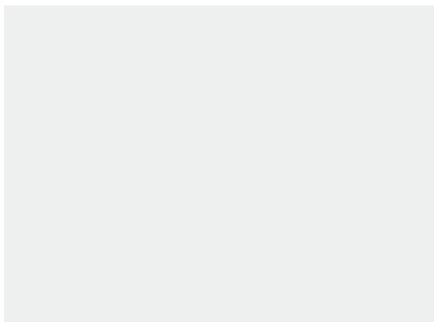
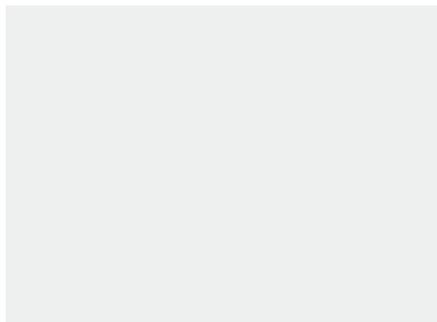
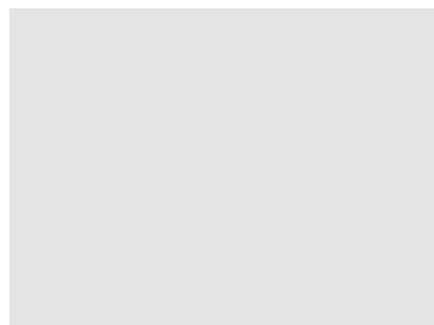
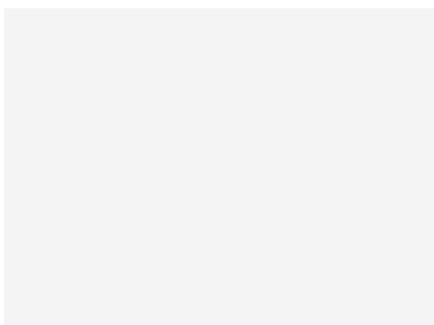
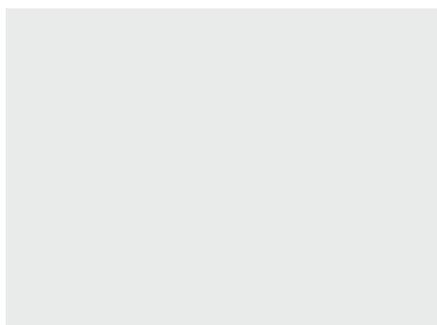




# LMA Protector™ *Cuff Pilot™* and LMA Protector™

Instructions for use

English version



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

**WARNING:** LMA Protector™ and LMA Protector™ Cuff Pilot™ are supplied sterile for single use only which shall be discarded after use and must not be re-used. Re-use may cause cross infection and reduce product reliability and functionality.

Re-processing of LMA Protector™ and LMA Protector™ 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. LMA Protector™ and LMA Protector™ Cuff Pilot™ are terminally sterilised by Ethylene Oxide gas. Validated cleaning and sterilisation methods and instructions for reprocessing to original specifications are not available for this product. LMA Protector™ and LMA Protector™ Cuff Pilot™ are not designed to be cleaned, disinfected, or re-sterilised.

## GENERAL INFORMATION

Unless otherwise stated, the reference to “device” stated on this IFU applies to both versions of LMA Protector™ and LMA Protector™ Cuff Pilot™.

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

## DEVICE DESCRIPTION

Both LMA Protector™ and LMA Protector™ Cuff Pilot™ are not made with natural rubber latex and phthalates. They are supplied sterile (sterilised by Ethylene Oxide) for single use only.

