The Laryngeal Mask Company Limited

English

Instructions For Use – LMA Fastrach™, LMA Fastrach™ Single Use, LMA Fastrach™ ETT & LMA Fastrach™ ETT Single Use

WARNING: LMA Fastrach™ and LMA Fastrach™ ETT are supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

WARNING: LMA Fastrach™ Single Use (LMA Fastrach™ SU) and LMA Fastrach™ ETT Single Use (LMA Fastrach™ ETT SU) are supplied sterile for single use, should be discarded after use and must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.

General Information:

Unless otherwise stated, "LMA Fastrach™ ETT" or "ETT" shown on this IFU is applied to both versions of the ETT (LMA Fastrach™ ETT and LMA Fastrach™ ETT SU). And "LMA Fastrach" is applied to both versions of the airway devices (LMA Fastrach™ and LMA Fastrach™ SU).

LMA Fastrach™ and LMA Fastrach™ ETT are latex free.

The Laryngeal Mask Company Limited (LMC) recommends LMA Fastrach™ (reusable) and LMA Fastrach™ ETT (reusable) be used a maximum of 40 and 10 times respectively before being discarded. 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.

LMA Fastrach™ SU and LMA Fastrach™ ETT SU are latex free and are supplied sterile (sterilized by Ethylene Oxide) for single use only.

LMA Fastrach™ ETT is radio-opaque along its full length.

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

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.

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

Contraindication:

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

The LMA Fastrach™ ETT should not be placed in patients eligible for procedures which involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device.

Adverse Effects (for LMA Fastrach™):

Both minor adverse events (e.g. sore throats) and major adverse events (e.g. aspiration) following LMA™ airway use have been reported in literature. In addition to minor sore throat and hoarseness, there have been reports of blood staining and oral trauma, pharyngeal oedema, and epiglottis oedema associated with the use of LMA Fastrach™. Review of published literature shows that the incidence of aspiration with the LMA™ airway is low (~2:10,000), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia. Aspiration with the LMA Fastrach™ has been described in the context of emergency and/or difficult airway management. There is one report of an oesophageal perforation following intubation attempts through the LMA Fastrach™. The patient was subsequently found to have radiological evidence of pre-existing oesophageal pathology.

Other adverse effects are unspecific to LMA Fastrach™, but reported with the use of supraglottic airways devices including LMA™ airway.

- The incidence of sore throat following LMA™ airway use is approximately 10% and is usually mild and short-lived. However, adverse or prolonged sore throats, sometimes accompanied by dysphasia and tissue burns, have been reported in patients in whom improperly cleaned or sterilised devices have been used.
- Infrequent neurovascular events reported with LMA™ airway use include cases of hypoglossal nerve injury, tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, recurrent laryngeal nerve injury, and vocal cord paralysis. These complications are most likely the result of either poor insertion technique or excessive cuff pressure, causing compression of nerves and/or blood vessels. Cuff malposition or excessive cuff pressure can be exacerbated by incorrect mask size, prolonged surgery, and use of nitrous oxide; however, a clear relationship to the use of the LMA™ airway has not been established.
- Adverse events reported with LMA™ airway use include airway obstruction, arytenoid dislocation, aspiration, bleeding, breath holding, bronchospasm, coughing, dental/denture damage, dry mouth/throat, dysarthria, dysphasia, dysphonia, dysrhythmia, ear pain, gagging, gastric dilatation/insufflations/rupture, glottis closure, head and neck oedema, hearing impairment, hiccup, hoarseness, hypersalivation, hypoglossal nerve paralysis, hypoxia, laryngeal hematoma, laryngeal spasm, lingual nerve paralysis, mouth ulcer, myocardial ischemia, nausea, parotid gland swelling, pharyngeal dysesthesia, pharyngeal ulcer, pulmonary oedema, recurrent laryngeal nerve injury, regurgitation, retching, sore jaw, sore mouth, sore throat, stridor, submandibular gland swelling, temporomandibular joint dislocation, tissue trauma (epiglottis, larynx, lip, mouth, posterior pharyngeal wall, soft palate, uvula, tonsils), tongue cyanosis, tongue macroglossia, vocal cord paralysis, and vomiting.

