EN – English

INSTRUCTIONS FOR USE – LMA® Unique™ (Silicone Cuff) & LMA® Unique™ (Silicone Cuff) *Cuff Pilot™*

Laryngeal Mask Airway

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

WARNING: 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.

WARNING: Re-processing of LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) *Cuff Pilot*™ intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilisation methods and instructions for reprocessing to original specifications are not available for these products. LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) *Cuff Pilot*™ are not designed to be cleaned, disinfected, or re-sterilised.

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.

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.

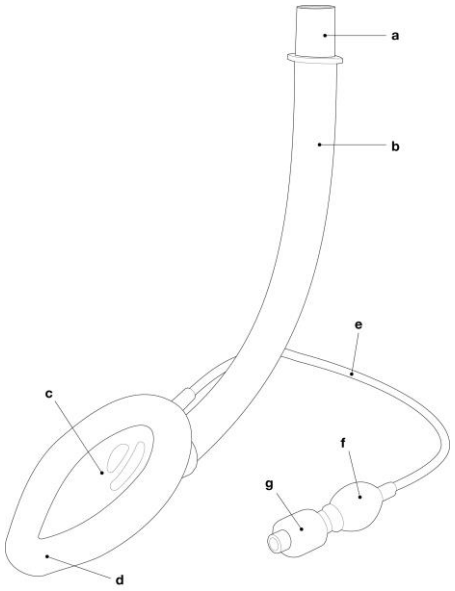
The inflation system of LMA® Unique™ (Silicone Cuff) consists of an Inflation Line with Pilot Balloon and Check Valve for cuff inflation and deflation. The Pilot Balloon provides an indication of the pressure within the cuff and the Check Valve prevents leakage of air and maintains the pressure in cuff.

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 inside mask cuff pressure. It replaces the standard pilot balloon and to be used in the same way for cuff inflation and deflation.

LMA® Unique™ (Silicone Cuff) is MR conditional. Refer to MRI information section prior using the device in MRI environment.

LMA® Unique™ (Silicone Cuff) *Cuff Pilot™* is MR Safe. The term 'MR Safe' means that it poses no known hazards in all MR environments.

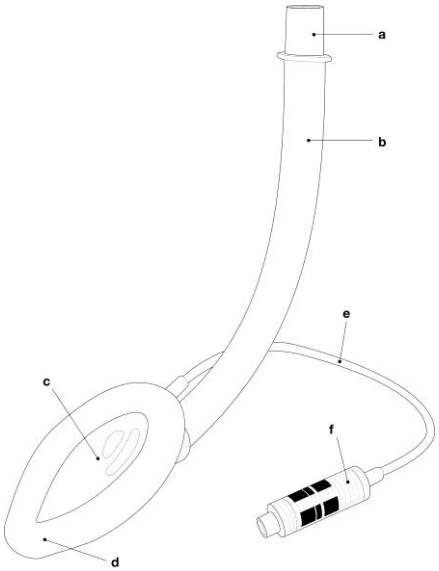
Figure 1: The LMA® Unique™ (Silicone Cuff) components



LMA® Unique™ (Silicone Cuff) components **(Figure 1):**

a) Connector
b) Airway Tube
c) Backplate
d) Cuff
e) Inflation Line
f) Pilot Balloon
g) Check Valve

Figure 2: The LMA® Unique™ (Silicone Cuff) *Cuff Pilot*™ components



LMA® Unique™ (Silicone Cuff) *Cuff Pilot™* components (**Figure 2**):

a) Connector
b) Airway Tube
c) Backplate
d) Cuff
e) Inflation Line
f) Cuff Pilot™

Table 1: Specification for the device

	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 (ISO 5356-1)							
Internal Volume of ventilator pathway (ml)	4	5	7	11	18	19	25	28
Pressure drop (mm H_2O)	< 22 at 15 ℓ/min	< 10 at 15 ℓ/min	< 19 at 30 ℓ/min	< 9 at 30 ℓ/min	< 15 at 60 ℓ/min	< 15 at 60 ℓ/min	< 8 at 60 ℓ/min	< 8 at 60 ℓ/min
Min. interdental gap (mm)	16	18	21	24	25	30	34	38
Normal length of the internal ventilatory pathway (cm)	10.5	12.0	13.8	15.0	19.5	19.5	21.3	21.8

A summary of the methods, materials, data and results of clinical studies that validate the requirements of this international standard is available on request, if applicable.

