One report of an oesophageal perforation following intubation have been reports of blood staining and oral trauma, for magnetic resonance imaging (MRI) investigation oesophageal or pharyngeal pathology. Adequately answer questions regarding their medical history. Condition associated with delayed gastric emptying, 2. Confirmed and in other situations where there may be retained gastric - fas...LMA Fastrach™ is radio...Adverse effects (for LMA Fastrach™ ETT) Adverse reactions have been reported with the use of endotracheal tubes during the intubation period or subsequent to extubation: Abstraction of the arytenoid cartilage nasal process; consequences of failure to ventilate, including death; damage to the perichondrium; development of dense or diffuse fibrosis invading the entire glottis area; development of tracheoesophageal fistulae; emphysema; endobronchial intubation; endobronchial aspiration; endobronchial intubation (stomach distention); excoriated membranes of the pharynx; eye trauma; fibrosis of the stoma; formation of a posterior pharyngeal wall; glottis closure; laryngeal stenosis; laryngeal submucosal haemorrhage; laryngeal submucous puncture of the larynx; temporomandibular joint dislocation; trauma (epiglottis, larynx, lip, mouth, posterior pharyngeal wall, soft palate, uvula, tonsils), tongue cyanosis, tongue macroglossia, vocal cord paralysis, and vomiting. The LMA Fastrach™ is available in a range of sizes (6, 6.5, 7, 7.5 and 8) of LMA Fastrach™ ETT and LMA Fastrach™ ETT SU. However, only size 6 and LMA Fastrach™ ETT SU are compatible with LMA Fastrach™ and LMA Fastrach™ SU. All sizes (6, 6.5, 7, 7.5 and 8) of 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 SU are compatible with LMA Fastrach™ and LMA Fastrach™ ETT. However, only size 6, 5, 7, 6.5 and 7 of LMA Fastrach™ ETT SU are compatible with LMA Fastrach™. Caution: Clinical judgment should be used in the selection of the appropriate device size for an individual patient.

Pre-Use Checks: 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.

These tests should be carried out as follows:
1. Examine the internal diameter of the airway tube to ensure it is free from blockade or loose particles. Examine the tube throughout its length. Should any defects be found, replace 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 correctly as the epiglottis may obstruct the airway. Do not attempt to repair or remove a broken EEB.
Intubation: Describe various methods of intubation using LMA Fastrach™ with and without an assisting device. It is recommended to use LMA Fastrach™ with LMA Fastrach™ ETT for optimal intubation. IMC will not be recommended for intubation with a bag valve mask.

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

**Warning:** Ensure that the patient is anesthetized, paralyzed, and preoxygenated. Inadequate anaesthesia depth and/or muscle paralysis may cause the glottis to close, preventing entry of the ETT into the larynx.

Trachéal intubation with the LMA Fastrach™

1. Pass the ETT into the LMA Fastrach™ airway tube and distribute the lubricant within the shaft by moving the ETT up and down until it travels freely through the ETT airway tube.
2. Position the longitudinal line of ETT to face the LMA Fastrach™ handle. Gently insert the ETT into the device airway tube; ETT should not impact the LMA Fastrach™ unless protected by the ETT. Otherwise its tip may be deviated or damaged by the ETT.
3. Advance the ETT up to 25cm, verify with the FOB that the ETT tip contacts the EBB of the device.
4. At 16.5cm depth, verify with the FOBT that the ETT lifts the glottis.
5. Advance the ETT into the trachea; avoid pushing on the EBB with the FOBT.
6. Inflate the cuff of the ETT.

Conventional trachéal 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 anesthetic technique.

1. Intubate using currently accepted medical techniques. A lubricated malleable intubation stylet may 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 regular placement by confirming breathing sounds and monitoring end-tidal CO₂.
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 trachéal intubation

**Warning:** There are reports of pharyngeal edema and increased mucosal pressure attributed to the rigidity of the airway tube. It is recommended to remove the cuff post-induction if it has been inflated. 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 ETT. If repositioning is recommended, in these cases a correctly deflated LMA Fastrach™ should be reinflated without delay to prevent patient oxygenation.

1. Using the LMA™ Stabiliser Rod, measure the approximate distance between the proximal end of the ETT and the patient’s head.
2. After ensuring that the patient is well oxygenated, disconnect the circuit leaving the ETT connector attached. Fully deflate the LMA Fastrach™ ETT to ensure that the ETT cuff remains inflated.
3. Gently tap or swing the device handle caudally around the chin.
4. 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).
5. When the proximal end of the ETT is level with the proximal end of the ETT and the patient’s head, carefully slide the stabiliser rod away from the ETT to ensure the cuff remains inflated.
6. Remove the LMA™ Stabiliser Rod when the LMA Fastrach™ cuff’s clear of the mouth while holding the ETT in place to prevent accidental disconnection (Fig.7). Grasp the ETT firmly while gently unthreading the inflation line and pilot balloon from the LMA Fastrach™ tube (Fig.8).
7. Caution: The pilot balloon should not be detached from the ETT before completely removing the LMA Fastrach™ may result in the ETT being accidentally pulled out or the pilot balloon or inflation line tube being damaged.
8. Use 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™, the pilot balloon of the ETT has occurred, an adjacent adjustment will need to be made.
9. Replace the ETT connector and ventilate the patient.

