Use applies to both versions of the airway devices (LMA® Fastrach™ and LMA® Fastrach™ Single Use (LMA® Fastrach™ SU)).

For detailed instructions on use of LMA® Fastrach™, LMA® Fastrach™ Single Use and LMA® Fastrach™ ETT Single Use, please refer to the respective Instructions For Use.

DEVICE DESCRIPTION:

The LMA® Fastrach™ Endotracheal Tube (LMA® Fastrach™ ETT) has been developed specifically for use with the LMA® Fastrach™. It is a straight, cuffed tube with a Murphy Eye and a standard 15mm connector.

The LMA® Fastrach™ ETT has a pilot balloon with a luer check valve and a unique, soft, moulded tip for atraumatic passage through the vocal cords. As a reference during intubation, the LMA® Fastrach™ ETT has depth markers to indicate the distance to the distal tip of the LMA™ airway. The LMA® Fastrach™ ETT is radiopaque along its full length and its tip is made out of a radio opaque material to enhance its visibility in x-rays.

The LMA® Fastrach™ ETT is a reusable device, made of wire-reinforced silicone. It is not made with natural rubber latex.

The LMA® Fastrach™ ETT should not be reused more than 10 times. Continued use beyond the maximum number of times is not recommended as degradation of the components may result in impaired performance or abrupt failure of the device. Steam autoclave is the only recommended method for sterilization.

Accessory device: The LMA® Fastrach™ Stabiliser Rod is an accessory and it is indicated for use during removal of the reusable LMA® Fastrach™ and LMA® Fastrach™ Single Use (SU) after intubation to keep the Endotracheal Tube (ETT) in place. It is supplied non-sterile and autoclavable. The LMA® Fastrach™ Stabiliser Rod is made of silicone. Not made with natural rubber latex.

The LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod devices are only for use by medical professionals trained in airway management.

INDICATIONS FOR USE:

The LMA® Fastrach™ ETT is indicated for tracheal intubation through the LMA® Fastrach™ or for conventional intubation of the trachea using direct or indirect laryngoscopy.

The LMA® Fastrach™ Stabiliser Rod is indicated for use during removal of the LMA® Fastrach™ and LMA® Fastrach™ SU after intubation to keep the LMA® Fastrach ™ ETT in place.

CONTRAINDICATIONS:

The LMA® Fastrach™ ETT should not be placed in patients eligible for procedures which involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device.

There are no known contraindications associated with the **LMA ® Fastrach™ Stabiliser Rod** accessory device.

ADVERSE EFFECTS:

There are reported adverse reactions associated with the use of endotracheal tubes. Potential side effects may include airway trauma, dysphagia, sore throat, dysphonia, laryngospasm, obstruction, stridor, bronchospasm, hoarseness, nausea and vomit, regurgitation, aspiration, gastric distension, patient intolerance e.g. coughing, and mouth, lip or tongue injury.

WARNINGS:

1. Do not use a device if it is damaged.
2. Do not immerse or soak the device in liquid prior to use.
3. Do not cut the LMA® Fastrach™ ETT.
4. If a malleable stylet is used in the LMA® Fastrach™ ETT during intubation, ensure that it does not protrude from the patient end or Murphy Eye of the tube.
5. Do not overinflate the cuff of the LMA® Fastrach™ ETT as this can result in rupture and subsequent deflation, or cuff distortion, which may lead to airway blockage and/or patient injury.
6. Deflate LMA® Fastrach™ ETT cuff prior to repositioning LMA® Fastrach™ ETT. Movement of the LMA® Fastrach™ ETT with the cuff inflated could result in patient injury or cuff damage.
7. Displacement of the LMA® Fastrach™ ETT (esophageal intubation, accidental extubation) may occur if the LMA® Fastrach™ removal procedure is not performed correctly. In these cases a correctly deflated LMA® Fastrach™ should be re-inserted without delay to ensure patient oxygenation.
8. To avoid trauma, excessive force should not be used at any time when using the device.
9. Ensure that the patient is anaesthetised, paralysed and pre-oxygenated. Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the LMA® Fastrach™ ETT into the larynx.
10. It is most important that pre-use checks are carried out on LMA® Fastrach ETT prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.
11. When applying lubricant avoid blockage of the airway aperture with the lubricant.
12. A water soluble lubricant, such as K-Y Jelly, should be used. Do not use silicone-based lubricants as they degrade the LMA® Fastrach™ ETT components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.
13. Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex), ethylene oxide, phenol-based cleaners or iodine-containing cleaning agent to clean or sterilize the LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances. The cleaning agents must not contain skin or mucous membrane irritants.
14. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilization.
15. Gently fit the connector into the LMA® Fastrach™ ETT prior to applying lubricant to the distal end of the tube. Excessive amounts of lubricant may cause partial or full blockage of the lumen and airway which may cause a risk of aspiration.
16. Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure.
In order to ensure that cuff pressures do not become excessive, cuff pressure should be measured regularly during a case with a cuff pressure monitor.
17. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention. The device may be flammable in the presence of lasers and electrocautery equipment.
18. Refer to MRI information section prior to using the device in MRI environment.

