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Instructions For Use

EN–English Version

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LMA[®] ProSeal[™]

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

WARNING: LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer accessory are 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.

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

1. DEVICE DESCRIPTION

The LMA[®] 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.

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. The LMA[®] ProSeal[™] should not be reused more than 40 times. 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.
- 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).

Accessory Device: The LMA[®] ProSeal[™] Introducer is an accessory of LMA[®] ProSeal[™]. It is a removable introducer tool to aid insertion of LMA[®] ProSeal[™] without placing fingers in the mouth. The LMA[®] ProSeal[™] Introducer is supplied in the recommended curvature for immediate use. It is supplied non-sterile and

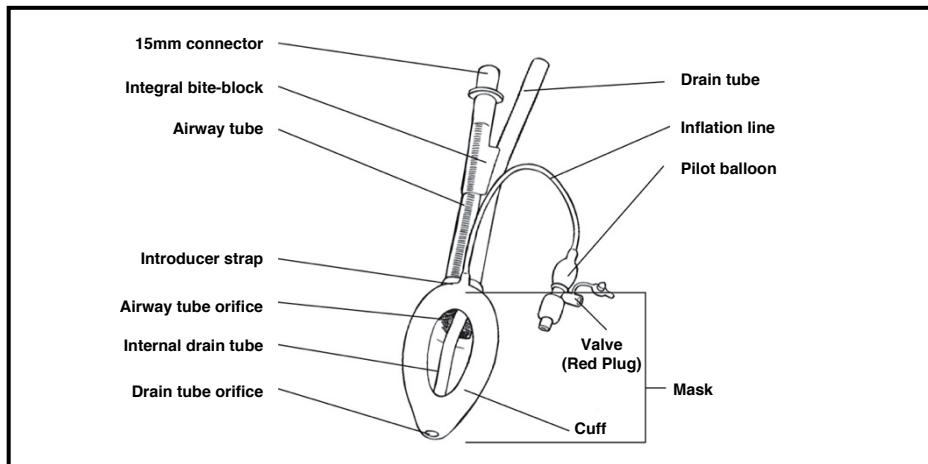


Figure 1: The components of the LMA[®] ProSeal[™] in sizes 1 1/2, 2, 2 1/2, 3, 4, and 5.

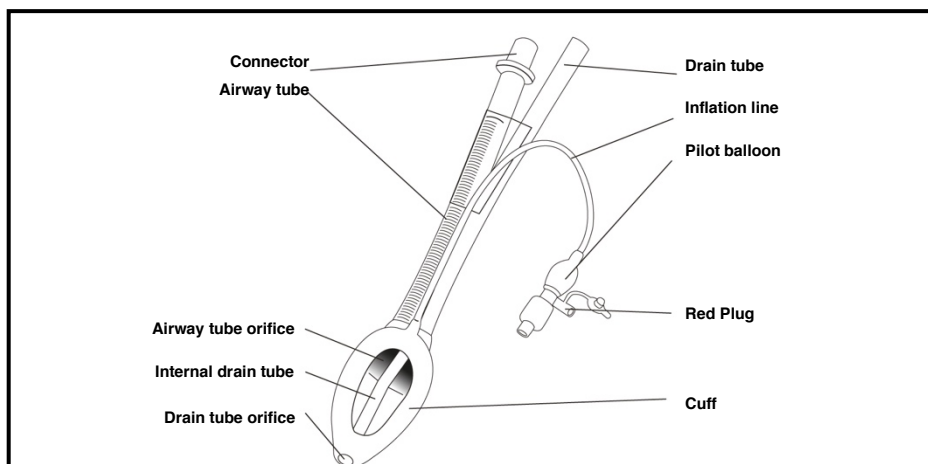


Figure 2: The components of the LMA[®] ProSeal[™] size 1.

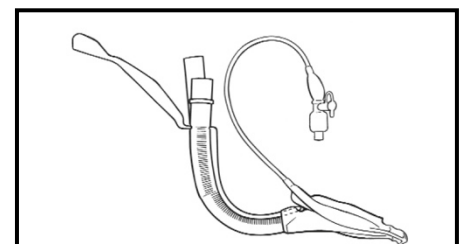


Figure 3: LMA[®] ProSeal[™] airway with LMA[®] ProSeal[™] Introducer in place.

autoclavable. The LMA[®] ProSeal[™] Introducer is available in the following two models with different sizes and usage range:

