Teleflex®

LMA®
Better by Design

Instructions For Use

EN–English Version

LMA | ProSeal™

LMA ProSeal™

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

WARNING: LMA ProSeal™ is supplied 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.

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 ProSeal™ is an advanced form of LMA™ airway that may be used for the same indications as the LMA Classic™. The LMA ProSeal™ is designed to provide additional benefits over the LMA Classic™ that extends the range of procedures for which an LMA™ airway is indicated. While the LMA Classic™ may be used with low-pressure positive pressure ventilation (PPV), the LMA ProSeal™ has been specifically designed for use with PPV with and without muscle relaxants at higher airway pressures. The LMA ProSeal™ does not protect the airway from the effects of regurgitation and aspiration.

The LMA ProSeal™ has four main components: mask, inflation line with pilot balloon, airway tube and drain tube (figure 1). 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 the larger sizes also have 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 red plug is also fitted to the valve assembly to allow residual air in the mask to be vented during autoclaving. It prevents expansion of the cuff when left open during steam autoclaving. The plug must be detached before autoclaving and replaced before clinical use. Some older LMA ProSeal™ devices may not have a red plug fitted. 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 15 mm connector. A malleable introducer tool (the LMA ProSeal™ Introducer) is available in adult and paediatric sizes 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 but may be bent to any desired shape. A dedicated deflation device (LMA ProSeal™ Cuff-Deflator) is available to aid complete deflation for successful sterilisation, optimum insertion and positioning in the patient.

In order to accommodate the neonatal anatomy, the LMA ProSeal™ size 1 does not have the bite block (figure 2). The LMA ProSeal™ size 1 also differs from the other sizes in that it has a relatively larger drain tube (8fr).

All components are not made with natural rubber latex. Teleflex Medical 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 LMA ProSeal™ offers the following features:

- A softer cuff material, deeper mask bowl and special cuff shape allows a higher seal than the LMA Classic™ for a given intracuff pressure with the adult sizes.
- A revised cuff arrangement, which allows a higher seal than the LMA Classic™, for a given intracuff pressure.
- 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 (except LMA ProSeal™ size 1) which reduces the danger of airway obstruction or tube damage.

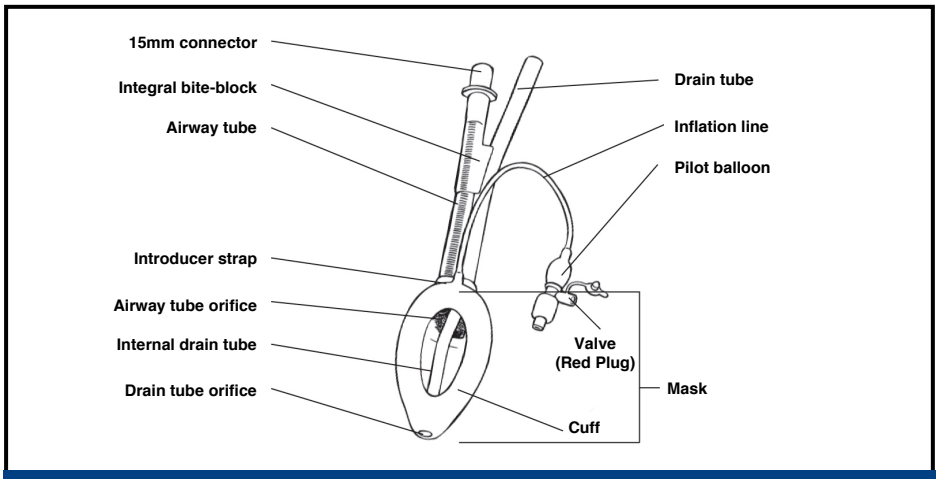


Figure 1: The components of the LMA ProSeal™ in sizes 1 1/2, 2, 2 1/2, 3, 4, and 5.

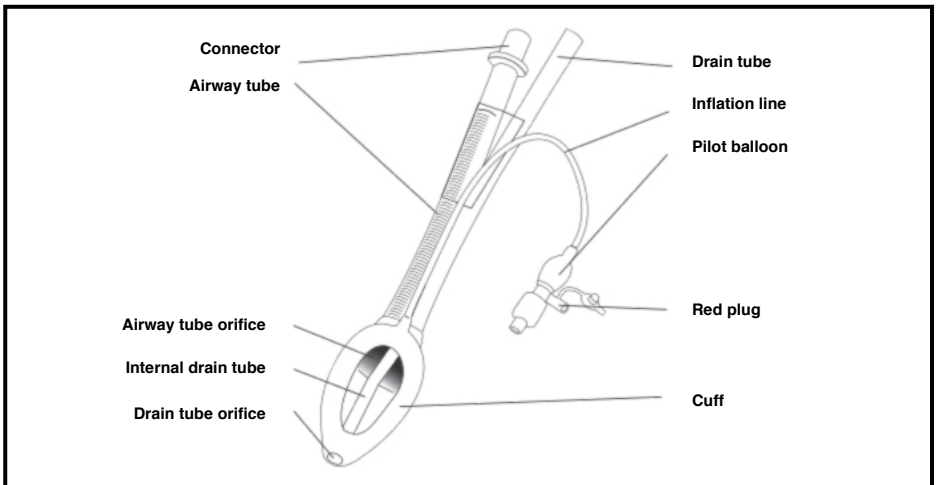


Figure 2: The components of the LMA ProSeal™ size 1.

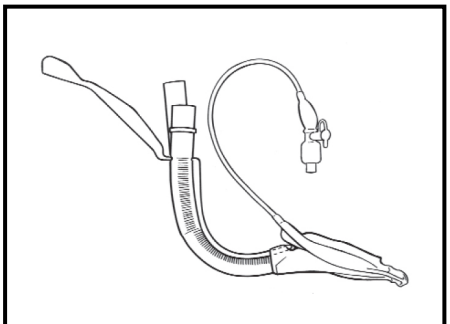


Figure 3: LMA ProSeal™ with LMA ProSeal™ Introducer in place.

- A location strap for the LMA ProSeal™ Introducer, which also accommodates the index finger or thumb for manual insertion (figure 3).
- The position of the drain tube inside the cuff prevents the epiglottis occluding the airway tube. This eliminates the need for aperture bars.

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 4).

