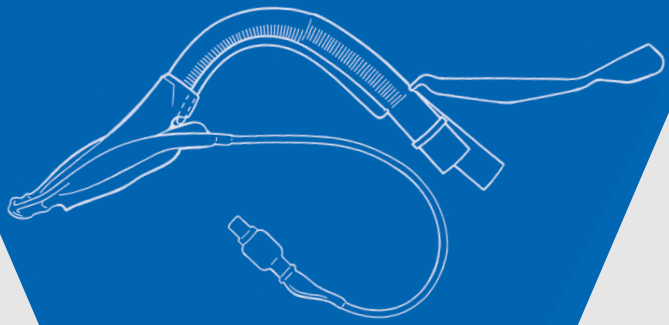
LMA -ProSeal™

Instruction Manual



The LARYNGEAL MASK Company Limited

LMA -ProSeal™

Instruction Manual

The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Manufacturer's Warranty: The *LMA-ProSeal*™ is reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

LMA-PROSEAL™ USAGE OVERVIEW

Preparation

- Fully deflate the *LMA-ProSeal*™ to a high vacuum immediately before it is sterilised
- Do not allow water to enter the *LMA-ProSeal*™
- Carry out the performance tests before each use

Insertion

- Ensure correct deflation of the *LMA-ProSeal*™ before attempting insertion
- Use one of the recommended insertion techniques; do not use non-recommended techniques
- Do not use excessive force to insert the *LMA-ProSeal*™
- If using the *LMA-ProSeal*™ *Introducer*, always remove it from the *LMA-ProSeal*™ after insertion and before inflation
- Use sufficient lubricant to prevent the mask folding backwards during insertion

Inflation and positioning

- Inflate to a "just seal" pressure. Do not inflate to more than 60cm H_20 intracuff pressure
- Check for correct placement of the *LMA-ProSeal*™ by gentle lung inflation
  - If gas leaks through the drain tube, the device must be repositioned more deeply
  - If there is obstruction to lung inflation, remove the device and reinsert
- Ensure the bite-block is between the teeth

Oro-gastric tube

- Do not pass an oro-gastric tube when there is either airway obstruction or an inadequate seal
- Do not pass an oro-gastric tube when there is known or suspected oesopharyngeal damage
- Do not cool or refrigerate an oro-gastric tube before use

Reuse

- Do not use the *LMA-ProSeal*™ more than 40 times

CONTENTS

1 DEVICE DESCRIPTION

The *LMA*™ is an innovative supraglottic airway management device. Since its commercial introduction in 1988, the *LMA*™ has been used in over 100 million patients for routine and emergency procedures.

The *LMA-ProSeal*™ is an advanced form of *LMA*™ that may be used for the same indications as the original *LMA*™ (now known as the *LMA-Classic*™). The *LMA-ProSeal*™ is designed to provide additional benefits over the *LMA-Classic*™ that extend the range of procedures for which an *LMA*™ is indicated.

The *LMA-ProSeal*™ has four main components: mask, inflation line with pilot balloon, airway tube and drain tube (figure 1).

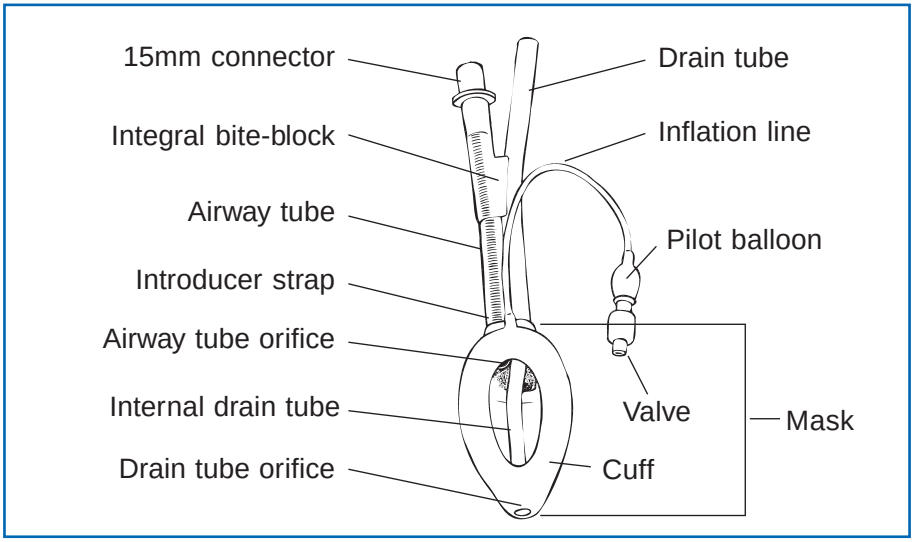


Figure 1: The components of the *LMA-ProSeal™*

The mask is designed to conform to the contours of the hypopharynx, with its lumen facing the laryngeal opening. The mask has a main cuff that seals around the laryngeal opening and a rear cuff which helps to increase the seal. Attached to the mask is an inflation line terminating in a pilot balloon and valve for mask inflation and deflation.

A drain tube passes lateral to the airway tube and traverses the floor of the mask opening at the mask tip opposite the upper oesophageal sphincter. The airway tube is wire reinforced to prevent collapse and terminates with a standard 15mm connector.

A removable introducer tool (the *LMA-ProSeal*™ *Introducer*) is available to aid insertion if it is desirable to avoid placing a finger in the patient's mouth. It is supplied in the recommended curvature for immediate use.

A dedicated deflation device (*LMA-ProSeal*™ *Cuff-Deflator*) is available to aid complete deflation for successful sterilisation, optimum insertion and positioning in the patient.

All components are latex free. The Laryngeal Mask Company recommends that the *LMA-ProSeal*™ be used a maximum of 40 times before being discarded.

In addition to the well known characteristics of the *LMA-Classic*™, the new *LMA-ProSeal*™ offers the following features:

- A revised cuff arrangement, which allows a higher seal than the *LMA-Classic*™ for a given intra-cuff pressure[1, 2, 3].
- A channel (or drain tube) opening at the upper oesophageal sphincter to permit drainage of gastric secretions and access to the alimentary tract. The tube is also intended to prevent inadvertent gastric insufflation.
- A drain tube which allows for blind insertion of standard oro-gastric tubes, in any patient position, without the need to use Magill's forceps.
- A double tube arrangement which reduces the likelihood of mask rotation; the revised cuff profile, together with the flexible tubes, result in the device being more securely anchored in place.
- A built-in bite-block which reduces the danger of airway obstruction or tube damage.
- A location strap for the *LMA-ProSeal*™ *Introducer*, which also accommodates the index finger or thumb for manual insertion (figure 2).
- The position of the drain tube inside the cuff prevents the epiglottis occluding the airway tube. This eliminates the need for aperture bars.