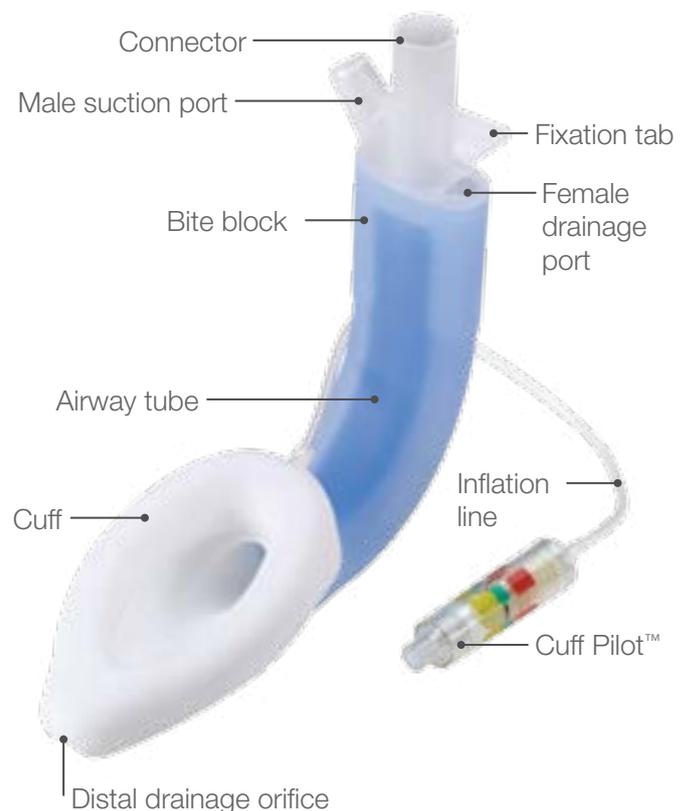
The device provides access to, and functional separation of, the respiratory and digestive tracts. The anatomically shaped airway tube is elliptical in cross section and ends distally at the laryngeal mask. The inflatable cuff is designed to conform to the contours of the hypopharynx, with the bowl and the mask facing the laryngeal opening.

The device contains two drainage channels which emerge as separate ports proximally. The drainage channels continue distally and enter a chamber located behind the cuff bowl. The chamber narrows distally into the orifice located at the end of the cuff which communicates distally with the upper oesophageal sphincter. A suction tube may be attached to the male suction port, offering removal of gastric fluid through the upper oesophageal sphincter. Alternatively, a well lubricated gastric tube may be passed through the female drainage port to the stomach, offering easy access for evacuation of gastric contents. The drainage channel through the female drainage port may be used as a monitor of correct positioning of the device following insertion, and then for continuous monitoring of mask displacement during use.

**Figure 1: LMA Protector™ components**



**Figure 2: LMA Protector™ Cuff Pilot™ components**



The device provides easy insertion without the need for digital or introducer tool guidance. It has enough flexibility to permit the device to remain in place if the patient's head is moved in any direction. A built-in bite block reduces the potential for damage to, or obstruction of the airway tube in the event of biting.

The device's fixation system prevents proximal displacement. If correctly used it enhances the seal of the distal end around the upper oesophageal sphincter, isolating the respiratory tract from the digestive tract, thus reducing the risk of aspiration of gastric contents.

The inflation system of LMA Protector™ consists of an Inflation Line with Pilot Balloon and Check Valve for cuff inflation and deflation. The Pilot Balloon provides a rough 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 Protector™ *Cuff Pilot*™ consists of an Inflation Line with a *Cuff Pilot*™. The *Cuff Pilot*™ enables constant visualisation of pressure inside the mask cuff. It replaces the standard pilot balloon and is to be used in the same way for cuff inflation and deflation.

LMA Protector™ is MR conditional. Refer to MRI information section prior to using the device in MRI environment.

LMA Protector™ *Cuff Pilot*™ is MR Safe. The term 'MR Safe' means that it poses no known hazards in all MR environments.

## INDICATION FOR USE

The LMA Protector™ and LMA Protector™ *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.

It is also indicated for use as a rescue airway device in CPR procedures, in which LMA ProSeal™, LMA Classic™ or the LMA Unique™ have traditionally been used. This device is also indicated as a "rescue airway device" in known, or unexpected difficult airway situations. This device may be used to establish an immediate, clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation.

It may also be used to secure an immediate airway when tracheal intubation is precluded due to lack of available expertise or equipment, or when attempts at tracheal intubation have failed.

## 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

This device must not be used in the case of the following:

- Patients who have had radiotherapy to the neck involving the hypopharynx as there is risk of trauma and/or a potential failure to seal effectively.
- Patients with inadequate mouth opening to permit insertion.
- Patients presenting for emergency surgery who are at risk of massive reflux due to such conditions as acute intestinal obstruction or ileus, or patients who have been injured shortly after ingesting a substantial meal (see above under Indications for Use).
- Patients requiring head or neck surgery where the surgeon will be unable to gain adequate access due to the presence of the device.
- Patients undergoing CPR who are responsive with an intact gag reflex.
- Patients who have ingested caustic substances.