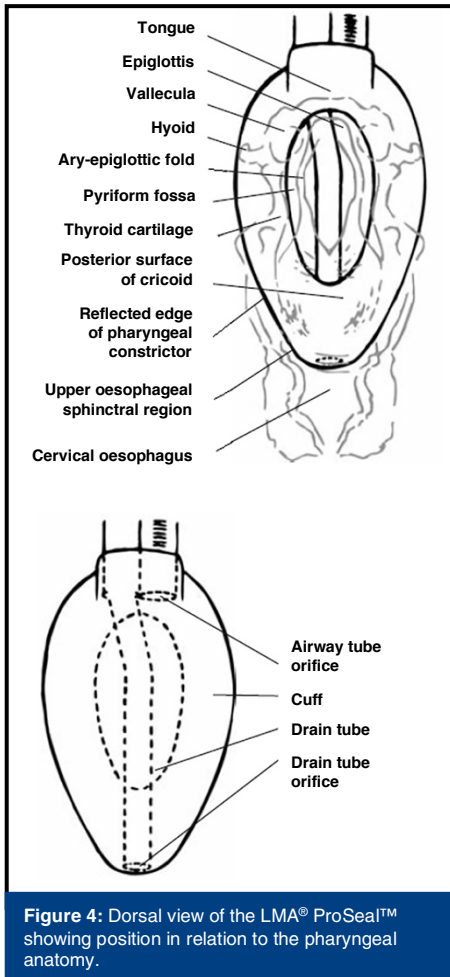


Figure 4: Dorsal view of the LMA[®] ProSeal[™] showing position in relation to the pharyngeal anatomy.

LMA[®] ProSeal[™] Introducer size 1–2.5 : This introducer is intended to use with LMA[®] ProSeal[™] size 1 to size 2.5. The main components that made up this introducer are handle and body. Both components are made of medical grade stainless steel material.

LMA[®] ProSeal[™] Introducer size 3-5 : This introducer is intended to use with LMA[®] ProSeal[™] size 3 to 5. The main components that made up this introducer are handle, body and sleeve. Handle and body are made of medical grade stainless steel material. Sleeve is made of medical grade silicone material.

The LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer accessory are only for use by medical professionals trained in airway management.

2. INDICATIONS FOR USE

LMA[®] ProSeal[™]

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.

LMA[®] ProSeal[™] Introducer

The LMA[®] ProSeal[™] Introducer is intended to use as a removable introducer tool to aid insertion of LMA[®] ProSeal[™] without placing fingers in the mouth. It is indicated for use as a tool to aid insertion of LMA[®] ProSeal[™] without placing fingers in the mouth.

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

LMA[®] ProSeal[™]

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 H₂O 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[™].

LMA[®] ProSeal[™] Introducer

There are no known contraindications associated with the LMA[®] ProSeal[™] Introducer accessory device.

5. WARNINGS & CAUTIONS

Throughout this instruction manual, appropriate warnings and cautionary statements are given describing potential safety hazards associated with use of LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer.

LMA[®] ProSeal[™] Introducer, 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[™] and LMA[®] ProSeal[™] Introducer.

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 H₂O. The cuff is designed to be inflated to a low pressure (approximately 60 cm H₂O). 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 Pre-use Check/ Performance Tests must be conducted before each use of LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer. 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[™] and LMA[®] ProSeal[™] Introducer 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 cleaning agents, iodine-containing cleaning agents 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.

Potential side effects may include airway trauma, dysphagia, sore throat, dysphonia, laryngospasm, obstruction, stridor, bronchospasm, hoarseness, nausea and vomit, regurgitation, aspiration, gastric distension, patient intolerance e.g. coughing, and mouth, lip or tongue injury.

Note: For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

7. PREPARATION FOR USE

Warning: LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer are 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.

Warning: The LMA[®] ProSeal[™] Introducer accessory should be cleaned and sterilised in the same manner as the LMA[®] ProSeal[™].

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 Reprocessing

General Warnings, Precautions and Restrictions

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard to hospital hygiene and sterilisation technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilisation is performed using appropriate equipment, materials, and personnel to achieve the desired result. Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

The equipment used during reprocessing should be validated for effectiveness according to internationally recognized standards:

- Washers-disinfectors meeting the requirements of ISO 15883 series and/or ANSI / AAMI ST15883 Series.
- Steam sterilizers meeting the requirements of EN 13060/EN 285 in conjunction with ISO 17665 and / or ANSI AAMI ST8, ANSI AAMI ST79.

The World Health Organization (WHO) guidelines and published literature indicate that the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer cleaning and sterilisation procedures outlined below are sufficient for inactivation of conventional pathogens (i.e., bacteria, fungi, and viruses). In patients known or suspected to have transmissible spongiform encephalopathy, it is recommended that the institutions follow WHO guidelines by destroying rather than reusing LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer after use.

Warning: Before initial use and any subsequent use, all devices must be subjected to reprocessing as described in the following sections. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

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.

Warning: With proper cleaning, sterilisation, and handling, the LMA[®] ProSeal[™] can be used a maximum of 40 times. Proper cleaning and sterilisation of the airway is essential to ensure continued safe usage up to 40 times. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

REPROCESSING PRIOR TO FIRST AND ANY SUBSEQUENT USE

Preparation at the point of use prior to processing

Remove all traces of contamination immediately after use to avoid incrustation. Do not use fixative agents or hot water (>40°C/104°F). Storage and transport of the devices to the reprocessing location must be ensured in a sealed container.