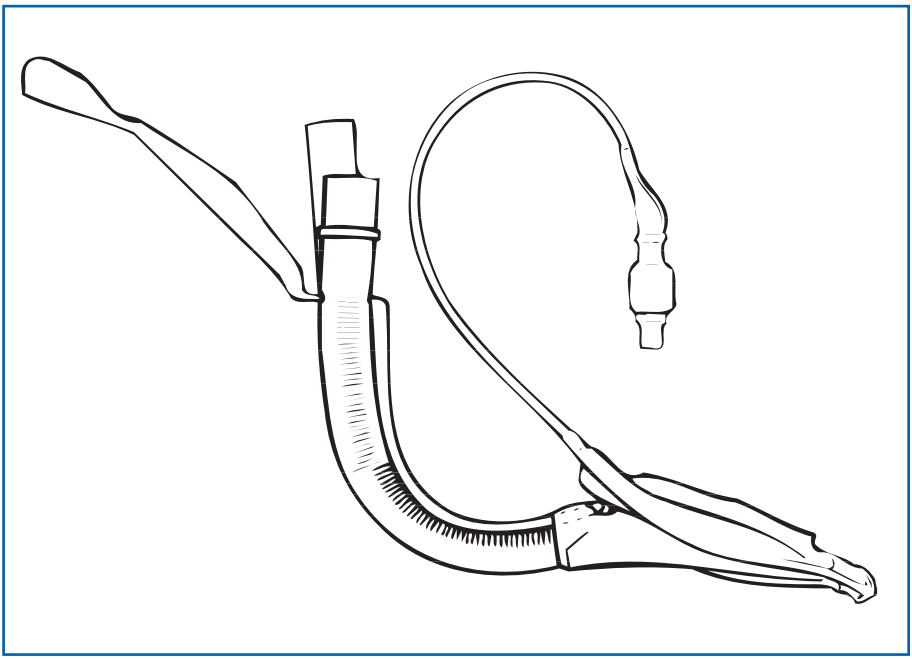


Figure 2: *LMA-ProSeal™* with *LMA-ProSeal™ Introducer* in place

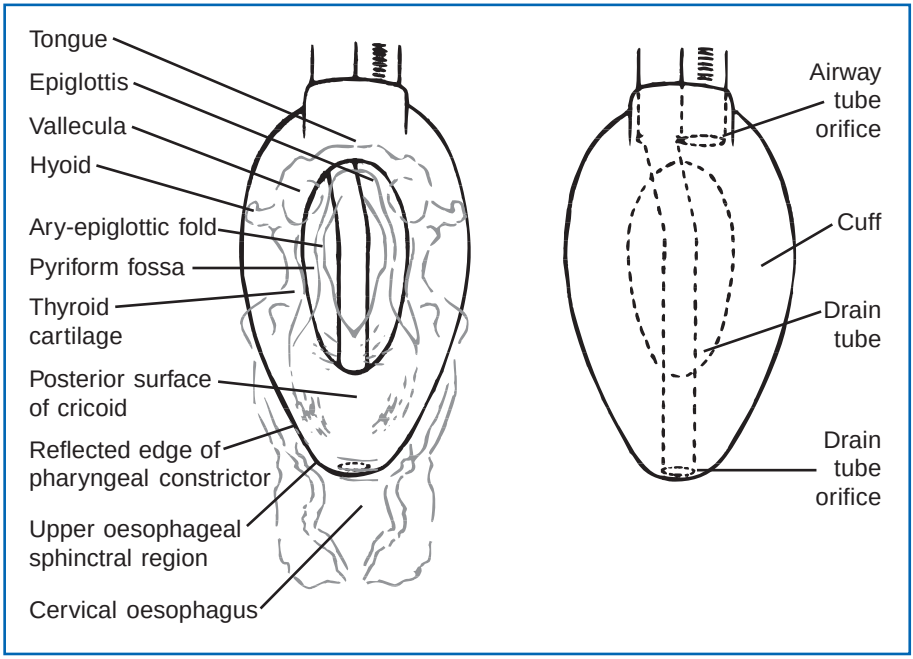


Figure 3: Dorsal view of the *LMA-ProSeal™* showing position in relation to pharyngeal anatomy

The *LMA-ProSeal™* is designed to be a minimally stimulating airway device. When fully inserted using the recommended insertion technique, the distal tip of the cuff presses against the upper oesophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue (figure 3).

2 INDICATIONS AND CONTRAINDICATIONS

2.1 Indications

The *LMA-ProSeal™* is indicated for use in achieving and maintaining control of the airway. It may be used with spontaneous and Positive Pressure Ventilation (PPV) during routine and emergency anaesthetic procedures, in fasted patients. It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.

The *LMA-ProSeal™* may be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes requiring artificial ventilation. 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.

2.2 Contraindications

There is currently insufficient data to support the use of the *LMA-ProSeal*™ in non-fasted patients. It is therefore contraindicated in non-fasted patients or patients who may have retained gastric contents until such time as data becomes available[4], (except in the "cannot intubate-cannot ventilate" situations in which the user must decide on the risk-benefit ratio of using this device).

When used in the profoundly unresponsive patient in need of CPR, the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway in a potentially "non-fasted" patient.

Do not attempt to pass an oro-gastric tube through the *LMA-ProSeal*™ in the following circumstances: gas leaking through the drain tube (section 6.11), or the presence of known or suspected oesophageal damage.

3 WARNINGS

The user should be familiar with the following warnings when considering or attempting *LMA-ProSeal*™ use:

- As with all devices, the components will degrade over time and therefore the number of uses must be limited. With proper cleaning, sterilisation and handling, the *LMA-ProSeal*™ has **a maximum of 40 uses**. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device. The manufacturer can accept no liability for failure beyond 40 uses.
- A 40-Use record card is supplied with every *LMA-ProSeal*™ to record the number and dates of usage. Completion of the record card validates the warranty of the device.
- The performance tests described in section 5.4 of this manual must be carried out before each use of the device. Failure of any one performance test indicates that the device has passed its useful life and must be discarded.
- Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.
- The cuff is designed to be inflated to a low pressure (approximately 60cm H_2O). Overinflation may not improve the seal, may be associated with mucosal ischaemia, may cause the device to be dislodged, and may cause the drain tube to collapse. If higher pressures are required to achieve a seal, it is recommended that a larger size *LMA-ProSeal*™ be used. In general, it is recommended that the largest size which remains in place when inflated to a pressure of 60cm H_2O should be used.
- Inadequate anaesthesia may lead to coughing, breath-holding or laryngeal spasm.
- Do not attempt to pass an oro-gastric tube that has been refrigerated through the *LMA-ProSeal*™.
- Do not use excessive force.

4 ADVERSE EFFECTS

There is currently no data documenting significant adverse effects. Until such time as data becomes available, it should be assumed that a similar incidence and range of adverse events may occur with the *LMA-ProSeal™* as occurs with the *LMA-Classic™*.

Some instances of minor adverse effects (eg sore throat) and major adverse effects (eg aspiration), following use of the *LMA-Classic™*, have been reported in the published literature. However, there have been no reports of death directly attributable to the *LMA-Classic™* in over 100 million uses of the device worldwide.

- A review of published literature suggests that the incidence of aspiration with the *LMA-Classic™* is low (~2:10,000) and is comparable to the incidence of aspiration associated with outpatient general anaesthesia using the facemask or endotracheal tube.
- The incidence of sore throat following *LMA-Classic™* use is approximately 10% (range 0-70%) and is usually mild and short-lived. Severe or prolonged sore throat, sometimes accompanied by dysphagia, has been reported in patients in whom an improperly cleaned or sterilised device has been used.
- Unusual neurovascular events reported with *LMA-Classic™* use include rare cases of hypoglossal nerve injury, transient tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, and vocal cord paralysis. These complications could result from poor insertion techniques or excessive cuff pressure. However, a clear relationship to the use of the *LMA-Classic™* has not been established.

5 PREPARATION FOR USE

With proper cleaning, sterilisation and handling, the *LMA-ProSeal™* can be safely used 40 times.

The device is delivered non-sterile and must be cleaned and sterilised before initial use **and before each subsequent use.** The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

5.1 Cleaning

Thoroughly wash the cuff, airway tube and drain tube in warm water, using a dilute (8-10% w/w) sodium bicarbonate solution until all visible foreign matter is removed. Ensure the areas behind the *LMA-ProSeal™ Introducer* strap and under the internal drain tube are clean. Clean the tubes using a small soft bristle brush (approximately ¼ inch or 6mm in diameter for adult size devices). Gently insert the brush through the proximal (outer) end of the drain tube.

Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues. Carefully inspect the *LMA-ProSeal™* to ensure that all visible foreign matter has been removed. Care should be taken to ensure that water does not enter the device through the valve.

Repeat the above as necessary.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with *LMA-ProSeal*™ use is Endozime® (Ruhof, Valley Stream, NY).

Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (eg Cidex®), ethylene oxide, phenol-based cleaners or iodine-containing cleaners for cleaning or sterilising. Such substances are absorbed by the materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use an *LMA-ProSeal*™ that has been exposed to any of these substances.

Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

5.2 Sterilisation

Steam autoclaving is the only recommended method for sterilisation of the *LMA-ProSeal*™. Adherence to the following procedure is essential to ensure sterilisation without damage:

- **Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backwards to obtain a high vacuum. For complete deflation, it is recommended that the *LMA-ProSeal*™ *Cuff-Deflator* (available from the distributor) is used. Ensure that both the syringe used to deflate the cuff and the valve are dry.** (Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage to the cuff.) Remove the syringe from the valve port after deflation.
- If a deflated mask immediately and spontaneously re-inflates after the syringe has been removed, do not autoclave or reuse the mask. This indicates that the device is defective. It is normal, however, for the cuff to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.
- Always follow the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilisation, provided the maximum temperature does not exceed 135°C or 275°F. The integrity of the materials may be adversely affected by exceeding these temperatures.
- Autoclaves vary in design and performance characteristics. Cycle parameters should therefore always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.
- Healthcare personnel are responsible for adhering to the appropriate sterilisation processes which have been specified. Failure to do so may invalidate the sterilisation process of the healthcare facility.
- After autoclaving, allow to cool to room temperature before use.

Note: Do not use the *LMA-ProSeal*™ if it displays any visible damage.

5.3 Cleaning and sterilisation of the *LMA-ProSeal™ Introducer* and *Cuff-Deflator*

The *LMA-ProSeal™ Introducer* and *Cuff-Deflator* should be cleaned and sterilised in the same manner as the *LMA-ProSeal™*. The same cautions apply.

5.4 Performance tests

All of the non-clinical tests described below must be conducted before each use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimises contamination before insertion.

Failure of any one test indicates that the device has passed its useful life and should be replaced.

Performance test 1: Visual inspection

- Ensure that the thin-walled section of the drain tube lying within the mask bowl is not torn or perforated, and that there is no contamination between the tube and the mask.
- Examine the transparency of the tubes. The tubes will gradually discolour with age and reuse. Do not use the *LMA-ProSeal™* if the tubes are discoloured as this impairs the ability to see and effectively remove foreign particles during cleaning, or to see regurgitated fluids during use.
- Examine the surface of the device for damage, including cuts, tears or scratches. Do not use if the device is damaged in any way. Examine the interior of the mask bowl and of the airway and drain tubes to ensure that they are free from blockages or loose particles. Any particles present in the mask or tubes should be removed as they may be inhaled by the patient after insertion.
- Examine the 15mm connector. It should fit tightly into the outer end of the airway tube. Ensure that it cannot easily be pulled off by hand using reasonable force. Do not use excessive force or twist the connector as this may break the seal.

Performance test 2: Inflation and deflation

- Using a syringe, fully deflate the device so that the cuff walls are tightly flattened against each other. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other. Do not use if the cuff walls re-inflate immediately and spontaneously, even if only slightly.
- Inflate the cuff from complete vacuum with 50% more air than the recommended maximum inflation volume (see table on inside rear cover of manual). Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes. Examine the symmetry of the inflated cuff. There should be no asymmetrical bulging at either end or sides. Inspect the interior of the drain tube from both ends of the mask. Ensure that the thin walled section of the tube is not collapsed where it passes through the distal end of the mask.
- While the device remains 50% over-inflated, examine the inflation pilot balloon. The balloon shape should be a thin, slightly flattened elliptical shape, not spherical.

5.5 Pre-insertion preparation

Prior to insertion (and sterilisation) of the device, the cuff should be fully deflated to a flattened wedge shape. The cuff walls should not have any wrinkles and the cuff should be straight at the distal end (figures 6a and 6b).

This shape facilitates atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the vallecullae or glottis and avoids it becoming caught against the epiglottis or the arytenoids.

The correct cuff shape can be accomplished through use of the *LMA-ProSeal™ Cuff-Deflator* (figure 4), available from the distributor.

Note: Gloves should be worn while handling the sterilised *LMA-ProSeal™* and pre-use checks should have been carried out as per the instruction manual.

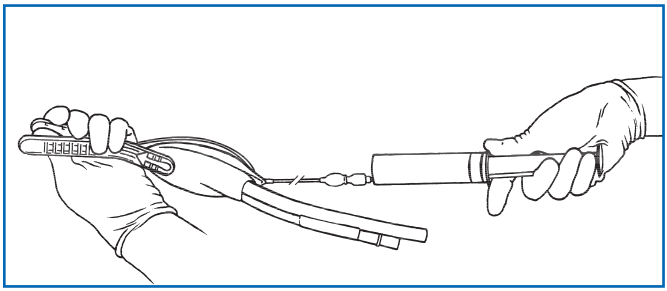


Figure 4: *LMA-ProSeal™* being used with the *LMA-ProSeal™ Cuff-Deflator*

Directions for use of the LMA-ProSeal™ Cuff-Deflator

- Squeeze the handles of the *Cuff-Deflator* to open the jaws
- Insert the *LMA-ProSeal™*, partially inflated, with its distal end exactly level with the tip of the indicating arrow, as shown
- The mask bowl should face the curved surface of the *Cuff-Deflator*
- Release the handles to compress the mask
- Use a syringe to deflate the cuff
- Whilst deflating, pull back gently on the inflation line to ensure all air is removed from the mask
- Deflate to a vacuum and disconnect the syringe whilst maintaining as high a vacuum as possible
- Squeeze the *Cuff-Deflator* handles again to release the *LMA-ProSeal™*
- Ensure that the back of the mask is straight, without any curvature of the distal end; the distal end should be maximally flattened.

Note: If the distal end is not maximally flattened or there is evidence of air in the cuff, partially reinflate the cuff and repeat the procedure.

Alternative methods of cuff deflation

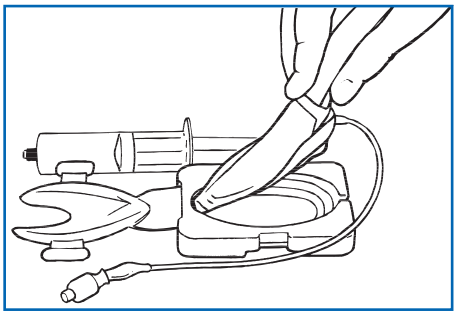


Figure 4a: *LMA-ProSeal™ being used with the silicone LMA-ProSeal™ Cuff-Deflator*

Figure 4a shows deflation using the original silicone *LMA-ProSeal™ Cuff-Deflator.* Alternatively, the device can be deflated manually by compressing the distal end between finger and thumb (figure 5) to obtain the correct cuff shape. The same principles and results apply in all methods of device deflation.