Adverse Effects (for LMA Fastrach™ ETT)

Adverse reactions have been reported with the use of endotracheal tubes during intubation procedures, during the intubation period or subsequent to extubation: Abrasion of the arytenoid cartilage vocal process: cartilage necrosis; cicatrix formation; 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 fistulas; emphysema; endobronchial aspiration; endobronchial intubation (hypoxemia); endotracheobronchial aspiration; epitasis; oesophageal intubation (stomach distension); excoriated membranes of the pharynx; eye trauma; fibrin deposition; formation of subglottic web; fracture-luxation of cervical column (spinal injury); fragmentation of cartilage; glottic oedema (supraglottic, subglottic retroarytenoidal); granuloma of the inner arytenoids area; infections (laryngitis, sinusitis, abscess, respiratory tract infection); inflammation; intermittent aphonia and recurrent sore throat; laryngeal granulomas or polyps; laryngeal obstruction, stenosis, ulcers or oedema; laryngotracheal membranes and webs; membranous glottic congestion; membranous tracheobronchitis; mild oedema of the epiglottis; mucosal changes; mucosal sloughing; paresis of the hypoglossal and/or lingual nerves; paresis or paralysis of tongue; perforation of oesophagus, larynx or trachea; pneumothorax; replacement of the tracheal wall with scar tissue; respiratory obstruction; retrobullar haemorrhage; retropharyngeal abscess or dissection; rupture of the trachea; sore throat; dysphasia; stricture of nostril; stridor; subcutaneous mediastinal emphysema; subglottic annular cicatricial stenosis; submucosal haemorrhage; submucous puncture of the larynx; superficial epithelial abrasion; swallowing tube; synechia of the vocal cords; teeth trauma; tissue burns: tracheal bleeding; tracheal stenosis; trauma to lips, tongue, pharynx, nose, trachea, glottis, palate, tonsil, etc; traumatic lesions of the larynx and trachea; ulceration exposing cartilaginous rings and minor erosions at cuff site; ulceration of the lips, mouth, pharynx; ulcers of the arytenoids; vocal cord congestion; vocal cord paralysis; and vocal cord ulceration.

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™

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 reusable LMA Fastrach™ ETT are compatible with LMA Fastrach™ and LMA Fastrach™ SU. However, only size 6, 6.5 and 7 of LMA Fastrach™ ETT SU are compatible with LMA Fastrach™ and LMA Fastrach™ SU.

Caution: Clinical judgment should be used in the selection of the appropriate device size for an individual patient.

Pre-Use Checks:

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.

For LMA Fastrach™:

These tests should be carried out as follows:
1. Examine the interior and exterior of the airway tube to ensure it is free from blockage or loose particles. Examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. Examine the angle between the straight part of the airway tube and the anterior plane of the inflated cuff. The angle should never exceed 90 degrees.
3. Examine the Epiglottis Elevating Bar (EEB). Gently probe the flexible EEB traversing the mask aperture to ensure the free end of the bar lie 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 wall is 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. Reflate 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.

For LMA Fastrach™ ETT:

1. Deflate the cuff completely then fully inflate the valve and cuff to test their integrity. Do not overinflate the cuff.
2. Visually check that the airway tube, cuff and balloon are free of debris and leaks, and are not damaged, kinked, nor occluded. Do not use if the device doesn't inflate symmetrically, shows sign of deterioration/abnormality or if there is a deficiency with the inflation mechanism.
3. Ensure that the connector is attached into the LMA Fastrach™ ETT.

Pre-insertion Preparation:

Deflate completely: Deflate the LMA Fastrach™ 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™, lubricate only the posterior surface of the deflated mask tip. Do not lubricate the front as this may result in blockage of the EEB or aspiration of lubricant.
Warning: For LMA Fastrach™ ETT, gently fit the connector into the LMA Fastrach™ ETT prior to applying lubricant to the distal end of the tube. Excessive amounts of lubricant may cause partial or full blockage of the lumen and airway which may cause a risk of aspiration.
Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA Fastrach™ & LMA Fastrach™ ETT components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.
Warning: Ensure all removable denture work is removed before inserting the device.

Insertion (for LMA Fastrach™)

Caution: gloves must be worn
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 contacts the chin. Rotate the mask into place in a circular movement, ensuing 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 of approximately 60 cm H_20, not exceeding the maximum inflation volume.
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) to minimize head or neck movement. 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 stabilized in a neutral position to prevent unnecessary movement.

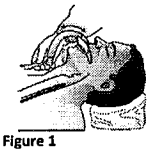


Figure 1

Figure 2

ETT with and without an assisting device. It is recommended to use LMA Fastrach™ with LMA Fastrach™ ETT for optimal intubation. LMC 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 anaesthetized, paralyzed 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. 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 entire 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 pass beyond the 15 cm transverse depth marker. Ensure that the **tip of the ETT does not enter the mask aperture (Fig.3).**
3. 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).**
4. 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.
5. Inflate the cuff of the ETT.
6. Confirm intubation by conventional means (e.g. end tidal CO_2).