CAUTIONS:

1. An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.
2. Careful handling is essential. Avoid contact with sharp or pointed objects at all times to prevent tearing or perforation of the device.
3. When passing a fibreoptic bronchoscope (FOB), it should not be passed through the LMA® Fastrach™ airway aperture unless protected by the LMA® Fastrach™ ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottis elevating bar.
4. When selecting seal pressure for the LMA® Fastrach™ ETT, an intracuff pressure measuring device should be used in conjunction with the Minimal Occluding Volume, or Minimum Leak techniques. Cuff inflation should be monitored regularly to a "just seal" pressure. Any deviation from the selected seal pressure should be investigated and corrected immediately.
5. Use only ventilators or anaesthesia equipment with standard 15mm connectors to ensure secure connection with the LMA® Fastrach™ ETT connector. Always ensure that the connector is securely seated in the breathing circuit to prevent disconnection during use.
6. Three-way stopcocks, or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve causing the cuff to deflate.
7. Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
8. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
9. Ensure all removable denture work is removed before inserting the device.
10. Gloves should be worn during preparation and insertion to minimize contamination of the device.
11. Only use with the recommended manoeuvres described in the instructions for use.

Note: For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website':

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

PREPARATION FOR USE:

Choose the correct size of LMA® Fastrach™ & LMA® Fastrach™ SU

Patient Weight/Size

Size 3: 30kg – 50kg
Size 4: 50kg – 70kg
Size 5: 70kg – 100kg

Compatibility of LMA® Fastrach™ ETT vs LMA® Fastrach™

Both reusable and single use LMA® Fastrach™ ETT are available in a variety of sizes and can be used conventionally as an endotracheal tube.

All sizes (6, 6.5, 7, 7.5 and 8) of reusable LMA® Fastrach™ ETT are compatible with both reusable and single use LMA® Fastrach™.

However, for LMA® Fastrach™ ETT SU, only sizes (6, 6.5 and 7) are compatible with both reusable and single use LMA® Fastrach™ as tabulated below:-

Device	Compatible with the below LMA® Fastrach™ ETT sizes	
LMA® Fastrach™ & LMA® Fastrach™ SU	**LMA® Fastrach™ ETT (Reusable)**	Size: 6, 6.5, 7, 7.5 & 8
	LMA® Fastrach™ ETT SU (Single Use)	Size: Only 6, 6.5 & 7

Caution: Clinical judgment should be used in the selection of the appropriate device size for an individual patient.

PRE-USE CHECKS:

Warning: It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use.

Warning: Failure of any one test indicates the device should not be used.

LMA® Fastrach™ ETT:
1. Deflate the cuff completely then fully inflate the valve and cuff to test their integrity. Do not overinflate the cuff.
2. Visually check that the airway tube, cuff and balloon are free of debris and leaks, and are not damaged, kinked, nor occluded. Do not use if the device doesn't inflate symmetrically, shows sign of deterioration/abnormality or if there is a deficiency with the inflation mechanism.
3. Ensure that the connector is attached into the LMA® Fastrach™ ETT.

LMA® Fastrach™ Stabiliser Rod:
Visually check that the device is free from debris and is not damaged or deteriorated, such as deformation, surface cracks, etc

PRE-INSERTION PREPARATION:

Warning: Gently fit the connector into the LMA® Fastrach™ ETT prior to applying lubricant to the distal end of the tube. Excessive amounts of lubricant may cause partial or full blockage of the lumen and airway which may cause a risk of aspiration.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA® Fastrach™ ETT components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

Caution: Ensure all removable denture work is removed before inserting the device.

INTUBATION:

Below describes various methods of intubation using LMA® Fastrach™ ETT with and without an assisting device. It is recommended to use LMA® Fastrach™ with LMA® Fastrach™ ETT for optimal intubation. Teleflex will not be liable for use of an inappropriate endotracheal tube.