CLEANING

Warnings and Precautions

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex[®]), ethylene oxide, phenol based cleaning agents, iodine containing cleaning agents or quaternary ammonium compounds to clean or sterilise the airway. Such substances are absorbed by the device materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer that has been exposed to any of these substances. The cleaning agents must not contain skin or mucous membrane irritants.

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If recommended cleaning agents / detergents that are indicated in the cleaning section are not available, mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. Please note that any deviation from these instructions, including the use of cleaning agents / detergents not specifically indicated in these instructions will require an evaluation of device specific efficacy and suitability of the cleaning process. Respective evaluation usually requires equipment qualification and device specific performance qualification / validation.

Warning: Failure to properly clean, rinse, and dry the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer may result in retention of potentially hazardous residue or inadequate sterilisation.

Freshly prepared purified water/ highly purified water or sterile water for final rinsing purposes is highly recommended.

Manual Cleaning

Always use a freshly prepared cleaning bath. Observe the cleaning agent manufacturer's instructions in regard to recommended temperatures, concentration and holding times.

Manual cleaning instructions have been validated using the following equipment / cleaning agents:

Cleaning Brush: An appropriate size soft bristle brush.

Cleaning Agents/Cleaning Process:

- A) Endozyme[®] Dual Enzymatic Detergent, Ruhof Healthcare.

Cleaning Process using cleaning agent A above:

- 1) Place the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer in a freshly prepared cleaning solution (concentration 0.8%) at 36°C to 40°C/97°F to 104°F and thoroughly clean the devices until all visible contamination is removed.
- 2) When cleaning the LMA[®] ProSeal[™], ensure the areas behind the LMA[®] ProSeal[™] Introducer strap and under the internal drain tube are clean.
- 3) Clean the airway tube by gently inserting the brush and stroking in and out.
- 4) Clean the drain tube by gently inserting the brush through the proximal (outer) end of the drain tube, taking care not to damage the drain tube.
- 5) Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
- 6) Carefully inspect all components for residual contamination.
- 7) If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Dry adequately at room temperature or in a drying cabinet with circulating air.

or,

- B) Dilute (8-10% v/v) sodium bicarbonate solution. 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water.

Cleaning Process using cleaning agent B above:

- 1) Place the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer in a freshly prepared cleaning solution at 36°C to 40°C/97°F to 104°F and thoroughly clean the devices until all visible contamination is removed.
- 2) Prepare a second freshly prepared cleaning solution as described above and thoroughly clean the devices using appropriate soft bristle brush.
- 3) When cleaning the LMA[®] ProSeal[™], ensure the areas behind the LMA[®] ProSeal[™] Introducer strap and under the internal drain tube are clean.
- 4) Clean the airway tube by gently inserting the brush and stroking in and out.
- 5) Clean the drain tube by gently inserting the brush through the proximal (outer) end of the drain tube, taking care not to damage the drain tube.
- 6) Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
- 7) Carefully inspect all components for residual contamination.
- 8) If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Dry adequately at room temperature or in a drying cabinet with circulating air.

Automated Cleaning

Automated cleaning instructions have been validated using the following equipment:

Washer: Miele Type G7735 CD, Miele Standard rack with rinse ports.

Cleaning Agents: Deconex[®] PowerZyme, Borer Chemie AG

Thoroughly deflate all cuffs. Place the devices in the instrument rack. Ensure adequate placement of all devices in a way that all internal and external areas of the devices are accessible. Connect the lumens of the airways with the rinse ports.

Start washing process: Miele G 7735 CD washer-disinfector, Vario TD programme.

- 1) 2 min pre-cleaning with cold water ($\leq 35^{\circ}\text{C}/95^{\circ}\text{F}$)
- 2) Drain
- 3) 5 min cleaning with Deconex[®] PowerZyme, 0.5% at $55^{\circ}\text{C}/131^{\circ}\text{F}$
- 4) Drain
- 5) 3 min neutralization with cold water ($\leq 35^{\circ}\text{C}/95^{\circ}\text{F}$)

- 6) Drain
- 7) 2 min rinsing with cold water ($\leq 35^{\circ}\text{C}/95^{\circ}\text{F}$)
- 8) *Optional thermal disinfection following automated cleaning
5 min thermal disinfection at $90^{\circ}\text{C}/194^{\circ}\text{F}$

Ensure adequate drying (e.g. circulating air $70^{\circ}\text{C}/158^{\circ}\text{F}$, 1 hour).

*Disinfection

Thermal disinfection may be performed as part of the automated cleaning process as in step no. 8 above for Vario TD programme.

