The Laryngeal Mask Company Limited

English

Instructions For Use – LMA Classic™, LMA Flexi™, LMA Flexible™ Single Use & LMA Unique™

WARNING: LMA Classic™ and LMA Flexi™ are supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The device cannot withstand the high temperatures of autoclaving and should be discarded before disposal.

WARNING: LMA Unique™ and LMA Flexible™ Single Use (LMA Flexible™ SU) are supplied sterile for single use only which shall be discarded after use and must not be re-used. Reuse may cause infection and reduce product reliability and functionality.

General Information:

LMA Classic™ and LMA Flexi™ are not made with natural rubber latex and they are supplied sterile (sterilized by Ethylene Oxide) for single use only.

Indication for Use:

It is indicated for use in achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or Positive Pressure Ventilation (PPV) when it is also indicated for use in securing the immediate airway in known or unexpected difficult airways. It is best suited for use in the emergency situation where intubation is not necessary. It may be used to establish an immediate, clear airway during cardio-pulmonary resuscitation of the profoundly unconscious patient with absent glottis (anaphylaxis) and laryngeal reflexes requiring artificial ventilation. In these cases, LMA™ airway should be used only when tracheal intubation is not possible.

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.

Contraindication:

Due to the potential risk of regurgitation and aspiration, do not use the LMA™ airway as a substitute for an endotracheal tube in the following elective or difficult airway patients on a non-emergency pathway:

1. Patients who have difficulty swallowing, including patients whose fasting cannot be confirmed.
2. Patients who are grossly or morbidly obese, more than 14 weeks pregnant or emergency resuscitation situations or any condition associated with delayed gastric emptying, or using opiate medication prior to fast.

The LMA™ airway is also contraindicated in:

1. Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure greater than 30 cm. H2O.
2. Patients who have received tracheal intubation.
3. Patients who have received tracheal intubation in the past.
4. Patients with traumatic neck injuries.
5. Patients with a previous history of crico-arytenoid muscle paralysis.

Adverse Effects:

Both minor adverse effects (e.g. sore throat) and major adverse effects (e.g. aspiration) following LMA™ airway use have been reported in the published literature. There have been no reports of death directly attributable to the LMA™ airway in over 300 million uses of the device worldwide.

A review of published literature suggests that the incidence of aspiration is low (< 2/10,000) and is comparable to the incidence of aspiration associated with outpatient general anaesthesia with the face mask and endotracheal tube. There have been no published reports of-long term morbidity or mortality associated with the LMA™ airway subsequent to aspiration.

The incidence of sore throat following LMA™ airway use is approximately 10% (range 0-70%) and is usually mild and short-lived. Severe or prolonged sore throat, sometimes accompanied by dysphagia, has been reported in patients in whom an improperly cleaned or sterilized mask has been used.

Unusual neurovascular events reported with LMA™ airway use include rare cases of hypoglossal nerve injury, transient tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, and glossopharyngeal nerve irritation. These complications are probably the result of poor insertion techniques or excessive cuff pressure. However, a clear relationship to the use of the device has not been established.

Preparation for Use:

Choose the correct size of LMA™ airway

Table: LMA Patient Size

<table>
<thead>
<tr>
<th>Size</th>
<th>Weight Range</th>
<th>Height Range</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1 to 5 kg neonatal</td>
<td>30cm to 50cm</td>
</tr>
<tr>
<td>2</td>
<td>5kg to 10kg paediatric</td>
<td>50cm to 70cm</td>
</tr>
<tr>
<td>2½</td>
<td>10kg to 20kg paediatric</td>
<td>70cm to 100cm</td>
</tr>
</tbody>
</table>

2% – 10kg - 50kg paediatric
6% – >10kg adult

Keep a clearly marked syringe for inflation and deflation of the cuff.

Pre-Use Checks:

It is most important that pre-use checks are carried out on LMA™ airway prior to use, in order to ensure its safe 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 of the airway to ensure that it is free from blockage or loose parts. Squeeze the tube to examine its throughout length. Should any cuts or indentations be found, discard the device.
2. Hold at each end the flex tube to increase its curvature up to but not beyond 180°. Should the tube kink during this procedure, discard the device.
3. Deflate the cuff fully. Deflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Figure 1

Figure 2

Size 1 6ml Size 2 11ml
Size 1¼ 5ml Size 2½ 11ml
Size 1½ 10ml Size 3 15ml
Size 2 15ml Size 4 45ml
Size 2½ 15ml Size 5 60ml
Size 2½ 21ml Size 6 75ml

Figure 3

Figure 4

Examine the cuff for leaks, herniations and uneven bulging. If any indication of weakness, or loss of shape is found, do not use. Any obstruction associated with outpatient general anaesthesia with the face mask is low (~2/10,000) and is comparable to the incidence of death directly attributable to the LMA™ airway. There have been no reports of death directly attributable to the LMA™ airway. The LMA™ airway is held with the thumb in the position occupied by the thumb of the standard technique (Figure 5). The tip of the mask is pressed against the front teeth and the mask is pressed posteriorly along the palate with the thumb. As the thumb nears the mouth, the fingers are stretched forward over the patient’s face (Figure 6).