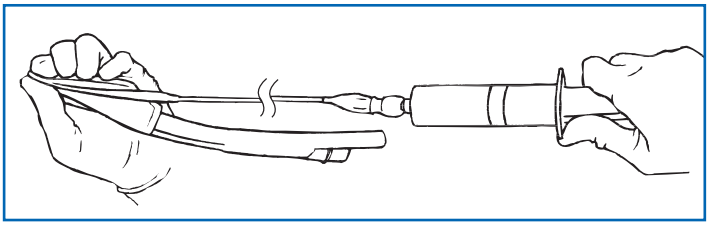
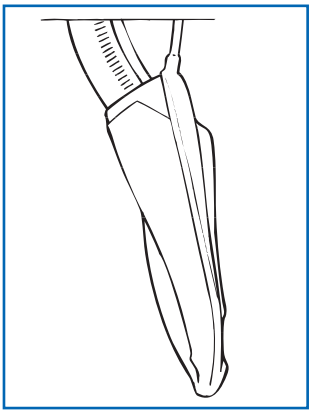
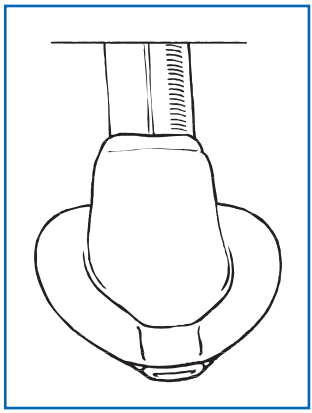


Figure 5: Manual deflation of *LMA-ProSeal™ (note manual pressure at tip)*





Figures 6a and 6b: *LMA-ProSeal™* cuff properly deflated for insertion

Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant. It is recommended that a bolus of lubricant be applied to the posterior tip of the deflated cuff. It is not necessary to spread the lubricant over the mask surface.

A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the *LMA-ProSeal™* components. Lubricants containing Lidocaine are not recommended. Lidocaine may delay the return of protective reflexes and may provoke an allergic reaction.

6 INSERTION

6.1 Introduction

Before using the *LMA-ProSeal™*, the user should be familiar with the instructions contained in this manual. If the device is inserted incorrectly, an unreliable or obstructed airway may be obtained. Before insertion, it is important to note the following points:

- Check that the size of the *LMA-ProSeal™* is appropriate for the patient (see table on inside rear cover of manual). The ranges are approximate and clinical judgment should be used in selecting an appropriate size.
- Check the shape of the cuff and its lubrication, as described in section 5.5.
- Have a spare sterile device ready and prepared for immediate use. Where possible, an alternative size should be available.
- Pre-oxygenate and implement standard monitoring procedures.
- Achieve an adequate level of anaesthesia before attempting insertion. Resistance, biting or retching indicates inadequate anaesthesia and/or inappropriate technique. In general, inexperienced users should choose a deeper level of anaesthesia.
- The ideal head position is extension of the head with flexion of the neck in the position normally used for tracheal intubation ("the sniffing position"). This can be achieved by pushing the head from behind with the non-dominant hand during the movement of insertion. A pillow can also be used to keep the neck flexed.
- When using the *LMA-ProSeal™ Introducer*, it may be possible to reduce or eliminate head and neck manipulation.
- Excess force must be avoided at all times.

6.2 Induction methods

The following induction methods are compatible with the insertion of the *LMA-ProSeal™*:

- **Propofol.** This is the agent of choice for insertion as it optimally obtunds upper airway reflexes. Between 2.5 and 3mg/kg may be necessary in unpremedicated ASA I patients (check the drug manufacturer's prescribing information for details). Insertion can often be achieved within 30 seconds after induction in fit young adults, particularly if induction is preceded by a sedative agent such as Midazolam (2-5mg intravenously).
- **Inhalational induction.** This provides excellent conditions for insertion in children and in some adults. The depth required is slightly more than that required for insertion of a Guedel-type airway. However, the inexperienced user should insert the device at an anaesthesia level closer to that required for surgical procedures.

- **Thiopentone or other barbiturate induction.** Barbiturates on their own are not ideal induction agents for insertion. If used on their own, it is recommended that anaesthesia be deepened using an inhalational agent for several minutes before attempting insertion. Co-induction, using Midazolam 2-5mg intravenously three minutes before induction with Thiopentone, optimises *LMA-ProSeal™* insertion conditions (ie simulates conditions using Propofol).

6.3 Insertion methods

To position the device correctly, the cuff tip must be prevented from entering the valleculae or the glottic opening and must not become caught up against the epiglottis or the arytenoids. To achieve this, the cuff must always be deflated to a vacuum by pulling firmly back on the deflating syringe in order to form the correct wedge shape shown in figures 6a and 6b. During insertion, this wedge shape should be kept pressed against the patient's pharyngeal wall.

Assuming correct preparation, the device may be inserted using one of three methods. The *LMA-ProSeal™ Introducer* may be used, or insertion may be performed using the index finger or the thumb in a similar manner to the *LMA-Classic™*. All three techniques follow the same principles.

6.4 *LMA-ProSeal™ Introducer* insertion technique

Place the tip of the *LMA-ProSeal™ Introducer* into the retaining strap at the rear of the cuff (figure 7a). Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the tool (figure 7b).

The device is shown mounted on the *LMA-ProSeal™ Introducer* in figure 8.

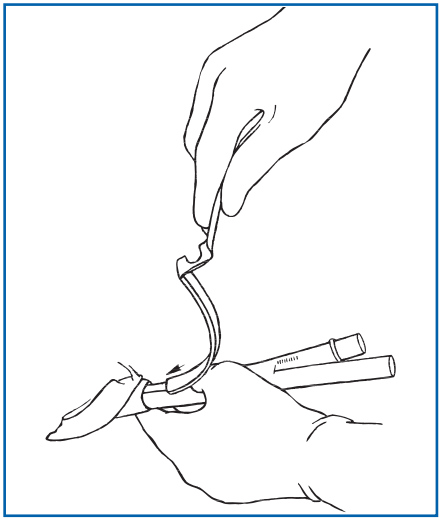


Figure 7a: Place the tip of the *LMA-ProSeal™ Introducer* into the strap

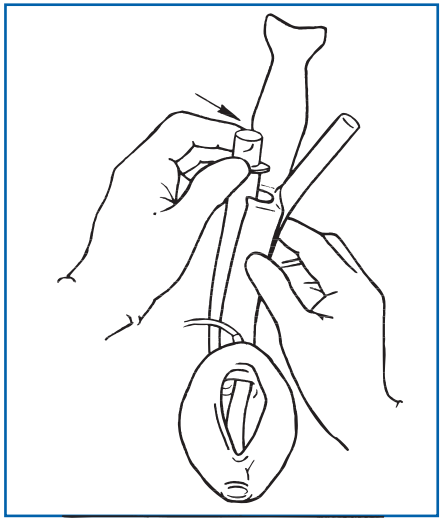


Figure 7b: Fold the tubes around the *LMA-ProSeal™ Introducer* and fit the proximal end of the airway tube in the matching slot

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it (figure 9). Slide the cuff further inwards against the palate (figure 10). You may push the jaw downwards momentarily to assist entry between the teeth.

A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff has not folded over.

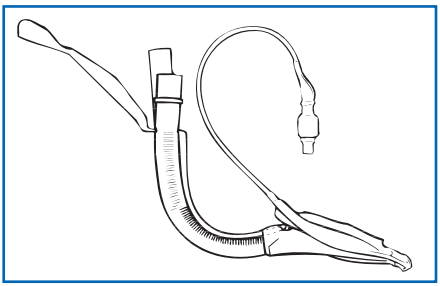


Figure 8: *LMA-ProSeal™* mounted on the *LMA-ProSeal™ Introducer*

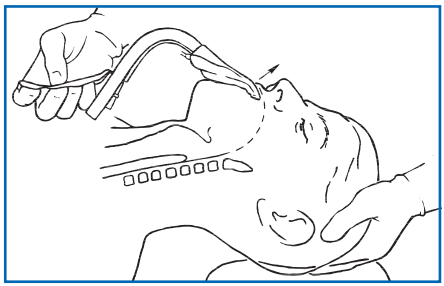


Figure 9: Press the tip of the cuff against the hard palate

Keeping the *LMA-ProSeal™ Introducer* blade close to the chin, rotate the device inwards in one smooth circular movement (figure 11). During insertion, follow the curve of the rigid insertion tool. The jaws should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downwards, blocking further passage of the mask. Do not use the handle as a lever to force the mouth open. Advance into the hypopharynx until a definite resistance is felt (figure 12).

