(For US only)

EN – English

INSTRUCTIONS FOR USE – LMA® Fastrach™, LMA® Fastrach™ Single Use, LMA® Fastrach™ ETT, LMA® Fastrach™ ETT Single Use, LMA® Fastrach™ Combo Pack

Laryngeal Mask Airway & Endotracheal Tube

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

LMA® Fastrach™ Combo Packs consist of LMA® Fastrach™ (reusable and/or single use) and LMA® Fastrach™ ETT (reusable and/or single use).

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.

WARNING: LMA® Fastrach™ Single Use (LMA® Fastrach™ SU), LMA® Fastrach™ ETT Single Use (LMA® Fastrach™ ETT SU) and LMA® Fastrach™ Stabiliser Rod Single Use (LMA® Fastrach™ Stabiliser Rod SU) are supplied sterile (sterilised by Ethylene Oxide) for single use, should be used straight from the pack and should be discarded after use. They must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.

WARNING: Re-processing of LMA® Fastrach™ SU, LMA® Fastrach™ ETT SU and LMA® Fastrach ™ Stabiliser Rod SU intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilisation methods and instructions for reprocessing to original specifications are not available for these products. LMA® Fastrach™ SU, LMA® Fastrach™ ETT SU and LMA® Fastrach ™ Stabiliser Rod SU are not designed to be cleaned, disinfected, or re-sterilised.

WARNING: LMA® Fastrach™(reusable), LMA® Fastrach™ ETT (reusable) and LMA® Fastrach™ Stabiliser Rod accessory (reusable) 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.

GENERAL INFORMATION:

Unless otherwise stated, the reference to "LMA® Fastrach™ ETT" or "ETT" stated on this Instruction For Use (IFU) applies to both versions of the Endrotracheal tubes (LMA® Fastrach™ ETT and LMA® Fastrach™ ETT SU). And, the reference to "LMA® Fastrach™" stated on this IFU applies to both versions of the airway devices (LMA® Fastrach™ (reusable) and LMA® Fastrach™ Single Use (LMA® Fastrach™ SU)).The reference to LMA® Fastrach™ Stabiliser Rod stated in this IFU applies to both single use and reusable versions, unless otherwise stated.

DEVICE DESCRIPTION:

- **LMA® Fastrach™ -** The intubating LMA® airway

The LMA® Fastrach™ is designed as a guide for blind intubation of the trachea without moving the head or neck and allows continuous ventilation between intubation attempts. The LMA® Fastrach™ Single Use is made of Polyvinyl Chloride (PVC) whilst the reusable LMA® Fastrach™ is made of Silicone. Both reusable and single use LMA® Fastrach™ are not made with natural rubber latex.

- **LMA® Fastrach™ Endotracheal Tube (ETT)**

The 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 single use ETT is made of wire-reinforced PVC whilst the reusable device is made of wire-reinforced silicone and both are not made with natural rubber latex. 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.

LMA Fastrach™ (reusable) and LMA Fastrach™ ETT (reusable) should not be used more than a maximum of 40 and 10 times respectively. 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 LMA® Fastrach™ after intubation to keep the Endotracheal Tube (ETT) in place.
Note: The LMA® Fastrach™ Stabiliser Rod SU is to be used with LMA® Fastrach™ ETT SU only.

The LMA® Fastrach™ Stabiliser Rod SU is made of PVC whilst the reusable LMA® Fastrach™ Stabiliser Rod is made of Silicone. Both versions of LMA® Fastrach™ Stabiliser Rod are not made with natural rubber latex.

These devices are only for use by medical professionals trained in airway management.

INDICATION FOR USE:

LMA® Fastrach™

1. The LMA® Fastrach™ is indicated for use as a guide for intubation of the trachea.
2. The LMA® Fastrach™ is indicated for achieving and maintaining control of the airway during routine and emergency situations, including anticipated or unexpected difficult airways.
3. The LMA® Fastrach™ is indicated as a method of establishing an airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

Caution: The LMA® Fastrach™ is not indicated for use as an alternative to the endotracheal tube (ETT).

LMA® Fastrach™ ETT

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™ after intubation to keep the LMA® Fastrach ™ ETT in place.
Note: The LMA® Fastrach™ Stabiliser Rod SU is to be used with LMA® Fastrach™ ETT SU only.

