

## Instructions For Use – LMA SureSeal™ PreCurved

**WARNING:** LMA SureSeal™ PreCurved is supplied sterile for single use only which shall be discarded after use and must not be re-used.

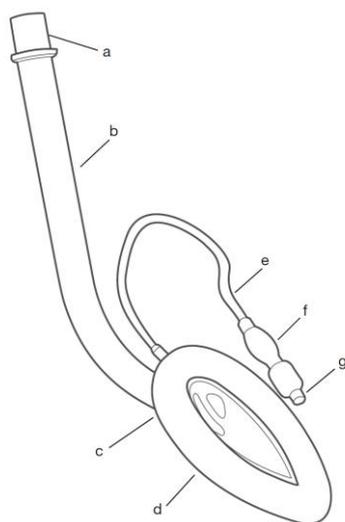
**WARNING:** Re-processing of LMA SureSeal™ PreCurved intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilisation methods and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

### General Information:

The LMA SureSeal™ PreCurved is not made with natural rubber latex and phthalates.

The LMA SureSeal™ PreCurved is supplied sterile (sterilised by Ethylene Oxide) for single use only and it provides easy insertion without the need for digital or introducer tool guidance.

Figure 1: LMA SureSeal™ PreCurved components



LMA SureSeal™ PreCurved components (Figure 1):

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

Table 1: Specification for LMA SureSeal™ PreCurved

	Size		
	3	4	5
Airway Connector	15 mm male (ISO 5356-1)		
Inflation Valve	Luer cone (ISO 594-1)		
Internal Volume of ventilator pathway	19 ml	19 ml	27 ml
Pressure drop	< 1.6 cm H <sub>2</sub> O at 60 l/min	< 1.6 cm H <sub>2</sub> O at 60 l/min	< 1.6 cm H <sub>2</sub> O at 60 l/min
Min. interdental gap	29 mm	30 mm	34 mm
Internal pathway	22.0 cm	22.0 cm	24.0 cm

### Correct Position of the LMA SureSeal™ PreCurved in relation to anatomical landmarks

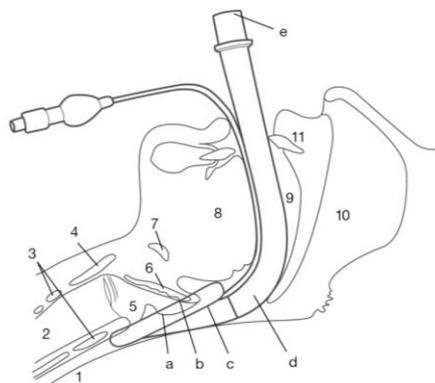


Table 2: Description of anatomical landmarks

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 LMA SureSeal™ PreCurved parts

LMA SureSeal™ PreCurved
a - Patient end
b - Sealing mechanism
c - Ventilatory opening
d - Ventilatory pathway
e - External end connector

### Indication for Use:

The LMA SureSeal™ PreCurved is indicated for use in achieving and maintaining control of the airway during routine anaesthetic procedures in fasted patients using either spontaneous or Positive Pressure Ventilation (PPV).

It is also indicated for securing the immediate airway in known or unexpected difficult airway situations.

When used in a difficult airway patient (i.e., “cannot intubate, cannot ventilate”), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway.

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

It 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 SureSeal™ PreCurved should be used only when tracheal intubation is not possible.

### Contraindication:

Due to the potential risk of regurgitation and aspiration, do not use the LMA SureSeal™ PreCurved 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 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.
3. Patients with inadequate mouth opening to permit insertion.

The LMA SureSeal™ PreCurved is also contraindicated in:

1. Patients with fixed decreased pulmonary compliance, or peak insufflation pressure anticipated to exceed 20 cm H<sub>2</sub>O, because the device forms a low-pressure seal (approximately 20 cm H<sub>2</sub>O) 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 LMA SureSeal™ PreCurved.
3. The LMA SureSeal™ PreCurved 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 and endotracheal tubes. Standard textbooks and published literature should be consulted for specific information.

#### Preparation for Use:

##### **Choose the correct size of LMA SureSeal™ PreCurved**

##### **Patient Weight/Size**

**Size 3: 30kg – 50kg adult**

**Size 4: 50kg – 70kg adult**

**Size 5: 70kg – 100kg adult**

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

#### Pre-Use Checks

It is most important that pre-use checks are carried out on LMA SureSeal™ PreCurved prior to use, in order to establish whether they are 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.** Reflate the device with a volume of air 50% greater than the maximum inflation value for each size.

**Size 3 30ml**

**Size 4 45ml**

**Size 5 60ml**

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.

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

**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 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 completely** using the LMA™ Cuff Deflator 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 LMA SureSeal™ PreCurved 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.

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

#### Insertion:

##### **Note: gloves must be worn**

**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.** Hold the LMA SureSeal™ PreCurved in position. (Fig. 1)

Position the head and neck as for normal tracheal intubation.