Before removing the *Introducer*, the non-dominant hand is brought from behind the patient's head to stabilise the tubes (figure 13). This prevents the device from being pulled out of place when it is removed. It also permits the device to be pushed further inwards in the event that full insertion has not been achieved by the *Introducer* alone. At this point, the *LMA-ProSeal™* should be correctly located with its tip firmly pressed up against the upper oesophageal sphincter.

Note: The Introducer tool should be removed prior to inflation and fixation of the *LMA-ProSeal™*.

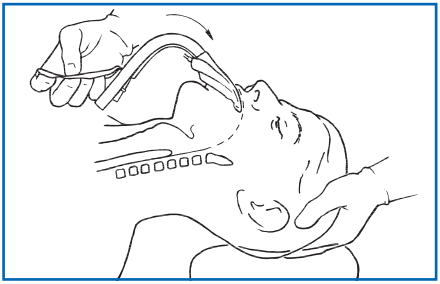


Figure 10: Press the cuff further into the mouth, maintaining pressure against the palate

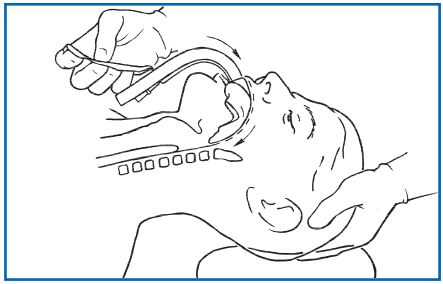


Figure 11: Swing the device inwards with a circular motion, pressing against the contours of the hard and soft palate

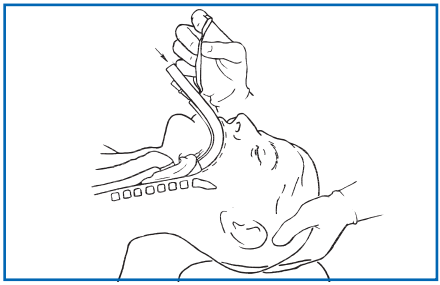


Figure 12: Advance the device into the hypopharynx until resistance is felt

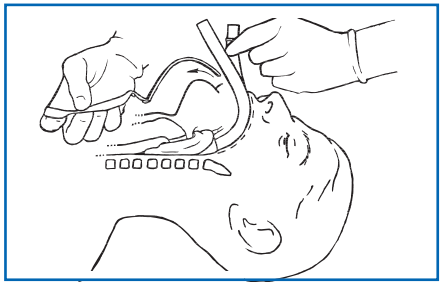


Figure 13: Hold the tubes in place whilst removing the *LMA-ProSeal™ Introducer*

6.5 Index finger insertion technique

Hold the *LMA-ProSeal™* like a pen, with the index finger pushed into the *Introducer* strap (figure 14). Note the flexion of the hand and wrist (figure 15).

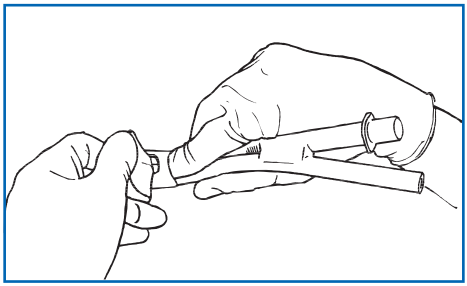


Figure 14: Hold the *LMA-ProSeal™* with the index finger in the strap

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it (figure 16). A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding.

As the index finger passes further into the mouth, the finger joint begins to extend (figure 17). The jaws should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downwards, blocking passage of the mask. Further opening of the mouth makes it easier to verify the position of the mask. You may push the jaw downwards with your middle finger or instruct an assistant to pull the lower jaw downwards momentarily.

Using the index finger to guide the device, press backwards toward the other hand, exerting counter pressure (figure 18). Do not use excessive force. Advance the device into the hypopharynx until a definite resistance is felt. Full insertion is not possible unless the index finger is fully extended and the wrist is fully flexed (figure 19).

Depending on patient size, the finger may be inserted to its fullest extent into the oral cavity before resistance is encountered. Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube (figure 20). This prevents the device from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point, the *LMA-ProSeal™* should be correctly located with its tip firmly pressed up against the upper oesophageal sphincter.

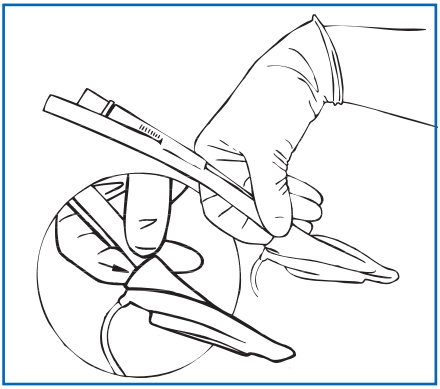


Figure 15: Hold the device with the index finger in the strap; note the flexed wrist

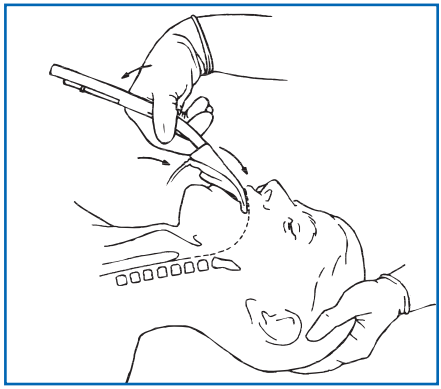


Figure 16: Press the mask up against the hard palate

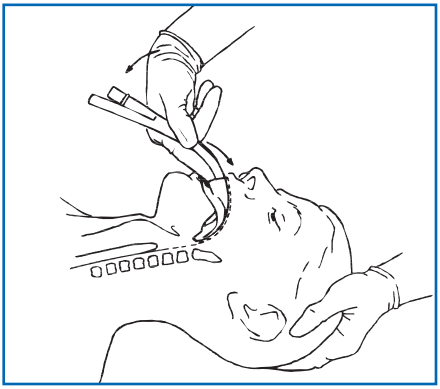


Figure 17: Slide the mask inward, extending the index finger

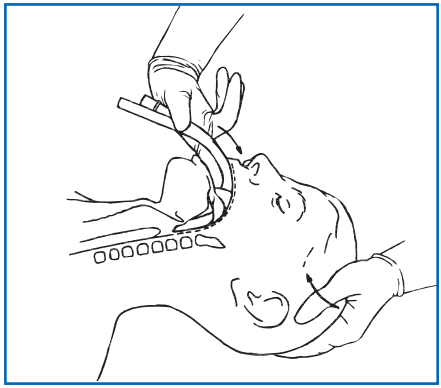


Figure 18: Press the finger towards the other hand which exerts counter pressure

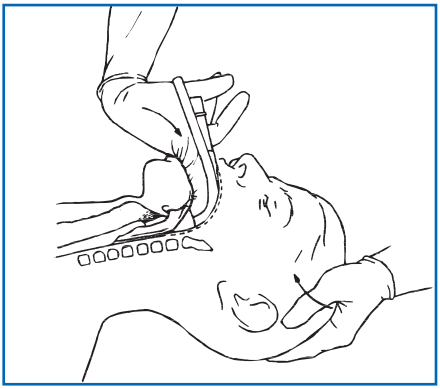


Figure 19: Advance the device into the hypopharynx until resistance is felt

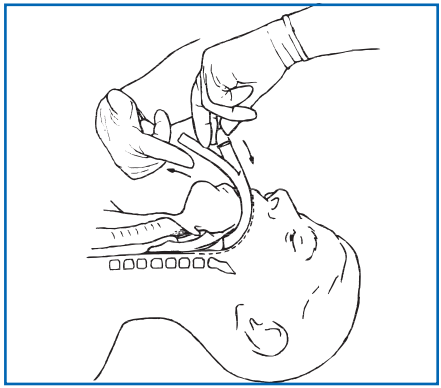


Figure 20: Gently press the outer end of the airway tube while removing the index finger

6.6 Thumb insertion technique

The thumb insertion technique is useful if it is impossible to get access to the patient from behind, or to rapidly gain an airway while initiating CPR. The thumb is inserted into the strap, as shown in figure 21. Insertion is similar to that using the index finger (figures 22-25). However, the thumb should be used to **extend** the head (as shown in figure 23) just prior to completing insertion. This prevents the unopposed backward movement of the thumb causing undesired head flexion.

