en

Teleflex®

LMA®
Better by Design

LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ Laryngeal Mask Airway

Rx only

GENERAL INFORMATION

Unless otherwise stated, the reference to “device” stated on this IFU applies to both versions of LMA Unique™ (Silicone Cuff) & LMA® Unique™ (Silicone Cuff) Cuff Pilot™.

The devices are only for use by medical professionals trained in airway management.

DEVICE DESCRIPTION

Both the LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are made primarily of clear polyvinylchloride (PVC) (Airway Tube) and silicone (Cuff) and are supplied sterile (sterilised by Ethylene Oxide) for single use only. The devices are not made with natural rubber latex and phthalates.

LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ have three main components: airway tube, cuff and inflation system.

The inflation system of LMA® Unique™ (Silicone Cuff) consists of an Inflation Line with Pilot Balloon and Check Valve for cuff inflation and deflation. The Pilot Balloon provides an indication of the pressure within the cuff and the Check Valve prevents leakage of air and maintains the pressure in cuff.

The inflation system of LMA® Unique™ (Silicone Cuff) Cuff Pilot™ consists of an Inflation Line with a Cuff Pilot™. The Cuff Pilot™ enables constant visualisation of the pressure inside the mask cuff pressure. It replaces the standard pilot balloon and is to be used in the same way for cuff inflation and deflation.

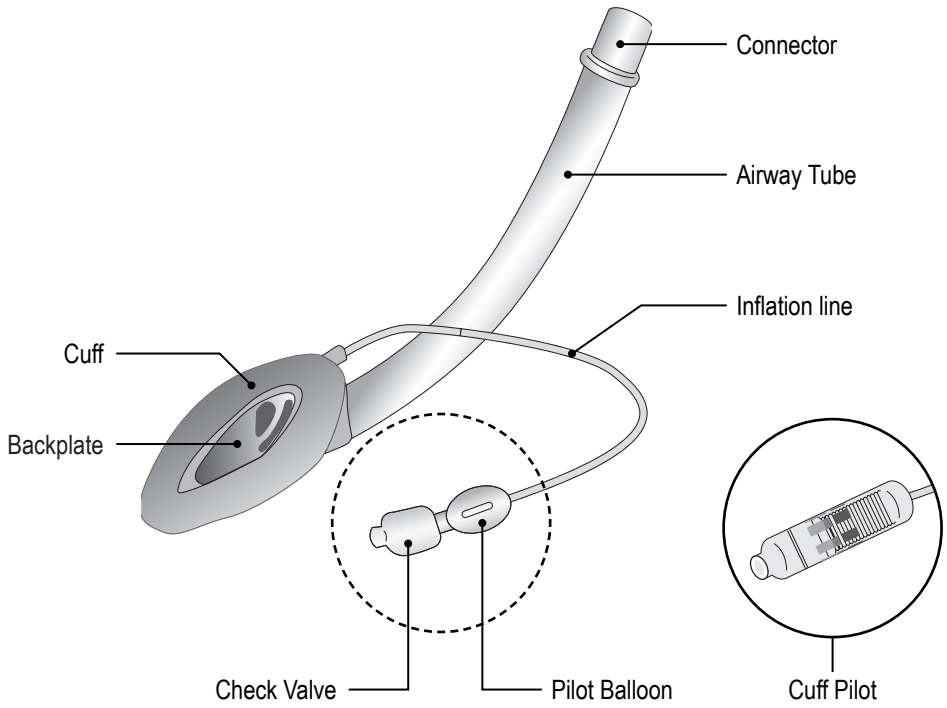

Figure 1. The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ components

INTENDED PURPOSE
The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are intended to be used to facilitate oxygenation and ventilation.

INDICATION FOR USE
The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are indicated for use in achieving and maintaining control of, the patient's airway during routine anaesthetic procedures, in fasted patients, using either spontaneous or Positive Pressure Ventilation (PPV).

They are also indicated for use as a rescue airway device in Cardiopulmonary Resuscitation (CPR) procedures, in which supraglottic airways have traditionally been used as highlighted in numerous international airway management guidelines. Similarly, these devices are also indicated as a "rescue airway device" in known, or unexpected difficult airway situations.

TARGET POPULATION
Size selection is based on ideal weight as outlined in table 1.