INSPECTION, MAINTENANCE AND TESTING

Perform device inspection and functionality checks as described in section "Pre-Use Check/Performance Tests".

All the functional tests and inspections described in this manual must be conducted as part of every reprocessing procedure prior to sterilisation of the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer. Failure in any of respective testing indicates that the device has passed its useful life and should be replaced.

PACKAGING

The selected packaging for thermal sterilization must comply to requirements according to ISO/ANSI AAMI ISO 11607. For USA: Use FDA-cleared sterilization wraps.

Visually check for residual moisture prior to packaging into sterilisation wrap.

STERILISATION

Warnings and Precautions

Steam autoclaving is the only recommended method for sterilisation of the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer.

Adherence to the following procedure is essential to ensure sterilisation without damage to the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer.

Caution: The integrity of the reusable LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer materials will be adversely affected by exceeding sterilisation cycle of 273°F or 134°C .

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare facility personnel are responsible for adhering to the processes specified and validated in their facility and for maintaining process control. Failure to do so may invalidate the healthcare facility's sterilisation process.

For the 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. Ensure that both the syringe used to deflate the cuff and the valve is dry.

To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving after deflation.

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If the cuff of a deflated LMA[®] ProSeal[™] without manual valve 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 device to re-inflate slowly over a period of several hours as the silicone rubber material is permeable to gas.

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

For the sterilisation of 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.

Sterilisation Settings

Steam sterilization is recommended either via pre-vacuum or gravity displacement process. Each of the following cycles has been validated in accordance with internationally harmonized standards to reach a sterility assurance level (SAL) that is appropriate for the intended use of the devices and in compliance with internationally recognized standards and guidelines.

Type	Temperature	Holding Time	Minimum Drying Time
Prevac Cycle	134°C (273°F)	3 Minutes	16 Minutes
Gravity Displacement	132°C (270°F)	10 Minutes	1 Minute

After autoclaving, allow the device to cool to room temperature before use.

STORAGE

Store the sterilised devices at room temperature in a dry and dust-free place, protected from direct sunlight.

Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

7.2 Pre-Use Check/ Performance Tests

Warning: All of the non-clinical inspections or tests described below must be conducted before each use of LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer accessory device. 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.

7.2.1 Performance Test 1: Visual Inspection

LMA[®] ProSeal[™] Device

- 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.

LMA[®] ProSeal[™] Introducer accessory

- Visually check that the device is free from debris and is not damaged or deteriorated, such as deformation, surface cracks, etc.

Warning: Do not use the LMA[®] airway or any of the accessories if they are damaged or deteriorated in any way.

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.

7.2.2 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.

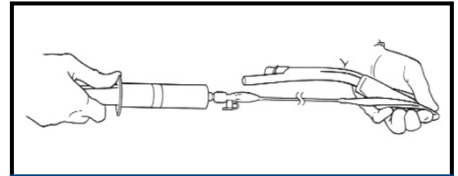


Figure 5: Manual deflation of the LMA[®] ProSeal[™] (note manual pressure at tip).

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.

7.3 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 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 valledulla or glottis and avoids it becoming caught against the epiglottis or the arytenoids.

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

Method of cuff deflation:

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.

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[™] and LMA[®] ProSeal[™] Introducer 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.

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

8. INSERTION

8.1 Introduction

Before using the LMA[®] ProSeal[™] and LMA[®] ProSeal[™] Introducer, 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 anaesthesia before attempting insertion. Resistance or swallowing, biting or retching indicates inadequate anaesthesia and/or inappropriate technique. 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.

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 vallecula 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 6a to 6b) 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 manoeuvre.