RISK-BENEFIT INFORMATION:

When used in the profoundly unresponsive patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e., "cannot intubate, cannot ventilate"), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway.

CONTRAINDICATION:

LMA® Fastrach™

The LMA® Fastrach™ does not reliably protect the airway from the effects of regurgitation and aspiration. When used out of the emergency and difficult airway management contexts, LMA® Fastrach™, on its own, is contraindicated for use under the following conditions:

1. Non-fasted patients, including patients whose fasting cannot be confirmed and in other situations where there may be retained gastric contents.
2. Patients who are, more than 14 weeks pregnant, or those with any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.
3. Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis or because the peak airway inspiratory pressures are anticipated to exceed 20 cm H_2O.
4. Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history.
5. Patients whose head needs to be turned to the side during the case.
6. Patients in the prone position.
7. Patients who are not profoundly unconscious and who may resist device insertion.
8. Intubation through the device is contraindicated in the presence of oesophageal or pharyngeal pathology.
9. The reusable LMA® Fastrach™ should not be used in patients eligible for magnetic resonance imaging (MRI) investigation. **LMA® Fastrach™ (reusable) is MR Unsafe.**

LMA® Fastrach™ ETT

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 laryngeal mask airways and endotracheal tubes. Potential side effects may include airway trauma, dysphagia, sore throat, dysphonia, laryngospasm, obstruction, stridor, bronchospasm, hoarseness, nausea and vomit, regurgitation, aspiration, patient intolerance e.g. coughing, and mouth, lip or tongue injury.

WARNING:

1. LMA® Fastrach™ SU and LMA® Fastrach ™ ETT SU contain Di (2-ethylhexyl) phthalate (DEHP). The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.
2. Do not use a device if it is damaged.
3. For single use devices, do not use the device if the unit packaging is damaged or opened.
4. Do not immerse or soak the device in liquid prior to use.
5. The use of a standard, curved, plastic endotracheal tube in conjunction with LMA® Fastrach™ is not recommended as it may be associated with increased likelihood of laryngeal trauma.
6. The rigid tube and handle of the LMA® Fastrach™ may make it unsuitable as the sole airway in cases where the head needs to be turned to the side or in cases where the patient is in the prone position.
7. Never over-inflate the cuff of LMA® Fastrach™ over 60cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
8. To avoid trauma, excessive force should not be used at any time when using the devices.
9. **If** the LMA® Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H_2O pressure. This low pressure stabilizes the airway in the pharynx. Avoid unnecessary movement of the device and maintain head or neck in a neutral position.
10. 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.
11. 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 ETT into the larynx.
12. It is most important that pre-use checks are carried out on the devices prior to use, in order to establish whether they are safe for use. Failure of any one test indicates the device should not be used.
13. When applying lubricant avoid blockage of the airway aperture with the lubricant.
14. A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA® Fastrach™ and 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.
15. Never use the handle of LMA® Fastrach™ to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult.
16. Do not cut the LMA® Fastrach™ ETT.
17. 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.
18. 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.
19. 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.
20. 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.
21. For reusable devices, 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™, 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.
22. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterili**s**ation.
23. 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.
24. When using the device in special environmental 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.
25. The LMA® Fastrach™ does not always protect against regurgitation or aspiration. Its use in anaesthetized patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anesthesia. **Do not use the device without taking appropriate precautions to ensure the stomach is empty.**
26. Refer to MRI information section prior to using the devices in MRI environment.
27. LMA® Fastrach™ (reusable) is MR Unsafe.

MR Unsafe

CAUTION:

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 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. The use of aerosolised local anaesthetic agents has been associated with the formation of pin holes in LMA® Fastrach™ ETT SU cuffs.
6. 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.
7. 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.
8. Laryngeal spasm may occur if the patient becomes too lightly anaesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, treat the cause. Only remove the device when airway protective reflexes are fully competent.
9. Do not pull or use undue force when handling the inflation line or try to remove the device from patient by the inflation tube as it may detach from the cuff spigot.
10. If airway problems persist or ventilation is inadequate, the LMA® Fastrach™ should be removed and an airway established by some other means.
11. Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
12. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
13. Ensure all removable denture work is removed before inserting the device.
14. Gloves should be worn during preparation and insertion to minimize contamination of the device
15. The LMA® Fastrach™ is not indicated for use as an alternative to the endotracheal tube (ETT).
16. Clinicians must weigh the theoretical risk against the benefits of establishing an airway with the LMA® Fastrach™ in patients in whom cervical spine motion is undesirable.
17. Only use with the recommended manoeuvres described in the instructions for use.

