LMA™

The Laryngeal Mask Company Limited

English

Instructions For Use – LMA Supreme™

1. DEVICE DESCRIPTION

The LMA Supreme™ is an innovative sterile single use supraglottic airway management device.

The LMA Supreme™ provides access to and functional separation of the respiratory and digestive tracts. The anatomically shaped airway tube is elliptical in cross section and ends distally at the laryngeal mask. The inflatable cuff is designed to conform to the contours of the hypopharynx, with the bowl and the mask facing the laryngeal opening.

The LMA Supreme™ also contains a drain tube which emerges as a separate port proximally and continues distally along the anterior surface of the cuff bowl, passing through the distal end of the cuff to communicate distally with the upper oesophageal sphincter. The drain tube may be used for the passage of a well lubricated gastric tube to the stomach, offering easy access for evacuation of gastric contents. The drain tube has an additional and important function – it may be used as a monitor of correct positioning of the LMA Supreme™ following insertion and then for continuous monitoring of mask displacement during use.

The LMA Supreme™ provides easy insertion without the need for digital or introducer tool guidance and enough flexibility to permit the device to remain in place if the patient's head is moved in any direction. The two lateral grooves in the airway tube are designed to prevent the airway tube kinking when flexed. A built-in bite-block reduces the potential for tube damage and obstruction by patient biting.

The LMA Supreme™ has a new fixation system which prevents proximal displacement. If correctly used, this enhance the seal of the distal end around the upper oesophageal sphincter thereby isolating the respiratory tract from the digestive tract, so reducing the danger of accidental aspiration.

Attached to the mask is a cuff inflation line terminating in a pilot balloon and one-way check valve for mask inflation and deflation. All components are not made with natural rubber latex.

The LMA Supreme™ is supplied sterile and for single use only. It is terminally sterilized by Ethylene Oxide gas.

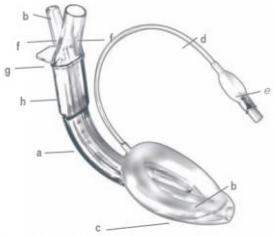

Figure 1: LMA Supreme™ components

LMA Supreme™ components (Figure 1):
(a) Anatomically-shaped airway tube
(b) A separate drain tube has been incorporated
(c) Inflatable cuff with interlocking proximal and distal segments
(d) Cuff inflation line
(e) Pilot balloon
(f) A rigid moulded proximal component which forms separate airway and drain tube ports
(g) Fixation tab
(h) Integral bite-block

2. INDICATION FOR USE

The LMA Supreme™ is indicated for use in achieving and maintaining control of airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or positive pressure ventilation.

It is also indicated for use as the rescue airway device in CPR procedures, in which the LMA ProSeal™, LMA Classic™ or the LMA Unique™ have traditionally been used. The LMA Supreme™ is also indicated as a "rescue airway device" in known or unexpected difficult airway situations. The LMA Supreme™ may be used to establish an immediate clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need an artificial ventilation.

It may also be used to secure an immediate airway when tracheal intubation is precluded by lack of available expertise or equipment, or when attempts at tracheal intubation have failed.

3. CONTRAINDICATIONS

- Patients who have had radiotherapy to the neck involving the hypopharynx (risk of trauma, failure to seal effectively)
- Patients with inadequate mouth opening to permit insertion
- Patients presenting for emergency surgery who are at risk of massive reflux, such as acute intestinal obstruction or ileus, or patients having been injured shortly after ingesting a substantial meal (but see above under Indication for Use)
- Patients requiring head or neck surgery where the surgeon cannot gain adequate access due to the presence of the device
- Responsive patients with an intact gag reflex (CPR).
- Patients who have ingested caustic substances

4. WARNINGS

- In spite of encouraging case reports, it is not currently known whether the LMA Supreme™ always affords protection from aspiration even when correctly fixed in place.
- The presence of a gastric tube does not rule out the possibility of aspiration if the device is not correctly located and fixed in place.
- The LMA Supreme™ may be ineffective for use in patients with decreased pulmonary compliance due to fixed obstructive airways disease because airway positive pressure requirement may exceed seal pressure.
- Do not attempt to pass a gastric tube into the stomach via the drain tube in the presence of known or suspected oesophageal pathology.
- There is a theoretical risk of causing oedema or haematoma if suction is applied directly to the end of the drain tube.
- The benefits of establishing ventilation with the LMA Supreme™ must be weighed against the potential risk of aspiration in some situations including: symptomatic or untreated gastro-oesophageal reflux, pregnancy over 14 weeks, multiple or massive injury, conditions associated with delayed gastric emptying, such as the use of opiate medication in patients with acute injury or peritoneal infectious or inflammatory processes.
- The LMA Supreme™ is a single use device and it shall not be reuse. Reuse may cause cross infection and reduce product reliability and functionality.
- Refer to Appendix for MRI information prior to using LMA Supreme™ in MRI environment.