	Size							
	1	**1.5**	**2**	**2.5**	**3**	**4**	**5**	**6**
Patient Weight (kg)	Up to 5	5-10	10-20	20-30	30-50	50-70	70-100	>100
Airway connector	15 mm male							
Internal volume of ventilatory pathway (ml)	4	5	7	11	17	19	23	26
Pressure drop (cm H_2O)	< 2.2 at 15 l/min	< 1.0 at 15 l/min	< 1.9 at 30 l/min	< 0.9 at 30 l/min	< 1.5 at 60 l/min	< 1.5 at 60 l/min	< 0.8 at 60 l/min	< 0.9 at 60 l/min
Min. interdental gap (mm)	16	18	21	24	25	30	34	34
Nominal length of the internal ventilatory pathway (cm)	10.5	12.0	13.8	15.0	19.5	19.5	21.3	21.8

Table 1

** LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are in conformity with the International Standard ISO 11712 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors. A summary of the methods, materials, data, and results of clinical studies that validate the requirements of this International Standard are available on request.*

RISK-BENEFIT INFORMATION
When used to facilitate oxygenation and ventilation during general anaesthesia the known benefits of the use of first generation supraglottic airways must be balanced against the known adverse events associated with that use. 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.

CLINICAL BENEFITS
The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ can facilitate oxygenation and ventilation both during general anaesthesia and as an airway rescue device in the setting of difficult or failed intubation.

DURATION OF USE
The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are intended for short term use.

CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do not use the device 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 emergency and resuscitation situations or any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The device is also contraindicated in:

- Patients with fixed decreased pulmonary compliance, or peak insufflation pressure anticipated to exceed 20 cm H_2O, because the device forms a low-pressure seal (approximately 20 cm H_2O) around the larynx.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for the device.
- The device should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist device insertion.

⚠ WARNINGS

- **Read all Instructions for Use warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.**
- **Single Use: Do not reuse, reprocess, or re-sterilise. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or loss of functionality.**
- LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are supplied sterile for single use only, should be used straight from the pack and should be discarded after use. They must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- The device may be flammable in the presence of lasers and electrocautery equipment.
- It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.
- Do not immerse or soak the device in liquid prior to use.
- Never overinflate the cuff over 60 cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- A water-soluble lubricant, such as K-Y Jelly®, should be used to lubricate the device prior to insertion. Do not use silicone- based lubricants as they degrade the device components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding organs, including the vocal cords.
- The device does not prevent regurgitation or aspiration. Its use in anaesthetized patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. Do not use the devices without taking appropriate precautions to ensure the stomach is empty.
- 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.
- Refer to MRI information section prior to using the devices in MRI environment.

⚠ CAUTIONS

- Do not use if the device is damaged or its unit packaging is damaged or opened.
- When applying lubricant avoid blockage of the airway aperture with the lubricant.
- To avoid trauma, excessive force must be avoided at all times.
- 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 line as it may detach from the cuff spigot.
- Only use a syringe with standard luer taper tip for inflation or deflation.
- Only use with the recommended manoeuvres described in the instructions for use.
- If airway problems persist or ventilation is inadequate, the device should be removed and an airway established by some other means.
- Careful handling is essential. Avoid contact with sharp or pointed objects at all times to prevent tearing or perforation of the device. Do not insert the device unless the cuffs are fully deflated as described in the instructions for insertion.

- Gloves should be worn during preparation and insertion to minimize contamination of the airway.
- Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
- Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
- 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.
- The patency of this device should be reconfirmed after any change in the patient's head or neck position.

ADVERSE EVENTS

There are reported adverse reactions associated with the use of laryngeal mask airways. Potential side effects may include airway trauma, vocal cord injury, mouth injury, oropharyngeal injuries, laryngeal nerve injury, dysphagia, sore throat, dysphonia, laryngospasm, stridor, bronchospasm, hoarseness, nausea, vomiting, regurgitation, aspiration, coughing.

PREPARATIONS FOR USE

Choose the correct size of device. Refer to Table 1 for patient weight and size information.

Keep a clearly marked syringe for inflation and deflation of the cuff.

PRE-USE PERFORMANCE TESTS

The following inspections and tests must be conducted before this device is used. The performance tests should be conducted in an appropriate clinical area, and in a manner consistent with accepted medical practice, that will minimize contamination of the device before insertion.

