The Laryngeal Mask Company Limited

English Instructions For Use – LMA Supreme™

1. DEVICE DESCRIPTION

The LMA Supreme™ is an innovative single use supraglottic airway device. It provides airway access in the absence of a functional endotracheal tube. The LMA Supreme™ provides access to and functional separation of the respiratory and digestive tracts. The anatomically shaped airway tube is flexible in its 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 laryngal opening. The LMA Supreme™ also contains a drain tube which emerges as a separate nasal airway and extends directly 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 aspiration of gastric material and any air entering 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 marker of correct position of the airway. The drain tube may be used for the passage of a well lubricated gastric tube to communicate distally with the upper oesophageal sphincter and 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.

- The LMA Supreme™ may be ineffective for use in patients with decreased pulmonary compliance and diffuse airway 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 drain tube. - The benefits of establishing ventilation with the LMA Supreme™ must be weighed against the potential risk of aspiration in situations including: symptomatic or untreated gastro-oesophageal reflux, pregnancy over 14 weeks, multiple or massive injury, conditions associated with distal gas exchange, such as the use of opiates in patients with acute injury or perioperative infectious or inflammatory processes. - The LMA Supreme™ is a single use device and it shall not be reused. 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.

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 facilitate airway exchange or to protect the airway when a larger airway device is required.

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.

3. Cautions

- Aspiration if the device is not correctly located and fixed in place.
- There is currently no data documenting adverse effects 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.
- The LMA Supreme™ is a single use device and it shall not be reused. Reuse may cause cross infection and reduce product reliability and functionality.
- The LMA Supreme™ may be ineffective for use in patients with decreased pulmonary compliance and diffuse airway 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 drain tube.
- The benefits of establishing ventilation with the LMA Supreme™ must be weighed against the potential risk of aspiration in situations including: symptomatic or untreated gastro-oesophageal reflux, pregnancy over 14 weeks, multiple or massive injury, conditions associated with distal gas exchange, such as the use of opiates in patients with acute injury or perioperative infectious or inflammatory processes.
- The LMA Supreme™ is a single use device and it shall not be reused. 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.

4. ADVERSE EFFECTS

There is 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 Classic™.

- 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 Supreme™ is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia.

5. SAFETY AND MANDATORY INSTRUCTIONS

- 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 currently no data documenting adverse effects 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 Supreme™ is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia.

6. DEFINING THE DEVICE PRIOR TO INSERTION

- 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 currently no data documenting adverse effects 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 Supreme™ is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia.

7. SIZE SELECTION

- 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 currently no data documenting adverse effects 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 Supreme™ is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia.

8. PRE-USE PERFORMANCE TESTS

- 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 currently no data documenting adverse effects 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 Supreme™ is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthesia.
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 5.
- Press the distal tip against the inner aspect of the upper teeth or gums to avoid causing injury to the upper oesophageal sphincter.
- Resistance should be felt when the distal end of the device meets the upper oesophageal sphincter. The device is now fully inserted.

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 against the skin.
- Do not rotate the tape around the fixation tab, as this may cause the drain tube to collapse and might theoretically injure to the upper oesophageal sphincter.

12. INFLATION
- Inflate the cuff with air to achieve a leak test. A similar test can be performed by inflating the cuff with just enough air to achieve a free seal against the glottis.

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 (1-2 ml) 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 movement of the lubricant following the application and release of gentle pressure in the supratracheal notch. This indicates that the distal end of the drain tube is correctly placed so that it seals around the upper oesophageal sphincter (the 'supratracheal 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 injure 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 IPPV 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 IPPV, 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 invasiveness 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 administrated 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 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 (3 T) to 12 T
  - Maximum spatial gradient magnetic field of 720 milliTesla per millisecond (mT/m/ms)
- MRI-Related Heating
  - Maximum temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3 T-sequence (b400 mm2/m/s, Excite, HDx, Software 14X, MS, General Electric Healthcare, Milwaukee, WI) MR system: 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 calorimeter 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.