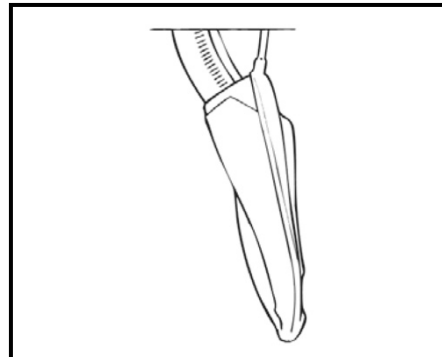


Figure 6a: LMA[®] ProSeal[™] cuff properly deflated for insertion

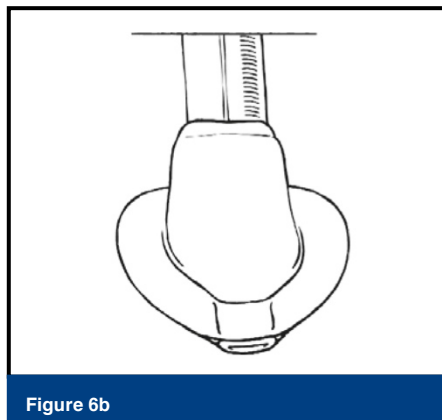


Figure 6b

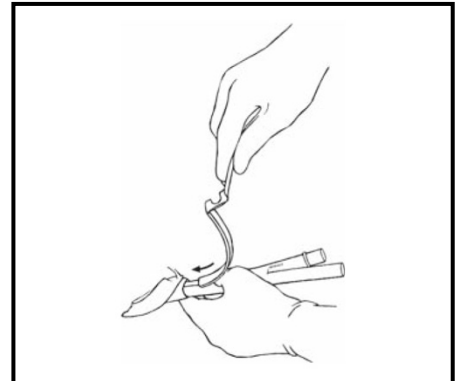


Figure 7a: Place the tip of the LMA[®] ProSeal[™] Introducer into the strap.

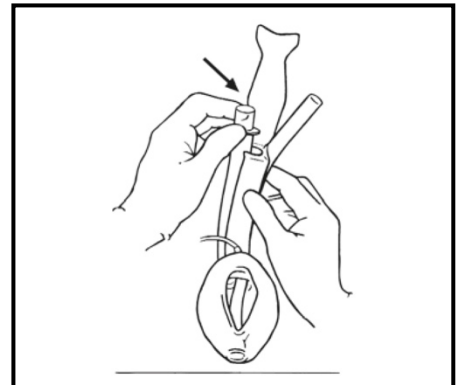


Figure 7b: Fold the tubes around the LMA[®] ProSeal[™] Introducer and fit the proximal end of the airway tube into the matching slot.

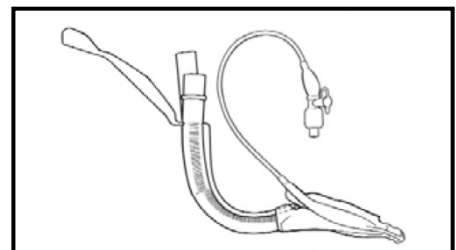


Figure 8: LMA[®] ProSeal[™] mounted on the LMA[®] ProSeal[™] Introducer.

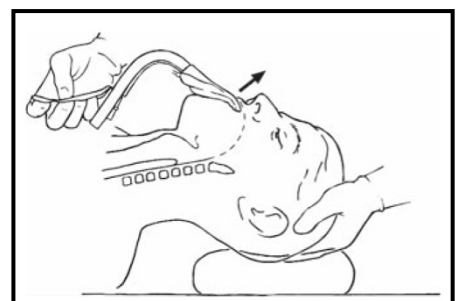


Figure 9: Press the tip of the cuff against the hard palate.

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 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 LMA[®] ProSeal[™] is shown mounted in the Introducer in Figure 8.

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it (Figure 9). 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 10). 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 11).

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 12).

Before removing the Introducer, the non-dominant hand is brought from behind the patient's head to stabilize the airway tube (Figure 13). 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[™].

8.5 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 and position of the hand and wrist (Figure 15).

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.

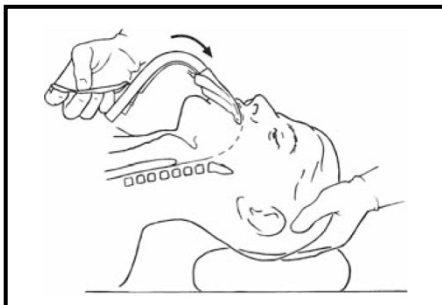


Figure 10: Press the cuff further into the mouth, maintaining pressure against the palate.

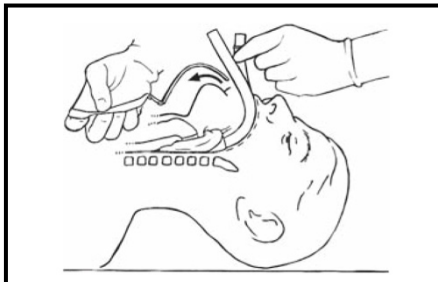


Figure 13: Hold the tubes in place whilst removing the LMA[®] ProSeal[™] Introducer.

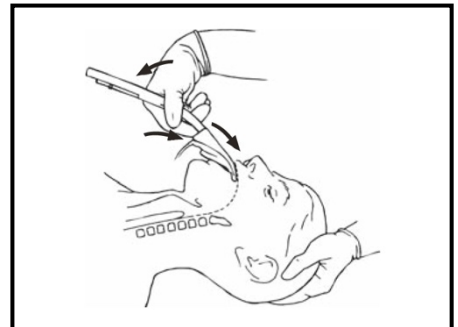


Figure 16: Press the mask up against the hard palate.

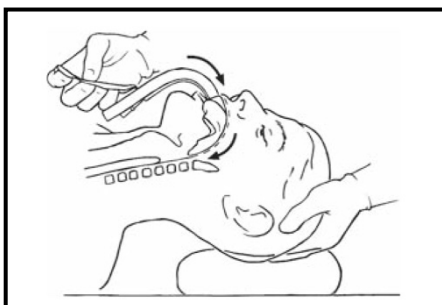


Figure 11: Swing the device inwards with a circular motion, pressing against the contours of the hard and soft palate.