Do not use the device should it fail any one of the following inspections or tests:

1. **Examine the interior of the airway tube to ensure it is free from blockage or loose particles.** Examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. **Holding at each end flex the airway tube to increase its curvature up to but not beyond 180°.** Should the tube kink during this procedure, discard the device.
3. **Deflate the cuff completely.** Once deflated, check the cuff for spontaneous inflation. Do not use the device if the cuff spontaneously inflates.

For LMA® Unique™ (Silicone Cuff)

Re-inflate the device with a volume of air 50% greater than the maximum inflation value for each size.

	Device Size							
	1	**1.5**	**2**	**2.5**	**3**	**4**	**5**	**6**
Over-inflation cuff in pressure (cm H_2O)	Approximately 90	Approximately 90	Approximately 90	Approximately 90	Approximately 90	Approximately 90	Approximately 90	Approximately 90

Table 2: Test cuff over-inflation

Examine the cuff for leaks, herniations and uneven bulging. If any indications of these problems exist, discard the device. A herniating mask may cause obstruction during use.

While the device remains 50% over-inflated, examine the inflation pilot balloon. The balloon shape should be elliptical, not spherical. Then, deflate the mask again.

For LMA® Unique™ (Silicone Cuff) Cuff Pilot™

Re-inflate the device to Red Zone of Cuff Pilot™ **(Figure 12)** with a volume of air > 70 cm H_20.

Examine the cuff for leaks, herniations and uneven bulging. If any indications of these problems exist, discard the device. A herniating mask may cause obstruction during use. Then, deflate the mask again.

4. **Examine the airway connector.** It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
5. **Discolouration.** Discolouration affects visibility of fluid in the airway tube.
6. Gently pull the inflation line to ensure it is securely attached to both the cuff and balloon.
7. **Examine the aperture in the mask.** Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. If the aperture bars are not intact, the epiglottis may obstruct the airway. Do not use if the aperture bar is damaged.

DEFLATING THE DEVICE PRIOR TO INSERTION

1. Firmly connect a syringe of at least 50 mL to the inflation port.
2. Move the connected syringe away from the device until the inflation line is slightly stretched.
3. Compress the distal end of the device between the index finger and thumb while withdrawing air until a vacuum has been obtained.
4. While deflating, hold the device so that the distal end is curled slightly anteriorly.
5. Deflate the device until the tension in the syringe indicates a vacuum has been created in the mask.
6. Keep the syringe under tension whilst rapidly disconnecting it from the inflation port. This will ensure that the mask remains correctly deflated.

DIRECTIONS/INSTRUCTIONS FOR USE

Refer to Cautions and Warnings for additional guidance.

INSERTION

Standard Insertion Method:

1. **Anaesthesia must be deep enough to permit insertion.**
   Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given.
2. Position the head and neck as for normal tracheal intubation.
   Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand **(Figure 2)**.
3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube **(Figure 2)**. Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.
4. Using the index finger, push the mask backwards **still maintaining pressure against the palate (Figure 3).**

