LMA™

The Laryngeal Mask Company Limited

English

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

WARNING: LMA Classic™ and LMA Flexible™ 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 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 cross infection and reduce product reliability and functionality.

General Information:

LMA Classic™ and LMA Flexible™ are not made with natural rubber latex.

The Laryngeal Mask Company Limited (LMC) recommends LMA Classic™ and the LMA Flexible™ be used a maximum of 40 times before being discarded. Continued use beyond the maximum 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 Unique™ and LMA Flexible™ SU 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).

It is also indicated for securing the immediate airway in known or unexpected difficult airway situations. It is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

It may be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal 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 not fasted, including patients whose fasting cannot be confirmed.

2. Patients who are grossly or morbidly obese, more than 14 weeks pregnant or emergency and rescucitation situations or any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The LMA™ airway is also contraindicated in:

3. Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 20 cm H_2O, because the device forms a low-pressure seal (approximately 20 cm H_2O) around the larynx.

4. Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for LMA™ airway use.

5. The LMA™ airway should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist device insertion.

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 or 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 sterilised 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 vocal cord paralysis. 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

Patient Weight/Size

1:	**up to 5kg neonatal**	**3:**	**30kg - 50kg paediatric**
1½ :	**5kg - 10kg paediatric**	**4:**	**50kg – 70kg adult**
2:	**10kg - 20kg paediatric**	**5:**	**70kg – 100kg adult**
2½ :	**20kg - 30kg paediatric**	**6:**	**>100kg 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™ 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 interior 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. Holding at each end flex the airway 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. Reflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 1	**6ml**	**Size 3**	**30ml**
Size 1½	**10ml**	**Size 4**	**45ml**
Size 2	**15ml**	**Size 5**	**60ml**
Size 2½	**21ml**	**Size 6**	**75ml**

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. Then deflate the mask again. While the device remains 50% over-inflated, examine the blue inflation pilot balloon. The balloon shape should be elliptical, not spherical.

4. Examine the airway connector. It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.

5. Discoloration. Discoloration affects visibility of fluid in the airway tube.

6. Gently pull the inflation line to ensure it is securely attached to both the cuff and balloon.

7. Examine the aperture in mask. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. If the aperture bars are not intact, the epiglottis may obstruct the airway. Do not use if the aperture bar is damaged.

Pre-insertion Preparation:

Deflate completely using the LMA™ Cuff Deflator in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold back away from the aperture bars. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in blockage of aperture bar 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 the LMA™ airway 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:

Note: gloves must be worn

Standard Insertion Method:

1. Anaesthesia must be deep enough to permit insertion

Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given.

2. Position the head and neck as for normal tracheal intubation. Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand **(Fig.1).**

3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube **(Fig.1).** Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.

4. Using the index finger, push the mask backwards **still maintaining pressure against the palate (Fig.2).**

5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion **(Fig.3).** Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. **(Fig.3).**

AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.

When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth **(Fig 4).**

6. Check that the black line on the tube faces the upper lip.

Now immediately inflate the cuff **without holding the tube.**

Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.

Warning: NEVER OVERINFLATE THE CUFF.

Maximum inflation volumes (ml)

Size 1	**4ml**	**Size 3**	**20ml**
Size 1½	**7ml**	**Size 4**	**30ml**
Size 2	**10ml**	**Size 5**	**40ml**
Size 2½	**14ml**	**Size 6**	**50ml**

7. Connect to gas supply, holding tube, to prevent displacement. **Gently** inflate lungs to confirm correct placement. Insert roll of gauze as bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the device, it is important to remember to insert a bite block at the end of the procedure.

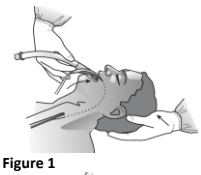

Figure 1

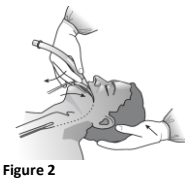

Figure 2

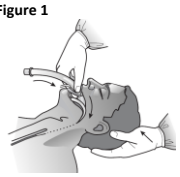

Figure 3

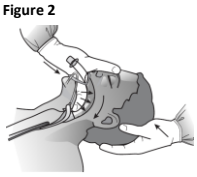

Figure 4

Thumb Insertion Method:

This technique is suitable for patients in whom access to the head from behind is difficult or impossible and during cardiopulmonary resuscitation. The LMA™ airway is held with the thumb in the position occupied by the index finger in the standard technique (**Fig.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 (**Fig.6**). Advance the thumb to its fullest extent (**Fig.7**). The pushing action of the thumb against the hard palate also serves to press the head into extension. Neck flexion may be maintained with a head support. Before removing the thumb, push the tube into its final position using the other hand (**Fig.8**).

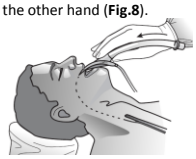

Figure 5

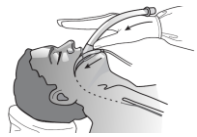

Figure 6

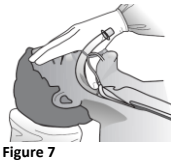

Figure 7

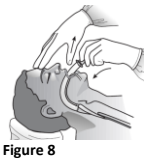

Figure 8

Maintaining the airway

1. 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.

2. Malposition of mask tip into the glottis may mimic bronchospasm.

3. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.

4. Keep the bite-block in place until the device is removed.

5. Do not deflate the cuff until reflexes have fully returned.

6. Air may be withdrawn from the cuff during anaesthesia to maintain a constant intracuff pressure (ideally about 60cm H_2O).

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 leave 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 patient by the inflation tube as it may detach from the cuff spigot.

4. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention.

5. Use only syringe with standard luer taper tip for inflation or deflation.

6. Do not immerse or soak single use devices (LMA Flexible™ 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 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 or iodine-containing cleaners to clean or sterilise 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 properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

Sterilisation (for LMA Classic™ & LMA Flexible™ only):

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 (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 sterilisation of the LMA™ airway, provided 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 sterilisation 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 Classic™, LMA Flexible™, LMA Flexible™ SU and LMA Unique™ 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.

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

Highest 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 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 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™:

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 Flexible™:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	10,299-mm^2	7,753-mm^2	44,445-mm^2	25,837-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

LMA Unique™:

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 Flexible™ SU:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	10,299-mm^2	7,753-mm^2	44,445-mm^2	25,837-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Symbol Definition:

	Manufacturer
EC REP	Authorized representative in the European Community
eIFU indicator	Consult IFU on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
LATEX	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
REF	Product Code
LOT	Lot Number
CE 0086	CE Mark
SN	Serial Number
	Do not Re-use
41	Do not reuse more than 40 times
NON STERILE	Non-sterile
PHT DEHP	Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)
STERILE EO	Sterilised by Ethylene Oxide
	Use By
	Do not use if package is damaged

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 Classic™ and LMA Flexible™ are 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 Unique™ and LMA Flexible™ 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.

EC REP

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