PREPARATION FOR USE:

Choose the correct size of LMA® Fastrach™
Patient Weight/Size

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

LMA® Fastrach™ ETT and LMA® Fastrach™ ETT SU 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 LMA® Fastrach™ ETT and LMA® Fastrach™ ETT SU are compatible with LMA® Fastrach™ and LMA® Fastrach™ SU.

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 LMA® airways prior to use, in order to establish whether they are safe for use.

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

LMA® Fastrach™
These tests should be carried out as follows:
1. Examine the interior and exterior of the airway tube to ensure it is free from blockage or loose particles. Examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. Examine the angle between the straight part of the airway tube and the anterior plane of the inflated cuff. The angle should never exceed 90 degrees.
3. Examine the Epiglottis Elevating Bar (EEB). Gently probe the flexible EEB traversing the mask aperture to ensure the free end of the bar lies in contact with the mask and is not broken or damaged. Do not use if the EEB is not intact and positioned correctly as the epiglottis may obstruct the airway. Do not attempt to remove or repair a broken/damaged bar.

4. Deflate the cuff fully. Ensure that the cuff walls are tightly flattened against each other. Discard if cuff reinflates immediately or spontaneously, even if only slightly, indicating possible damage to device or valve.

5. Overinflate the Cuff. Reinflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 3 30ml
Size 4 45ml
Size 5 60ml

Keep a clearly marked syringe for inflation and deflation of the cuff.

Examine the cuff for leaks, herniations and uneven bulging. If any indication of these, discard the device. A herniating mask may cause obstruction during use. While the device remains 50% over-inflated, examine the inflation pilot balloon and inflation line. The balloon shape should be elliptical, not spherical or with any bulges.

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:

Deflate completely the cuff of LMA® Fastrach™ by using a syringe to create a fully deflated and smooth leading edge, facilitating insertion and avoiding contact with the epiglottis.

Warning: For LMA® Fastrach™, lubricate only the posterior surface of the deflated mask tip. Do not lubricate the front as this may result in blockage of the EEB or aspiration of lubricant.

Warning: For LMA® Fastrach ™ ETT, 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™ and 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.

INSERTION (for LMA® Fastrach ™):

Caution: Gloves should be worn during preparation and insertion to minimize contamination of the device.

Caution: The patency of the airway should be reconfirmed after any change in the patient's head and neck position.

Warning: Do not use force under any circumstances

1. Anaesthesia must be deep enough or with adequate pharyngeal topicalisation to permit insertion.

2. Position the head in a neutral position, with a pillow under the head. Do not extend the head.

3. Hold LMA® Fastrach™ by its handle, approximately parallel to the patient's chest. Position the mask tip against the hard palate and slide the tip briefly back and forth to distribute the lubricant and prevent folding of the tip, before sliding the mask further backwards following the curve of the rigid airway tube **(Fig.1)**. Do not use the device handle as a lever to force the mouth open.

4. Advance (without rotation) the curved airway tube until the straight part of the airway tube is in contact with the chin. Rotate the mask into place in a circular movement, ensuring pressure is maintained against the soft palate and posterior pharynx **(Fig.2)**.

Warning: Never use the handle to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult.

5. After insertion, check the tube emerging from the mouth is parallel to the plane of the inner surface of the upper incisors.

6. Inflate the cuff to a pressure sufficient to prevent a leak during positive pressure ventilation, but not exceeding either a cuff pressure of 60 cm H_20, or the maximufm inflation volume for each size.

Warning: NEVER OVERINFLATE THE CUFF.

Maximum inflation volumes (ml)

Size 3 20ml
Size 4 30ml
Size 5 40ml

7. Connect to the anaesthetic system. Exercise care to prevent dislodgement of the device.

8. Stabilize the device in neutral position (e.g. with bilateral bite blocks. Bite block should be removed prior to intubation to allow adjustment of LMA® Fastrach™ position.