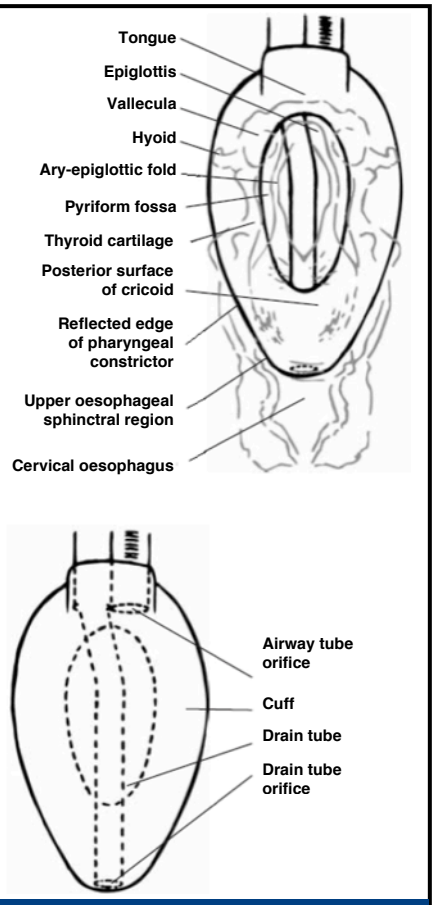


Figure 4: Dorsal view of the LMA ProSeal™ showing position in relation to the pharyngeal anatomy.

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

2. INDICATIONS FOR USE

The LMA ProSeal™ is indicated for use in achieving and maintaining control of airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or positive pressure ventilation. It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.

The LMA ProSeal™ is not indicated for use as a replacement for the endotracheal tube, and is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

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. In these cases, LMA ProSeal™ should be used only when tracheal intubation is not possible.

3. RISK-BENEFIT INFORMATION

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 risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway.

4. CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do not use the LMA ProSeal™ as a substitute for an endotracheal tube 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 grossly or 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.

The LMA ProSeal™ is also contraindicated in:

- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the airway forms a low-pressure seal around the larynx.
- Patients where the peak airway inspiratory pressures are anticipated to exceed 30 cm H_2O with LMA ProSeal™.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for use with LMA ProSeal™.

5. WARNINGS & CAUTIONS

Throughout this instruction manual, appropriate warnings and cautionary statements are given describing potential safety hazards associated with use of LMA ProSeal™, limitations during use, and steps that should be taken should they occur. The user should be familiar with the followings and all other warnings and cautionary statements included throughout this instruction manual prior to use of the LMA ProSeal™.

5.1 Warnings

- The LMA ProSeal™ does not protect the patient from the effects of regurgitation and aspiration.
- The presence of a gastric tube does not rule out the possibility of regurgitation and may even make regurgitation more likely because the gastric tube may make the lower esophageal sphincter incompetent.
- Should the device 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. 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 all other attempts to establish an airway have failed.
- LMA ProSeal™ displays magnetic field interactions in the MRI environment. Refer to Section 11 for MRI Information prior to using this device in MRI environment. The appropriate fixation of this device is required to prevent possible movement due to magnetic field interactions.
- Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. In order to ensure that cuff pressures do not become excessive, cuff pressure should be measured regularly during a case with a cuff pressure monitor.
- When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and cautions have been taken, especially with regard to fire hazards and prevention. The device may be flammable in the presence of lasers and electrocautery equipment.
- To avoid trauma, excessive force should not be used at any time when using the devices. Excessive force must be avoided at all times.
- Do not use the LMA™ airway or any of the accessories if they are damaged in any way.
- Never overinflate the cuff after insertion. Avoid intracuff pressures greater than 60 cm H_2O. The cuff is designed to be inflated to a low pressure (approximately 60 cm H_2O). Over inflation 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.
- Excessive intracuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- All of the non-clinical tests described at Performance Tests must be conducted before each use of LMA ProSeal™. The performance tests should be conducted in an area and in a manner consistent with

accepted medical practice that minimizes contamination of the airway device before insertion. Failure of any one test indicates that the device has passed its useful life and should be replaced.

- When applying lubricant, lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.
- 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, or affect surrounding structures, including vocal cords.
- Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilise the airway. Such substances are absorbed by the materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an airway 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.
- Do not immerse or soak the device in liquid prior to use.

5.2 Cautions:

- Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
- Laryngeal spasm may occur if the patient becomes too lightly anaesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anaesthesia. If laryngeal spasm occurs, treat the cause. Only remove the device when airway protective reflexes are fully competent.
- Do not pull or use undue force when handling the inflation line or try to remove the device from patient by the inflation tube as it may detach from the cuff spigot.
- Ensure all removable denture work is removed before inserting the device.
- An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.
- Careful handling is essential. The LMA ProSeal™ is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.
- Only use with the recommended manoeuvres described in the instructions for use.
- Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
- If airway problems persist or ventilation is inadequate, the device should be removed and an airway established by some other means.
- A 40-Use record card is supplied with every device to record the number and date of usage. Completion of the record card validates the warranty of the device.
- Only use a syringe with standard luer taper tip for inflation or deflation.
- Gloves should be worn during preparation and insertion to minimize contamination of the device.

6. ADVERSE EVENTS

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks and published literature should be consulted for specific information.

7. PREPARATION FOR USE

Warning: With proper cleaning, sterilisation and handling, the LMA ProSeal™ can be safely used 40 times. Continued use beyond 40 uses 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.

Warning: LMA ProSeal™ is delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

Warning: The airway accessories, i.e., the LMA ProSeal™ Introducer and LMA ProSeal™ Cuff Deflator, should be cleaned and sterilised in the same manner as the LMA ProSeal™.

Caution: Careful handling is essential. The LMA ProSeal™ is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.

Caution: Only use a syringe with standard luer taper tip for inflation or deflation.

Caution: Gloves should be worn during preparation and insertion to minimize contamination of the device.

7.1 Cleaning

Thoroughly wash the cuff, airway tube and drain tube in warm water using a dilute (8-10% v/v) sodium bicarbonate/water solution until all visible foreign matter is removed.

Caution: Make sure the LMA ProSeal™ red plug is closed during cleaning to prevent exposure of the valve to any cleaning solution.

If moisture is noticed, the red plug should be opened and tapped against a towel to remove the excess moisture.

When cleaning the LMA ProSeal™, 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 1/4 inch or 6 mm in diameter for adult size devices). Gently insert the brush through the proximal (outer) end of the drain tube, taking care not to damage 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 or the red plug.

Repeat the above as necessary.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. The cleaners 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).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilise the airway. Such substances are absorbed by the materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an airway that has been exposed to any of these substances.

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

Caution: Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.

7.2 Sterilisation

Warning: 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:

7.2.1 Sterilisation of LMA ProSeal™ (without red plug)

Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backward to obtain a vacuum in the cuff. Then disconnect the syringe while maintaining the vacuum.

For complete deflation, it is recommended that LMA™ Cuff-Deflator or LMA ProSeal™ Cuff-Deflator (available from authorized distributor) be used for this purpose. Ensure that both the syringe used to deflate the cuff and the valve is dry.

Do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving to avoid damage to the valve.

If the cuff of a deflated LMA ProSeal™ without manual vent immediately and spontaneously reinflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the cuff to re-inflate slowly over a period of several hours as the silicone rubber material is gas permeable.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.

7.2.2 Sterilisation of LMA ProSeal™ (with red plug)

For the LMA ProSeal™ with red plug, it is not necessary to deflate the cuff prior to steam autoclaving, so it is normal for the LMA ProSeal™ to be inflated upon removal from the autoclave, provided the manual vent is in the open position.