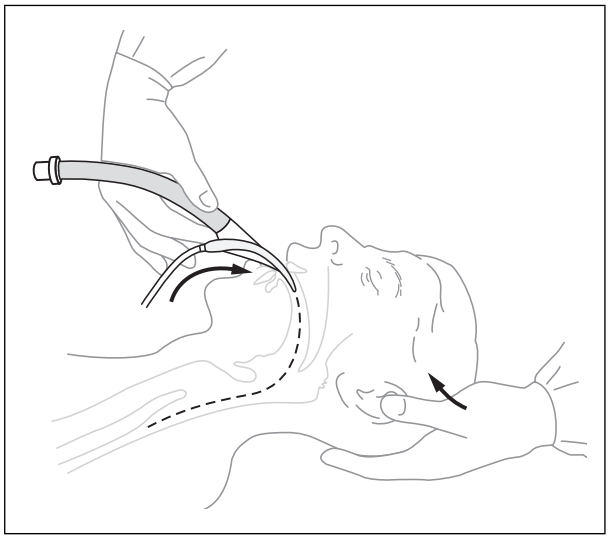

Figure 2

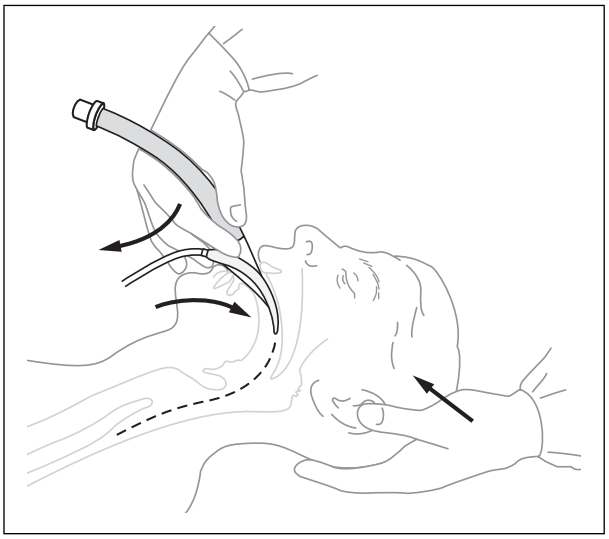

Figure 3

5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion **(Figure 4)**. Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. **(Figure 4)**.
   AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.
   When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth **(Figure 5)**.

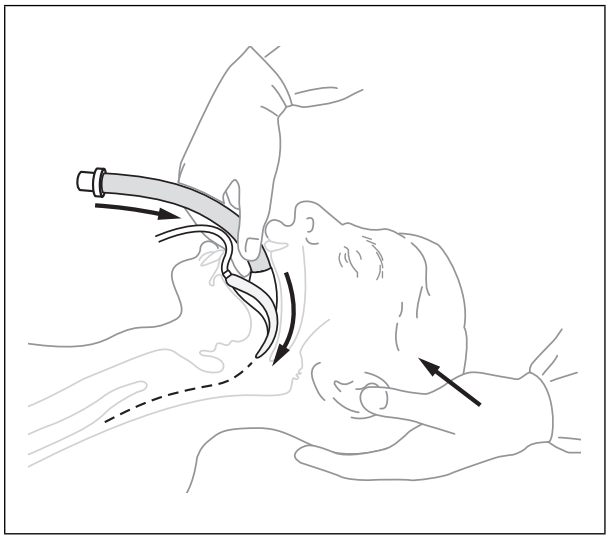

Figure 4

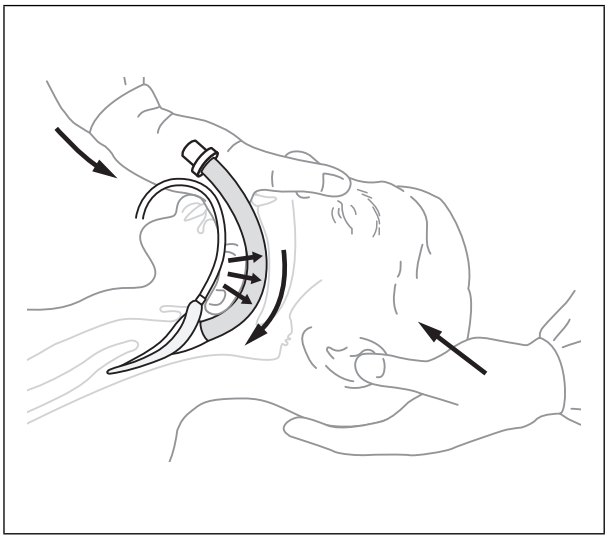

Figure 5

6. Check that the black line on the tube faces the upper lip. Now immediately inflate the cuff **without holding the tube.**
   Do this **BEFORE** connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. Refer to **Table 3** for inflation information. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.
   Warning: NEVER OVERINFLATE THE CUFF.

Product	Recommended	Device Size							
		1	1.5	2	2.5	3	4	5	6
LMA® Unique™ (Silicone Cuff)	**Intracuff pressure (cm H_2O)**	60	60	60	60	60	60	60	60
LMA® Unique™ (Silicone Cuff) Cuff Pilot™									

Table 3: Inflation Information

   Cuff volume maxima above are related to risk of cuff damage and are not recommendations for cuff inflation volume in clinical use. Inflating the cuff to maximum inflation volume may lead to cuff over inflation and excessive intracuff pressure (>60 cm H_2O).
7. Connect to the gas supply, holding the tube, to prevent displacement. **Gently** inflate the lungs to confirm correct placement. Insert a roll of gauze as a bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the device, it is important to remember to insert a bite block at the end of the procedure.