**Caution:** Verify correct positioning of the patient immediately after LMA Fastrach™ removal, or if the patient’s position is altered after intubation.

10. ETT should then be gently 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.

Cleaning reusable LMA Fastrach™ & LMA Fastrach™ ETT

1. Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed.
2. If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm running tap water, remove excess moisture, and allow it to dry. If moisture is noticed in the valve, tap a towel to remove excess moisture.
3. Clean the LMA Fastrach™ using a small soft bristle brush (approximately 1.7mm in diameter). Gently insert the brush through the EEB by the airway tube, taking care not to damage the valve. Ensure the whole interior of the metal tube is thoroughly cleaned.
4. Thoroughly rinse the device in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed.
5. Repeat the above as necessary.

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

**Cleaning reusable LMA Fastrach™ & LMA Fastrach™ ETT:**

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

**Warning:** Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage. Also ensure that the device is not submerged in the liquid. 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 before deflating.

1. If a deflated mask immediately and spontaneously reinflates after the waiting period, remove the mask to ensure that the mask 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 silicon rubber material may require some time to rehydrate.
2. Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the LMA™ airway, provided that the maximum autoclave temperature does not exceed 137°C or 276.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold of at least 10 minutes.

**Caution:** LMA Fastrach™ may be used for patients weighing less than 10 kg. This is due to the relatively small size of the device and the potential risk associated with the manoeuvre of removal of the device.

1. Use of aerosol anaesthetic agents has been associated with the formation of holes in LMA Fastrach™ ETT su. Do not use anesthetic agents in this device.
2. Use only ventilators or anesthesia equipment with standard 15mm connectors to ensure secure connection with the ETT connector. Always ensure that the connector is securely seated in the breathing circuit to prevent disconnection during use.
3. Three-way stopcocks, or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting suction could cause the valve to deflate.
4. Dilution of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. To decrease such differences, it is recommended that the cuff be inflated with the same gas mixture that will be in contact with the cuff’s external surface.

**Warning:**

1. LMA Fastrach™ SU & LMA Fastrach™ ETT SU contains Di (2-ethylhexyl) phthalate (DEHP). However, the devices are not meant for long-term use and there is no known risk to the patient.
2. Long-term haemodialysis in adults (testicular and fertility)
3. Transfusions in neonates
4. Long-term use is Endozime

1. Immunocompromised patients may be at increased risk of acquiring specific types of infections or sepsis.
2. Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the LMA™ airway, provided that the maximum autoclave temperature does not exceed 137°C or 276.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold of at least 10 minutes.

**Caution:** The integrity of the reusable (LMA™) airway material may be adversely affected by exceeding sterilization temperatures of 278.6°F or 137°C.

1. This device varies in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer’s written instructions for the specific autoclave and load configuration being used.

**Warning:** Healthcare personnel are responsible for adhering to the appropriate sterilization processes which have been specified. Failure to do so may invalidate the sterility assurance of the healthcare equipment.

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

**Use with Magnetic Resonance Imaging (MRI):**

1. Prior to using these devices in the MRI environment, the user should carefully compare the equipment and test conditions described with those planned for use in the actual clinical environment. Refer to the below for detailed results of device testing in the MRI environment.
The LMA Fastrach™ SU, LMA Fastrach™ ETT & LMA Fastrach™ ETT SU were determined to be MR Conditional. Non-clinical testing demonstrated that these devices are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

### Static Magnetic Field
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- LMA Fastrach™ ETT & LMA Fastrach™ ETT SU display magnetic field interactions in the MRI environment. However, during the intended use of these products, it is "fixed" in place using adhesive tape. The appropriate "fixation" of these products is required to prevent possible issues in the MRI environment because it will effectively prevent this object from being moved due to magnetic field interactions.

### MRI-Related Heating
In non-clinical testing, the device produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14.24.05, General Electric Healthcare, Milwaukee, WI) MRI system:
- Highest temperature change +1.6°C (LMA Fastrach™ SU)
- Highest temperature change +1.7°C (LMA Fastrach™ ETT & LMA Fastrach™ ETT SU)

Therefore, the MRI-related heating experiments for the device at 3-Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C (LMA Fastrach™ SU) and +1.7°C (LMA Fastrach™ ETT & LMA Fastrach™ ETT SU).

### Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

### LMA Fastrach™ SU

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<th>T1 SE</th>
<th>GRE</th>
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### LMA Fastrach™ ETT & LMA Fastrach™ ETT SU

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<th>T1 SE</th>
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### Symbol Definition:

- **Manufacturer**
- **Authorized representative in the European Community**
- **Consult IFU on this website:** www.LMACO.com
- **Air inflation volume**
- **Patient weight**
- **Read Instruction 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 re-use**
- **Do not re-use more than 10 times**
- **Do not reuse more than 40 times**
- **Non-sterile**
- **Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)**
- **Sterilised by Ethylene Oxide**
- **Use By**
- **Do not use if package is damaged**

### Copyright

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 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 patient use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor.

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