Caution: Make sure the LMA ProSeal™ manual vent is open during sterilisation to prevent herniation of the cuff.

7.2.3 Autoclave Settings

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.

Caution: The integrity of the device material may be adversely affected by exceeding sterilisation temperatures of 135°C or 275°F.

One steam sterilisation cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

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 the device to cool to room temperature before use.

7.3 Performance Tests

Warning: All of the non-clinical tests described below must be conducted before each use of LMA ProSeal™. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimizes contamination of the airway device before insertion. Failure of any one test indicates that the device has passed its useful life and should be replaced.

Warning: Do not use the LMA™ airway or any of the accessories if they are damaged in any way.

7.3.1 Performance Test 1: Visual Inspection

- Examine the surface of the airway tube, cuff and drain tube for damage, including cuts, tears, or scratches.
- Examine the interior of the airway tube, mask bowl and drain tube to ensure that they are free from blockages or loose particles. Any particles present in the tubes should be removed.
- Examine the transparency of the tubes. Reusable airway tubes will gradually discolor with age and re-use.

Warning: Do not use the LMA ProSeal™ if the tubes are discolored, as this impairs the ability to see and effectively remove foreign particles during cleaning or to see regurgitated fluids during use.

Warning: Do not use the LMA ProSeal™ if it is damaged or if visible particles cannot be removed from inside the airway tube as they may be inhaled by the patient after insertion.

- Examine the 15 mm 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.

Warning: Do not use the LMA ProSeal™ if the mask connector does not fit tightly into the outer end of the airway tube.

- Ensure that the section of the LMA ProSeal™ drain tube lying within the bowl of the mask is not torn or perforated, and that there is no contamination between the tube and the mask.
- Examine the rear cuff of the LMA ProSeal™, if present, for wrinkles or folds suggesting herniation.

7.3.2 Performance Test 2: Inflation and Deflation

- Carefully insert a syringe into the valve port and fully deflate the device so that the cuff walls are tightly flattened against each other. To deflate the LMA ProSeal™, make sure the red plug is closed. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other.

Warning: Do not use the device if the cuff walls reinflate immediately and spontaneously, even if only slightly.

- Examine the fully deflated LMA ProSeal™ mask for wrinkles or folds suggesting herniation. If obvious wrinkles are apparent, the rear cuff may be severely herniated and the LMA ProSeal™ should not be used.
- Inflate the cuff with 50% more air than the recommended maximum clinical inflation volume (Refer to Appendix - SPECIFICATIONS). 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 uneven bulging at either end or sides.

Warning: Do not use the LMA™ airway if cuff leakage is present or if there is uneven bulging of the cuff.

- While the device remains 50% over-inflated, examine the inflation balloon. The balloon shape should be a thin, slightly flattened elliptical shape, not spherical.

Warning: Do not use the LMA™ airway if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.

- While the device remains 50% over-inflated, inspect the interior of the LMA ProSeal™ drain tube from both ends of the mask. Ensure that the tube is not collapsed or perforated.

Warning: Use of an LMA ProSeal™ with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the LMA ProSeal™ from being inflated or allow for escape of anesthetic gases.

7.4 Pre-insertion preparation

Prior to insertion 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 7a and 7b). This shape facilitates atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the valledullae 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 5), available from the distributor.

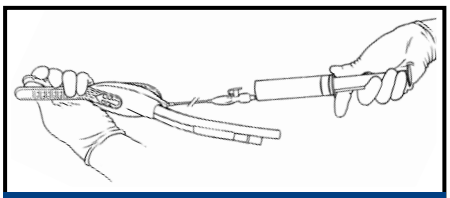


Figure 5: LMA ProSeal™ being used with the LMA ProSeal™ Cuff Deflator.

Prior to deflating the LMA ProSeal™ and during clinical use, make sure the red plug is closed.

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

- Squeeze the handles of the LMA ProSeal™ 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 on the cuff deflator
- The mask bowl should face the curved surface of the LMA ProSeal™ 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 LMA ProSeal™ 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.

If the distal end is not maximally flattened or there is evidence of air in the cuff, partially re-inflate the cuff and repeat the procedure.

Alternative methods of cuff deflation:

Alternatively, the device can be deflated manually by compressing the distal end between finger and thumb (figure 6) to obtain the correct cuff shape. The same principles and results apply in all methods of device deflation.

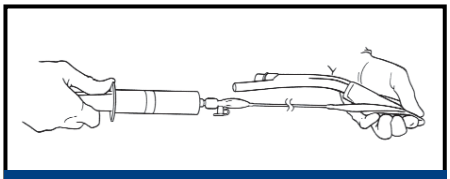


Figure 6: Manual deflation of the LMA ProSeal™ (note manual pressure at tip).

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.

Warning: 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, or affect surrounding structures, including vocal cords.

Warning: Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.

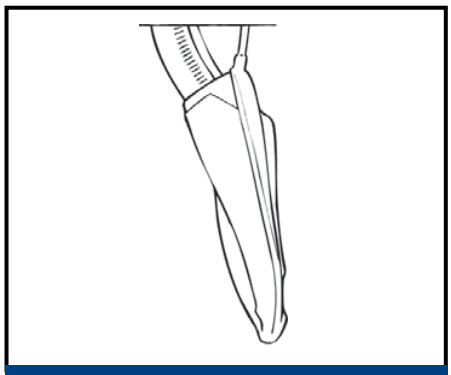


Figure 7a: LMA ProSeal™ cuff properly deflated for insertion

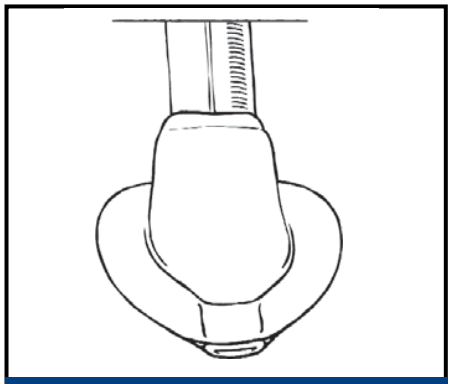


Figure 7b

8. INSERTION

8.1 Introduction

Before using the LMA ProSeal™ , the user should be familiar with the instructions contained in this manual.

Warning: An incorrectly placed mask may result in an unreliable or obstructed airway or failure of the LMA ProSeal™ drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflations if used with PPV. Always check for proper placement after insertion.

Warning: Make sure the red plug is closed during clinical use to prevent deflation of cuff.

Warning: To avoid trauma, excessive force must be avoided at any time during insertion of the LMA ProSeal™ or insertion of a gastric tube through the LMA ProSeal™ drain tube.

Warning: Inadequate anaesthesia may lead to coughing, breath-holding or laryngeal spasm.