Thumbs Indentation Method:

This technique should only be used in patients in whom access to the head from behind is difficult or impossible and during cardio-pulmonary resuscitation. The LMA™ airway is held with the thumb in the position occupied by the thumb of the standard technique (Figure 5). The tip of the mask is pressed against the front teeth and the mask is pressed posteriorly along the palate with the thumb. As the thumb nears the mouth, the fingers are stretched forward over the patient’s face (Figure 6).

Advance the thumb to its fullest extent (Figure 7). The pushing action of the thumb against the hard palate also serves to press the head into elevation (Figure 8) before removing the thumb, push the tube into its final position using the other hand (Figure 9).

Figure 5

Figure 6

Figure 7

Figure 8

Figure 9

Maintaining the airway:

Obstruction can occur if the device becomes dislodged or is incorrectly inserted. The epiglottis may be pushed down with poor insertion technique. Check by auscultation of the neck and correct by re-insertion or elevation of the epiglottis using a laryngoscope.

1. Malposition of mask tip into the glottis may mimic bronchoscopy.
2. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.
3. Keep the bite-block in place until the device is removed.
4. Do not deflate the cuff until reflexes have fully returned.
5. Air may be withdrawn from the cuff during anaesthesia to maintain a constant intra-cuff pressure (ideally about 60cm H2O).

Removal:

1. The LMA™ airway, together with the recommended bite-block, should be left in place until the return of consciousness. Oxygen should be administered using a "T" piece system and standard monitoring should be in place. Before attempting to remove or deflate the device, it is essential to have the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.

2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary to perform suction because the correctly used LMA™ airway protects the larynx from oral secretions. Patients will swallow secretions on removal. Suction equipment should however be available at all times.

3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

Caution:

1. The LMA™ airway does not prevent regurgitation or aspiration. Its use in anaesthetised patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. Do not use the device without taking appropriate precautions to ensure the stomach is empty.

2. 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 anaesthesia. If laryngeal spasm occurs, do not remove the LMA™ airway, but treat the cause. Only remove the device when airway protective reflexes are fully competent.

3. Do not pull or use undue force when handling the inflation line or try to remove the device from the patient by the inflation tube as it may detach from the cuff if jagged.

4. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and equipment are available.

5. The patient’s airway should not be obscured by the device.

6. Do not immerse or soak single use devices (LMA Flexi™ SU & LMA Unique™) in liquid prior to use.
Warning:
1. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
2. Excessive force must be avoided at all times.
3. Used reusable devices (LMA Classic™; LMA Flexible™) shall be decontaminated first in accordance with local hospital procedures for handling of bio-hazard products and subsequently disposed of by incineration or landfill in accordance with all local and national regulations.
4. Single use devices (LMA Flexible™ SU & LMA Unique™) contain Di (2-ethylhexyl) phthalate (DEHP). However, both devices are not meant for long term use in patients and shall not pose any known risk to the patient. There is no concern and/or known risk for use of these devices on children or nursing/ pregnant women. The risk and benefits of using these devices shall be carefully evaluated by clinician on a case by case basis.
5. Do not use if the device is damaged or the unit packaging for LMA Flexible™ SU & LMA Unique™ is damaged or opened.

Cleaning (for LMA Classic™ & LMA Flexible™ only):
Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10 v/v) sodium bicarbonate solution until all visible foreign material 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 Endosize® (Ruhrft, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaners or isopropyl containing cleaners to clean or sterilize the LMA™ airway. 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 blue 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 device using a small soft bristle brush (approximately 1/2 inch or 12.5mm in diameter), gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars. Thoroughly rinse the cuff and airway tube 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 prepare properly, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

Sterilisation (for LMA Classic™ & LMA Flexible™)
Immediately prior to steam autoclaving, deflate the cuff completely. Ensure that both the syringe used to deflate the cuff and the valve is 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 (deformation 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 cuff 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 sterilisation of the LMA™ airway, provided 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 time of at least 10 minutes.

Caution: The integrity of the reusable LMA™ airway materials may be adversely affected by exceeding sterilization temperatures of 276.6°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 sterilisation processes which have been specified. Failure to do so may invalidate the standards 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 Classic™, LMA Flexible™, LMA Flexible™ SU and LMA Unique™ with MRI. Price, performance and product specifications 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 Classic™, LMA Flexible™, LMA Flexible™ SU & LMA Unique™ 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 Flexible™ & LMA Flexible™ 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 144.4, General Electric Healthcare, Milwaukee, WI) MRI system:

- Temperature change +1.6°C (LMA Classic™ & LMA Unique™)
- Highest temperature change +1.7°C (LMA Flexible™ & LMA Flexible™ SU)

Therefore, the MRI-related heating experiments for the device at 3-Tesla using a transmit/receive RFI 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 was association with these specific conditions was equal to or less than +1.6°C (LMA Classic™ & LMA Unique™) and +1.7°C (LMA Flexible™ & LMA Flexible™ 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 Classic™:

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Symbol Definition:

Manufacturer
Authorized representative in the European Community
Consult IFU on this website: www.LMAcom.co
Air inflation volume
Patient weight
Read Instruction before use
Not made with natural rubber latex
Fragment, 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 reuse more than 40 times
Non-sterile
Contains or Presence of Phthalates: Bi(2-ethylhexyl) phthalate (DEHP)
Sterilised by Ethylene Oxide
Use By
Do not use if package is damaged