Place the head in the neutral or slight "sniffing" position (Sniffing = extension of head + flexion of neck) by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand. (Fig. 2)

**3.** Press the distal tip against the inner aspect of the upper teeth or gums. (Fig. 3)

**4.** Slide inwards using a slightly diagonal approach (direct the tip away from the mid-line). (Fig. 4)

**5.** Continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue. (Fig. 5)

**6.** Resistance should be felt when the distal end of the device meets final position in the lower pharynx. The device is now fully inserted. (Fig. 6)

**7.** Check that the black dotted line on the tube faces the upper lip.

Now immediately inflate the cuff **without holding the tube.** (Fig. 7)

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. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.

**Warning:** NEVER OVERINFLATE THE CUFF.

#### **Maximum inflation volumes (ml)**

**Size 3 20ml**

**Size 4 30ml**

**Size 5 40ml**

**8.** Connect to a gas supply, holding the tube, to prevent displacement. **Gently** inflate the lungs to confirm correct placement. Insert a roll of gauze as bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. (Fig. 8) 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.

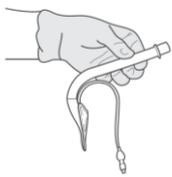


Figure 1: Hold the LMA SureSeal™ PreCurved in position

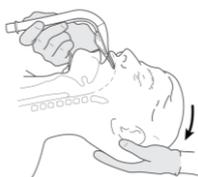


Figure 2: Position the head and neck as for normal tracheal intubation.

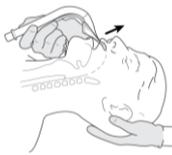


Figure 3: Press the tip of the mask against the hard palate



Figure 4: Press the cuff further into the mouth, maintaining pressure against the palate.

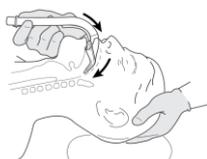


Figure 5: Swing the device inward with circular motion, pressing against the contours of the hard and the soft palate



Figure 6: Advance the device into the lower pharynx until resistance is felt.



Figure 7: Inflate the cuff without holding the tube



Figure 8: Insert a roll of gauze as bite-block, and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally.

### **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 laryngospasm and/or 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 intra-cuff pressure (never more than 60cm H<sub>2</sub>O).

### **Removal**

1. **The LMA SureSeal™ PreCurved, 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 LMA SureSeal™ PreCurved 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.

### **Caution:**

1. **The LMA SureSeal™ PreCurved 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 device without taking appropriate precautions to ensure the stomach is empty.**
2. Laryngeal spasm may occur if the patient becomes too lightly anaesthetised during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anaesthesia. If laryngeal spasm occurs, **do not remove the LMA SureSeal™ PreCurved**, but treat the cause. Only remove the device when airway protective reflexes are fully competent.
3. 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.
4. 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.
5. Use only syringe with standard luer taper tip for inflation or deflation.
6. Do not immerse or soak LMA SureSeal™ PreCurved in liquid prior to use.
7. Only use with the recommended manoeuvres described in the instructions for use.

8. When applying lubricant avoid blockage of the airway aperture with the lubricant.
9. If airway problems persist or ventilation is inadequate, the LMA SureSeal™ PreCurved should be removed and an airway established by some other means.
10. Careful handling is essential. Avoid contact with sharp or pointed objects at all times. Do not insert the device unless the cuff is fully deflated as described in the instructions for insertion.
11. Gloves should be worn during preparation and insertion to minimize contamination of the airway.
12. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.

### **Warning:**

1. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
2. Excessive force must be avoided at all times.
3. Do not use if the device is damaged or the unit packaging for LMA SureSeal™ PreCurved is damaged or opened.
4. Do not re-sterilise and/or reuse the LMA SureSeal™ PreCurved. The device is provided sterile and should be used straight from the package and is not designed to withstand reuse, cleaning or exposure to disinfecting or sterilising agents.
5. LMA SureSeal™ PreCurved may be flammable in the presence of lasers and electrocautery equipment.

### **Use with Magnetic Resonance Imaging (MRI)**



Testing has been performed to determine the compatibility of LMA SureSeal™ PreCurved with MRI. Prior to using LMA SureSeal™ PreCurved in **the MRI** environment, the user should carefully compare the equipment and test conditions described with those planned for use in the actual clinical environment. Refer to the below for detailed results of device testing in the MRI environment.

The **LMA SureSeal™ PreCurved** was determined to be MR conditional. Non-clinical testing demonstrated that the LMA SureSeal™ PreCurved is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 18,000-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Controlled Mode of operation for the MR system

**MRI-Related Heating**

In non-clinical testing, the **LMA SureSeal™ PreCurved with Metallic Spring** produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):  
 MR system reported, whole body averaged SAR 2.9-W/kg  
 Calorimetry measured values, whole body averaged SAR 2.7-W/kg  
 Highest temperature change 1.7°C  
 Temperature scaled to whole body averaged SAR of 4-W/kg 2.3°C

**Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the LMA SureSeal™ PreCurved with Metallic Spring. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 25-mm relative to the size and shape of the LMA SureSeal™ PreCurved with Metallic Spring.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	2,203-mm <sup>2</sup>	2,197-mm <sup>2</sup>	4,580-mm <sup>2</sup>	4,064-mm <sup>2</sup>
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

**Symbol Definition:**

	Manufacturer
	Consult IFU on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instruction before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot Number
	CE Mark
	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

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

**Manufacturer’s Warranty:**

The LMA SureSeal™ PreCurved is 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 APARTICULAR PURPOSE.

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