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

Before insertion it is important to note the following points:

- Check that the size of the device is appropriate for the patient (see Appendix at the back of manual).The ranges are approximate and clinical judgment should be used in selecting an appropriate size.
- The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.
- Check the shape of the cuff and its lubrication, as described previously.
- Have a spare sterile LMA™ airway ready and prepared for immediate use. Where possible, an alternative size of LMA™ airway should also be available.
- Pre-oxygenate and implement standard monitoring procedures.
- Achieve an adequate level of anesthesia before attempting insertion. Resistance or swallowing, biting or retching indicates inadequate anesthesia and/or inappropriate technique. Inexperienced users should choose a deeper level of anesthesia.
- 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.

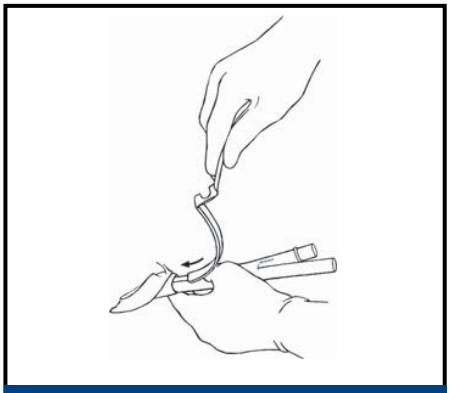


Figure 8a: Place the tip of the LMA ProSeal™ Introducer into the strap.

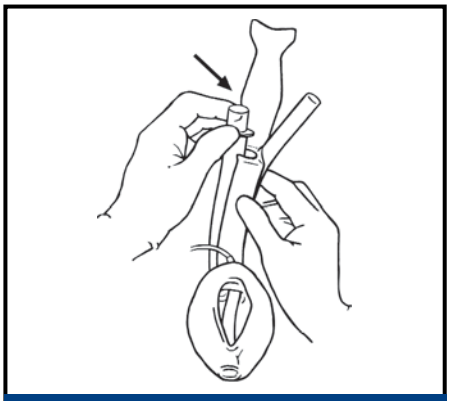


Figure 8b: Fold the tubes around the LMA ProSeal™ Introducer and fit the proximal end of the airway tube into the matching slot.

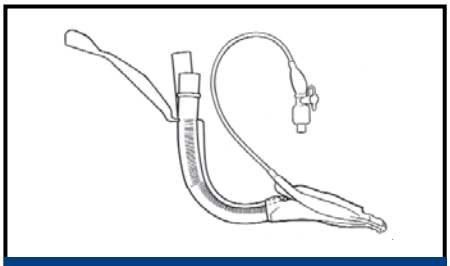


Figure 9: LMA ProSeal™ mounted on the LMA ProSeal™ Introducer.

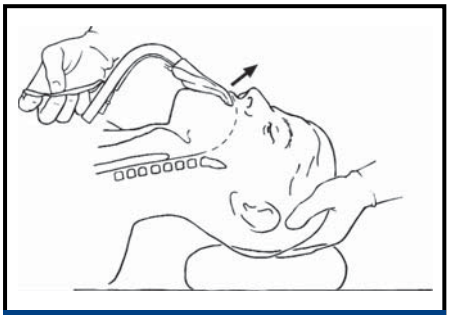


Figure 10: Press the tip of the cuff against the hard palate.

8.2 Induction Method

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.
- Inhalational induction: This provides excellent conditions for insertion in children and in some adults.
- Thiopentone or other barbiturate induction: Barbiturates on their own are not ideal induction agents for insertion.

8.3 Insertion Method

The LMA ProSeal™ may be inserted using the standard index finger or the thumb technique, depending on access to the patient.

The LMA ProSeal™ may also be inserted using the LMA ProSeal™ Introducer. The dedicated Introducer may provide a more useful method of insertion than the thumb/finger techniques, when using LMA ProSeal™ sizes 1 to 2½.

All three techniques follow the same principles. To position the LMA™ airway correctly, the cuff tip must avoid entering the valleculae or the glottic opening and must not become caught up against the epiglottis or the arytenoids. The cuff must be deflated in the correct wedge shape (Figure 7a to 7b) and should be kept pressed against the patient's posterior pharyngeal wall. To avoid contact with anterior structures during insertion, the inserting finger must press the tube upwards (cranially) throughout the insertion maneuver.

8.4 LMA ProSeal™ Introducer Insertion Technique

This technique is recommended for LMA ProSeal™ size 1 to 2½.

Choose the correct size of Introducer as shown in Appendix at the back of the manual.

Place the tip of the Introducer into the strap at the rear of the cuff (Figure 8a). 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 8b). The LMA ProSeal™ is shown mounted in the Introducer in Figure 9.

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it (Figure 10). During insertion, the back of the mask should be in contact with the hard palate and the bowl of the mask should be facing the tongue. Verify the position of the mask and slide the cuff further inward against the palate (Figure 11). Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

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. Keeping the Introducer blade close to the chin, rotate the device inward in one smooth circular movement (Figure 12).

During insertion, follow the curve of the rigid insertion device. The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking 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 13).

Before removing the Introducer, the non-dominant hand is brought from behind the patient's head to stabilize the airway tube (Figure 14). This prevents the LMA ProSeal™ from being pulled out of place when the Introducer is removed. It also permits completion of insertion 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 esophageal sphincter.

Caution: The introducer should be removed prior to inflation and fixation of the LMA ProSeal™.

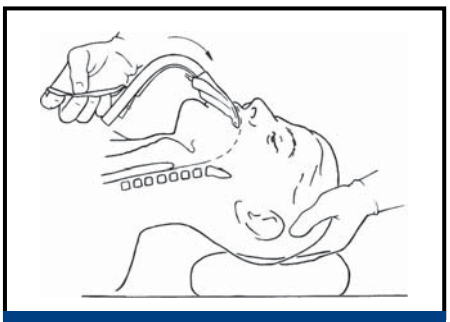


Figure 11: Press the cuff further into the mouth, maintaining pressure against the palate.

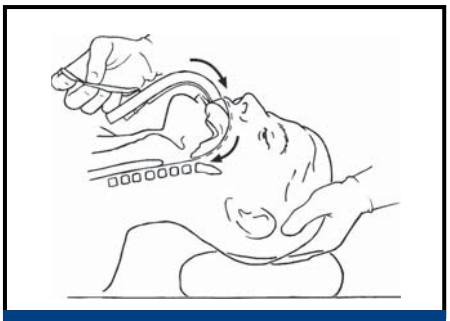


Figure 12: Swing the device inwards with a circular motion, pressing against the contours of the hard and soft palate.

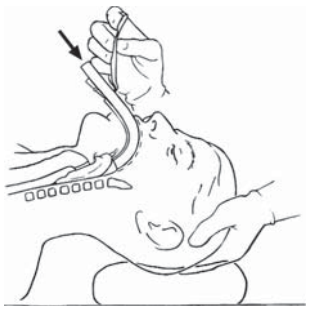


Figure 13: Advance the device into the hypopharynx until resistance is felt.

