*EN - English*

# INSTRUCTIONS FOR USE – LMA Fastrach™ ETT Single Use

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

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

**WARNING: Re-processing of LMA Fastrach™ ETT 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 this product. LMA Fastrach™ ETT SU is not designed to be cleaned, disinfected, or re-sterilised.**

## GENERAL INFORMATION:

Unless otherwise stated, the reference to "LMA Fastrach™" stated on this IFU 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, please refer to the respective Instructions For Use.

## DEVICE DESCRIPTION:

The LMA Fastrach™ Endotracheal Tube (ETT) SU 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 SU 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 SU has depth markers to indicate the distance to the distal tip of the LMA™ airway. The LMA Fastrach™ ETT SU 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 SU is made of wire-reinforced polyvinylchloride (PVC) and is not made with natural rubber latex.

The device is only for use by medical professionals trained in airway management.

## INDICATIONS FOR USE:

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

## CONTRAINDICATIONS:

The LMA Fastrach™ ETT SU 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.

## ADVERSE EFFECTS:

There are reported adverse reactions associated with the use of endotracheal tubes. Standard textbooks and published literature should be consulted for specific information.

## WARNINGS:

**1.** LMA Fastrach™ ETT SU contains 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 or its unit packaging is damaged or opened.
**3.** Do not immerse or soak the device in liquid prior to use.
**4.** Do not cut the LMA Fastrach™ ETT SU.
**5**. If a malleable stylet is used in the LMA Fastrach™ ETT SU during intubation, ensure that it does not protrude from the patient end or Murphy Eye of the tube.
**6**. Do not overinflate the cuff of the LMA Fastrach™ ETT SU as this can result in rupture and subsequent deflation, or cuff distortion, which may lead to airway blockage and/or patient injury.
**7.** Deflate LMA Fastrach™ ETT SU cuff prior to repositioning LMA Fastrach™ ETT SU. Movement of the LMA Fastrach™ ETT SU with the cuff inflated could result in patient injury or cuff damage.
**8.** Displacement of the LMA Fastrach™ ETT SU (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.
**9.** To avoid trauma, excessive force should not be used at any time when using the device.
**10.** 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 SU into the larynx.
**11.** It is most important that pre-use checks are carried out on LMA Fastrach™ ETT SU 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.
**12**. When applying lubricant avoid blockage of the airway aperture with the lubricant.
**13.** 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 SU 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.
**14.** Gently fit the SU connector into the LMA Fastrach™ ETT SU 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.
**15.** 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.
**16.** 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.
**17.** 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 SU. Otherwise, the FOB tip may be damaged by contact with the epiglottis elevating bar.
**4.** When selecting seal pressure for the LMA Fastrach™ ETT SU, 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 SU 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.** Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
**9.** Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
**10.** Ensure all removable denture work is removed before inserting the device.
**11.** Gloves should be worn during preparation and insertion to minimize contamination of the device.
**12.** Only use with the recommended manoeuvres described in the instructions for use.

## PREPARATION FOR USE:

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

Patient Weight/Size

**Size 3: 30kg – 50kg children**
**Size 4: 50kg – 70kg adult**
**Size 5: 70kg – 100kg adult**

**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 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.

**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 SU connector is attached into the LMA Fastrach™ ETT SU.

## PRE-INSERTION PREPARATION:

**Warning:** Gently fit the SU connector into the LMA Fastrach™ ETT SU 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 SU 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 SU with and without an assisting device. It is recommended to use LMA Fastrach™ with LMA Fastrach™ ETT SU for optimal intubation. Teleflex Medical 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 LMA Fastrach ™ ETT SU into the larynx.**

