

English

LMA | Supreme[®]

Instruction Manual



Instruction Manual

English

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1 DEVICE DESCRIPTION

The LMA® airway is an innovative supraglottic airway management device. Since its commercial introduction in 1988, the LMA® airway has been used in over 200 million patients for routine and emergency procedures.

The LMA Supreme® is an advanced form of LMA® airway that may be used for the same indications as the LMA ProSeal®, but is a sterile, single use device.

The LMA Supreme® which is terminally sterilised by Ethylene oxide gas, has four main components: an anatomically shaped airway tube into which a separate drain tube has been incorporated, a modified inflatable cuff and a cuff inflation line with pilot balloon (figure 1).

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 proximally at the laryngeal inlet. The airway tube contains a drain tube within it

(Figure 1). The drain tube runs distally along the posterior surface of the cuff and ends as an open tip designed to communicate distally with the upper esophageal sphincter, when inserted with recommended insertion technique.

The anatomically shaped airway tube is elliptical in cross-section and is more rigid than the airway tube of the LMA ProSeal® but not as rigid as the metallic airway tube of the ILMA®. This configuration permits easy and reliable insertion without the need for digital or introducer tool guidance. The patented grooves in the airway tube are designed to prevent airway tube kinking which could lead to airway obstruction.

The airway tube and the drain tube end on a manifold at the proximal end of the LMA Supreme® from which two rigid tubes project. The larger standard 15 mm diameter tube is designed to be connected to the airway circuit. The narrower tube is a continuation of the drain tube and allows equalization of the pressures at the upper oesophageal sphincter and atmosphere. It provides a useful conduit for venting gastrointestinal gases and liquids and may be used for the passage of a well lubricated gastric tube to the

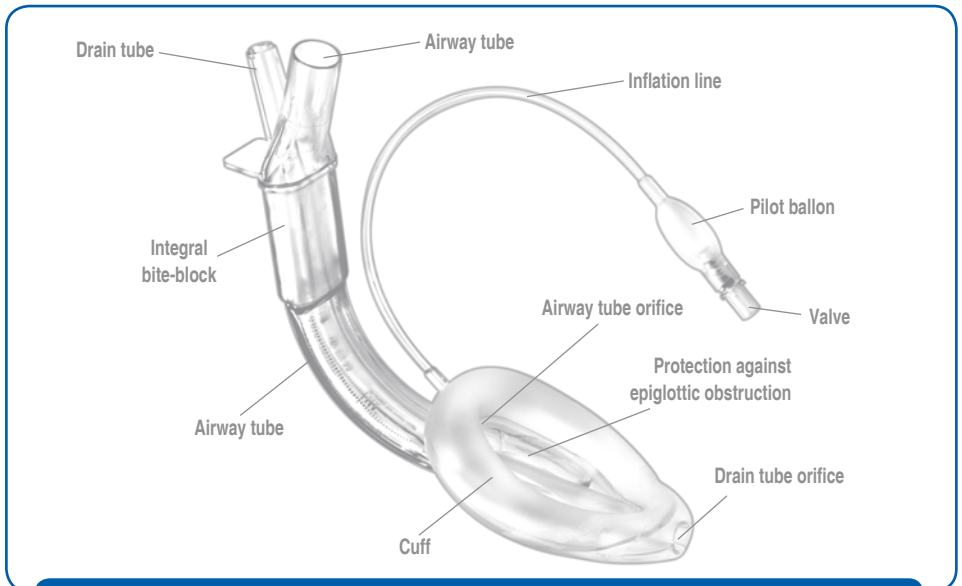


Figure 1 – The components of the LMA Supreme®.

stomach, offering easy access to liquid stomach 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. Incorrect positioning of the LMA Supreme® results in a poor airway seal and an audible and immediately detectable leak through the drain tube. Thus leakage of gases through the drain tube during Positive Pressure Ventilation immediately alerts the user to the displacement of the device from its optimal position.