## WARNINGS

- In spite of encouraging case reports for 2nd Generation LMA devices, it is not currently known whether this device always affords protection from aspiration, even when correctly fixed in place.
- The presence of a gastric tube does not rule out the possibility of aspiration if the device is not correctly located and fixed in place.
- This device may be ineffective for use in patients with decreased pulmonary compliance due to fixed obstructive airway disease because airway positive pressure requirement may exceed seal pressure.
- Do not attempt to pass a gastric tube into the stomach via the drainage channel in the presence of known, or suspected, oesophageal pathology.
- There is a theoretical risk of causing oedema or haematoma if suction is applied directly to the end of the drainage channel.

- The benefits of establishing ventilation with this device must be weighed against the potential risk of aspiration in some situations including: symptomatic or untreated gastro-oesophageal reflux; pregnancy over 14 weeks; multiple or massive injury; conditions associated with delayed gastric emptying, such as the use of opiate medication in patients with acute injury or peritoneal infectious or inflammatory processes.
- A water-soluble lubricant, such as K-Y® Jelly, should be used. Do not use silicone-based lubricants as they degrade device components. Lubricants containing Lidocaine are not recommended for use. Lidocaine can delay the return of the patient's protective reflexes after removal of the device; may possibly provoke an allergic reaction, or may affect the surrounding organs, including the vocal cords.
- This device may be flammable in the presence of lasers and electrocautery equipment.

## CAUTIONS

- Do not immerse or soak the device in liquid prior to use.
- Only use the device with the recommended manoeuvres described in the instructions for use.
- Do not use this device if the device is damaged or the unit packaging is damaged or opened.
- When applying lubricant, avoid blockage of the airway aperture.
- To avoid trauma, excessive force should not be used at any time during insertion of this device, or during insertion of a gastric tube through the drainage channel.
- Never overinflate the cuff after insertion. An appropriate intra-cuff pressure is 60 cm H<sub>2</sub>O. This pressure should not be exceeded. Excessive intra-cuff pressure can result in incorrect positioning which may cause pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- If airway problems persist or ventilation is inadequate, this device should be removed and an airway established by some other means.
- Careful handling is essential. This device is made of medical-grade silicone, which can be torn or perforated. 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.
- Surgical gloves should be worn during preparation and insertion to minimize contamination of the airway.

- Store the device in a dark, cool environment, avoiding direct sunlight and extremes of temperature.
- Once used, the device should be subject to a handling and elimination process for bio-hazard products in accordance with local and national regulations.
- Only use a syringe with a standard luer taper tip for inflation and deflation of the cuff.
- Nitrous oxide diffuses into the cuff causing a rise in 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, and the percentage of nitrous oxide in the inhaled mixture.