Caution: If LMA® Fastrach™ is used, ensure it is properly positioned before attempting intubation.

Warning: Ensure that the patient is anaesthetised, paralysed and pre-oxygenated. **Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the LMA® Fastrach ™ ETT into the larynx.**

TRACHEAL INTUBATION WITH THE LMA® FASTRACH™:

1. After checking the cuff seal, deflate the LMA® Fastrach™ ETT cuff completely before the insertion of LMA® Fastrach™ ETT into the airway tube of LMA® Fastrach™.
2. Pass the LMA® Fastrach™ ETT into the airway tube of LMA® Fastrach™ and distribute the lubricant within the shaft by moving the LMA® Fastrach™ ETT up and down until it travels freely through the entire airway tube.

Warning: Avoid the LMA® Fastrach™ ETT down and up movements with high speed and large amplitude as this manoeuvre could result in cuff damage.

3. Position the longitudinal line of the LMA® Fastrach™ ETT to face the handle of LMA® Fastrach™. Gently insert the LMA® Fastrach™ ETT into the device airway tube. The LMA® Fastrach™ ETT should not pass beyond the 15 cm transverse depth marker. Ensure that **the tip of the LMA® Fastrach™ ETT does not enter the mask aperture (Fig. 1).**
4. Grip the handle firmly and lift the device using the handle to draw the larynx forward by a few millimetres to increase seal pressure and optimize alignment of the trachea and LMA® Fastrach™ ETT axes (Fig. 2).
5. Slide the LMA® Fastrach™ ETT gently into the LMA® Fastrach™ another 1.5cm past the 15cm mark. If no resistance is felt, continue to advance the LMA® Fastrach™ ETT while holding the device steady until intubation is accomplished.
6. Inflate the cuff of the LMA® Fastrach ETT™.
7. Confirm intubation by conventional means (e.g. end tidal CO_2).


Figure 1

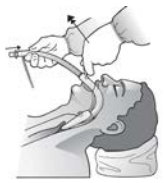
Figure 2

INTUBATION WITH LMA® FASTRACH™ AND WITH FIBREOPTIC BRONCHOSCOPE (FOB) ASSISTANCE:

1. Pass a self-sealing connector with a suitable side-arm through the LMA® Fastrach™ ETT to permit continued ventilation.
2. Select an FOB of an appropriate diameter and length to pass within the LMA® Fastrach™ ETT. When fully inserted, the FOB should not protrude through the end of the assembled LMA® Fastrach™ ETT and sealing port. It should also not pass beyond the EEB of LMA® Fastrach™ unless protected by the LMA® Fastrach™ ETT. Otherwise its tip may be deviated or damaged by the EEB.
3. Insert the LMA® Fastrach™ ETT up to 15cm depth, verify with the FOB that the LMA® Fastrach™ ETT tip contacts the EBB of the device.
4. At 16.5cm depth, verify with the FOB that the LMA® Fastrach™ ETT lifts the EEB showing the glottis.
5. Advance the LMA® Fastrach™ ETT into the trachea; avoid pushing on the EEB with the FOB.
6. Inflate the cuff of the LMA® Fastrach™ ETT.

CONVENTIONAL TRACHEAL INTUBATION WITH LMA® FASTRACH™ ETT UNDER DIRECT OR INDIRECT LARYNGOSCOPY:

LMA® Fastrach™ ETT is designed to be used conventionally as an endotracheal tube.

Warning: Always use an aseptic technique.

1. Intubate using currently accepted medical techniques. A lubricated malleable intubation stylet may need to be used due to the flexibility of the airway tube of the LMA® Fastrach™ ETT.
2. Inflate the cuff with the minimum amount of gas mixture to provide an effective seal at the desired lung inflation pressure. Using Minimal Occluding Volume and Minimum Leak Techniques along with routine monitoring of intracuff pressure may reduce the occurrence of many adverse reactions associated with the use of cuffed endotracheal tubes.
3. Remove the luer-tip syringe from the valve.
4. Check LMA® Fastrach™ ETT placement by confirming breathing sounds and monitoring end-tidal CO_2.
5. Connect LMA® Fastrach™ ETT to the anaesthesia or ventilator circuit.
6. Securely anchor the LMA® Fastrach™ ETT using a bite block to avoid unnecessary movement or damage.
7. Monitor cuff pressure regularly.