Correct Position of the device in relation to anatomical landmarks

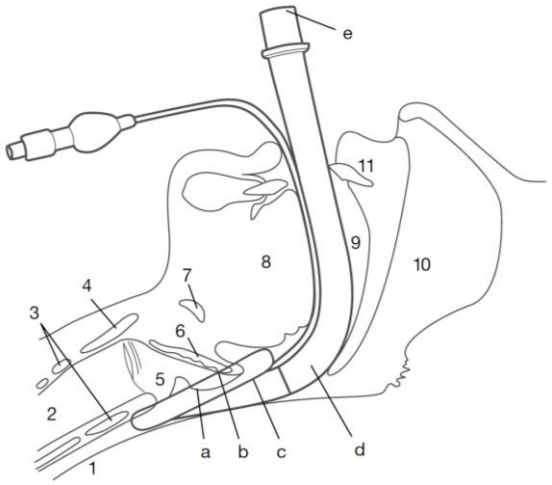


Table 2: Description of anatomical landmarks

Anatomical Landmarks	
1 - Esophagus	7 - Hyoid bone
2 - Trachea	8 - Tongue
3 - Cricoid cartilage	9 - Buccal cavity
4 - Thyroid cartilage	10 - Nasopharynx
5 - Laryngeal inlet	11 - Incisors
6 - Epiglottis	

Table 3: Description of the device parts

a - Patient end	d - Ventilatory pathway
b - Ventilatory opening	e - External end connector
c - Sealing mechanism	

INDICATION FOR USE:

The LMA® Unique™ (Silicone Cuff) and LMA® Unique™ (Silicone Cuff) *Cuff Pilot*™ are is indicated for use in achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or Positive Pressure Ventilation (PPV).

They are also indicated for securing the immediate airway in known or unexpected difficult airway situations.

They are best suited for use in elective surgical procedures where tracheal intubation is not necessary.

They may be use 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, the devices should be used only when tracheal intubation is not possible.

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.

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:

1. Patients who have not fasted, including patients whose fasting cannot be confirmed.

2. 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:

1. 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.

2. 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.

3. 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.

ADVERSE EFFECTS:

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.

WARNINGS:

1. To avoid trauma, excessive force must be avoided at all times.
2. Do not use if the device is damaged or its unit packaging is damaged or opened.
3. When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention. The device may be flammable in the presence of lasers and electrocautery equipment.
4. 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.
5. Do not immerse or soak the device in liquid prior to use.
6. When applying lubricant avoid blockage of the airway aperture with the lubricant.
7. Never overinflate the cuff over 60cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
8. A water-soluble lubricant, such as K-Y Jelly®, should be used. 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 structures, including the vocal cords.
9. The device does not prevent regurgitation or aspiration. Its use in anaesthetised 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.
10. 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.
11. Refer to MRI information section prior to using the devices in MRI environment.

CAUTIONS:

1. 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.
2. 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.
3. Only use a syringe with standard luer taper tip for inflation or deflation.
4. Only use with the recommended manoeuvres described in the instructions for use.
5. If airway problems persist or ventilation is inadequate, the device should be removed and an airway established by some other means.
6. 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.
7. Gloves should be worn during preparation and insertion to minimize contamination of the airway.
8. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
9. Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
10. Ensure all removable denture work is removed before inserting the device.
11. An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.

PREPARATION 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 CHECKS:

Warning: 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.

Warning: Failure of any one test indicates the device should not be used.

These tests should be carried out as follows:
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 fully.

For LMA® Unique™ (Silicone Cuff)
Re-inflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Table 4: Test cuff over-inflation volumes

	Device Size							
	1	**1.5**	**2**	**2.5**	**3**	**4**	**5**	**6**
Over-inflation cuff volumes (ml)	**6**	**10**	**15**	**21**	**30**	**45**	**60**	**75**

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™ (Fig 13) with a volume of air > 70cm$H_2$0.