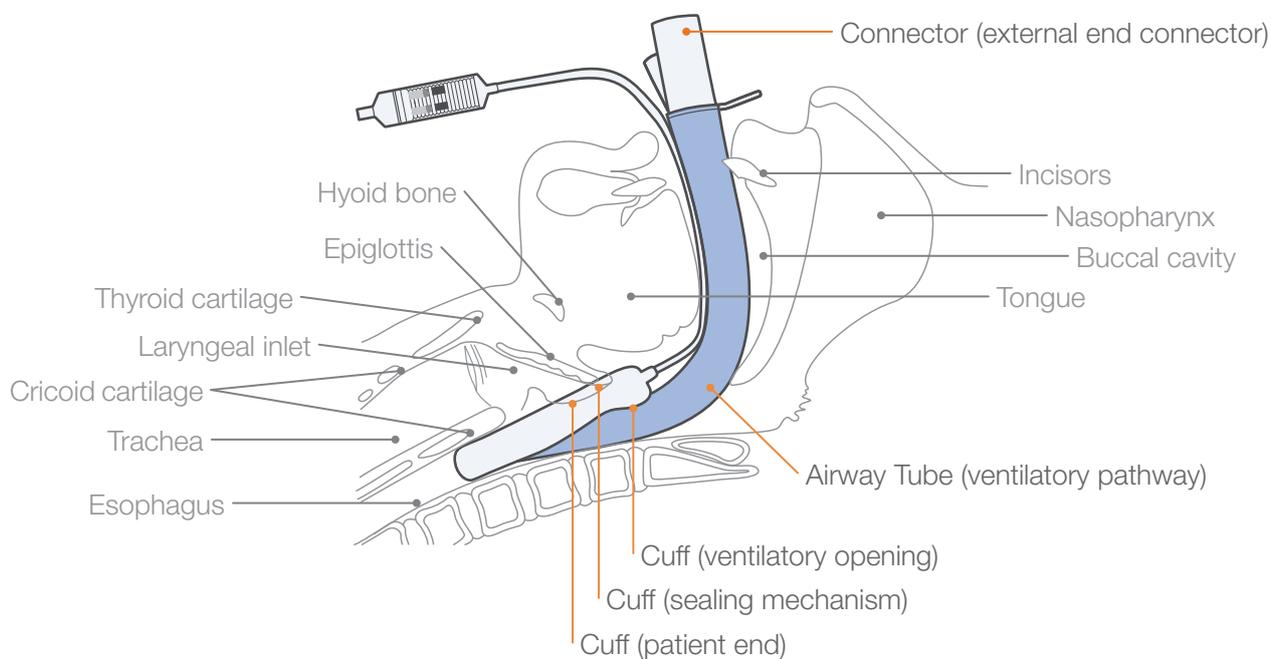
## ADVERSE EVENTS

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.

**Table 1: Specification for LMA Protector™**

	Size		
	3	4	5
Airway connector	15 mm male (ISO 5356-1)		
Inflation valve	Luer cone (ISO 594-1)		
Internal volume of ventilatory pathway	19 ml	22 ml	23 ml
Internal volume of drainage pathway	33 ml	41 ml	42 ml
Nominal length of the Internal ventilatory pathway	17.5 cm	18 cm	20 cm
Nominal length of the Internal drainage pathway	19.3 cm	21 cm	23 cm
Pressure drop	<0.8 cm H <sub>2</sub> O at 60 l/min	<0.5 cm H <sub>2</sub> O at 60 l/min	<0.5 cm H <sub>2</sub> O at 60 l/min
Cuff pressure maximum	60 cm H <sub>2</sub> O	60 cm H <sub>2</sub> O	60 cm H <sub>2</sub> O
Min. interdental gap	28 mm	32 mm	32 mm

**Correct position of the LMA Protector™ in relation to anatomical landmarks**



## SIZE SELECTION

For normal adults, use the size 4 device as a first choice. After inserting, fixing the device in place, and then inflating to the recommended pressure, there should be a minimum of a 1 cm gap between the fixation tab and the patient's upper lip.

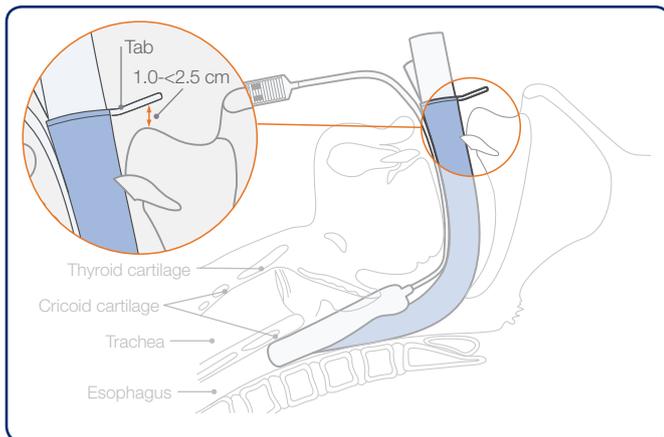


Figure 3: LMA Protector™ sizing

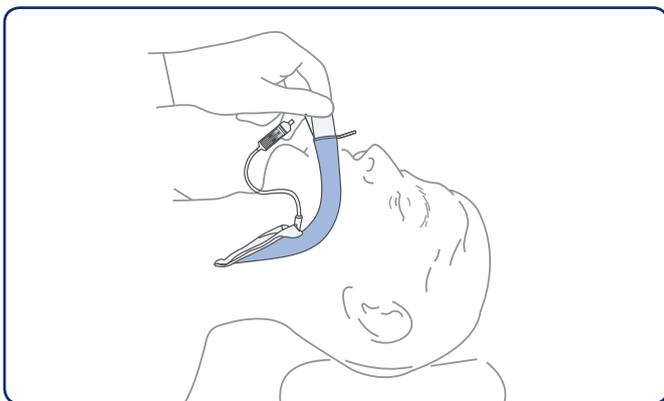


Figure 4: LMA Protector™ sizing (method 2)

For adult patients who are either smaller or larger than normal, it is often possible to obtain a good result using the size 4 device. In either case, the cuff should be inflated with sufficient air to abolish a leak with positive pressure ventilation but which does not exceed a cuff pressure of 60 cm H<sub>2</sub>O. In smaller patients this pressure is achieved with a relatively small volume of air, while larger patients will require larger volumes. However, when in doubt, an approximate estimate of suitable sizing can be made by holding each device against the side of the patient's face in the position corresponding to that shown in Figure 4.