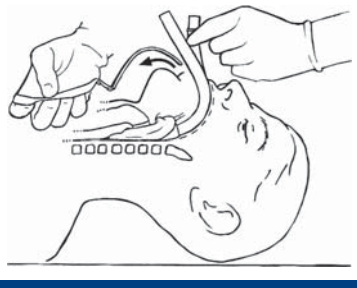


Figure 14: Hold the tubes in place whilst removing the LMA ProSeal™ Introducer.

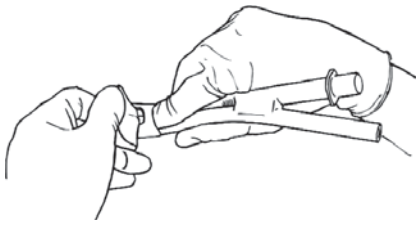


Figure 15: Hold the LMA ProSeal™ with the index finger in the strap.

Figure 16: Hold the device with the index finger in the strap; note the flexed wrist.

8.5 Index Finger Insertion Technique

Hold the LMA ProSeal™ like a pen, with the index finger pushed into the Introducer strap (figure 15). Note the flexion and position of the hand and wrist (figure 16).

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. Note the position of the hand and wrist (Figure 17). 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.

Further opening of the mouth makes it easier to verify the position of the mask. Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

As the index finger passes further into the mouth, the finger joint begins to extend (Figure 18). The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask.

Using the index finger to guide the device, press backward toward the other hand, which exerts counter pressure (Figure 19). 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 20).

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 21). This prevents the LMA ProSeal™ 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 esophageal sphincter.

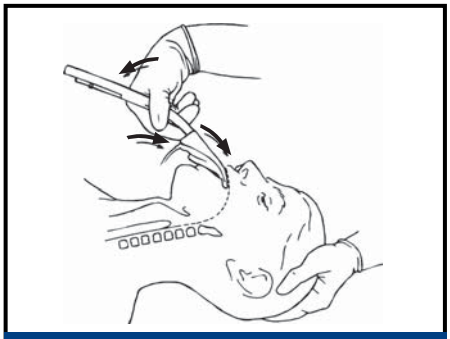


Figure 17: Press the mask up against the hard palate.

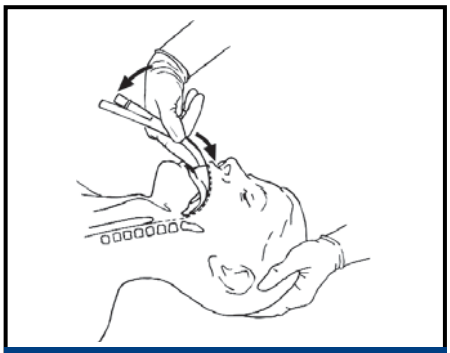


Figure 18: Slide the mask inward, extending the index finger.

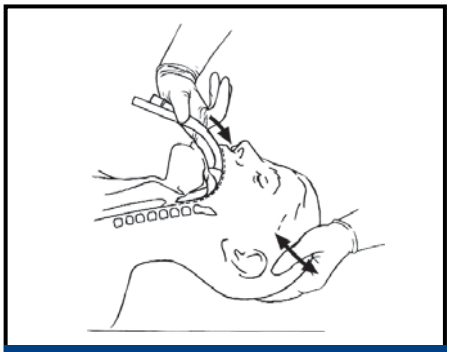


Figure 19: Press the finger towards the other hand which exerts counter pressure.

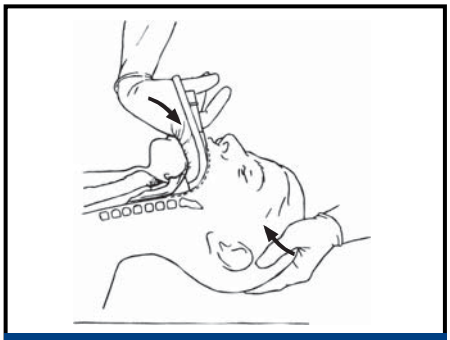


Figure 20: Advance the device into the hypopharynx until resistance is felt.

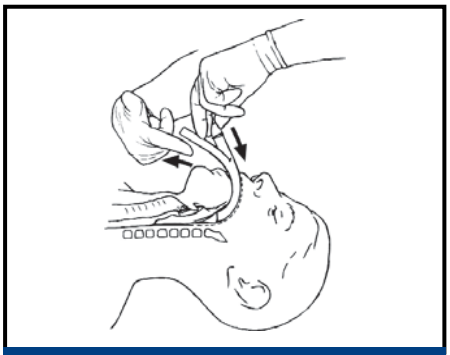


Figure 21: Gently press the outer end of the airway tube while removing the index finger.

8.6 Thumb Insertion Technique

The thumb insertion technique is useful if it is difficult 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 22. Insertion is similar to that using the index finger.

As the thumb nears the mouth, the fingers are stretched forward over the patient's face. The thumb is advanced to its fullest extent. The pushing action of the thumb against the hard palate also serves to press the head into extension (Figures 23-26).

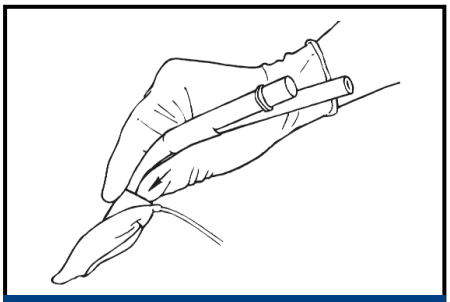


Figure 22: Hold the device with the thumb in the strap.

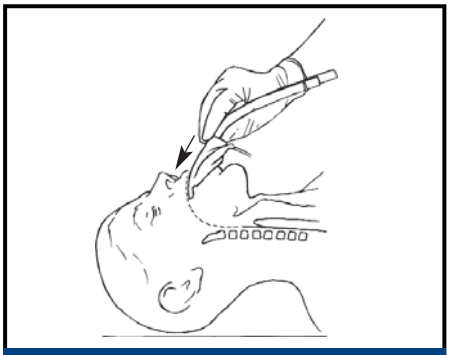


Figure 23: Place the mask against the palate.

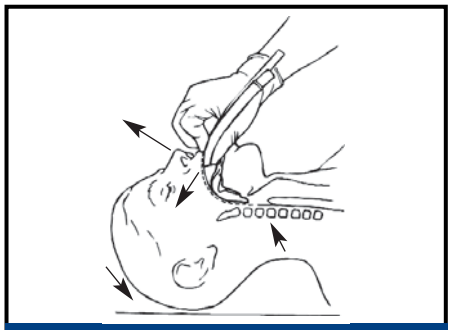


Figure 24: When the thumb is opposite the palate, press cranially (see arrow) to extend the head.