## TRACHEAL INTUBATION WITH THE LMA FASTRACH™:

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

**Warning**: Avoid the LMA Fastrach™ ETT SU 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 SU to face the handle of LMA Fastrach™. Gently insert the LMA Fastrach™ ETT SU into the device airway tube. The LMA Fastrach™ ETT SU should not pass beyond the 15 cm transverse depth marker. Ensure that the tip of the LMA Fastrach™ ETT SU 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 millimeters to increase seal pressure and optimize alignment of the trachea and LMA Fastrach™ ETT SU axes (Fig.2).
**5.** Slide the LMA Fastrach™ ETT SU gently into the LMA Fastrach™ another 1.5cm past the 15cm mark. If no resistance is felt, continue to advance the LMA Fastrach™ ETT SU while holding the device steady until intubation is accomplished.
**6**. Inflate the cuff of the LMA Fastrach™ ETT SU.
**7.** Confirm intubation by conventional means (e.g. end tidal $CO_2$).

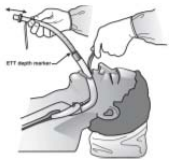


**Figure 1**

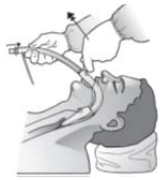


**Figure 2**

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

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

LMA Fastrach™ ETT SU 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 SU.
**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 SU placement by confirming breathing sounds and monitoring end-tidal $CO_2$.
**5.** Connect LMA Fastrach™ ETT SU to the anaesthesia or ventilator circuit.
**6.** Securely anchor the LMA Fastrach™ ETT SU 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 SU (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 SU and the patient's teeth.
**2.** Following pre-oxygenation of the patient, disconnect the circuit leaving the LMA Fastrach™ ETT SU connector attached. Fully deflate the LMA Fastrach™ cuff, making sure the LMA Fastrach™ ETT SU 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 SU with the finger **(Fig.3)**.
**4.** When the proximal end of the LMA Fastrach™ ETT SU is level with the proximal end of the airway tube, remove the LMA Fastrach™ ETT SU connector and insert the Stabiliser Rod to keep the LMA Fastrach™ ETT SU in place. Holding the Stabiliser Rod, slide out the LMA Fastrach™ over the LMA Fastrach™ ETT SU 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 SU in place to prevent accidental dislodgment **(Fig.5)**. Grasp the LMA Fastrach™ ETT SU firmly while gently unthreading the inflation line and pilot balloon from the LMA Fastrach™ tube **(Fig.6)**.

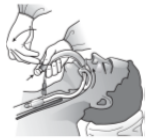
**Caution:** Failure to remove the LMA™ Stabiliser Rod from airway tube before completely removing the LMA Fastrach™ may result in the LMA Fastrach™ ETT SU being accidentally pulled out or the pilot balloon or inflation line tubing being damaged.

**6.** Using the LMA™ Stabiliser Rod, check the position of the LMA Fastrach™ ETT SU 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 SU has occurred, an appropriate adjustment will need to be made.
**7.** Replace the LMA Fastrach™ ETT SU 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 SU 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 SU to provide an immediate airway if deep extubation is planned or extubation is clinically determined to be hazardous.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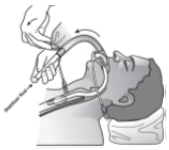
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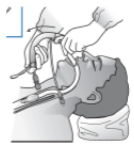
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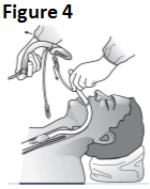
Figure 6

## REMOVAL OF THE LMA FASTRACH™ ETT SU:

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

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

## USE WITH MAGNETIC RESONANCE IMAGING (MRI):

MR Conditional

The LMA Fastrach™ ETT SU 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 SU 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 |
| eIFU indicator | Consult IFU on this website: www.LMACO.com |
| | Air inflation volume |
| | Patient weight |
| | Read Instructions before use |
| 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 |
| | Do not Re-use |
| STERILIZE | Do not Re sterilise |
| PHT DEHP | Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP) |
| STERILE EO | Sterilised by Ethylene Oxide |
| | Use By |
| | Do not use if package is damaged |
| MR | MR Conditional |



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

**Manufacturer's Warranty:**
The LMA Fastrach™ ETT SU is 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 MEDICAL 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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