The inflatable cuff is designed to conform to the contours of the hypopharynx, with its airway lumen facing the laryngeal opening. The new cuff design offers higher seal pressures around the laryngeal opening than the cuff of the LMA® airway during positive pressure ventilation (PPV). The distally placed, open end of the drain tube is designed to be at, and forms a sealed junction with the upper oesophageal sphincter. The proximal end of the drain tube terminates at the airway manifold, as a rigid small bored tube.

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 latex free.

The LMA Supreme® design offers the following features:

- It is supplied sterile and ready for use. It is terminally sterilised by Ethylene oxide gas.
- It is designed as a single use device, unlike the reusable LMA ProSeal®
- A cuff that allows a higher seal pressure than the LMA® airway
- A drain tube that permits venting of the stomach contents and blind insertion of standard gastric tubes. The configuration of this tube includes a dual cuff and internal webbing to prevent occlusion of the drain tube.
- A specially designed rigid tab fixed above the bite-block area that permits a novel fixation method using adhesive tape. In the event of the device being displaced from the optimal position, leakage through the drain tube or around the cuff will alert the user to displacement of the device, and the tab is easily manipulated to 're-position' the device to the optimal position to prevent the leaks. The tab is then used to re-fix the device in this position. The distance of the tab from the upper lip should be more than 0.5 cm and less than 2 cm. If the tab is flush against the upper lip, it indicates that a larger size of LMA Supreme® should be used and if the tab is more than 1.5 cm from the upper lip then

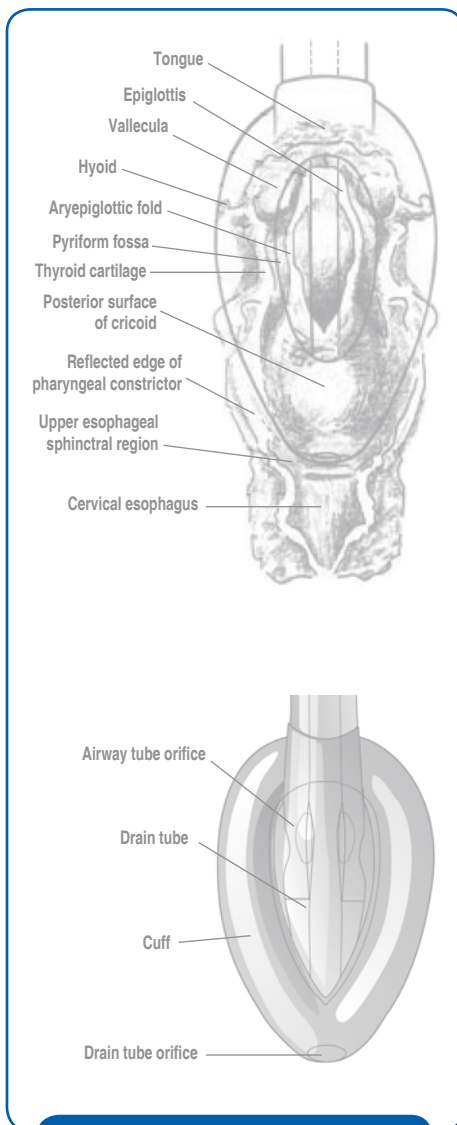


Figure 2 – Dorsal view of the LMA Supreme® showing position in relation to pharyngeal anatomy.

a smaller sized device should be used instead.

- A built-in bite-block reduces the potential for airway obstruction or tube damage.
- The design of the cuff bowl includes patented 'fins' and positioning of the drain tube in the bowl prevent epiglottic occlusion of the airway. Aperture bars are therefore not required.
- The LMA Supreme® is designed to be a minimally stimulating airway device. When fully inserted using the recommended insertion technique, the distal tip of the cuff is at the upper oesophageal sphincter, its sides face into the pyriform fossae and the upper border rests against the base of the tongue (figure 2).

2 INTENDED USE

The LMA Supreme® is intended for use in achieving and maintaining control of the airway during routine anaesthesia (fasted patients) and when tracheal intubation fails in non fasted patients during anaesthetic procedures. It is also intended for use in cardiopulmonary resuscitation (CPR) procedures as well as in the 'failed intubation' and the 'cannot-intubate-cannot-ventilate' situation.