REMOVAL OF THE LMA® FASTRACH™ AFTER TRACHEAL INTUBATION:

Warning: There are reports of pharyngeal oedema and increased mucosal pressure attributed to the rigidity of the airway tube. It is recommended to remove LMA® Fastrach™ once intubation has been accomplished. High pressures may develop against the pharyngeal wall if the head or neck is moved from the neutral position, due to the rigidity of the curved airway tube. The risk of maintaining in place the LMA® Fastrach™ must be weighed against the potential risks associated with the manoeuvre of removal of the device.

Warning: If the LMA® Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H_20 pressure. This low cuff pressure stabilizes the airway in the pharynx. Avoid unnecessary movement of the device and maintain head or neck in a neutral position.

Warning: Displacement of the LMA® Fastrach™ ETT (oesophageal intubation, accidental extubation) may occur if the LMA® Fastrach™ removal procedure is not performed correctly. In these cases, a correctly deflated LMA® Fastrach™ should be reinserted without delay to ensure patient oxygenation.

1. Using the LMA® Stabiliser Rod, measure the approximate distance between the proximal end of the LMA® Fastrach™ ETT and the patient's teeth.
2. Following pre-oxygenation of the patient, disconnect the circuit leaving the LMA® Fastrach™ ETT connector attached. Fully deflate the LMA® Fastrach™ cuff, making sure the LMA® Fastrach™ ETT cuff remains inflated.
3. Gently tap or swing the device handle caudally around the chin. Using the curvature of the airway tube, slide the device out of the pharynx into the oral cavity, applying counter pressure to the LMA® Fastrach™ ETT with the finger **(Fig. 3)**.
4. When the proximal end of the LMA® Fastrach™ ETT is level with the proximal end of the airway tube, remove the LMA® Fastrach™ ETT connector and insert the Stabiliser Rod to keep the LMA® Fastrach™ ETT in place. Holding the Stabiliser Rod, slide out the LMA® Fastrach™ over the LMA® Fastrach™ ETT and LMA® Stabiliser Rod until it is clear of the mouth. **(Fig.4)**
5. Remove the LMA® Stabiliser Rod when the LMA® Fastrach™ cuff is clear of the mouth while holding the LMA® Fastrach™ ETT in place to prevent accidental dislodgment **(Fig. 5)**. Grasp the LMA® Fastrach™ ETT firmly while gently unthreading the inflation line and pilot balloon from the LMA® Fastrach™ tube **(Fig. 6)**.

Caution: Failure to remove the LMA® Stabiliser Rod from airway tube before completely removing the LMA® Fastrach™ may result in the LMA® Fastrach™ ETT being accidentally pulled out or the pilot balloon or inflation line tubing being damaged.

6. Using the LMA® Stabiliser Rod, check the position of the LMA® Fastrach™ ETT by measuring the distance of the proximal end from the teeth. If, during removal of the LMA® Fastrach™, any displacement of the LMA® Fastrach™ ETT has occurred, an appropriate adjustment will need to be made.
7. Replace the LMA® Fastrach™ ETT connector and ventilate the patient.

Caution: Verify correct tube placement and patient oxygenation immediately after LMA® Fastrach™ removal, or if the patient's position is altered after intubation.

8. LMA® Fastrach™ ETT should be securely anchored using a bite-block to avoid unnecessary movement or damage.

In elective cases, after removal, LMA® Fastrach™ may be re-inserted behind the LMA® Fastrach™ ETT to provide an immediate airway if deep extubation is planned or extubation is clinically determined to be hazardous.

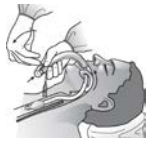

Figure 3

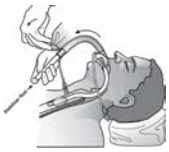

Figure 4

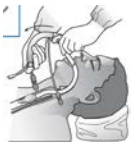

Figure 5

Figure 6

REMOVAL OF THE LMA® FASTRACH™ ETT:

Clinical judgment should be used to determine how long LMA® Fastrach™ ETT is to remain in the patient.

1. Immediately prior to extubation or repositioning of the LMA® Fastrach™ ETT, completely deflate the cuff using a syringe.
2. Extubate using currently accepted medical techniques.

REPROCESSING:

(Applicable to the reusable version of LMA® Fastrach™ ETT device and LMA® Fastrach™ Stabiliser Rod accessory device only.)