Warnings:

- **Do not use a Guedel (oropharyngeal) airway as a bite block, as it prevents correct positioning of the device increasing trauma and reducing seal effectiveness.**
- **Once correctly positioned, the device must be securely taped in position to the patient's face to prevent its movement during use and loss of the patients' airway.**
- **Do not move the patient or reposition the device during anaesthesia/surgery to prevent stimulation of the airway that this may cause.**

- **The anaesthetic breathing system must be adequately supported once connected to the device to avoid rotation of the mask and to ensure the tube is bent only downwards on to the chin and never upwards to avoid loss of the patient's airway due to displacement.**
- **Ensure anaesthesia is adequate for the level of surgical stimulus to avoid gagging, coughing and laryngospasm leading to displacement of the device.**

Thumb Insertion Method:

Refer to Cautions and Warnings for additional guidance.

This technique is suitable for patients in whom access to the head from behind is difficult or impossible and during cardiopulmonary resuscitation. The LMA® airway is held with the thumb in the position occupied by the index finger in the standard technique **(Figure 6)**. The tip of the mask is pressed against the front teeth and the mask is pressed posteriorly along the palate with the thumb. As the thumb nears the mouth, the fingers are stretched forward over the patient's face **(Figure 7)**. Advance the thumb to its fullest extent **(Figure 8)**. The pushing action of the thumb against the hard palate also serves to press the head into extension. Neck flexion may be maintained with a head support. Before removing the thumb, push the tube into its final position using the other hand **(Figure 9)**.