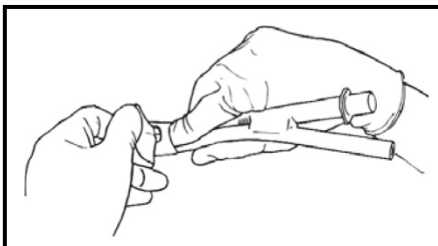


Figure 14: Hold the LMA[®] ProSeal[™] with the index finger in the strap.



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

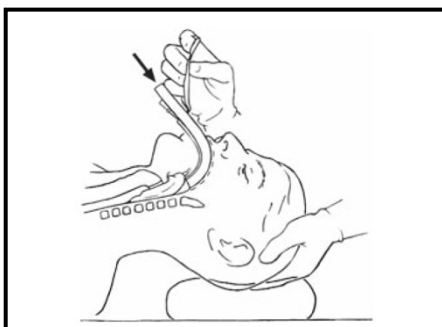


Figure 12: Advance the device into the hypopharynx until resistance is felt.

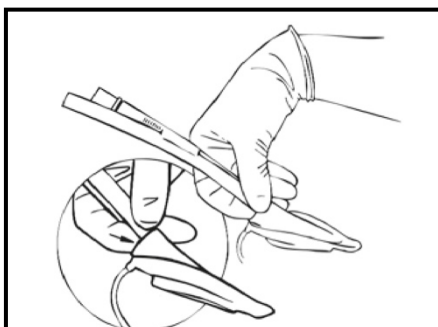


Figure 15: Hold the device with the index finger in the strap; note the flexed wrist.

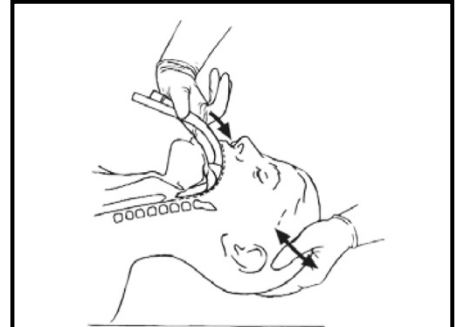


Figure 18: Press the finger towards the other hand which exerts counter pressure.

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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 17). 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 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.

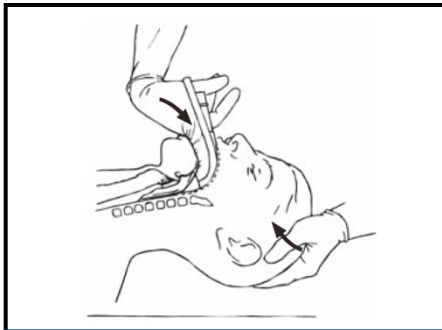


Figure 19: Advance the device into the hypopharynx until resistance is felt.

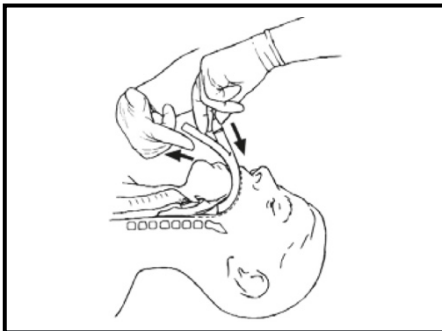


Figure 20: Gently press the outer end of the airway tube while removing the index finger.

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 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.

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 21. 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 22-25).

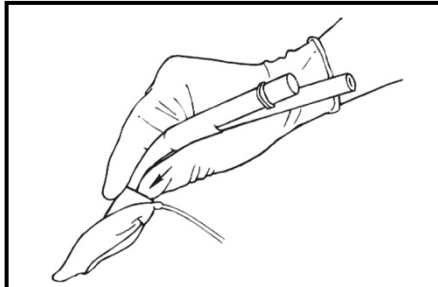


Figure 21: Hold the device with the thumb in the strap.

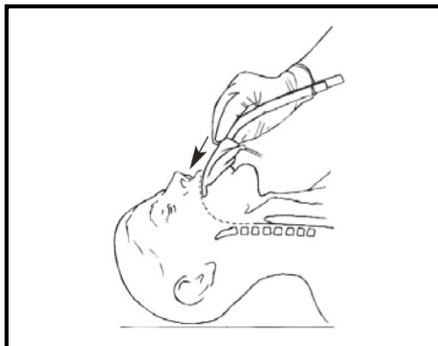


Figure 22: Place the mask against the palate.