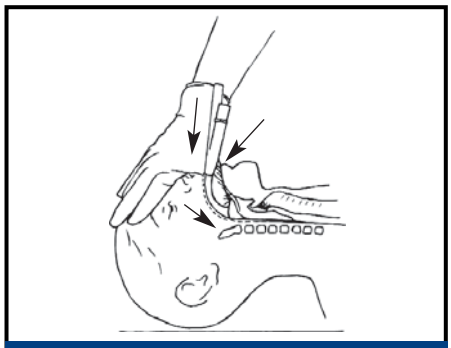


Figure 25: Extend fingers over head, allowing the thumb to pass inward.

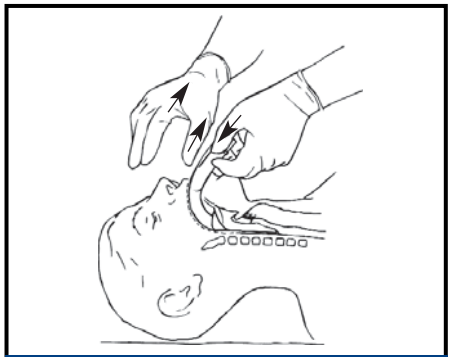


Figure 26: Use other hand to complete insertion as shown.

8.7 Insertion Problems

An inadequate depth of anesthesia may result in coughing and breath-holding during insertion. If this occurs, anesthesia 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 downward. This maneuver 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 the tube against the palate throughout the insertion maneuver, otherwise the tip may fold on itself or impact on an irregularity or swelling in the posterior pharynx (e.g., 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 above should be used.

8.8 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 achieve an intracuff pressure of 60 cm H_2O (Figure 27). The inflation amounts shown in Appendix at the back of the manual are the maximum inflation volumes. Frequently, only half the maximum volumes are sufficient to obtain a seal and/or achieve 60 cm H_2O intracuff pressure.

Warning: Never overinflate the cuff after insertion. Avoid intracuff pressures greater than 60 cm H_2O. The cuff is designed to be inflated to a low pressure (approximately 60 cm H_2O). Over inflation 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.

Warning: Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.

The initial cuff volume will vary according to the patient, size of device, head position, and anesthetic 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 sometimes 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.

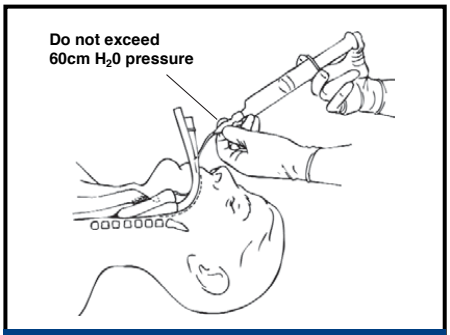


Figure 27: Inflate the LMA ProSeal™, do not exceed 60cm H_20 pressure.

8.9 Connecting to the anesthetic system

Taking care to avoid dislodgment, connect the device to the anesthetic 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 anesthesia.

8.10 Diagnosis of correct or incorrect mask position

When inserting and inflating the LMA ProSeal™, 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 (Figure 28a) should produce a leak-free seal against the glottis (seal 1) with the mask tip wedged against the upper esophageal 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 anesthesia, obstruction worsens if the mask is pressed in further. The mask should be removed and reinserted. To facilitate diagnosis of correct mask placement or detection of incorrect placement, place a small bolus (1-2 ml) of lubricant gel 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. If there is no movement or the bolus of lubricant is ejected, the mask may be 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, noninvasive method to test for this problem would be to pass a gastric tube down to the end of the mask tip to verify that the drainage tube is patent. If the gastric tube cannot reach the distal end of the drain tube, the mask tip is likely folded over. Alternatively, this may be confirmed with a fiberoptic scope. The mask should be removed and reinserted.

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.

Warning: 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). If the device is damaged in any way, it should not be used.

A guide for facilitating correct LMA ProSeal™ position is included in the Appendix.

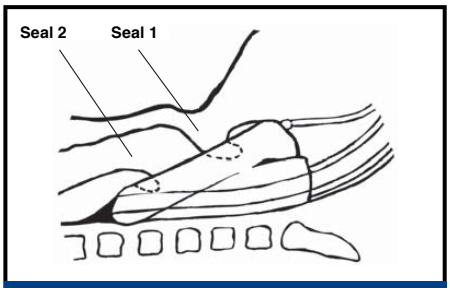


Figure 28a: Correct placement: LMA ProSeal™ correctly placed: good seal with no gastric insufflation.

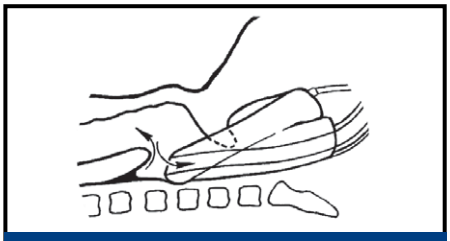


Figure 28b: Incorrect placement. LMA ProSeal™ placed too high in pharynx: poor seal, allowing gas and fluid to pass in directions shown by arrows; leakage through the drain tube can be eliminated by pressing the mask in further.

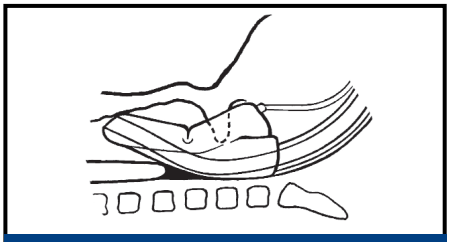


Figure 28c: Incorrect placement. LMA ProSeal™ placed with tip in laryngeal vestibule; ventilation is obstructed and deteriorates if the mask is pressed further distally.

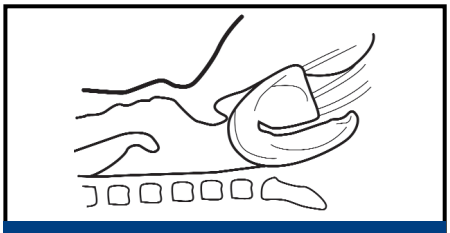


Figure 28d: Incorrect placement. LMA ProSeal™ mask folded back on itself in the hypopharynx, causing the drain tube to become obstructed.

8.11 Device Fixation

All sizes of LMA ProSeal™ has a built-in bite-block except LMA ProSeal™ size 1. Once inflated, the device should be fixed in place using adhesive tape, exactly as shown in figure 29. 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. To prevent the risk of device rotation, fix the device with the outer end extending over the chin in the mid-line as shown in figure 29.

During use of LMA ProSeal™ size 1, take extra care during fixation of the airway to ensure that the cuff doesn't rotate and become displaced. Although the double tube design makes the airway tube more stable and less likely to rotate but the absence of the bite block requires extra caution.

Warning: Extra care to be taken during fixation due to the absence of bite block in LMA ProSeal™ size 1.

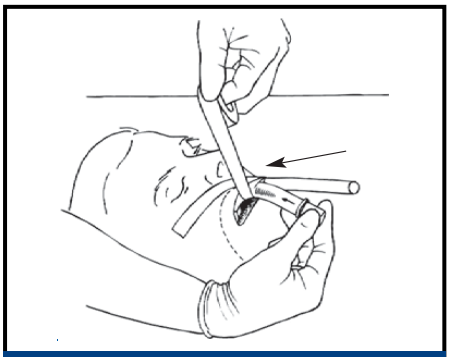


Figure 29: Fix the device in place using adhesive tape.

