EN – English

INSTRUCTIONS FOR USE – LMA Fastrach™ Single Use

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

WARNING: LMA Fastrach™ Single Use (LMA Fastrach™ SU) is supplied sterile 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™ 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™ SU is not designed to be cleaned, disinfected, or re-sterilised.

GENERAL INFORMATION:

Unless otherwise stated, the reference to "LMA Fastrach™ ETT" or "ETT" stated on this IFU applies to both versions of the ETT (LMA Fastrach™ ETT and LMA Fastrach™ ETT SU).

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

DEVICE DESCRIPTION:

LMA Fastrach™ SU is the intubating LMA airway. It is designed as a guide for blind intubation of the trachea without moving the head or neck and allows continuous ventilation between intubation attempts.

LMA Fastrach™ SU is made primary of medical grade polyvinylchloride (PVC) and is supplied sterile (sterilised by Ethylene Oxide) for single use only. It is not made with natural rubber latex.

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

INDICATIONS FOR USE:

1. The LMA Fastrach™ SU is indicated for use as a guide for intubation of the trachea.
2. The LMA Fastrach™ SU 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™ SU is indicated as a method of establishing an airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

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

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.

CONTRAINDICATIONS:

The LMA Fastrach™ SU 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™ SU, 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.

ADVERSE EFFECTS:

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

WARNINGS:

1. LMA Fastrach™ 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. The use of a standard, curved, plastic ETT in conjunction with LMA Fastrach™ SU is not recommended as it may be associated with increased likelihood of laryngeal trauma.
5. The rigid tube and handle of the LMA Fastrach™ SU 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.
6. Never over-inflate the cuff over 60cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
7. To avoid trauma, excessive force should not be used at any time when using the device.
8. If the LMA Fastrach™ SU 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.
9. Displacement of the LMA Fastrach™ ETT (esophageal intubation, accidental extubation) may occur if the LMA Fastrach™ SU removal procedure is not performed correctly. In these cases a correctly deflated LMA Fastrach™ SU should be re-inserted without delay to ensure patient oxygenation.
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 ETT into the larynx.
11. It is most important that pre-use checks are carried out on LMA Fastrach™ 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 LMA Fastrach™ 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. Never use the handle of LMA Fastrach™ SU to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult.
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 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.
17. The LMA Fastrach™ SU 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.**
18. Refer to MRI information section prior to using the devices 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™ SU airway aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottis elevating bar.
4. 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.
5. 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.
6. If airway problems persist or ventilation is inadequate, the LMA Fastrach™ SU should be removed and an airway established by some other means.
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. The LMA Fastrach™ SU is not indicated for use as an alternative to the endotracheal tube (ETT)
12. Clinicians must weigh the theoretical risk against the benefits of establishing an airway with the LMA Fastrach™ SU in patients in whom cervical spine motion is undesirable.
13. Only use with the recommended manoeuvres described in the instructions for use.

PREPARATION FOR USE:

Choose the correct size of LMA Fastrach™ SU
Patient Weight/Size
Size 3: 30kg – 50kg children
Size 4: 50kg – 70kg adult
Size 5: 70kg – 100kg adult

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 LMA Fastrach™ SU 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.

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.

PRE-INSERTION PREPARATION:

Deflate completely: Deflate the LMA Fastrach™ SU by using the syringe or LMA™ Cuff Deflator to create a fully deflated and smooth leading edge, facilitating insertion and avoiding contact with the epiglottis.

Warning: For LMA Fastrach™ SU, 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: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA Fastrach™ 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.

INSERTION:

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™ SU 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 maximum 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™ SU position.

Warning: If the LMA Fastrach™ SU 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.

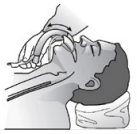
Figure 1


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™ SU with LMA Fastrach™ ETT for optimal intubation. Teleflex Medical will not be liable for use of an inappropriate ETT.

Caution: If LMA Fastrach™ SU 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™ SU :

1. After checking the cuff seal, deflate the ETT cuff completely before the insertion of ETT into the airway tube of LMA Fastrach™ SU.
2. Pass the ETT into the airway tube of LMA Fastrach™ SU 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 manoeuvre could result in cuff damage.

3. Position the longitudinal line of the ETT to face the handle of LMA Fastrach™ SU. 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™ SU 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).

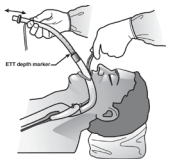

Figure 3

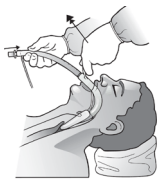

Figure 4

INTUBATION WITH LMA FASTRACH™ SU 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™ SU 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.

REMOVAL OF THE LMA FASTRACH™ SU 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™ SU 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™ SU must be weighed against the potential risks associated with the manoeuvre of removal of the device.

Warning: If the LMA Fastrach™ SU 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™ SU removal procedure is not performed correctly. In these cases a correctly deflated LMA Fastrach™ SU 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™ SU 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™ SU 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™ SU 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™ SU tube **(Fig.8)**.

Caution: Failure to remove the LMA™ Stabiliser Rod from airway tube before completely removing the LMA Fastrach™ SU 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™ SU, 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™ SU 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™ SU 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.

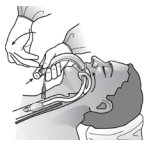

Figure 5

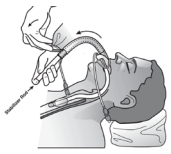

Figure 6

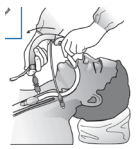

Figure 7

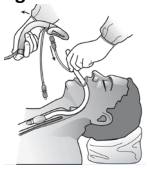

Figure 8

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.

USE WITH MAGNETIC RESONANCE IMAGING (MRI):

MR Conditional

The LMA Fastrach™ 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™ SU is expected to produce a maximum temperature rise of 2.2°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 20-mm relative to the size and shape of the LMA Supreme™, Size 5 which is representative of the LMA Fastrach™ SU.

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
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	Do not Re-use
	Do not Re sterilise
	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)
	Sterilised by Ethylene Oxide
	Use By
	Do not use if package is damaged
	MR Conditional

Manufacturer's Warranty:
The LMA Fastrach™ Single Use 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.

Teleflex Medical
IDA Business and Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

Contact Information in USA:
International: (919)544-8000
USA: (866) 246-6990

www.LMACO.com

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