## 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 area, and in a manner consistent with accepted medical practice, that will minimise contamination of the device before insertion.

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

- Examine the surface of this device for damage, including cuts, tears, scratches or kinks.
- Examine the interior of the airway tube to ensure it is free from blockages or loose particles. Any particles present in the channels should be removed. Do not use the airway if a blockage or particle cannot be removed.
- Deflate the cuff completely. Once deflated, check the cuff for spontaneous inflation. Do not use the device if the cuff spontaneously inflates.

## DEFLATING THE DEVICE PRIOR TO INSERTION

1. After firmly connecting a syringe of at least 50 ml to the inflation port, hold the device exactly as shown in Figure 5. Move the connected syringe away from the device until the inflation line is slightly stretched as shown. Compress the distal end of the device between the index finger and thumb while withdrawing air until a vacuum has been obtained.
2. While deflating, hold the device so that the distal end is curled slightly anteriorly as shown in Figure 5.

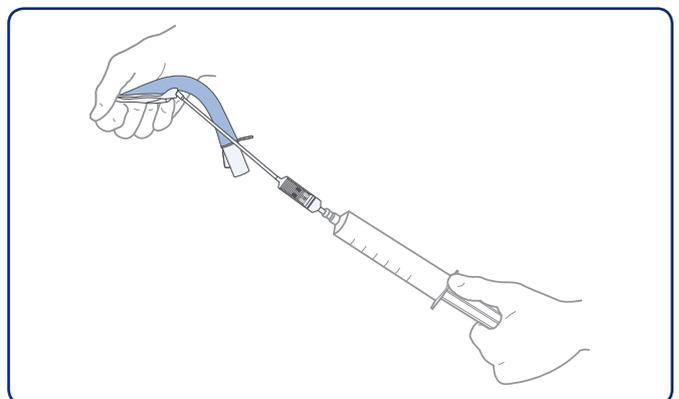
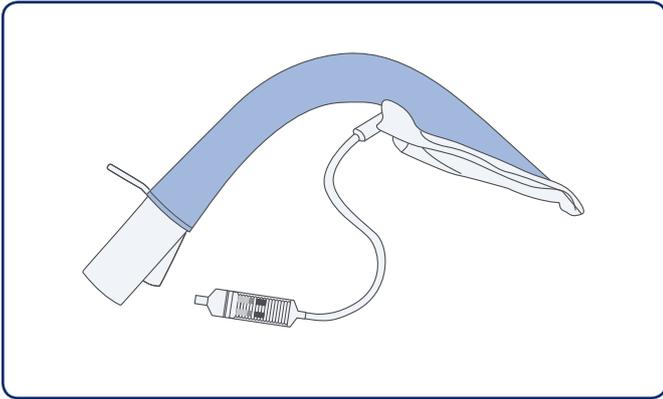


Figure 5: LMA Protector™ deflation

3. Deflate the device until the tension in the syringe indicates a vacuum has been created in the mask.
4. Keep the syringe under tension whilst rapidly disconnecting it from the inflation port. This will ensure that the mask remains correctly deflated, as shown in Figure 6.



**Figure 6:** After achieving wedge shape cuff during deflation, disconnect the syringe from the inflation line

## INSERTION

1. Lubricate the posterior surface of the mask and airway tube just prior to insertion.
2. Stand behind or beside the patient's head.
3. Place the head in the neutral, or slight "sniffing" position (sniffing position = extension of the head and flexion of the neck).
4. Hold the device exactly as shown in Figure 7.
5. Press the distal tip against the inner aspect of the upper teeth or gums.
6. Slide inwards using a slightly diagonal approach (direct the tip away from the mid-line).
7. Continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue.
8. Resistance should be felt when the distal end of the device meets the upper oesophageal sphincter. The device is now fully inserted.