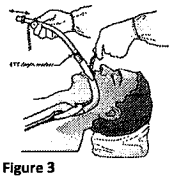


Figure 3

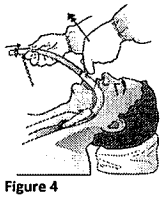


Figure 4

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

Conventional tracheal intubation with LMA Fastrach™ ETT under direct or indirect laryngoscopy
LMA Fastrach™ ETT is designed to be used conventionally as an endotracheal tube.
Warning: Always use an aseptic technique.
1. Intubate using currently accepted medical techniques. A lubricated malleable intubation stylet may need to be used due to the flexibility of the airway tube of the ETT.
2. Inflate the cuff with the minimum amount of gas mixture to provide an effective seal at the desired lung inflation pressure. Using Minimal Occluding Volume and Minimum Leak Techniques along with routine monitoring of intracuff pressure may reduce the occurrence of many adverse reactions associated with the use of cuffed endotracheal tubes.
3. Remove the luer-tip syringe from the valve.
4. Check ETT placement by confirming breathing sounds and monitoring end-tidal CO_2.
5. Connect ETT to the anaesthesia or ventilator circuit.
6. Securely anchor the ETT using a bite block to avoid unnecessary movement or damage.
7. Monitor cuff pressure continuously.

Removal of the LMA Fastrach™ after tracheal intubation
Warning: There are reports of pharyngeal oedema and increased mucosal pressure attributed to the rigidity of the airway tube. It is recommended to remove LMA Fastrach™ once intubation has been accomplished. High pressures may develop against the pharyngeal wall if the head or neck is moved from the neutral position, due to the rigidity of the curved airway tube. The risk of maintaining in place the LMA Fastrach™ must be weighed against the potential risks associated with the manoeuvre of removal of the device.

Warning: If the LMA Fastrach™ is retained in the patient after intubation, the cuff should be deflated to 20-30 cm H_20 pressure. This low cuff pressure stabilizes the airway in the pharynx. Avoid unnecessary movement of the device and maintain head or neck in a neutral position.

Warning: Displacement of the LMA Fastrach™ ETT (oesophageal intubation, accidental extubation) may occur if the LMA Fastrach™ removal procedure is not performed correctly. In these cases a correctly deflated LMA Fastrach™ should be reinserted without delay to ensure patient oxygenation.

1. Using the LMA™ Stabiliser Rod, measure the approximate distance between the proximal end of the ETT and the patient's teeth.
2. After ensuring that the patient is well oxygenated, 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 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).**
Rod to keep the ETT in place. Holding the Stabiliser Rod, slide out the LMA Fastrach™ over the ETT and LMA™ Stabiliser Rod until it is clear of the mouth. **(Fig.6)**
5. Remove the LMA™ Stabiliser Rod when the LMA Fastrach™ cuff is clear of the mouth while holding the ETT in place to prevent accidental dislodgment **(Fig.7).** Grasp the ETT firmly while gently unthreading the inflation line and pilot balloon from the LMA Fastrach™ tube **(Fig.8).**
Caution: Failure to remove the LMA™ Stabiliser Rod from airway tube before completely removing the LMA Fastrach™ may result in the ETT being accidentally pulled out or the pilot balloon or inflation line tubing being damaged.
6. Using the LMA™ Stabiliser Rod, check the position of the ETT by measuring the distance of the proximal end from the teeth. If, during removal of the LMA Fastrach™, any displacement of the ETT has occurred, an appropriate adjustment will need to be made.
7. Replace the ETT connector and ventilate the patient.
Caution: Verify correct tube placement and patient oxygenation immediately after LMA Fastrach™ removal, or if the patient's position is altered after intubation.
8. ETT should be securely anchored using a bite-block to avoid unnecessary movement or damage.

In elective cases, after removal, LMA Fastrach™ may be re-inserted behind the ETT to provide an immediate airway if deep extubation is planned or extubation is clinically determined to be hazardous.

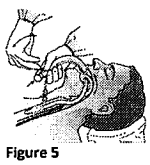
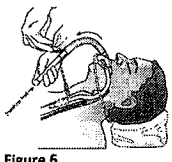


Figure 5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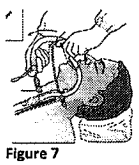
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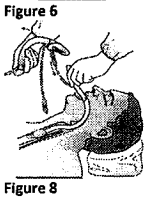
Figure 8

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 ETT, completely deflate the cuff using a syringe.
2. Extubate using currently accepted medical techniques.

