EN – English

Instructions For Use – LMA® Supreme™

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

WARNING: LMA® Supreme™ is supplied sterile for single use, should be used straight from the pack and should be discarded after use. It must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.

WARNING: Re-processing of LMA® Supreme™ intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilisation methods and instructions for reprocessing to original specifications are not available for this product. LMA® Supreme™ is not designed to be cleaned, disinfected, or re-sterilised.

WARNING: Read all Instructions for Use warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

1. DEVICE DESCRIPTION:

The LMA® Supreme™ is an innovative, second generation, 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 First Seal™.

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 Second Seal™.

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 - Second Seal™ 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.

The LMA® Supreme™ is made primarily of medical grade polyvinylchloride (PVC) and is supplied sterile for single use only. It is terminally sterilized by Ethylene Oxide gas.

All components are not made with natural rubber latex.

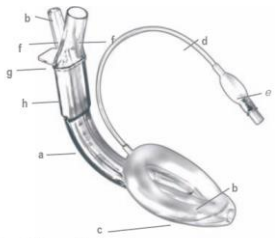

Figure 1: LMA® Supreme™ components

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

The device is only for use by medical professionals trained in airway management.

2. INDICATIONS 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 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. RISK-BENEFIT INFORMATION:

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-esophageal 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 infections or inflammatory processes.

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 LMA® Supreme™ is the preferential airway "rescue" device to ensure oxygenation. The risk of regurgitation and aspiration is minimized as the LMA® Supreme™ offers easy access to liquid gastric contents. However, the ultimate choice of the definite airway "rescue" device remains with the airway manager.

In patients with severe oropharyngeal trauma, the device should only be used when other attempts to establish an airway have failed.

4. 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.
- Patients who have ingested caustic substances.

5. WARNINGS:

5.1 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.

5.2 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.

5.3 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.

5.4 Do not attempt to pass a gastric tube into the stomach via the drain tube in the presence of known or suspected oesophageal pathology.

5.5 There is a theoretical risk of causing oedema or haematoma if suction is applied directly to the end of the drain tube.

5.6 To avoid trauma, excessive force should not be used at any time when using the devices. Excessive force must be avoided at all times.

5.7 This device contains Di (2-ethylhexyl) phthalate (DEHP). The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.

5.8 Do not use the LMA® Supreme™ if the device is damaged or the unit packaging is damaged or opened.

5.9 Never over-inflate the cuff of the device over 60 cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.

5.10 Do not immerse or soak the device in liquid prior to use.

5.11 It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.

5.12. When applying lubricant avoid blockage of the airway aperture with the lubricant.

5.13 A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade LMA® Supreme™ 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.

5.14 Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. In order to ensure that cuff pressures do not become excessive, cuff pressure should be measured regularly during a case with a cuff pressure monitor.

5.15 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. The device may be flammable in the presence of lasers and electrocautery equipment.

5.16 Refer to section 18 for MRI information prior to using the devices in MRI environment.

6. CAUTIONS:

6.1 Only use with the recommended manoeuvres described in the instructions for use.

6.2 If airway problems persist or ventilation is inadequate, the LMA® Supreme™ should be removed and an airway established by some other means.

6.3 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.

6.4 Gloves should be worn during preparation and insertion to minimize contamination of the airway.

6.5 Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperature.

6.6 Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.

6.7 Only use a syringe with standard luer taper tip for inflation/deflation of the cuff.

6.8. 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, treat the cause. Only remove the device when airway protective reflexes are fully competent.

6.9. 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.

6.10 Ensure all removable denture work is removed before inserting the device.

6.11 An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.

7. ADVERSE EFFECTS:

There are reported adverse reactions associated with the use of laryngeal mask airways. Potential side effects may include airway trauma, dysphagia, sore throat, dysphonia, laryngospasm, obstruction, stridor, bronchospasm, hoarseness, nausea and vomit, regurgitation, aspiration, gastric distension, patient intolerance e.g. coughing, and mouth, lip or tongue injury.

8. 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 2.5cm 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.

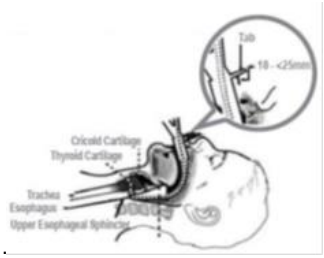

Figure 2: LMA® Supreme™ sizing

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 60cm 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.

9. 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.

10. 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.

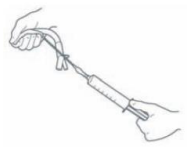

Figure 4: LMA® Supreme™ deflation

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

11. INSERTION:

Caution: The patency of the airway should be reconfirmed after any change in the patient's head and neck position.

- 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.

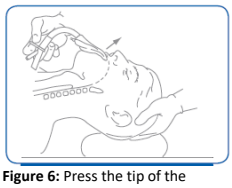

Figure 6: Press the tip of the mask against the hard palate.

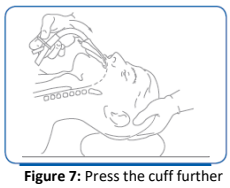

Figure 7: Press the cuff further into the mouth, maintaining pressure against the palate.

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

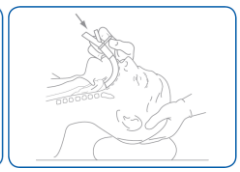

Figure 9: Advance the device into the hypopharynx until resistance is felt.

12. 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.

13. 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.

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

Table 1: LMA® Supreme™ selection guide

14. 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.

15. GASTRIC DRAINAGE:

The drain tube facilitates channeling 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.

16. 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 Positive Pressure Ventilation (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 glottis 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.

17. 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.

18. USE WITH MAGNETIC RESONANCE IMAGING (MRI):

MR Conditional

The LMA® Supreme™ is 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:

- Before the patient enters the MRI system room, the airway must be fixed properly in place with adhesive tape, cloth tape or other appropriate means to prevent movement or dislodgement.
- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 720 gauss/cm (7.2T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence).

MRI-Related Heating

Under the scan conditions defined above, the LMA® Supreme™ is expected to produce a maximum temperature rise of 2.2°C after 15 minutes of continuous scanning.

Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 20-mm relative to the size and shape of the LMA® Supreme™, Size 5.

19. SYMBOLS DEFINITION:

	Manufacturer
	Consult IFU on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instructions before use
	Not made with natural rubber 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
	Do not Re-use
	Do not Re-sterilise
	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
	MR Conditional

The information given in this document is correct at the time of publication. 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 use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor. TELEFLEX INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR APARTICULAR PURPOSE.

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