9. 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.

9.1 Spontaneous ventilation

The LMA ProSeal™ is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anesthesia provided anesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.

Coughing, breath-holding, or movement may result from inadequate anaesthesia if the induction agent is allowed to wear off before adequate levels of anesthesia 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 anesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

9.2 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™.

The following points should be observed when using the LMA ProSeal™ with PPV:

- 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 up to 30 cm H_2O with the LMA ProSeal™ which is 10 cm H_2O higher than the LMA Classic™.
- If leaks occur during PPV, this may be due to:
  - Light anesthesia causing a degree of glottic closure,
  - Inadequate neuromuscular blockade,
  - Reduction in lung compliance related to the procedure or patient factors, or
  - Displacement or migration of the cuff by head turning or traction.
- 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.
- 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.

9.3 Use of drain tube

Warning: Do not attempt to pass a gastric tube through the LMA ProSeal™ drain tube if there is gas leaking through the drain tube and in the presence of known or suspected esophageal pathology or damage.

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.

Warning: Suction should not be applied directly to the end of drain tube, as this may cause the drain tube to collapse and cause possible injury to the upper esophageal sphincter.

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 orogastric tube at any time during the anaesthetic (figure 30). Refer to Appendix at the back of this manual for maximum gastric tube sizes.

The oro-gastric tube should be well-lubricated and passed slowly and carefully. 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, **Warning:** do not use oro-gastric tubes which have been stiffened by refrigeration. Ensure the tube is at or above room temperature.

Upon insertion (figure 31), 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 judgement should be used in deciding when the orogastric tube should be removed.

Warning: To avoid trauma, force should not be used at any time during insertion of a gastric tube through the LMA ProSeal™ drain tube.

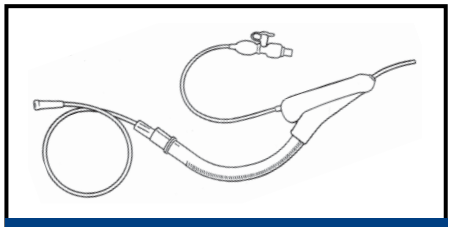


Figure 30: LMA ProSeal™ with oro-gastric tube.

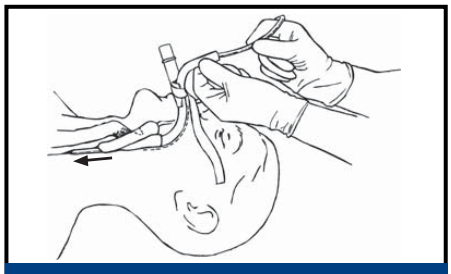


Figure 31: Passage of an oro-gastric tube through the LMA ProSeal™ into the upper oesophageal sphincter.

9.4 Potential problem after insertion

Inadequate level of anesthesia

The most common problem following insertion is failure to maintain an adequate level of anesthesia. 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 intracuff pressure. Diffusion rate and resulting peak pressure may vary with the initial volume of air injected into the cuff, the type of gases used to inflate the cuff, the percentage of nitrous oxide in the inhaled mixture, and the size of the device.

The incidence of post-operative sore throat may increase if intracuff pressure becomes excessive. To reduce the risk of a sore throat or possible neurovascular injury, the cuff pressure should be periodically checked and gas intermittently withdrawn to maintain 60 cm H_2O intracuff pressure or the minimal “just seal” pressure. This can be achieved in several different ways. First, a pressure monitor or pressure transducer may be used. Pressure manometers are commercially available from Posey, Mallinckrodt, Portex, and VBM-Medical. Secondly, simply feeling the inflation indicator balloon can be performed. At intracuff pressure of 60 cm 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.

Warning: Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.

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 anesthesia is adequate and deepen if necessary.
- Check cuff pressures at start and periodically during a case, especially if using nitrous oxide.
- Ensure intracuff pressures are not >60 cm H_2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the mask is seated too high in the pharynx, then press in further to confirm contact with the upper esophageal sphincter.
- Ensure proper fixation by applying palatal pressure while taping in place.
- Always confirm cuff integrity prior to placement.

Malposition of airway product

In general, malposition of the airway product can be assessed by capnography or by observation of changes in tidal volume, e.g., a reduced expired tidal volume. If malposition is suspected, check whether there is a smooth, oval neck swelling extending below the thyroid

cartilage. If absent, it may indicate anterior misplacement of the mask tip into the laryngeal inlet, particularly if there is an unusually prolonged expiratory phase. If malposition is suspected, the airway product may be removed and reinserted once anesthetic depth is adequate for reinsertion.

Specific malpositions of the LMA ProSeal™ were discussed in Section 8.10. In addition, migration/rotation of the LMA ProSeal™ during use may occur due to overinflation of the cuff, a herniated cuff and/ or accidental displacement. Check cuff pressure at the start and periodically during a case, verify cuff integrity prior to use and ensure proper fixation. If the LMA ProSeal™ pops out of the mouth during insertion, the mask may be incorrectly positioned with the distal tip folded backward in the pharynx. Remove and reinsert or digitally sweep behind the tip.

Unexpected regurgitation

Even in fasted patients, regurgitation may occur for a variety of reasons (for example, if anesthesia 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.

If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the airway should not be removed. 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 anesthetic circuit so that gastric contents are not forced into the lungs. Verify that anesthetic depth is adequate and deepen anesthesia intravenously, if appropriate. Reposition the device to ensure the distal end is lying against the upper esophageal sphincter and secure it in place using the fixation method described in Section 8.11. Suction should then be applied through the airway tube. Suction of the tracheobronchial tree using a fiberoptic bronchoscope through the airway tube 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.

Airway obstruction with the LMA ProSeal™

There have been reports of airway obstruction occurring with the LMA ProSeal™. Some of the reports were associated with noisy respiration and negative pressure, causing air to be drawn into the esophagus with inspiration. Other clinicians have reported an increased incidence of stridor with the LMA ProSeal™. One proposed mechanism of the airway obstruction is pressure from the distal mask causing narrowing of the glottic inlet and subsequent mechanical closure of the vocal cords. Another mechanism is folding of the cuff wall medially, causing a physical airway obstruction. Should the patient show signs of airway obstruction, one or more of the following measures may be taken:

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Ensure intracuff pressures are not >60 cm H_2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the patient is spontaneously breathing, provide expiratory PEEP up to a clinically safe level or use PPV.
- Try placing the patient's head and neck in a sniffing position (head extended and neck flexed).
- Consider fiberoptic examination to evaluate cuff position and vocal cord function.
- If all else fails, remove and reinsert.
- If appropriate, consider insertion of a smaller sized LMA ProSeal™.