3 INDICATIONS

The LMA Supreme® is indicated for use during routine anaesthetic procedures and in emergency procedures in which tracheal intubation has failed, or in which attendant personnel have limited intubation skills e.g. failed tracheal intubation in fasted and non fasted patients and 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. In these cases, the LMA Supreme® should be used only when tracheal intubation is not possible.

4 CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do not use the LMA Supreme® as a 'First Choice Airway' in the following elective or difficult airway patients on a non-emergency pathway:

- Patients who have not fasted, including patients whose fasting cannot be confirmed.
- Patients who are morbidly obese, more than 14 weeks pregnant or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting. However, in all these clinical scenarios, the LMA Supreme® is ideally suited to serve as an 'airway rescue device' in preference to the LMA Classic® or the LMA Unique®.

The LMA Supreme® is relatively also contraindicated in:

- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the LMA Supreme® may not always provide an adequate seal around the larynx.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history.

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® should be used preferentially to the LMA Unique® as an 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, unlike the LMA Unique®. However, the ultimate choice of the definitive airway 'rescue' device remains with the airway manager. The LMA Supreme® should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist LMA Supreme® insertion.

5 WARNINGS

- The LMA Supreme® is a single use device and it shall not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- The single-use LMA Supreme® contains Di (2-ethylhexyl) phthalate (DEHP). However, the 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 the device in children or nursing/ pregnant women as it is not meant for the following exposure scenarios:
 - Long-term haemodialysis in adults (testicular effects, 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 the device shall be carefully evaluated by clinician on a case-by-case basis.

- Do not use the LMA Supreme® if the unit packaging is damaged or opened.
- Do not use if the LMA Supreme® is damaged or fails any of the pre-use tests.
- Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of 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 60 cm H₂O. This pressure should not be exceeded. Excessive intra-cuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.
- The LMA Supreme® does not always reliably protect the patient from the effects of pulmonary aspiration of gastric contents.
- Should the LMA Supreme® be used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed whenever possible. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.
- In patients with severe oropharyngeal trauma, the device should only be used when other attempts to establish an airway have failed.
- If airway problems persist or ventilation is inadequate, the LMA Supreme® should be removed and an airway established by some other means.

- The presence of a gastric tube does not rule out the possibility of regurgitation.
- Do not attempt to pass a gastric tube through the drain tube in the presence of known or suspected oesophageal pathology.
- To prevent injury to the upper oesophageal sphincter, do not apply suction directly to the end of the drain tube.
- 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.
- Gloves should be worn during preparation and insertion to minimize contamination of the airway.

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® 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 anaesthesia¹.
- The LMA ProSeal® is reported to offer some protection against the aspiration of gastric contents and, as the design of the LMA Supreme® is intended to mimic that of the LMA ProSeal®, it may be assumed that the LMA Supreme® will offer similar properties.
- The incidence of sore throat following LMA® airway use is approximately 13% and is usually mild and shortlived¹.
- 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. These complications are most likely the result of malposition or excessive intra-cuff pressure, causing 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 H₂O.

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

7 PREPARATION FOR USE

7.1 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.
- Over-inflate the cuff to the appropriate volume as specified in Table 1. Check that the inflated cuff is symmetrical and smooth. There should be no uneven bulging at either ends or sides. Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes.
- While the cuff remains over-inflated, examine the inflation balloon. The balloon shape should be a thin, slightly elliptical shape, not spherical.
- While the cuff remains over-inflated, examine the drain tube. Ensure the tube is not collapsed or kinked.

Table 1 – Over-inflation Test Volumes

| | Airway size | | | | |
|-----------------------|-------------|-------|-------|-------|-------|
| | 1 | 2 | 3 | 4 | 5 |
| Over-inflation volume | 10 mL | 24 mL | 45 mL | 60 mL | 60 mL |

Caution: The volumes provided in Table 1 are for test purposes only. These volumes are not to be used during clinical use. Refer to Table 2 for recommended inflation volumes.