5. CAUTIONS

- Do not re-sterilise and/or reuse the LMA Supreme™. The device is provided sterile and should be used straight from the package and is not designed to withstand reuse, cleaning or exposure to disinfecting or sterilizing agents.
- Do not immerse or soak the device in liquid prior to use.
- Only use with the recommended manoeuvres described in the instructions for use.
- Do not use the LMA Supreme™ if the device is damaged or the unit packaging is damaged or opened.
- When applying lubricant avoid blockage of the airway aperture with the lubricant.
- To avoid trauma, excessive force should not be used at any time during insertion of the LMA Supreme™ or insertion of a gastric tube through the drain tube.
- Never over-inflate the cuff after insertion. An appropriate intra-cuff pressure is 60cm H_2O. This pressure should not be exceeded. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- If airway problems persist or ventilation is inadequate, the LMA Supreme™ should be removed and an airway established by some other means.
- Careful handling is essential. The LMA Supreme™ is made of medical-grade PVC which can be torn or perforated. Avoid contact with sharp or pointed objects at all times. Do not insert the device unless the cuff is fully deflated as described in the instructions for insertion
- Gloves should be worn during preparation and insertion to minimize contamination of the airway.
- Store device in a dark cool environment, avoiding direct sunlight or extremes of temperature.
- Used device shall be decontaminated first in accordance with local hospital procedures for handling bio-hazard products and subsequently disposed of by incineration or landfill in accordance with all local and national regulations.
- Only use syringe with standard luer taper tip for inflation/ deflation of the cuff.

This device contains Di(2-ethylhexyl)phthalate (DEHP) a substance which has been associated with toxicity when use for long-term procedures in transfusion equipment. However, this device is not meant for long term use and so is unlikely to pose any toxicity risk. There is no concern and/or known risk for use of this device on children or nursing/pregnant women as the device is not meant for the following exposure scenarios:

- Long term haemodialysis in adults (testicular, fertility, 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 clinician on a case by case basis.

6. ADVERSE EFFECTS

There is currently no data documenting adverse effects with the LMA Supreme™. Until data becomes available, it should be assumed that a similar incidence and range of adverse events might occur with the LMA Supreme™ as occurs with the LMA ProSeal™.

- Both minor adverse effects (e.g. sore throats) and major adverse effects (e.g. aspiration) following standard LMA™ (LMA Classic™) airway use have been reported in literature.
- Review of published literature shows the incidence of aspiration with the LMA™ airway is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia[1].
- The LMA ProSeal™ is reported to offer some protection against the aspiration of gastric contents and, as the design of the LMA Supreme™ is generally similar to that of the LMA ProSeal™ but with the additional of an enhanced oesophageal sealing mechanism, it is expected that the LMA Supreme™ will offer at least equal protection.
- The incidence of sore throat following LMA™ airway use is approximately 13% and is usually mild and shortlived[1].
- 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. Although this has not proven for individual cases, malposition and/ or excessive intracuff pressure are likely on anatomical grounds to cause compression of nerves and/or blood vessels. Cuff malposition is usually due to incorrect insertion technique or inadequate depth of anaesthesia, and excessive cuff pressure due to over-inflation of the cuff following insertion, inappropriate size selection or diffusion of nitrous oxide into silicone cuffs. The effects of an incorrectly positioned and over inflated cuff are most likely to be seen following prolonged surgery. The length of surgery is not an issue in a correctly inserted and inflated LMA™ airway provided intra-cuff pressure is kept at the recommended level of 60 cm H_2O.

[1] Brimacombe JR, Laryngeal Mask Anaesthesia. Principles and Practice, Saunders 2004.