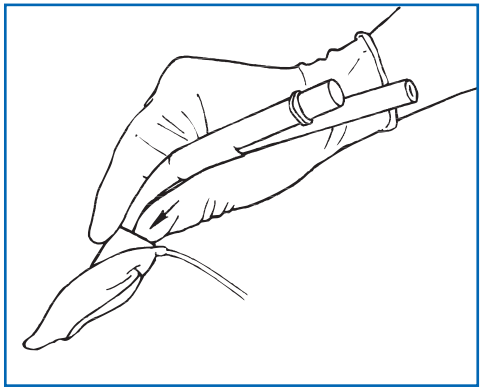


Figure 21: Hold the device with the thumb in the strap

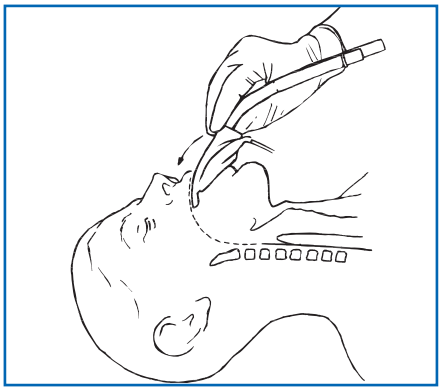


Figure 22: Place the mask against the palate

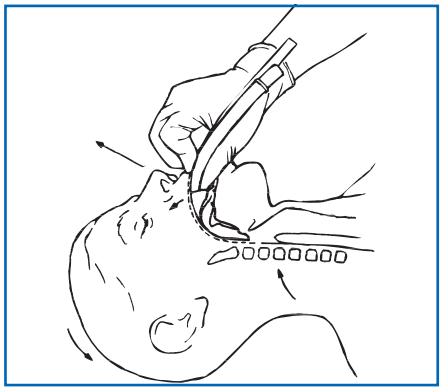


Figure 23: When the thumb is opposite the palate, press upwards to extend head

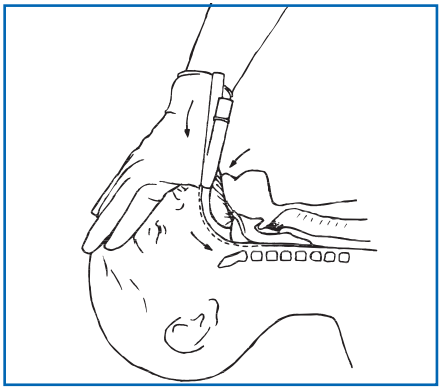


Figure 24: Extend fingers over head, allowing the thumb to pass inward

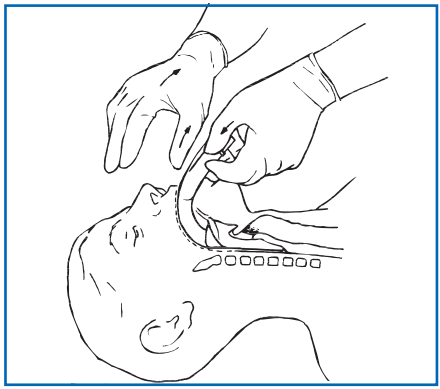


Figure 25: Use other hand to complete insertion as shown

6.7 Insertion problems

An inadequate depth of anaesthesia may result in coughing and breath-holding during insertion. Should this occur, anaesthesia should be deepened immediately with inhalational or intravenous agents and manual ventilation instituted.

If the patient's mouth cannot be opened sufficiently to insert the mask, first ensure that the patient is adequately anaesthetised. An assistant can be asked to pull the jaw downwards. 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.

The cuff must press against the palate throughout the insertion manoeuvre, otherwise the tip may fold back on itself or impact on an irregularity or swelling in the posterior pharynx (eg hypertrophied tonsils). 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, a diagonal shift of the mask is often successful.

If difficulty persists with the chosen technique, one of the other techniques described should be used.

6.8 Device inflation

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to obtain an intra-cuff pressure equivalent to approximately 60cm H_2O (figure 26). Never over-inflate the cuff. Avoid prolonged intra-cuff pressures greater than 60cm H_2O.

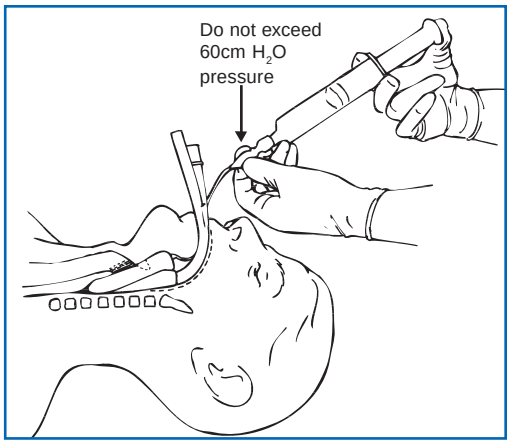


Figure 26: Inflate the *LMA-ProSeal™*; do not exceed 60cm H_2O pressure

For approximate inflation volumes, refer to the guide inside the rear cover of this manual.

The initial cuff volume will vary according to the patient, size of device, head position and anaesthetic depth. 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 often noted as the device seats itself in the hypopharynx.

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, or no cuff visible in the oral cavity.

Warning: never over-inflate the cuff after insertion.

6.9 Connecting to the anaesthetic system

Taking care to avoid dislodgment, connect the device to the anaesthetic circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. 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.

6.10 Diagnosis of correct and incorrect mask position

Correct placement (figure 28a) should produce a leak-free seal against the glottis (seal 1) with the mask tip wedged against the upper oesophageal sphincter (seal 2). 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 and there will be little protection in the event of gastric reflux (figure 28b). This situation must be corrected by repositioning the mask. Do **not** attempt to overcome the leak by occluding the drain tube.

Occasionally a poorly deflated or inserted mask may enter the vestibule of the larynx (figure 28c). 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 facilitate detection of incorrect placement, place a small bolus (1-2ml) of lubricant gel in the proximal end of the drain tube. If the bolus is ejected when the lungs are inflated, the mask is incorrectly placed.

Poor insertion or deflation may also cause the tip of the mask to fold back on itself in the hypopharynx, causing the drain tube to become obstructed (Figure 28d). If the tip is folded back there may be a lack of meniscus movement in the lubricant gel. A simple, non-invasive method to test for this problem would be to pass an oro-gastric tube down to the end of the mask to verify that the drainage tube is patent. If the oro-gastric tube cannot reach the distal end of the drain tube, the mask tip is likely to be folded over. Alternatively, this may be confirmed with a fibreoptic scope. The mask should be removed and reinserted.

6.11 Device fixation

Once inflated, the device should be fixed in place using adhesive tape, as shown in figure 27. Note the gentle pressure applied to the outer end of the airway tube as it is fixed. This ensures that the tip of the mask is pressed securely against the upper oesophageal sphincter.