7.2 Pre-Insertion Preparation

- Deflate the cuff so that it forms a smooth wedge shape without wrinkles. This can be accomplished by firmly compressing the mask tip between a gloved thumb and a forefinger or between a thumb and a sterile hard surface. While firmly compressing the cuff tip and bending the cuff slightly towards the hollow side, pull the syringe gently away from the cuff to stretch the inflation line and deflate the cuff with the syringe. Maintain a vacuum when disconnecting the syringe from the valve.
- Lubricate only the posterior surface just before insertion. A water-soluble lubricant, such as K-Y Jelly® should be applied. Lubrication of the anterior surface of the airway tube may be helpful if there is excessive dryness of the oral mucosa (e.g. use of anti-sialogogues or pre-existing medical conditions). Use of lubricants containing local anaesthetic agents such as lidocaine is not recommended.

8 INSERTION

8.1 Introduction

Before insertion, it is essential that the airway manager using the LMA Supreme® is familiar with the indications, contraindications and warnings found in this manual. Before insertion, it is also important to note the following points:

- Using clinical judgment and the guidelines in Table 2, verify the correct size has been selected.
- Always have a spare sterile LMA® airway available for immediate use. Where possible, an alternative size should be available.
- Verify correct deflation and lubrication of the device.
- Pre-oxygenate and implement standard monitoring procedures.
- Check that the level (depth) of anaesthesia (or unconsciousness) is adequate before attempting insertion. A reliable clinical sign is slackness of the jaw – easy movement of the mandible following induction of anaesthesia. The absence of swallowing, during insertion, confirms adequacy of the 'depth of anaesthesia.' If swallowing is observed during insertion, remove the device and 'deepen' anaesthesia before re-insertion.

- The curvature of the device is midway between the curve of the ILMA® and the curve of the LMA Classic® or LMA Unique®. In consequence, the most successful insertion is in a semi-sniffing position. The full 'sniffing' position may cause the device to enter the glottis. The neutral position may make it hard to get around the corner at the back of the tongue.
- Excessive insertion force is never required for successful insertion and must be avoided at all times.

Table 2 – LMA® airway selection guidelines

| | Airway size | | | | |
|-----------------------------|------------------------|------------|------------|------------|-------------|
| | 1 | 2 | 3 | 4 | 5 |
| Patient weight | < 5 kg | 10 - 20 kg | 30 - 50 kg | 50 - 70 kg | 70 - 100 kg |
| Maximum inflation volume | 5 mL | 12 mL | 30 mL | 45 mL | 45 mL |
| Optimum intra-cuff pressure | 60 cm H ₂ O | | | | |

8.2 Insertion Technique

During insertion, stand behind the patient's head, hold the LMA Supreme® by the connector end with the hollow side facing away and the distal end pointing downwards. Under direct vision, position the mask tip so that it is flat (i.e. not folded) against the hard palate just inside the mouth immediately posterior to the upper incisors. Slide the mask tip briefly back and forth on the palate to distribute lubricant while pressing it against the palate to prevent accidental folding of the tip. It may be necessary to draw the mouth open momentarily to permit the widest part of the mask to enter

the oral cavity. Do not use the airway tube as a lever to force the mouth open. Keeping the airway tube close to the chin, rotate the device inwards in one smooth circular movement. While rotating the device inwards, it is often helpful to direct the distal end of the mask somewhat towards the right or left side of the throat. Advance the airway into the hypopharynx until a definite resistance is felt. At this point, the LMA Supreme® should be correctly located with the drain tube near the upper oesophageal sphincter.

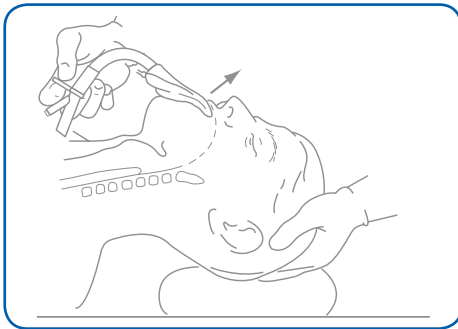


Figure 3 – Press the tip of the cuff against the hard palate.