7. SIZE SELECTION

For normal adults, use the size 4 device as a first choice. After inserting, fixing the device in place, and then inflating to the recommended pressure, there should be a minimum of one cm gap between the fixation tab and the patient's upper lip. If the tab is pressing on the lip or very near to it, this indicates the device is too small for the patient and the size 5 should be used instead to avoid the risk of (a) poor seal against the oesophagus and (b) possible pressure trauma to the lip. If the fixation tab is more than 2.5 cm from the upper lip after fixation, it may be advisable to use the size 3 device. The decision to change to a smaller device will depend on the quality of airway, device stability and seal pressure achieved.

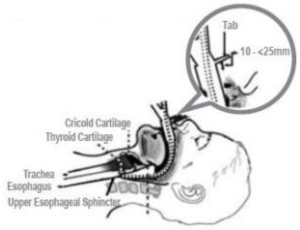

Figure 2: LMA Supreme™ sizing

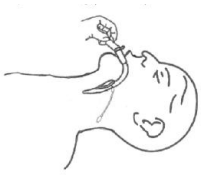

Figure 3: LMA Supreme™ sizing (method 2)

The sizing method described above requires that all three adult sizes of the LMA Supreme™ should be available to hand before inducing anaesthesia.

For adult patients who are either smaller or larger than normal, it is often possible to obtain a good result using the size 4 device, provided the quantity of air used to inflate the cuff is always based on achieving 60 cm H_2O intracuff pressure. In smaller patients this pressure is achieved with a relatively small volume of air, while larger patients will require larger volumes. However, when in doubt, an approximate estimate of suitable sizing can be made by holding each device against the side of the patient's face in the position corresponding to that shown in figure 3.

8. PRE-USE PERFORMANCE TESTS

The following inspections and tests must be conducted before use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimise contamination of the LMA Supreme™ before insertion.

Warning: Do not use the device should it fails any one of the inspections or tests.

- Examine the surface of the LMA Supreme™ and drain tube for damage, including cuts, tears, scratches or kinks.
- Examine the interior of the airway tube and drain tube to ensure they are free from blockages kinking of the drain tube within the airway tube or loose particles. Any particles present in the tubes should be removed. Do not use the airway if the blockage or particle cannot be removed.
- Deflate the cuff completely. Once deflated, check the cuff for spontaneous inflation. Do not use the airway if the cuff spontaneously inflates.

9. DEFLATING THE DEVICE PRIOR TO INSERTION

- After firmly connecting a syringe of at least 50ml to the inflation port, hold the syringe and the LMA Supreme™ exactly as shown in figure 4. Move the connected syringe away from the device until the inflation line is slightly stretched as shown. Compress the distal end of the device in between the index finger and thumb while withdrawing air until a vacuum has been obtained.
- While deflating, hold the device so that the distal end is curled slightly anteriorly as shown in Figure 4
- Deflate the device until the tension in the syringe indicates a vacuum has been created in the mask. Keep the syringe under tension whilst rapidly disconnecting it from the inflation port. This will ensure the mask remains correctly deflated, as shown in Fig 5.

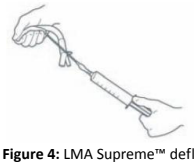

Figure 4: LMA Supreme™ deflation

Figure 5: After achieving wedge shape cuff during deflation, disconnect the syringe from the inflation line

10. INSERTION

- Lubricate the posterior surface of the mask and airway tube just prior to insertion
- Stand behind or beside patient's head
- Place the head in the neutral or slight "sniffing" position (Sniffing = extension of head + flexion of neck)
- Hold the device exactly as shown in figure 6
- Press the distal tip against the inner aspect of the upper teeth or gums
- Slide inwards using a slightly diagonal approach (direct the tip away from the mid-line)
- Continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue
- Resistance should be felt when the distal end of the device meets the upper oesophageal sphincter. The device is now fully inserted

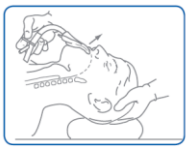

Figure 6: Press the tip of the mask against the hard palate.

Figure 7: Press the cuff further into the mouth, maintaining pressure against the palate.

Figure 8: Swing the device inward with a circular motion, pressing against the contours of the hard and the soft palate.

Figure 9: Advance the device into the hypopharynx until resistance is felt.