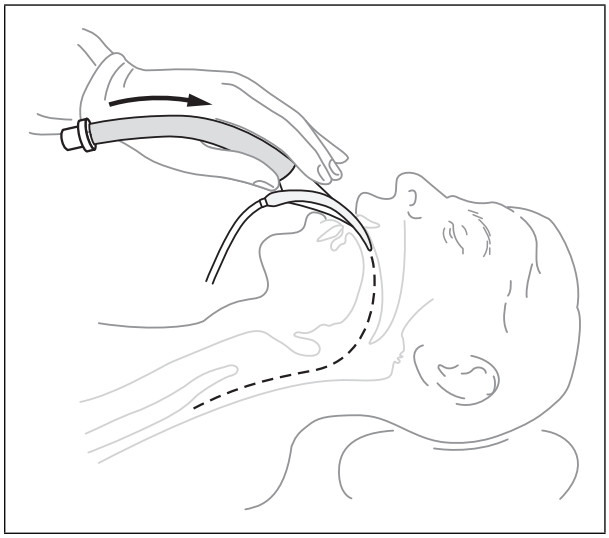

Figure 6

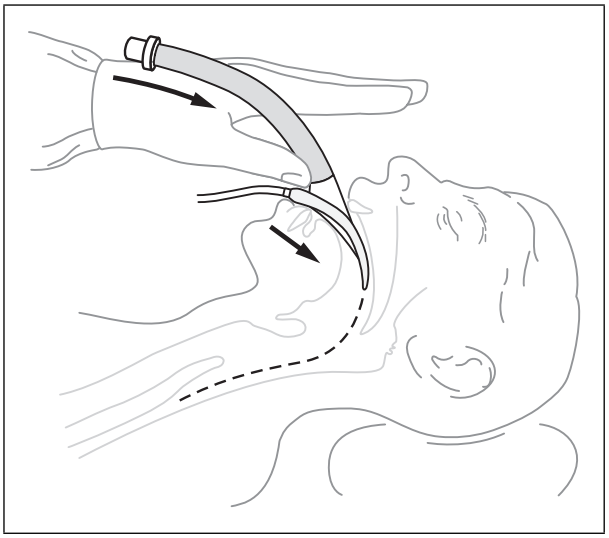

Figure 7

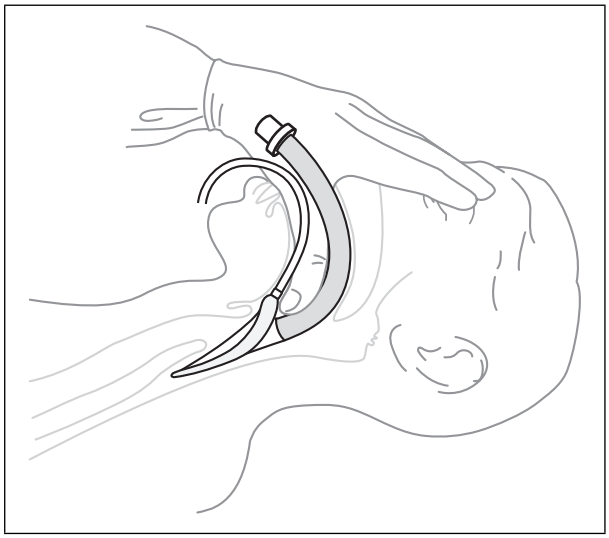

Figure 8

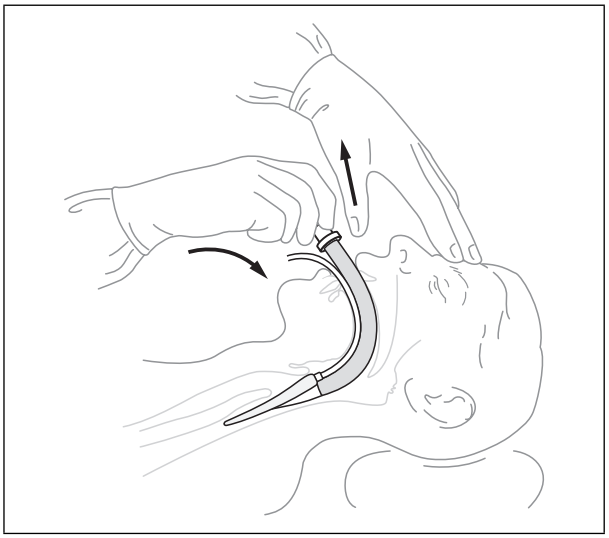

Figure 9

INFLATION OF LMA® UNIQUE™ (SILICONE CUFF)

Firmly connect syringe to pilot balloon and inflate cuff with sufficient air to prevent a leak with positive pressure ventilation (refer to **Table 1** for maximum cuff pressure). If no manometer is available, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

INFLATION SYSTEM OF LMA® UNIQUE™ (SILICONE CUFF) CUFF PILOT™:

Firmly connect syringe to cuff pilot valve and inflate cuff with sufficient air to prevent a leak with positive pressure.

The LMA® Unique™ (Silicone Cuff) Cuff Pilot™ has a cuff pilot valve, which enables the end user to monitor the intracuff pressure of the mask through visual means while it is inserted in the patient's airway. There are three pressure zones on the Cuff Pilot™ Valve – **Yellow, Green and Red.** The position of the black line on the bellows indicates the pressure within the cuff.