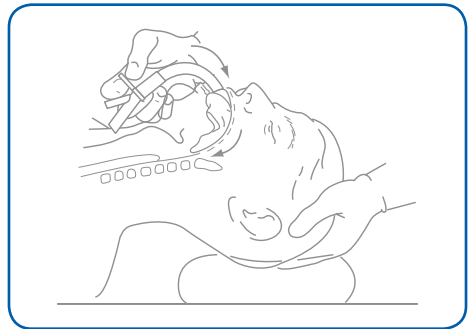


Figure 5 – Swing the device inward with a circular motion, pressing against the contours of the hard and soft palate.

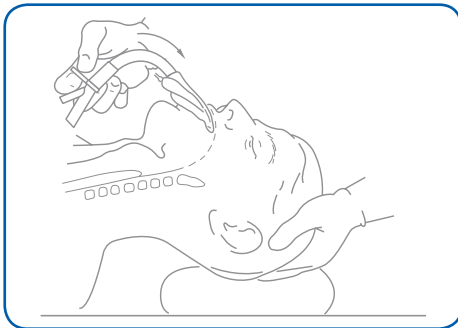


Figure 4 – Press the cuff further into the mouth maintaining pressure against the palate.

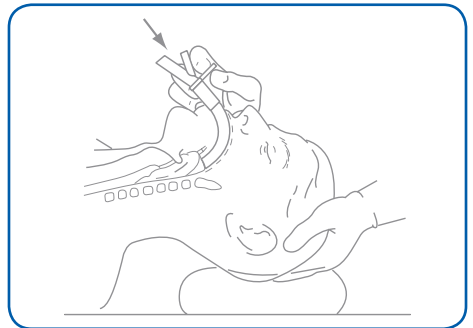


Figure 6 – Advance the LMA Supreme® into the hypopharynx until resistance is felt.

8.3 Insertion Problems

An adequate depth of anaesthesia allows easy mouth opening. An inadequate depth of anaesthesia may result in difficulty in mouth opening, swallowing during insertion attempts, coughing and breath-holding during insertion. If this occurs, deepen anaesthesia immediately with inhalational or intravenous agents and institute manual ventilation.

If the patient's mouth cannot be opened sufficiently to insert the mask, first ensure that the patient is adequately anesthetized. An assistant can be asked to pull the jaw downward. This manoeuvre makes it easier to see into the mouth and verify the position of the mask. However, do not maintain downward jaw traction once the mask has passed beyond the teeth.

An important part of the technique is observation of insertion with the cuff pressed against the hard palate behind the upper incisors and then the soft palate en route the upper oesophageal sphincter, otherwise the tip may fold on itself or collide with the epiglottis and not arrive at the upper oesophageal sphincter. If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it. In case of tonsillar obstruction or a high arched palate, a lateral approach or a diagonal shift of the mask is recommended.

8.4 Inflation

After insertion, the airway tube should emerge from the mouth directed caudally. Without holding the tube, inflate the cuff with just enough air to achieve a 'just seal' pressure to positive pressure ventilation or an intra-cuff pressure of 60 cm H₂O. (Note: see Table 2 for maximum clinical inflation volume). Frequently, only half the maximum inflation volumes are sufficient to obtain an adequate seal. (Warning: Never overinflate the cuff). Avoid intra-cuff pressures greater than 60 cm H₂O. It is important to appreciate that incremental amounts of air added to the PVC cuff of the LMA Supreme® above that required to achieve the recommended intra-cuff pressure of 60 cm H₂O may result in disproportionate increases in intra-cuff pressures. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location. A small outward movement of the tube is sometimes noted as the device seats itself in the hypopharynx.