Warning: If the LMA® Fastrach™ is the sole airway, it is very important to monitor cuff pressure and to ensure that the device is stabilised in a neutral position to prevent unnecessary movement.

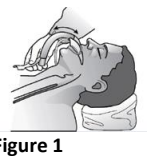


Figure 1

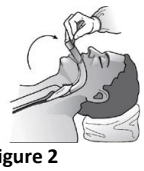


Figure 2

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 ETT.

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 ETT into the larynx.**

TRACHEAL INTUBATION WITH THE LMA® FASTRACH™:

1. After checking the cuff seal, deflate the ETT cuff completely before the insertion of ETT into the airway tube of LMA® Fastrach™.

2. Pass the ETT into the airway tube of LMA® Fastrach™ and distribute the lubricant within the shaft by moving the ETT up and down until it travels freely through the entire airway tube.

Warning: Avoid the ETT down and up movements with high speed and large amplitude as this manoeuver could result in cuff damage.

3. Position the longitudinal line of the ETT to face the handle of LMA® Fastrach™. Gently insert the ETT into the device airway tube. The ETT should not pass beyond the 15 cm transverse depth marker. Ensure that the **tip of the ETT does not enter the mask aperture (Fig.3).**

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 ETT axes (**Fig.4**).

5. Slide the ETT gently into the LMA® Fastrach™ another 1.5cm past the 15cm mark. If no resistance is felt, continue to advance the ETT while holding the device steady until intubation is accomplished.

6. Inflate the cuff of the ETT.

7. Confirm intubation by conventional means (e.g. end tidal CO_2).

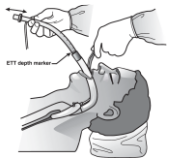


Figure 3

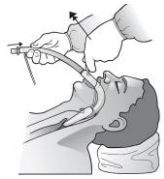


Figure 4

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

1. Pass a self-sealing connector with a suitable side-arm through the ETT to permit continued ventilation.

2. Select an FOB of an appropriate diameter and length to pass within the ETT. When fully inserted, the FOB should not protrude through the end of the assembled ETT and sealing port. It should also not pass beyond the EEB of LMA® Fastrach™ unless protected by the ETT. Otherwise its tip may be deviated or damaged by the EEB.

3. Insert the ETT up to 15cm depth, verify with the FOB that the ETT tip contacts the EBB of the device.

4. At 16.5cm depth, verify with the FOB that the ETT lifts the EEB showing the glottis.

5. Advance the ETT into the trachea; avoid pushing on the EEB with the FOB.

6. Inflate the cuff of the 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 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 ETT placement by confirming breathing sounds and monitoring end-tidal CO_2.
5. Connect ETT to the anesthesia or ventilator circuit.
6. Securely anchor the ETT using a bite block to avoid unnecessary movement or damage.
7. Monitor cuff pressure continuously.

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 ETT and the patient's teeth.
2. Following pre-oxygenation of the patient, disconnect the circuit leaving the ETT connector attached. Fully deflate the LMA® Fastrach™ cuff, making sure the 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 ETT with the finger **(Fig.5)**.
4. When the proximal end of the ETT is level with the proximal end of the airway tube, remove the ETT connector and insert the Stabiliser Rod to keep the ETT in place. Holding the Stabiliser Rod, slide out the LMA® Fastrach™ over the ETT and LMA™ Stabiliser Rod until it is clear of the mouth. **(Fig.6)**
5. Remove the LMA® Stabiliser Rod when the LMA® Fastrach™ cuff is clear of the mouth while holding the ETT in place to prevent accidental dislodgment **(Fig.7)**. Grasp the ETT firmly while gently unthreading the inflation line and pilot balloon from the LMA® Fastrach™ tube **(Fig.8)**.

Caution: Failure to remove the LMA® Stabiliser Rod from airway tube before completely removing the LMA® Fastrach™ may result in the 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 ETT by measuring the distance of the proximal end from the teeth. If, during removal of the LMA® Fastrach™, any displacement of the ETT has occurred, an appropriate adjustment will need to be made.
7. Replace the 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. 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 ETT to provide an immediate airway if deep extubation is planned or extubation is clinically determined to be hazardous.