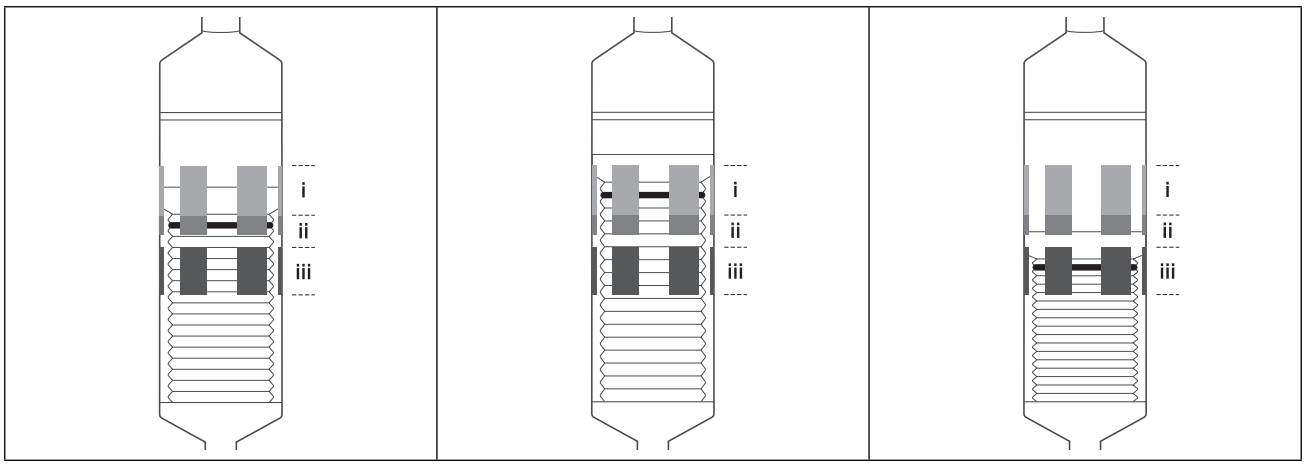

Figure 10. Cuff Pilot™ cuff pressure valve in Green Zone (ii)

Figure 11. Cuff Pilot™ cuff pressure valve in Yellow Zone (i)

Figure 12. Cuff Pilot™ cuff pressure valve in Red Zone (iii)

1. The **Green Zone (ii)** designates optimal pressure of the cuff, between 40–60 cm H_2O. Air is introduced into the cuff until the black line is within this zone and a seal has been obtained **(Figure 10)**.
2. The **Yellow Zone (i)** indicates a pressure of less than 40 cm H_2O. A seal may be obtained in the Yellow Zone; however, movement of the black line on the bellows into the Yellow Zone during the procedure may indicate a possible decrease in pressure or under-inflation **(Figure 11)**.
3. The **Red Zone (iii)** indicates a pressure of more than 70 cm H_2O. This indicates a possible increase in pressure or over-inflation. It is recommended that the pressure be released until the black bellows line is back in the Green Zone **(Figure 12)**.
   Warning: NEVER OVERINFLATE THE CUFF.

CORRECT POSITION

When correctly placed the tube emerging from the mouth is parallel to the plane of the inner surface of the upper incisors. The tube should be pressed back into the palate and posterior pharyngeal wall.

Correct placement should produce a leak-free seal against the glottis with the mask tip at the upper oesophageal sphincter.

In general, incorrect positioning of an airway product can be assessed in two ways: by capnography, or by observation of changes in tidal volume, e.g., a reduced, expired tidal volume. If incorrect positioning 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 the position of the device is incorrect, the device may be removed and reinserted once anaesthetic depth is adequate for reinsertion.

If the device pops out of the mouth during insertion, the mask may be incorrectly positioned due to the distal tip being folded backward in the pharynx. In such a case, remove and reinsert.

Obstruction can occur if the device becomes dislodged or is incorrectly inserted. The epiglottis may be pushed down with poor insertion technique. Check by auscultation of the neck and correct by re-insertion or elevation of the epiglottis using a laryngoscope.

Malposition of mask tip into the glottis may mimic laryngospasm and/or bronchospasm.