The initial cuff volume will vary according to the patient, size of airway used, head position, and anaesthetic depth. The signs of correct placement may include one or more of the following :

- the slight outward movement of the tube upon inflation.
- the presence of a smooth oval swelling in the neck around the thyroid and cricoid area.
- cuff not visible in the oral cavity.

8.5 Connecting to the anaesthetic system

Taking care to avoid dislodgment, connect to the anaesthetic circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. Auscultation and capnography should be used to confirm adequate gas exchange. Auscultate in the anterolateral neck region to check for abnormal sounds that might indicate mild laryngeal spasm or light anaesthesia.

8.6 Diagnosis of Correct Position

When inserting and inflating the LMA Supreme®, look carefully at the front of the neck to observe whether the cricoid cartilage moves forward, indicating correct passage of the mask tip behind it. Correct placement should produce a leak-free seal against the glottis with the mask tip at the upper oesophageal sphincter. The bite block should lie between the teeth. If the mask lies too proximal as the result of incomplete insertion, gas will leak from the proximal end of the drain tube when the lungs are inflated. This situation must be corrected by repositioning the mask. Do not attempt to overcome the leak by occluding the drain tube, or by over-inflation of the cuff.

The drain tube provides additional means to diagnose correct placement. To facilitate diagnosis of correct mask placement, place a small bolus (1-2 ml) of water soluble gel as a continuous column 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 during PPV. A similar 'up and down' movement of the meniscus should be seen following the application and release of gentle pressure in the suprasternal notch and indicates that the distal end of the drain tube is not occluded (the 'supra sternal notch

test'). If there is no movement of the meniscus, the device needs to be re-positioned or the patency of the drain tube confirmed by the passage of an adequately sized (16 Fr or less), lubricated gastric tube to the tip. This distance is easily measured by the passage of a gastric tube into a similar sized LMA Supreme® to the tip. Alternatively, this may be confirmed with a fibre optic scope.

It is not necessary to insert the gastric tube into the stomach to confirm patency of the distal tip as this may cause unwanted stimulation or may be undesirable in patients with suspected oesophageal pathology. Poor insertion or poor deflation may also cause the tip of the mask to fold back on itself in the hypopharynx, causing the drain tube to become obstructed. If the tip is folded back, there may be a lack of meniscus movement in the lubricating gel when performing the 'supra sternal notch test'.

Occasionally a poorly deflated or inserted mask may enter the vestibule of the larynx. In this situation, there may be some obstruction to ventilation and gas may leak from the proximal end of the drain tube. In spite of adequate anaesthesia, obstruction worsens if the mask is pressed in further. The mask should be removed and reinserted.

To distinguish between the mask lying too high and having entered the glottis, press the mask further inwards. This overcomes a leak if the mask is too high, but causes increased obstruction to ventilation if the mask tip has entered the glottis. If leaks occur from the drain tube even though the device is correctly positioned, this may indicate a damaged device (e.g., a torn or perforated internal drain tube). Warning: Do not use if the device is damaged in any way.

8.7 Device Fixation

Secure the LMA Supreme® to the patient's face with adhesive tape. The LMA Supreme® has an integral fixation tab. Hold a length of adhesive tape horizontally by both ends, lay the middle transversely across the fixation tab and press both ends of the tape down onto each of the patient's maxillae; this presses the device inwards. This operation should be done gently without excessive force. If the fixation tab is then found to be in contact with the patient's upper lip, the device may be too small for the patient. If after fixation, the fixation tab is more than 2.5 cm from the upper lip, this indicates that the device may be too big for the patient. (Caution: Do not use an oral Guedel airway as a bite block because it will prevent correct positioning of the cuff increasing the risk of trauma and reducing seal effectiveness.) The LMA Supreme® has a built-in bite block.