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. Discoloration. Discoloration 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.

PRE-INSERTION PREPARATION:

Deflate the cuff of the device completely in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold back away from the aperture bars. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in blockage of aperture bar or aspiration of lubricant.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. 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 structures, including the vocal cords.

Caution: Ensure all removable denture work is removed before inserting the device.

INSERTION:

Caution: Gloves should be worn during preparation and insertion to minimize contamination of the airway.
Caution: The patency of this device should be reconfirmed after any change in the patient's head or neck position.

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 **(Fig.3)**.
3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube **(Fig.3**). 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 (Fig.4)**.
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 **(Fig.5**). 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. **(Fig.5)**.

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 **(Fig.6).**
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 5** 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.

Table 5: Inflation Information

Product	**Recommended**	**Device Size**							
		1	**1.5**	**2**	**2.5**	**3**	**4**	**5**	**6**
LMA® Unique™ (Silicone Cuff)	Maximum Cuff inflation volume (ml/60cm$H_2$0)	**4**	**7**	**10**	**14**	**20**	**30**	**40**	**50**
LMA® Unique™ (Silicone Cuff) *Cuff Pilot™*	Intracuff pressure (cmH_2O)	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**

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.

Figure 3

Figure 4

Figure 5

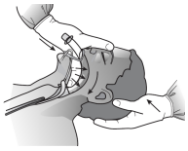


Figure 6

Thumb Insertion Method:

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 **(Fig.7)**. 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 **(Fig.8)**. Advance the thumb to its fullest extent **(Fig.9).** 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 **(Fig.10)**.

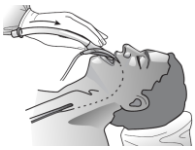


Figure 7

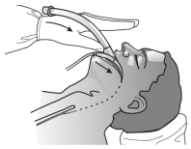


Figure 8

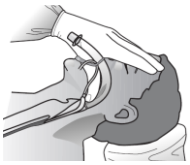


Figure 9

Figure 10

Inflation System of LMA® Unique™ (Silicone Cuff) *Cuff Pilot™*:

1. 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.

2. The Green Zone designates optimal pressure of the cuff, between 40 - 60 cmH_20. Air is introduced into the cuff until the black line is within this zone and a seal has been obtained.

Figure 11: Cuff Pilot Valve in Green Zone

3. The Yellow Zone indicates a pressure of less than 40cmH_20. 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.

Figure12: Cuff Pilot Valve in Yellow Zone

4. The Red Zone indicates a pressure of more than 70cmH_20. 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 13: Cuff Pilot Valve in Red Zone

Warning: NEVER OVERINFLATE THE CUFF.

MAINTAINING THE AIRWAY:

1. 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.

2. Malposition of mask tip into the glottis may mimic bronchospasm.

3. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.

4. Keep the bite-block in place until the device is removed.

5. Do not deflate the cuff until reflexes have fully returned.

6. Air may be withdrawn from the cuff during anaesthesia to maintain a **constant** intracuff pressure (always less than 60cm H_2O).

REMOVAL:

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):

For LMA® Unique™ (Silicone Cuff)

MR Conditional

The 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.:

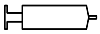
Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-T and 3-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	10-T/m (1,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, 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 Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters to minimize artifacts 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 lateral 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.

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

MR Safe

The LMA® Unique™ (Silicone Cuff) *Cuff Pilot™* is MR Safe (i.e., an item that poses no known hazards in all MR environments).

SYMBOL DEFINITION:

	Manufacturer
	Consult IFU on this website: www.LMACO.com
	Air inflation volume/Intra-cuff pressure
	Patient weight
	Read Instructions before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	Do not Re-use
	Do not Re-sterilise
	This product not made with phthalates
	Sterilised by Ethylene Oxide
	Use By
	Do not use if package is damaged
	MR Conditional
	MR Safe
	Single Sterile Barrier System
Rx Only	Prescription Only

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 DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR APARTICULAR PURPOSE.

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www.LMACO.com

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