General Warnings, Precautions and Restrictions

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard to hospital hygiene and sterilization technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilization is performed using appropriate equipment, materials, and personnel to achieve the desired result.
Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

The equipment used during reprocessing should be validated for effectiveness according to internationally recognized standards:

- Washers-disinfectors meeting the requirements of ISO 15883 series and /or ANSI / AAMI ST15883 Series
- Steam sterilizers meeting the requirements of EN 13060/EN 285 in conjunction with ISO 17665 and / or ANSI AAMI ST8, ANSI AAMI ST79.

The World Health Organization (WHO) guidelines and published literature indicate that the LMA® Fastrach™ ETT and LMA®Fastrach Stabiliser Rod cleaning and sterilization procedures outlined below are sufficient for inactivation of conventional pathogens (i.e., bacteria, fungi, and viruses). In patients known or suspected to have transmissible spongiform encephalopathy, it is recommended that the institutions follow WHO guidelines by destroying rather than reusing LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod after use.

Warning:
Before initial use and any subsequent use, all devices must be subjected to reprocessing as described in the following sections.
Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

Caution: Careful handling is essential. The LMA® Fastrach™ ETT is made of medical - grade silicone which can be torn or perforated. Always avoid contact with sharp or pointed objects .

With proper cleaning, sterilization, and handling, the LMA® Fastrach™ ETT can be used up to a maximum number of re-use as tabulated below. Proper cleaning and sterilization of the devices is essential to ensure continued safe usage up to the maximum number of re-use. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt fail**ure.**

Devices	Maximum number of Re-use
LMA® Fastrach™ ETT	10 times

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

REPROCESSING PRIOR TO FIRST AND ANY SUBSEQUENT USE

Preparation at the point of use prior to processing

Remove all traces of contamination immediately after use to avoid incrustation. Disassemble the removable LMA® Fastrach™ ETT connector seated on airway tube. Do not use fixative agents or hot water (>40°C/104°F). Storage and transport of the devices to the reprocessing location must be ensured in a sealed container.

The re-processing parameters for LMA® Fastrach™ ETT are also applicable for LMA® Fastrach™ Stabiliser Rod.

CLEANING:

Warnings and Precautions
Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaning agents, iodine-containing cleaning agents or quaternary ammonium compounds to clean or sterilise LMA® Fastrach™ ETT and LMA® Fastrach™Stabiliser Rod. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances. The cleaning agents must not contain skin or mucous membrane irritants.

If recommended cleaning agents / detergents that are indicated in the cleaning section are not available, mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. Please note that any deviation from these instructions, including the use of cleaning agents / detergents not specifically indicated in these instructions will require an evaluation of device-specific efficacy and suitability of the cleaning process. Respective evaluation usually requires equipment qualification and device specific performance qualification / Validation.

Warning: Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilis**a**tion.

Freshly prepared purified water/ highly purified water or sterile water for final rinsing purposes is highly recommended.

Manual Cleaning

Always use a freshly prepared cleaning bath. Observe the cleaning agent manufacturer's instructions in regard to recommended temperatures, concentration and holding times.

Manual cleaning instructions have been validated using the following equipment / cleaning agents:

Cleaning Brush:
An appropriate size soft bristle brush.
Cleaning Agent/ Cleaning Process:
A) Endozime® Dual Enzymatic Detergent, Ruhof Healthcare.

Cleaning Process using cleaning agent A above:

1. Place the LMA® Fastrach™ ETT, Stabiliser Rods and the removable connectors in a freshly prepared cleaning solution (concentration: 0.8%) at 36°C to 40°C / 97 °F to 104°F and thoroughly clean the devices until all visible contamination is removed.
2. Clean the airway tubes by gently inserting the brush and stroking in and out, taking care not to damage the devices.
3. Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
4. Carefully inspect all components for residual contamination.
5. If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.
Dry adequately at room temperature or in a drying cabinet with circulating air.

Or,
B) Dilute (8-10% v/v) sodium bicarbonate solution. 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water

Cleaning Process using cleaning agent B above:-

1. Place the LMA® Fastrach™ ETT, Stabiliser Rods and the removable connectors in a freshly prepared cleaning solution at 36°C to 40°C/ 97 °F to 104°F and thoroughly clean the devices until all visible contamination is removed.
2. Prepare a second freshly prepared cleaning solution as described above and thoroughly clean the devices using appropriate soft bristle brush.
3. Clean the airway tubes by gently inserting the brush and stroking in and out, taking care not to damage the devices.
4. Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
5. Carefully inspect all components for residual contamination.
6. If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.
Dry adequately at room temperature or in a drying cabinet with circulating air.