9 ANAESTHESIA MAINTENANCE AND RECOVERY

9.1 Spontaneous Ventilation

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. Coughing, breath-holding, or movement may result if the induction agent is allowed to wear off before adequate levels of anaesthesia for maintenance have been obtained. This is particularly likely to occur following the introduction of an external stimulus such as surgery or turning the patient when the level of anaesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

9.2 Positive Pressure Ventilation (PPV)

The following points should be observed when using the LMA Supreme® with PPV:

- Tidal volumes should not exceed 8 ml/kg and peak inspiratory pressures should be kept within 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.
- Should air leakage through the drain tube be observed during PPV, even though anaesthesia is adequate, this may be due to the mask having migrated proximally. Ensure the securing tape is still in place and readjust as necessary while pressing the tube downward to relocate the mask tip against the upper oesophageal sphincter. (Caution: In the event of a leak around the cuff, do not simply add more air to the cuff. This will not necessarily improve the seal pressure and may make the leak worse by adding tension to the normally soft cuff, pushing it away from the larynx.) The leak may indicate returning tone of the pharyngeal muscles and indicate that anaesthesia needs to be 'deepened'.

9.3 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 3 for maximum gastric tube sizes.

If it is clinically indicated to pass a gastric tube into the stomach, 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 cause possible injury to the upper oesophageal sphincter.

The gastric tube should be well lubricated and passed slowly and carefully. When such tubes are used, it is important to avoid the potential for trauma associated with excessive tube rigidity. For this reason, do not use gastric tubes that have been stiffened by refrigeration. Ensure the tube is at or above room temperature. Some initial resistance is often detected as the tip of the gastric

tube is pressed gently against the upper oesophageal sphincter. This may be due to reflex tightening of the sphincter in response to the stimulus being applied. The resistance produced in this way usually vanishes after three to four seconds provided the tube is not repeatedly poked against the sphincter. Force must never be used.

If a tube of appropriate size fails to pass even when correctly used, the mask or drain tube may be kinked or malpositioned. In these cases, the mask should be removed and reinserted. Never try to force the tube through.

Table 3 – Maximum Gastric tube sizes

| Airway size | Largest OG Tube |
|-------------|-----------------|
| 1 | 6 Fr |
| 2 | 10 Fr |
| 3 | 14 Fr |
| 4 | 14 Fr |
| 5 | 14 Fr |

9.4 Potential Problems after Insertion

9.4.1 Inadequate level of anaesthesia

The most common problem following insertion is failure to maintain an adequate level of anaesthesia. Administer an additional bolus of induction agent and/or increase the concentration of volatile agent, while gently assisting ventilation.

9.4.2 Poor airway seal / Air leak

Should signs of a poor airway seal or air leak occur at the beginning or during a case, one or more of the following measures may be taken:

- Verify the depth of anaesthesia is adequate and deepen if necessary.
- Check cuff pressures at start and periodically during a case.
- Ensure intra-cuff pressures are not more than 60 cm H₂O; reduce intra-cuff pressure, if necessary, while maintaining an adequate seal.
- If the mask is seated too high in the pharynx, leakage will occur through the drain tube and indicates that the mask should be

inserted further into the oropharynx.

- Ensure proper fixation as described in the Device Fixation section of this manual on the correct device fixation method.
- Always confirm cuff integrity prior to placement.

9.4.3 Malposition of the LMA Supreme®

In general, malposition of the LMA Supreme® becomes clinically obvious as soon as it occurs and malposition is diagnosed without the need for fibre-optic laryngoscopy. During positive pressure ventilation (PPV), the detection of a leak through the drain tube suggests that the tip of the cuff has not reached the upper oesophageal sphincter or has been displaced outwards. Failure to achieve an adequate seal together with gas leakage around the cuff as well as through the drain tube suggests that the distal end of the cuff is in the laryngeal inlet. An abnormal capnographic trace and a large discrepancy between inspired and expired tidal volumes will confirm the clinical observation of incorrect cuff position causing leakage. If malposition is suspected, the LMA Supreme® may be removed and reinserted once anaesthetic depth is adequate for reinsertion.

9.4.4 Unexpected regurgitation

Even in fasted patients, regurgitation may occur for a variety of reasons (for example, if anaesthesia becomes inadequate), resulting in fluid emerging from the drain tube.