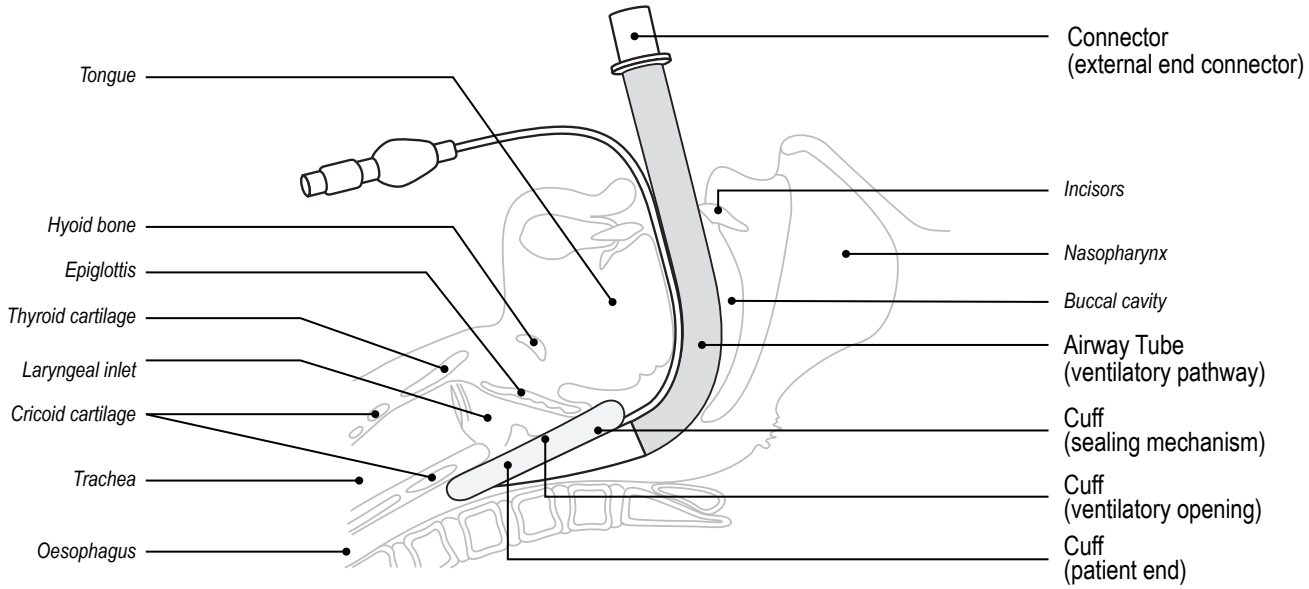

Figure 13. Intended position of LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ with anatomic landmarks

ANAESTHESIA MAINTENANCE

Refer to cautions and warnings for additional guidance.

This device is well tolerated in spontaneously breathing patients when used with inhalational or intravenous anaesthesia, provided anaesthesia is adequate to match the level of surgical stimulus.

During Positive Pressure Ventilation (PPV) when using this device, tidal volumes should not exceed 8 ml/kg, and peak inspiratory pressures should be kept below the maximum airway seal pressure.

REMOVAL

Removal should only be carried out by appropriately trained and equipped personnel.

1. **The device, together with the recommended bite-block, should be left in place until the return of consciousness.** Oxygen should be administered using a "T" piece system and standard monitoring should be in place. Before attempting to remove or deflate the device, **it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.**
2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary to perform suction because the correctly used device protects the larynx from oral secretions. Patients will swallow secretions on removal. **Suction equipment should however be available at all times.**
3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

USE WITH MAGNETIC RESONANCE IMAGING (MRI)

MR LMA® Unique™ (Silicone Cuff) Cuff Pilot™ is MR Safe.

MR LMA® Unique™ (Silicone Cuff) is MR Conditional.

Non-clinical testing demonstrated that this product is MR Conditional. A patient with LMA® Unique™ (Silicone Cuff) can be scanned safely immediately after placement under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-T and 3-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	10-T/m (1,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.).
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks).
MR Image Artefact	The presence of this implant produces an imaging artefact. Therefore, carefully select pulse sequence parameters to minimize artefacts if the implant is located in the area of interest.
Important Condition of Use During MRI	During the intended use of the device, it is held in place or otherwise “fixed in place” to prevent inadvertent displacement using surgical tape, cloth material, bandaging material, and/or a plastic device. When using adhesive tape as a fixation means, at a minimum, the surgical tape should extend to the laterals sides of the patient’s face. Note that the proper fixation of this device will effectively prevent this device from being moved or displaced due to magnetic field interactions.

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

EXPLANATION OF SYMBOLS			
Symbol	**Definition**	**Symbol**	**Definition**
	Intra-cuff pressure		Keep dry
	Batch Code		Manufacturer
	Caution		Medical Device
	Catalogue Number		MR Conditional
	Consult instructions for use.		MR Safe
Rx only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		Not made with natural rubber latex.
	Date of manufacture		Patient Weight
	Do not use if package is damaged and consult instructions for use.		Single Sterile Barrier System
	Do not Re-use.		Sterilised by ethylene oxide.
	Do not Resterilise.		This way up
	Fragile, handle with care		Use by Date
	Keep away from sunlight		

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® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) Cuff Pilot™ are designed for single use and warranted against manufacturing defects at the time of delivery.

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

Teleflex MEDICAL

IDA Business and Technology Park,
Dublin Road,
Athlone,
Co. Westmeath, Ireland

CE 2797

CH REP
Swiss AR Services GmbH
Industriestrasse 47
6300 Zug, Switzerland

en **For Instructions for Use visit:**
www.teleflex.com/IFU

Contact Information:
USA: (866) 246-6990
International: +1 (919) 544-8000

PBQ-2100-000 Rev D UK 2024-04