Automated Cleaning:

Automated cleaning instructions have been validated using the following equipment:

Washer: Miele Type G7735 CD, Miele Standard rack with rinse ports

Cleaning agents:
Deconex® PowerZyme, Borer Chemie AG

Thoroughly deflate all cuffs. Place the LMA® Fastrach ETT™, Stabiliser Rods and the removable connectors in the instrument rack. Ensure adequate placement of all devices in a way that all internal and external areas of the devices are accessible. Connect the lumens of the airways with the rinse ports.

Start Washing Process:
Miele G 7735 CD washer-disinfector, Vario TD programme:

1. 2 min pre-cleaning with cold water (≤ 35° C/ 95 ° F).
2. Drain
3. 5 min cleaning with Deconex® PowerZyme, 0.5% at 55°C/ 131 °F .
4. Drain
5. 3 min neutralization with cold water (≤ 35°C/ 95 °F).
6. Drain
7. 2 min rinsing with cold water (≤ 35°C/ 95 °F).
8. *Optional thermal disinfection following automated cleaning.
   5 min thermal disinfection at 90°C/194°F.

***Disinfection**

Thermal disinfection may be performed as part of the automated cleaning process as in step no. 8 above for Vario TD programme.

Ensure adequate drying (e.g. circulating air 70°C/ 158 °F, 1 hour).

INSPECTION, MAINTENANCE AND TESTING

Perform device inspection and functionality checks as described in section "Pre-Use Checks".
All of the functional tests and inspections described in this manual must be conducted as part of every reprocessing procedure prior to sterilization of the LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod. Failure in any of respective testing indicates that the device has passed its useful life and should be replaced.

PACKAGING

The selected packaging for thermal sterilization must comply to requirements according to ISO/ANSI AAMI ISO 11607. For USA: Use FDA-cleared sterilization wraps.

Visually check for residual moisture prior to packaging into sterilization wrap.

STERILISATION:

Warnings and Precautions

Adherence to the following procedure is essential to ensure sterilization without damage to the LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod.

Caution: The integrity of the reusable LMA® Fastrach™ ETT and and LMA® Fastrach™ Stabiliser Rod materials may be adversely affected by exceeding sterilization cycle of 134°C/ 273°F.

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare facility personnel are responsible for adhering to the processes specified and validated in their facility and for maintaining the process control. Failure to do so may invalidate the sterilization process of the healthcare facility.

Immediately prior to steam autoclaving, deflate the cuff completely. Ensure both the syringe (used to deflate the cuff) and the valve are dry.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures environment of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.
To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port after deflation. If the cuff of a deflated LMA® Fastrach ™ ETT immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

STERILISATION SETTING

Steam sterilization is recommended either via pre-vacuum or gravity displacement process. Each of the following cycles has been validated in accordance with internationally harmonized standards to reach a sterility assurance level (SAL) that is appropriate for the intended use of the devices and in compliance with internationally recognized standards and guidelines.

Type	Temperature	Holding Time	Minimum Drying Time
Prevac Cycle	134°C (273°F)	3 Minutes	16 Minutes
Gravity Displacement	132°C (270°F)	10 Minutes	1 Minute

After autoclaving, allow the device to cool to room temperature before use.

STORAGE

Store the sterilized devices at room temperature in a dry and dust-free place, protected from direct sunlight.

Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

USE WITH MAGNETIC RESONANCE IMAGING (MRI):

The LMA® Fastrach™ ETT is MR Conditional. Non-clinical testing demonstrated that this product is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence).

MRI-Related Heating
Under the scan conditions defined above, LMA® Fastrach™ ETT is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

Artifact Information
The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 50mm relative to the size and shape of the LMA® Fastrach™ ETT, Size 8.

SYMBOL DEFINITION:

	Manufacturer
	Consult IFU on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instructions before use
	Not made with natural rubber latex
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
REF	Product Code
LOT	Lot Number
CE 0086	CE Mark
SN	Serial Number
	Do not re-use more than 10 times
	Non-sterile
	MR Conditional
MD	An indication that the device is a Medical Device.
	Date of Manufacture
Rx only	Prescribed only

The information given in this document is correct at the time of publication. The manufacturer reserves the right to improve or modify the products without prior notification.

Manufacturer's Warranty:
The LMA® Fastrach™ ETT is reusable and warranted against manufacturing defects for ten (10) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

Warranty is applicable only if purchased from an authorized distributor. TELEFLEX 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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