If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the LMA Supreme® **should not be removed**. Check that the device is still correctly fixed in place and has not become displaced. When correctly placed and fixed in position, published experiences and experimental work (using the LMA ProSeal®) both indicate that liquid gastric contents normally pass harmlessly from the oesophagus into the drain tube and exit at its proximal end.

In the event that the device has become displaced, it should at once be repositioned and re-taped into place. In this situation, gastric contents may have entered the airway tube or the larynx or both. To facilitate removal and prevent lung contamination, the patient should immediately be tilted head down. Verify that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate.

Momentarily disconnect the anaesthetic circuit so that gastric

contents are not forced into the lungs, and can pass out through the wide bored airway tube. Pass a suction catheter down the airway tube and suction out any contents. Re-connect the airway tube to 100% oxygen and gently insufflate the lungs. Next, pass a well lubricated gastric tube of appropriate bore down the drain tube and into the stomach and suction out any liquid left in the stomach. Verify that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate.

Pass a fibreoptic bronchoscope down the airway tube and inspect the laryngeal inlet and then further down in the trachea. Suction out any contents seen. If aspiration is suspected, the patient should be treated expectantly and kept under observation with pulse oximetry and if indicated, arterial blood gas analysis. Radiological examination and appropriate antibiotic therapy should be instituted in keeping with clinical findings. Tracheal intubation is rarely necessary and should not be used 'prophylactically'. It should be reserved for use only if clinically warranted.

9.5 Emergence from Anaesthesia and Removal

If applicable, reverse the neuromuscular block or allow the block to wear off before switching off the anaesthetic agents at the end of the surgical or diagnostic procedure. With gentle assisted ventilation, the patient should be allowed to start breathing spontaneously. At this stage, it is advisable to check and if necessary reduce the intra-cuff pressure since returning pharyngeal constrictor tone tends to increase intracuff pressure, sometimes to a level which constitutes a painful pharyngeal stimulus.

The correctly placed LMA Supreme® is well tolerated until the return of protective reflexes, if intra-cuff pressures are kept around 60 cm H₂O. This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal should always be carried out by trained personnel in the operating theatre or in the post anaesthetic care unit i.e with access to suction and other appropriate equipment. The following procedure should be followed :

- Patient monitoring should continue throughout the recovery stage. Oxygen should be continuously administered through the anaesthetic circuit or via a T-piece. Suctioning is rarely necessary because the device effectively protects the larynx from oral secretions and should only be removed when an effective swallowing reflex is present.
- Leave the patient undisturbed until reflexes are restored, except

to administer oxygen and perform monitoring procedures. It is not necessary to position the patient in the 'classical' recovery position, unless clinically indicated.

- Avoid suctioning the airway with the LMA Supreme® in place. The inflated cuff protects the larynx from oral secretions and suctioning is not likely to be required. Suctioning and physical stimulation may provoke 'glottic closure' which mimics laryngeal spasm if anaesthesia is light.
- Watch for signs of swallowing. It is usually safe and convenient to remove adhesive tape when swallowing begins. However, the interval between the beginning of swallowing and the ability to open the mouth varies from patient to patient according to the length and type of anaesthesia.
- Deflate the cuff and simultaneously remove the device only when the patient can open the mouth on command. If the cuff is deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm. Verify airway patency and respiratory depth. Oral suctioning may now be performed, if required.

If the LMA Supreme® is to be removed in a Post-Anaesthesia Care Unit (PACU), recovery room staff should receive training in all aspects of LMA® airway management. An anaesthesiologist should always be readily available if the device is to be removed away from the operating room.

10 SPECIALIZED USE

- The LMA Supreme® is not designed to be used for fibre optic guided intubations or blind tracheal intubations and this should not be attempted.
- MR conditional testing has been performed to determine the compatibility of LMA Supreme® with MRI. Prior to using LMA Supreme® in MRI environment, the equipment and test conditions described with those planned for use in the actual clinical environment should be compared. Refer 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 the 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 IMR 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 the device may be necessary.

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