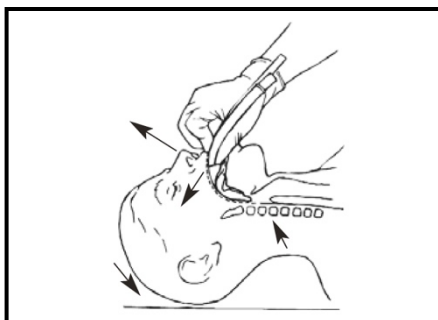


Figure 23: When the thumb is opposite the palate, press cranially (see arrow) to extend the head.

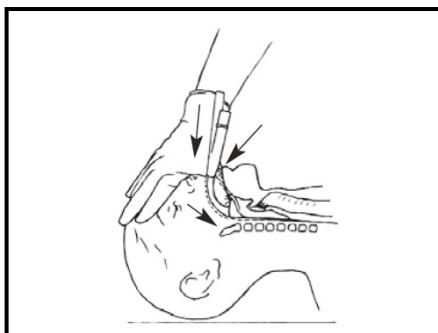


Figure 24: Extend fingers over head, allowing the thumb to pass inward.

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 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 the tube against the palate throughout the insertion manoeuvre, 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 H₂O (Figure 26). 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 H₂O intracuff pressure.

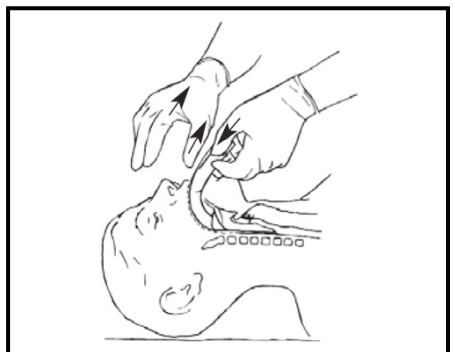


Figure 25: Use other hand to complete insertion as shown.

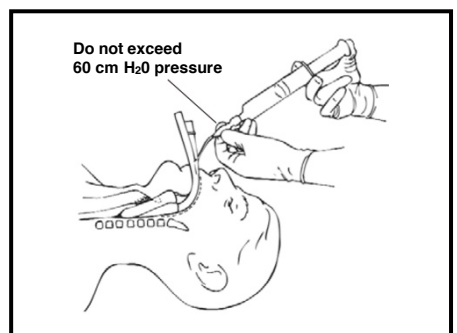


Figure 26: Inflate the LMA[®] ProSeal[™], do not exceed 60cm H₂O pressure.

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Warning: Never overinflate the cuff after insertion. Avoid intracuff pressures greater than 60 cm H₂O. The cuff is designed to be inflated to a low pressure (approximately 60 cm H₂O). 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.

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.

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 27a) 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 27b). 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 27c). 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 27d). 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.

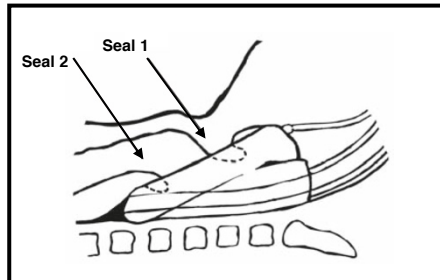


Figure 27a: Correct placement: LMA[®] ProSeal[™] correctly placed: good seal with no gastric insufflation.

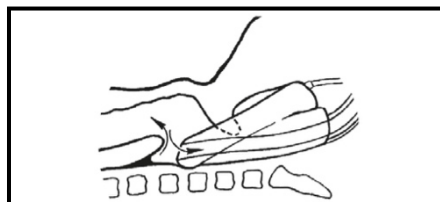


Figure 27b: Incorrect placement. LMA[®] ProSeal[™] placed too high in pharynx: poor seal, allowing gas and fluid to pass in directions shown by arrows; leakage through the drain tube can be eliminated by pressing the mask in further.

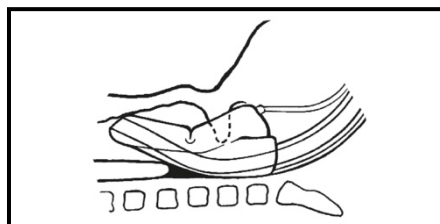


Figure 27c: Incorrect placement. LMA[®] ProSeal[™] placed with tip in laryngeal vestibule; ventilation is obstructed and deteriorates if the mask is pressed further distally.

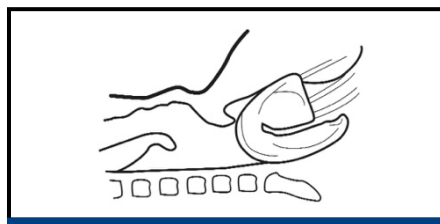


Figure 27d: Incorrect placement. LMA[®] ProSeal[™] mask folded back on itself in the hypopharynx, causing the drain tube to become obstructed.

To distinguish between the mask lying too high (Figure 27b) and having entered the glottis (Figure 27c), 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.