Caution
1. An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.
2. Careful handling is essential. Avoid contact with sharp or pointed objects at all times to prevent tearing or perforation of the device.
3. When passing a fibreoptic bronchoscope (FOB), it should not be passed through the LMA Fastrach™ airway aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottis elevating bar.
4. When selecting seal pressure for the ETT, an intracuff pressure measuring device should be used in conjunction with the Minimal Occluding Volume, or Minimum Leak techniques. Cuff inflation should be monitored continuously to a "just seal" pressure. Any deviation from the selected seal pressure should be investigated and corrected immediately.
5. The use of aerosol 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 ETT connector. Always ensure that the connector is securely seated in the breathing circuit to prevent disconnection during use.
7. Three-way stopcocks, or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve causing the cuff to deflate.
8. Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. To decrease such diffusion, 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 inpatient and there is no known risk to the patient. There is no known risk associated with the use of these devices in children or nursing/ pregnant women as they are not meant to be used in the following exposure scenarios:
• Long-term haemodialysis in adults (testicular effects, fertility, and toxicity to kidneys and developmental)
• Long-term blood transfusion in children (testicular)
• Transfusions in neonates (testicular and fertility)
• Extracorporeal oxygenation in children (testicular effects, fertility and toxicity to kidneys)
The risk and benefits of using this device shall be carefully evaluated by a clinician on a case-by-case basis.
2. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
3. Used reusable device shall be decontaminated first in accordance with local hospital procedures for handling biohazard products and subsequently disposed of by incineration or landfill in accordance with local and national regulations.
4. Do not use a device if it is damaged or the unit packaging for LMA Fastrach™ SU and LMA Fastrach™ ETT SU is damaged or opened.
5. Do not immerse or soak the device in liquid prior to use.
cervical spine motion is undesirable.
7. 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.
8. 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.
9. Do not cut the LMA Fastrach™ ETT.
10. If a malleable stylet is used in the LMA Fastrach™ ETT during intubation, ensure that it does not protrude from the patient end or Murphy Eye of the tube.
11. Do not overinflate the cuff of the LMA Fastrach™ ETT as this can result in rupture and subsequent deflation, or cuff distortion, which may lead to airway blockage and/or patient injury.
12. Deflate LMA Fastrach™ ETT cuff prior to repositioning ETT. Movement of the ETT with the cuff inflated could result in patient injury or cuff damage.

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

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Endozime® (Ruhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilise LMA Fastrach™ and LMA Fastrach™ ETT. 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.
Caution: Do not expose the valve (the white plastic piece protruding from the inflation balloon) to any cleaning solution as it may cause premature valve failure.

If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm flowing tap water, remove excess moisture, and allow it to dry. If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Clean the LMA Fastrach™ using a small soft bristle brush (approximately 17mm in diameter). Gently insert the brush through the EEB bars into the airway tube, taking care not to damage the bars. Ensure the whole interior of the metal tube is thoroughly cleaned.

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.

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.

Sterilizations of reusable LMA Fastrach™ & LMA Fastrach™ ETT
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 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 a deflated mask 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.
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 278.6°F. One steam sterilization cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.
Caution: The integrity of the reusable LMA™ airway materials may be adversely affected by exceeding sterilization temperatures of 278.6°F or 137°C.
Autoclaves vary 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.
Healthcare personnel are responsible for adhering to the appropriate sterilization processes which have been specified. Failure to do so may invalidate the sterilization process of the healthcare facility.
After autoclaving, allow the device to cool to room temperature before use.

Use with Magnetic Resonance Imaging (MRI)

MR Conditional

Testing has been performed to determine the compatibility of the LMA Fastrach™ SU, LMA Fastrach™ ETT & LMA Fastrach™ ETT SU with MRI. 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.

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 14X.M5, General Electric Healthcare, Milwaukee, WI) MR 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 MR 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:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	5,481-mm^2	3,400-mm^2	12,343-mm^2	7,394-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

LMA Fastrach™ ETT & LMA Fastrach™ ETT SU:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	24,565-mm^2	4,821-mm^2	45,233-mm^2	11,554-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

	Read Instruction before use
	Latex Free
	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

Manufacturer's Warranty:
The LMA Fastrach™ is reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

The LMA Fastrach™ ETT is reusable and warranted against manufacturing defects for ten (10) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

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

Warranty is applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED 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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