Caution: If airway problems persist or ventilation is inadequate, LMA ProSeal™ airway should be removed and an airway to be established by some other means.

9.5 Emergence from anaesthesia and removal

If applicable, reverse the neuromuscular block or allow the block to wear off before switching off the anesthetic 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 the intracuff pressure.

The correctly placed LMA Proseal™ is well tolerated until the return of protective reflexes, provided that intracuff pressures are kept around 60 cm H_2O.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 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 anesthetic circuit or via a T-piece. If suction is required around the oral cavity or down the airway or drain tube, 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 in this position under adequate anaesthesia.
- Avoid suctioning 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 anesthesia 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 anesthesia.
- 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 airway 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 anesthesiologist should always be readily available if the device is to be removed away from the operating room.

10. PEDIATRIC USE

The smaller airway sizes have been shown to function effectively in children despite the differences between the adult and the infant larynx. It is recommended that airway use in neonates and small children be performed by anaesthesiologists familiar with pediatric patients and already experienced in adult airway anaesthesia.

Appendix at the back of this manual provides basic guidelines for sizing. In children at the transition weights, substitution of one size for another may be necessary.

LMA™ airway insertion in children is carried out in the same way as described for adults following either intravenous or gaseous induction, provided an adequate depth of anesthesia is achieved. Insertion should be successful at the same plane of anesthesia that would be suitable for tracheal intubation. The incidence of airway problems in children with the LMA™ airway seems to follow the same trend as in adults. However, as with any form of anaesthesia and airway management in infants and children where ventilation is inadequate, desaturation is likely to occur faster due to their higher oxygen consumption.

LMA™ airway anaesthesia in children and infants is associated with maintenance of higher oxygen saturation compared to a face mask and Guedel airway and the ability to cough and cry while waking up. The LMA™ airway is suitable for many short pediatric ambulatory surgical or diagnostic procedures and those where access to the head and neck would otherwise be limited by the use of a face mask.

11. USE WITH MAGNETIC RESONANCE IMAGING (MRI)

MR Conditional

Non-clinical testing demonstrated that the LMA ProSeal™ is MR Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

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

MRI-Related Heating

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

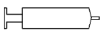
Artifact Information

The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MRI system extends approximately 50-mm relative to the size and shape of the LMA ProSeal™, Size 5.

12. SYMBOL DEFINITION


Manufacturer

Consult IFU on this website: www.LMACO.com


Air inflation volume


Patient weight


Read Instructions before use

Not made with natural rubber latex


Fragile, handle with care


Keep away from sunlight


Keep Dry


This way up

Product Code

Lot Number

CE Mark

Serial Number

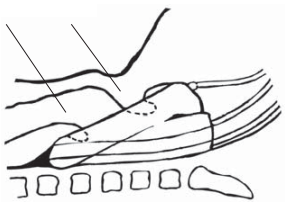
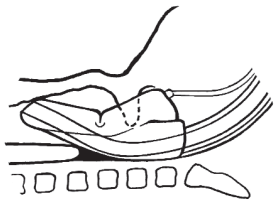
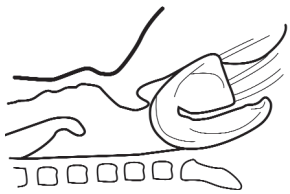
Do not reuse more than 40 times

Non-sterile

MR Conditional

13. APPENDIX A: STEPS TO FACILITATE CORRECT MASK POSITION

- After insertion, inflate the cuff to no more than 60 cm H_2O intracuff pressure.
- Connect to anesthesia circuit and check for leaks from the drain tube and airway tube.
- Verify position of bite block.
- Place a small bolus of lubricant gel on the proximal end of the drain tube and gently squeeze the bag to assess movement.
- If necessary, pass an orogastric tube to the end of the mask tip to verify the drain tube is patent.
- Once correctly positioned, apply palatal pressure to tubes while taping in place.

	✓ **Correct placement**	× **Incorrect placement**	× **Incorrect placement**	× **Incorrect placement**
				
Mask position	Tip behind arytenoid and cricoid cartilages	Tip too high in pharynx	Tip in laryngeal vestibule	Tip folded backwards
Gas leak from drain tube	No	Yes	Yes	No
Bite block	Approximately midway between teeth	Too high	Approximately midway between teeth	Too high
Lubricant test	Slight meniscus movement	May have movement depending on position	• Marked up/down movement • Ejection of lubricant or spontaneous bubble formation	No meniscus movement
Additional verification	Passing OG tube to mask tip demonstrates drain tube is patent	Pressing in further eliminates leak	Pressing in further increases obstruction	Difficulty passing OG tube indicates occluded drain tube

14. APPENDIX B: TIPS FOR TROUBLE SHOOTING PROBLEMS AFTER LMA PROSEAL™ INSERTION

Problems after insertion	Possible cause(s)	Possible solution(s)
Poor airway seal/air leak (audible air leak, poor ventilation)	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Inadequate anaesthesia	Deepen anaesthesia
	Poor fixation	Ensure palatal pressure and proper fixation
	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O (adjust if necessary)
	Herniation of cuff	Confirm cuff integrity prior to use; deflate entirely prior to autoclaving
Gas leakage up to drain tube with or without PPV	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Open upper esophageal sphincter	Monitor
Airway obstruction (difficult ventilation, phonation, stridor)	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Distal tip of mask pressing on glottis inlet with mechanical closure of vocal cords	- Ensure adequate anaesthesia and correct cuff inflation pressures - Place patent's head/neck in sniffing position - Try PPV or add PEEP
	Folding of cuff walls medially	- Consider insertion of one size smaller LMA ProSeal™ - Ensure correct cuff inflation pressures
Gastric insufflation	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
Migration/Rotation/Mask popping out of mouth	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O
	Herniation of cuff	Confirm cuff integrity prior to use
	Accidental displacement	Ensure proper fixation
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Poor fixation	Ensure palatal pressure and proper fixation
Resistance to OG tube insertion	Insufficient lubrication	Add lubricant and re-attempt passing OG tube
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Gross overinflation of cuff	Check off pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O

15. APPENDIX C: 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 judgement 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.

LMA ProSeal™ size	Patient selection information	Maximum inflation volume	Maximum Diameter of Oro-gastric Tube	Introducer size
1	Neonates up to 5kg	4ml	2.7mm / 8fr	1 - 2½
1½	Infant 5-10kg	7ml	3.5mm / 10fr	1 - 2½
2	Child 10-20kg	10ml	3.5mm / 10fr	1 - 2½
2½	Child 20-30kg	14ml	4.9mm / 14fr	1 - 2½
3	Child 30-50kg	20ml	5.5mm / 16fr	3 - 5
4	Adult 50-70kg	30ml	5.5mm / 16fr	3 - 5
5	Adult 70-100kg	40ml	6.0mm / 18fr	3 - 5

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.

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Teleflex Medical
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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.

Issue: PAB-2100-001 Rev B UK

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LMA | ProSeal™