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 28. 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 28.

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.

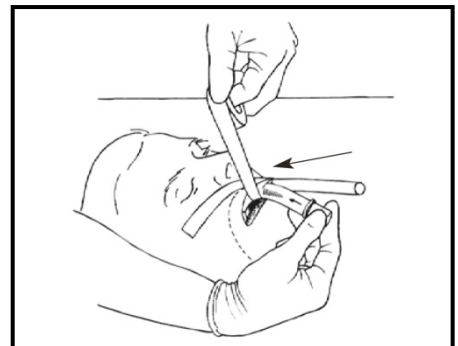


Figure 28: Fix the device in place using adhesive tape.

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 anaesthesia provided anaesthesia 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 anaesthesia for maintenance have been obtained. This is particularly likely to occur following the introduction of an external stimulus such as surgery or turning the patient when the level of anaesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

9.2 Positive Pressure Ventilation (PPV)

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:

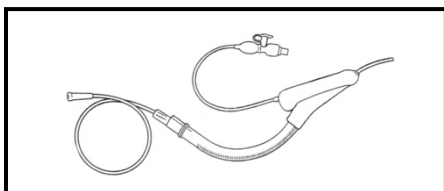


Figure 29: LMA® ProSeal™ with oro-gastric tube.

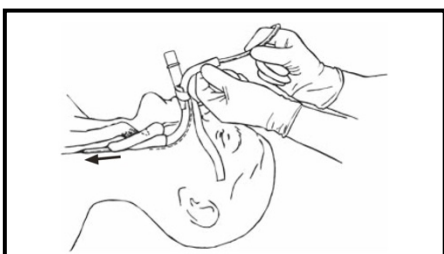


Figure 30: Passage of an oro-gastric tube through the LMA® ProSeal™ into the upper esophageal sphincter.

- 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 H₂O with the LMA® ProSeal™ which is 10 cm H₂O higher than the LMA® Classic™.
- If leaks occur during PPV, this may be due to:
 - Light anaesthesia 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 29). 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 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 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™ airway drain tube.

9.4 Potential problem 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 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 H₂O 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. Secondly, simply feeling the inflation indicator balloon can be performed. At intracuff pressure of 60 cm H₂O, 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 anaesthesia 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 H₂O; 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 anesthetic 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 H₂O; 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[™] 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 H₂O. This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal should always be carried out 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[™] airway 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 anaesthesia is achieved. Insertion should be successful at the same plane of anaesthesia 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

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LMA[®] ProSeal[™]

- 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.

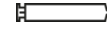
12. SYMBOL DEFINITION



Manufacturer



Consult IFU on this website:
www.LMACO.com



Air inflation volume



Patient weight



Read Instructions before use



Not made with natural rubber latex



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



An indication that the device is a Medical Device.



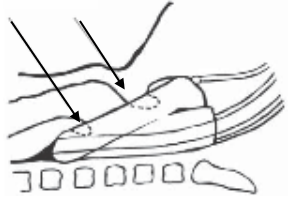

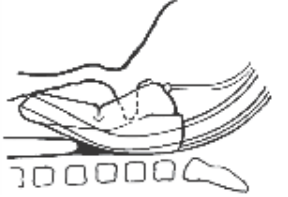
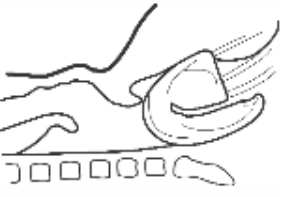
Date of Manufacture

Rx only

Prescription only

13. APPENDIX A: STEPS TO FACILITATE CORRECT MASK POSITION

- After insertion, inflate the cuff to no more than 60 cm H₂O 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	<ul style="list-style-type: none"> • 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 ₂ O (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	<ul style="list-style-type: none"> - Ensure adequate anaesthesia and correct cuff inflation pressures - Place patient's head/neck in sniffing position - Try PPV or add PEEP
	Folding of cuff walls medially	<ul style="list-style-type: none"> - 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 ₂ O
	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 ₂ O

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	Up to 5kg	4ml	2.7mm / 8fr	1 - 2½
1½	5-10kg	7ml	3.5mm / 10fr	1 - 2½
2	10-20kg	10ml	3.5mm / 10fr	1 - 2½
2½	20-30kg	14ml	4.9mm / 14fr	1 - 2½
3	30-50kg	20ml	5.5mm / 16fr	3 - 5
4	50-70kg	30ml	5.5mm / 16fr	3 - 5
5	70-100kg	40ml	6.0mm / 18fr	3 - 5

This typically corresponds to an intra-cuff pressure of 60 cm H₂O. 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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The information given in this document is correct at the time of publication. The manufacturer reserves the right to improve or modify the products without prior notification.

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.

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

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Date Of Issue: 2021-12



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