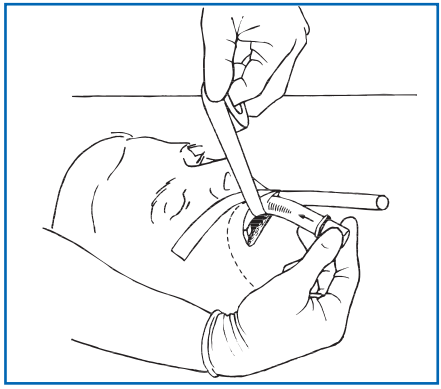


Figure 27: Fix the device in place using adhesive tape

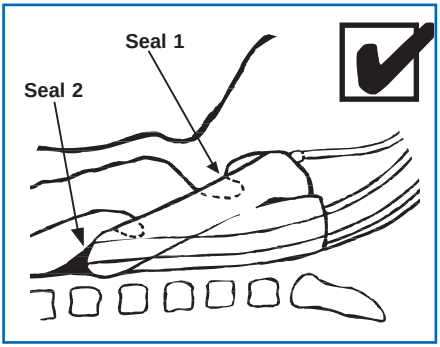


Figure 28a: Correct placement

LMA-ProSeal™ correctly placed: good seal with no gastric insufflation

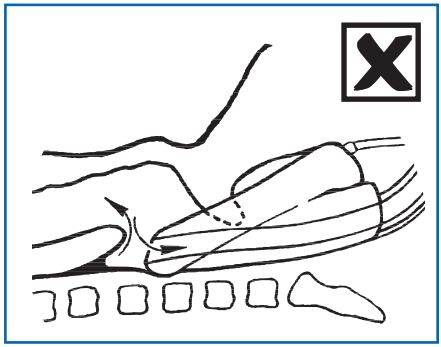


Figure 28b: Incorrect placement

LMA-ProSeal™ placed too high in pharynx: poor seal, allowing gas and fluid to pass in directions shown by arrows; leakage through the drain tube can be eliminated by pressing the mask in further

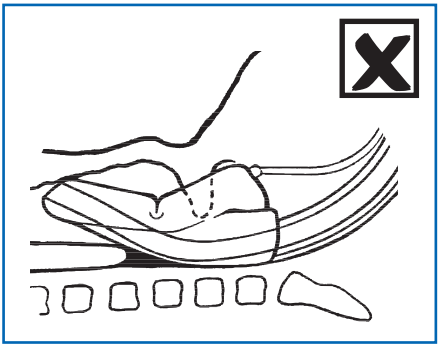


Figure 28c: Incorrect placement

LMA-ProSeal™ incorrectly placed with tip in laryngeal vestibule; ventilation is obstructed and deteriorates if the mask is pressed further distally

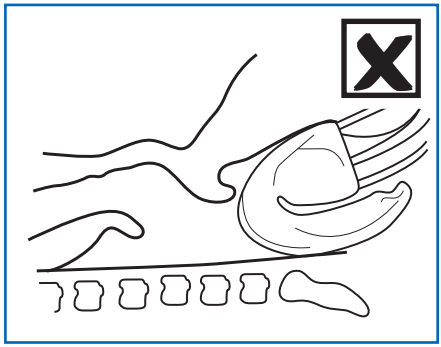


Figure 28d: Incorrect placement

LMA-ProSeal™ mask folded back on itself in the hypopharynx, causing the drain tube to become obstructed

To distinguish between the mask lying too high (figure 28b) and having entered the glottis (figure 28c), 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.

Note: If leaks occur from the drain tube, even though the device is correctly positioned, this may indicate a torn or perforated internal drain tube and the *LMA-ProSeal*™ should not be used.

7 ANAESTHESIA MAINTENANCE AND RECOVERY

As with other methods of airway management, the use of pulse oximetry and capnography is recommended when using the *LMA-ProSeal*™. It may be used for either spontaneous or controlled ventilation.

7.1 Spontaneous ventilation

Coughing, breath-holding or movement may result from inadequate anaesthesia.

7.2 Positive Pressure Ventilation (PPV)

Although it may be used in spontaneously breathing patients, the *LMA-ProSeal*™ has been designed for use with PPV, with and without muscle relaxants.

When a relaxant technique is chosen, the relaxant drug may be given either before or after insertion. Alternatively, if a change in the surgical or diagnostic procedure requires conversion to a relaxant technique, a muscle relaxant can be given at any time.

The softer cuff material, deeper mask bowl and special cuff shape of the *LMA-ProSeal*™ result in a gentler but also more effective seal against the laryngeal inlet when compared to the *LMA-Classic*™[1,2]. The drain tube may also act as a relief conduit to prevent gastric insufflation during PPV. However, tidal volumes should not exceed 8ml/kg and peak inspiratory pressures should be kept within the maximum airway seal pressure which will be found to vary between individual patients, but is on average 10cm H_2O higher than the *LMA-Classic*™.

Should 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 tapes are still in place and readjust as necessary, while pressing the tubes inwards to relocate the mask tip against the upper oesophageal sphincter.

7.3 Use of the drain tube

The primary function of the drain tube is to provide a separate conduit from and to the alimentary tract. It may direct gases or liquids from the patient and may also serve as a guide for blind insertion of an oro-gastric tube at any time during the anaesthetic (figure 29). The oro-gastric tube should be well-lubricated and passed carefully, without haste. When such tubes are used in conjunction with the *LMA-ProSeal*™, it is important to avoid the potential for trauma associated with excessive tube rigidity. **For this reason do not use oro-gastric tubes which have been stiffened by refrigeration.** Ensure the tube is at or above room temperature.

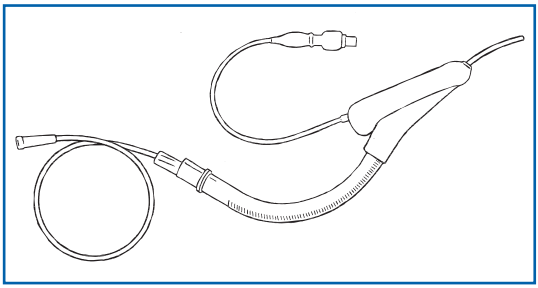


Figure 29: *LMA-ProSeal™* with oro-gastric tube

Upon insertion (figure 30), some resistance is often detected as the tip of the catheter is pressed gently against the upper sphincter. Force must never be used. If a tube of appropriate size fails to pass, the mask may be kinked or malpositioned. In these cases, the mask should be removed and reinserted. Do not use excessive force.

Clinical judgment should be used in deciding when the oro-gastric tube should be removed.

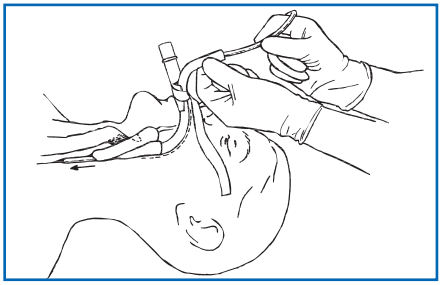


Figure 30: Passage of an oro-gastric tube through the *LMA-ProSeal™* into the upper oesophageal sphincter

7.4 Problems after insertion

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.

Nitrous Oxide Diffusion. Nitrous oxide diffuses into the cuff, causing a rise in intra-cuff pressure. Diffusion rate and resulting peak pressure vary with inflation gases used, the percentage of nitrous oxide in the inhaled mixture, and the size of the device. The incidence of post-operative throat soreness may increase if cuff pressure becomes excessive. To reduce the risk of a sore throat, the cuff pressure should be periodically checked, either by monitoring with a pressure transducer or simply by feeling the tension in the inflation indicator balloon. At an intra-cuff pressure of 60cm H_2O, the inflation balloon should feel very compliant. If the inflation indicator balloon becomes stiff or olive shaped, this indicates excessive pressure. Cuff volume should be reduced to maintain a pressure close to the initial control pressure.