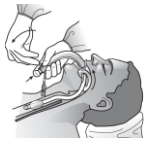


Figure 5

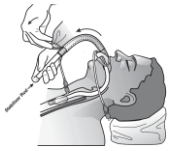


Figure 6

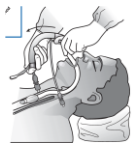


Figure 7

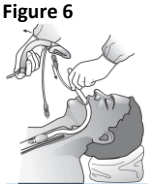


Figure 8

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:

(Reprocessing is applicable to the reusable version of LMA ®Fastrach device, 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™, LMA® Fastrach ETT and LMA®Fastrach Stabiliser Rod accessory 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 the devices 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.

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

With proper cleaning, sterilization, and handling, the devices 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 reuse. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

Devices	Maximum number of Re-use
LMA® Fastrach™	40 times
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 from the LMA® Fastrach™ and LMA® Fastrach™ ETT devices after use to avoid incrustation. For LMA® Fastrach™ ETT, dissemble the removable 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™ and LMA® Fastrach™ ETT are also applicable for LMA® Fastrach™ Stabiliser Rod.

CLEANING:

Warnings and Precautions

Warning: 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™, 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 agent 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 sterilisation.

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.

Manual cleaning for LMA® Fastrach™ :-

Cleaning Agent/ Cleaning Process:
A) Endozime® Dual Enzymatic Detergent, Ruhof Healthcare.

1. Place the LMA® Fastrach™ 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.
3. Gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars.
4. Ensure the whole interior of the metal tube is thoroughly cleaned.
5. 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.)
6. Carefully inspect all components for residual contamination.
7. 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™ 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.
4. Gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars.
5. Ensure the whole interior of the metal tube is thoroughly cleaned.
6. 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).
7. Carefully inspect all components for residual contamination.
8. 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.

Manual cleaning for LMA® Fastrach™ ETT:-

Cleaning Agent/ Cleaning Process:
A) Endozime® Dual Enzymatic Detergent, Ruhof Healthcare.

1. Place the LMA® Fastrach™ ETT, Stabiliser Rod and removable ETT connector 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 and components 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 Rod and removable ETT connector 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.
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, LMA® Fastrach™ ETT, the removable ETT connector and LMA® Fastrach™ Stabiliser Rod 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 cycle:

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 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™, 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™, LMA® Fastrach™ ETT and LMA® Fastrach™ Stabiliser Rod.

Caution: The integrity of the reusable LMA® Fastrach™, LMA® Fastrach™ ETT 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™ and 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 in regard to its suitability and efficacy for the devices.

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): -

LMA® Fastrach™ (reusable)

Warning : LMA® Fastrach™ (reusable) is MR unsafe

MR Unsafe

LMA® Fastrach™ SU, LMA® Fastrach ™ ETT SU and LMA® Fastrach ™ ETT are MR Conditional

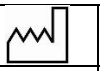
MR Conditional

Non-clinical testing demonstrated that these products are MR Conditional. A patient with LMA® Fastrach™ SU, LMA® Fastrach ™ ETT SU or LMA® Fastrach ™ ETT can be scanned safely immediately after placement under the following conditions. Failure to follow these conditions may result in injury to the patient.:

Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-T and 3-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	10-T/m (1,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters to minimize artifacts if the implant is located in the area of interest.
Important Condition of Use During MRI	During the intended use of the device, it is held in place or otherwise “fixed in place” to prevent inadvertent displacement using surgical tape, cloth material, bandaging material, and/or a plastic device. When using adhesive tape as a fixation means, at a minimum, the surgical tape should extend to the lateral sides of the patient’s face. Note that the proper fixation of this device will effectively prevent this device from being moved or displaced due to magnetic field interactions.

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
	Product Code
	Lot Number
	Do not Re-use
	Do not Re sterilise
	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)
	Sterilised by Ethylene Oxide
	Non-sterile
	Serial Number
	Do not re-use more than 10 times
	Do not reuse more than 40 times
	Use By
	Do not use if package is damaged
	MR Conditional
	MR Unsafe

	Date of Manufacture
Rx only	Prescription 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™ is reusable and warranted against manufacturing defects for forty (40) 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.

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.

The LMA® Fastrach™ Single Use and LMA® Fastrach™ ETT Single Use are designed for single use and warranted against manufacturing defects at the time of delivery.

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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