11. FIXATION

Secure the LMA Supreme™ to patient's face using adhesive tape as follows:

- Use a piece of adhesive tape 30-40cm long, holding it horizontally by both ends
- Press the adhesive tape transversely across the fixation tab, continuing to press downwards so that the ends of the tape adhere to each of the patient's cheeks and the device itself is gently pressed inwards by the tape
- Do not rotate the tape around the proximal end of the device
- Do not use a Guedel airway; the device has an integral bite block

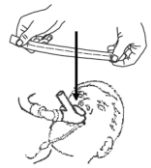

Figure 10a

Figure 10b

Figure 10: Fix the device in place using adhesive tape. Stretched the adhesive tape vertically downwards (See Figure 10a) ensure that the middle of the tape is pressed vertically downwards over the tab as shown in Figure 10b.

12. INFLATION

Inflate the cuff with air until relevant intra-cuff pressure is reached. The recommended intra-cuff pressure should never exceed 60cm H_2O. If no manometer is by hand, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

Airway Size	Patient Weight	Max Size OG Tube	Recommended Maximum Inflation Volume	Optimum Intra-Cuff Pressure
1	< 5kg	6Fr	5 ml	60cm H_2O
1.5	5-10kg	6Fr	8ml	
2	10-20kg	10Fr	12 ml	
2.5	20-30kg	10fr	20ml	
3	30-50kg	14Fr	30 ml	
4	50-70kg	14Fr	45 ml	
5	70-100kg	14Fr	45 ml	

Table 1: LMA Supreme™ selection guide

13. CORRECT POSITION

Correct placement should produce a leak-free seal against the glottis with the mask tip at the upper oesophageal sphincter. The integral bite block should lie between the teeth.

To facilitate diagnosis of correct mask placement, place a small bolus (1-2ml) of suitably viscous water soluble lubricant in the proximal end of the drain tube. In a properly placed mask, there should be a slight up-down meniscus movement of the lubricant following the application and release of gentle pressure in the suprasternal notch. This indicates that the distal end of the drain tube is correctly placed so that it seals around the upper oesophageal sphincter (the 'suprasternal notch test'). A similar movement may also be seen when gentle manual positive pressure is applied to the airway through the device.

14. GASTRIC DRAINAGE

The drain tube facilitates channelling of fluids and gases emerging from the stomach. To facilitate gastric drainage, a gastric tube may be passed through the drain tube into the stomach at any time during the anaesthetic procedure. Refer to Table 1 for maximum gastric tube sizes. The gastric tube should be well lubricated and passed slowly and carefully. Suction should not be performed until the gastric tube has reached the stomach. Suction should not be applied directly to the end of the drain tube, as this may cause the drain tube to collapse and might theoretically cause injury to the upper oesophageal sphincter.

15. ANAESTHESIA MAINTENANCE

The LMA Supreme™ is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anaesthesia, provided anaesthesia is adequate to match the level of surgical stimulus and the cuff is not over-inflated.

During PPV using the LMA Supreme™ tidal volumes should not exceed 8ml/kg and peak inspiratory pressures should be kept below the maximum airway seal pressure.

If leaks occur during PPV, this may be due to light anaesthesia causing a degree of glottic closure, severe reduction in lung compliance related to the procedure or patient factors or displacement or migration of the cuff by head turning or traction in an inadequately fixed mask.

16. RECOVERY

Removal should always be carried out by trained personnel. Although the device may not be removed in the operating theatre, its low invasivity makes it a good device to maintain the airway during recovery in the Post Anaesthetic Care Unit (PACU) provided staff are appropriately trained and equipped. Because recovery involves increase in pharyngeal tone, it makes sense to reduce the volume of air in the cuff before sending the patient to the PACU; however, the cuff must never be fully deflated at this point.

Fully deflate the cuff and simultaneously remove the device ONLY when the patient can open the mouth on command. If the cuff is FULLY deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm.

Patient monitoring should continue throughout the recovery stage. Where appropriate, oxygen may be continuously administered through the anaesthetic circuit or via a T-piece attached to the proximal end of the airway device.

17. USE WITH MAGNETIC RESONANCE IMAGING (MRI)

MR

MR Conditional

Testing has been performed to determine the compatibility of LMA Supreme™ with MRI. Prior to using LMA Supreme™ in this 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 Supreme™** was determined to be MR-conditional. Non-clinical testing demonstrated that the LMA Supreme™ is 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

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

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

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.

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

18. SYMBOLS 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
2	Do not Re-use
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.

Consult the instructions on indications, contraindications, warnings and precautions, or information on which LMA™ airways are best suited for different clinical applications.

Manufacturer's Warranty:
The LMA Supreme™ is designed for a 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 APARTICULAR PURPOSE.

Caution: Federal (US) law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.

EC REP

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