Unexpected Regurgitation. Even in fasted patients, some regurgitation may occur - for example, if anaesthesia becomes inadequate, resulting in fluid emerging from the drain tube. It has been shown in cadavers that fluids pass up the drain tube without laryngeal contamination when the mask has been correctly placed[4]. Therefore, provided that oxygen saturation remains at acceptable levels, the device should not be removed in such cases. Verify that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate.

If reflux occurs in association with a misplaced mask, aspiration is theoretically possible.

In the event of suspected aspiration when using the device, the patient should immediately be tilted head down. Momentarily disconnect the anaesthetic circuit so that gastric contents are not forced into the lungs. Verify that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate. Repositioning the device to ensure the distal end is lying against the upper oesophageal sphincter and secure it in place using the fixation method described in section 6.11. Suction should then be applied through the airway tube. Suction of the tracheobronchial tree using a fibreoptic bronchoscope through the *LMA-ProSeal™* may be employed if the airway reflexes are adequately obtunded. If the presence of further gastric contents is suspected, an oro-gastric tube may be passed through the drain tube.

Provided oxygen saturation is maintained at an acceptable level, the device should not be removed. If clinically indicated, commence preparation for immediate tracheal intubation of the patient. If aspiration has occurred, the patient should receive a chest X-ray and be treated, as clinically appropriate, with antibiotics, physiotherapy, and tracheal suction.

7.5 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. At this stage, it is advisable to check the position of the bite-block and intra-cuff pressure.

The correctly placed *LMA-ProSeal*™ is well tolerated until the return of protective reflexes, provided that intra-cuff pressures are kept at around 60cm H_2O. This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal of the device should always be carried out in an area where suction equipment and the facilities for rapid tracheal intubation are present. 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. If suction is required around the oral cavity or down the airway or drain tubes, it should be carried out prior to recovery of reflexes.
- Leave the patient undisturbed until reflexes are restored, except to administer oxygen and perform monitoring procedures. It is not advisable to move the patient from the supine to the lateral recumbent position unless there is urgent reason to do so, such as regurgitation or vomiting. If the patient needs to be awakened in the lateral position, the patient must be turned to this position under adequate anaesthesia.
- Avoid suctioning of the airway tube with the *LMA-ProSeal*™ 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 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 device is to be removed in a Post-Anaesthesia Care Unit (PACU), recovery room staff should receive training in all aspects of *LMA-ProSeal*™ management. An anaesthetist should always be readily available if the device is to be removed away from the operating theatre.

8 REFERENCES

Two papers regarding the *LMA-ProSeal*™ have been published, with a further two papers accepted for publication. Abstracts of two papers have been reproduced below.

1. Brain AIJ, Verghese C, Strube PJ, The LMA 'ProSeal' – a laryngeal mask with an oesophageal vent (Br J Anaesth 2000; 84: 650-4)

   "We describe a new laryngeal mask airway (LMA) that incorporates a second tube placed lateral to the airway tube and ending at the tip of the mask. The second tube is intended to separate the alimentary and respiratory tracts. It should permit access to or escape fluids from the stomach and reduce the risks of gastric insufflation and pulmonary aspiration. It can also determine the correct positioning of the mask. A second posterior cuff is fitted to improve the seal. A preliminary cross over comparison with the standard mask in 30 adult female patients showed no differences in insertion, trauma or quality of airway. At 60cm H_20 intracuff pressure, the new LMA gave twice the seal pressure of the standard device ($P<0.0001$) and permitted blind insertion of a gastric tube in all cases. It is concluded that the new device merits further study."

2. Brimacombe J, Keller C, The ProSeal Laryngeal Mask Airway. A Randomized Crossover Study with the Standard Laryngeal Mask Airway in Paralysed, Anesthetized Patients. (Anesthesiology 2000; 93: 104-9)

3. Keller C & Brimacombe J, Mucosal Pressure and Oropharyngeal Leak Pressure with the ProSeal Versus the Classic Laryngeal Mask Airway. (Br J Anaesth 2000; 85: 262-6)

4. Keller C & Brimacombe J, Does The ProSeal Laryngeal Mask Prevent Aspiration of Regurgitated Fluid. A Comparative Study with the Classic™ Laryngeal Mask in Fresh Cadavers. (Anaesth Anal 2000; 91: 1017-20)

   "A new laryngeal mask device, the ProSeal laryngeal mask airway (PLMA), has been developed with a drainage tube intended to provide a channel for regurgitated fluid. In this randomised, crossover cadaver study, we determine if the PLMA prevents aspiration of regurgitated fluid. Five male and five female cadavers were studied. The infusion set of a pressure controlled, continuous flow pump was inserted into the upper oesophagus and ligated into place. OP was increased in 2 cm H_2O increments. This was performed without an airway device (controls) and over a range of cuff volumes (0-40 ml) for the Classic laryngeal mask airway (LMA) and the PLMA with the drainage tube clamped (PLMA-clamped) and unclamped (PLMA-unclamped). Regurgitation pressure (RP) was the OP at which fluid was first seen with a fibreoptic scope in the hypopharynx (controls) and above or below the cuff (PLMA-clamped/unclamped and LMA) or seen directly in the drainage tube (PLMA-unclamped). Mean (range) RP without any airway device was 9 (8-10) cm H_2O. RP was always higher for the PLMA-clamped and LMA compared with controls (all: $p<0.0001$). The mean (range) RP for the PLMA-unclamped was similar to controls at 10 (8-13) cm H_2O. For the PLMA-unclamped, fluid always appeared from the drainage tube other than in 2 patients at zero cuff volume. There was an increase in RP with increasing cuff volume for the LMA from 0 to 10 ml ($p<0.0001$), but no significant changes thereafter. There was a significant increase in RP for the PLMA-clamped with each incremental increase in cuff volume (all: $p<0.01$). The OP at which fluid was seen above the cuff was higher for the PLMA-clamped than the LMA at 40-ml cuff volume. The OP at which fluid was seen below the cuff was higher for the PLMA-clamped than the LMA at 20-40 ml cuff volume (all: $p<0.04$). For the PLMA-clamped and LMA, fluid appeared simultaneously above and below the cuff

at all cuff volumes. We conclude that the correctly placed PLMA, prevents aspiration of regurgitated fluid in cadavers. This may have implications for airway protection in unconscious patients."

LMA-PROSEAL™ SPECIFICATIONS

Patient selection

The patient selection information in the accompanying table is for guidance purposes only. Research regarding the *LMA-Classic*™ has indicated that a size 4 or 5 will suit most adults. However, when selecting the size of any medical device, clinical judgment should be used.

Inflation volume

The inflation volumes quoted in the table below are maximum values and should not be exceeded in use. After insertion, the cuff should be inflated until a "just seal" pressure is obtained. This typically corresponds to an intra-cuff pressure of 60cm H_2O. This pressure should not be exceeded.

If a seal is not obtained after inflating the cuff to this pressure, then the device is either malpositioned or a larger size may be required. Where possible, it is recommended that the largest suitable size is used at a lower intra-cuff pressure, rather than the reverse.

LMA-ProSeal™ **Size**	**Patient Selection Information**	**Maximum Inflation Volume**	**Maximum Diameter of Oro-gastric Tube**
3	Children 30-50kg	20ml	5.5mm 16fr
4	Adult 50-70kg	30ml	5.5mm 16fr
5	Adult 70-100kg	40ml	6.0mm 18fr

The LARYNGEAL MASK Company Limited

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Issue : I007E/3,0801