

INSTRUCTIONS FOR USE – LMA® Fastrach™

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

WARNING: LMA® Fastrach™ is supplied non-sterile and must be cleaned and sterilised before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

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

GENERAL INFORMATION:

Unless otherwise stated, the reference to “LMA® Fastrach™ Endotracheal Tube (ETT) ” or “ETT” stated on this IFU applies to both versions of the ETT (LMA® Fastrach™ ETT and LMA® Fastrach™ ETT Single Use (LMA® Fastrach™ ETT SU)).

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

DEVICE DESCRIPTION:

LMA® Fastrach™ 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™ is a reusable device, made primarily of medical grade silicone. It is not made with natural rubber latex.

The LMA® Fastrach™ should not be reused more than 40 times. Continued use beyond the maximum number of times is not recommended as degradation of the components may result in impaired performance or abrupt failure of the device. Steam autoclave is the only recommended method for sterilization.

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

INDICATIONS FOR USE:

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).

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™ 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 H₂O.
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.**

ADVERSE EFFECTS:

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

WARNINGS:

1. Do not use a device if it is damaged.
2. Do not immerse or soak the device in liquid prior to use.
3. The use of a standard, curved, plastic ETT in conjunction with LMA® Fastrach™ is not recommended as it may be associated with increased likelihood of laryngeal trauma.
4. 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.
5. Never over-inflate the cuff over 60cm H₂O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
6. To avoid trauma, excessive force should not be used at any time when using the device.
7. If the LMA® Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H₂O 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.
8. 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.

9. Ensure that the patient is anaesthetised, paralysed and pre-oxygenated. Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the ETT into the larynx.

10. It is most important that pre-use checks are carried out on the LMA® Fastrach™ prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.

11. When applying lubricant avoid blockage of the airway aperture with the lubricant.

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

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

14. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

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. Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. In order to ensure that cuff pressures do not become excessive, cuff pressure should be measured regularly during a case with a cuff pressure monitor.

17. When using the device in special environmental necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention. The device may be flammable in the presence of lasers and electrocautery equipment.

18. **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.**

19. LMA® Fastrach™ (reusable) is MR Unsafe.



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 fiberoptic 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. 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™ 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™ 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™ in patients in whom cervical spine motion is undesirable.
13. Only use with the recommended manoeuvres described in the instructions for use.

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

PREPARATION FOR USE:

Choose the correct size of LMA® Fastrach™

Patient Weight/Size

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

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™ 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:

Completely deflate the cuff of the LMA® Fastrach™ 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: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA® Fastrach™ 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™ 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 H₂O, 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™ 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 describe various methods of intubation using LMA® Fastrach™ ETT with and without an assisting device. It is recommended to use LMA® Fastrach™ with LMA® Fastrach™ ETT for optimal intubation. Teleflex will not be liable for use of an inappropriate endotracheal tube.

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

Warning: Ensure that the patient is anaesthetised, paralysed and pre-oxygenated. **Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the 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 manoeuvre 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 CO₂).

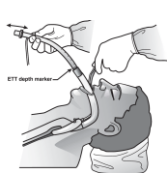


Figure 3



Figure 4

INTUBATION WITH LMA® FASTRACH™ AND WITH FIBROPTIC

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 EEB 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 FOSTRACH™ 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 H₂O 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™ 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™ 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® FOSTRACH™

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:

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

Warning:

Before initial use and any subsequent use, all devices must be subjected to reprocessing as described in the following sections.

Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

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

With proper cleaning, sterilization, and handling, the LMA® Fastrach™ can be used a maximum of 40 times. Proper cleaning and sterilization of the airway is essential to ensure continued safe usage up to 40 times. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

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

REPROCESSING PRIOR TO FIRST AND ANY SUBSEQUENT USE

Preparation at the point of use prior to processing

Remove all traces of contamination immediately after use to avoid incrustation. 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.

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™. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device that has been exposed to any of these substances. The cleaning agents must not contain skin or mucous membrane irritants.

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

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

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.

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 devices in the instrument rack. Ensure adequate placement of all devices in a way that all internal and external areas of the devices are accessible. Connect the lumens of the airways with the rinse ports.

Start Washing Process:

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

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

***Disinfection**

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

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

INSPECTION, MAINTENANCE AND TESTING

Perform device inspection and functionality checks as described in section "Pre-Use Checks"

All of the functional tests and inspections described in this manual must be conducted as part of every reprocessing procedure prior to sterilization of the LMA® Fastrach™. 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™.

Caution: The integrity of the reusable LMA® Fastrach™ 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™ immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

STERILISATION SETTING

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

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


















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

STORAGE

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

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

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
	Serial Number
	Do not reuse more than 40 times
	Non-sterile
	MR Unsafe
Rx only	Prescribed only

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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.

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.



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

www.LMACO.com



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