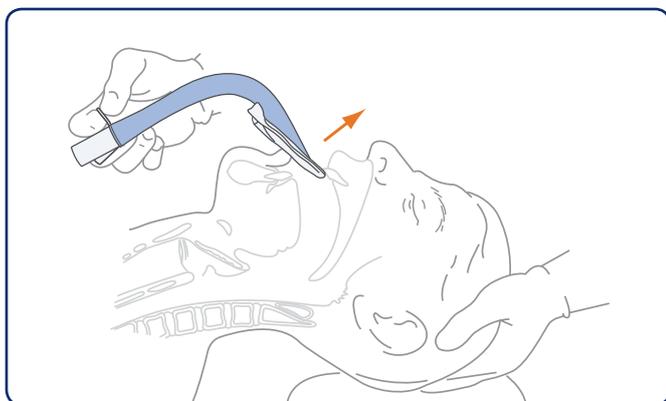


Figure 7: Press the tip of the mask against the hard palate

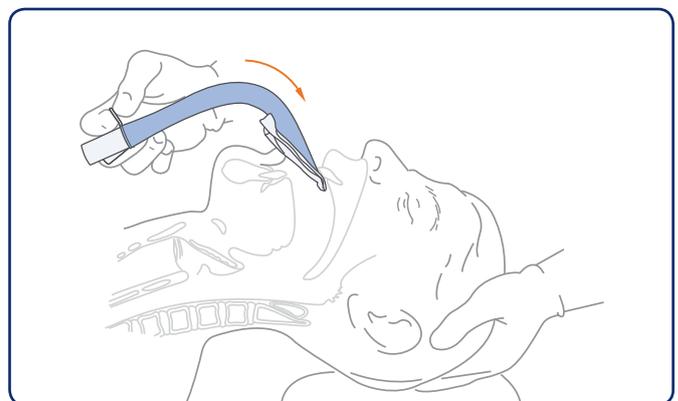


Figure 8: Press the cuff further into the mouth, maintaining pressure against the palate

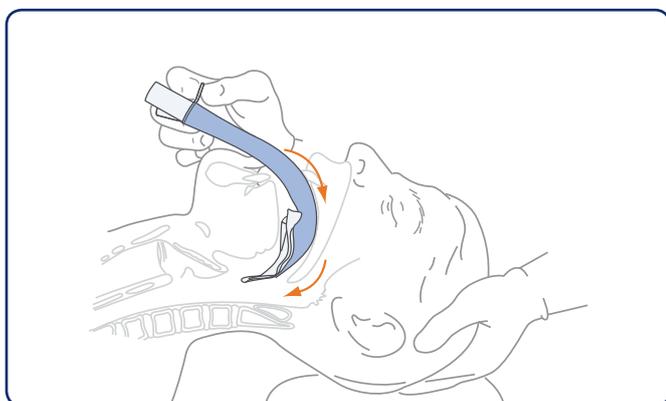


Figure 9: Swing the device inward with a circular motion, pressing against the contours of the hard and the soft palate

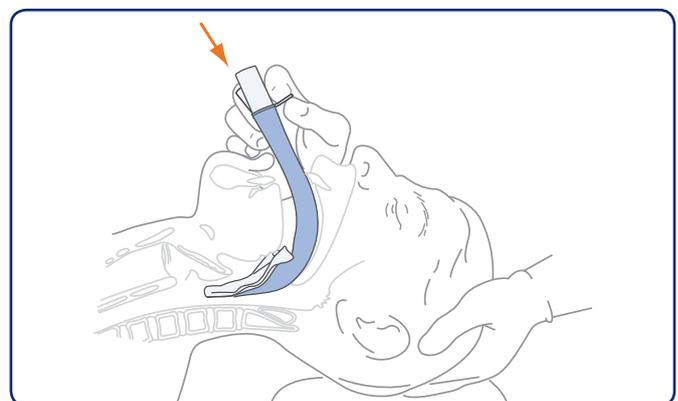


Figure 10: Advance the device into the hypopharynx until resistance is felt

## INSERTION ADVICE

An inadequate depth of anaesthesia may result in coughing and breath-holding during insertion. If this occurs, anaesthesia should be deepened immediately with inhalational or intravenous agents, and manual ventilation should be instituted.

If the patient's mouth cannot be opened sufficiently to be able to insert the mask, first ensure that he or she is adequately anaesthetised, then ask an assistant to pull the jaw downward. This manoeuvre makes it easier to see into the mouth in order to 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.

## FIXATION

Secure this device to the patient's face using adhesive tape as follows:

- Use a piece of adhesive tape 30-40 cm long, holding it horizontally by both ends.
- Press the adhesive tape transversely across the fixation tab, continuing to press downwards so that the ends of the tape adhere to the patient's cheeks, and the device itself is gently pressed inwards by the tape.
- Do not rotate the tape around the proximal end of the device.
- Do not use a Guedel airway as the device has an integral bite block.

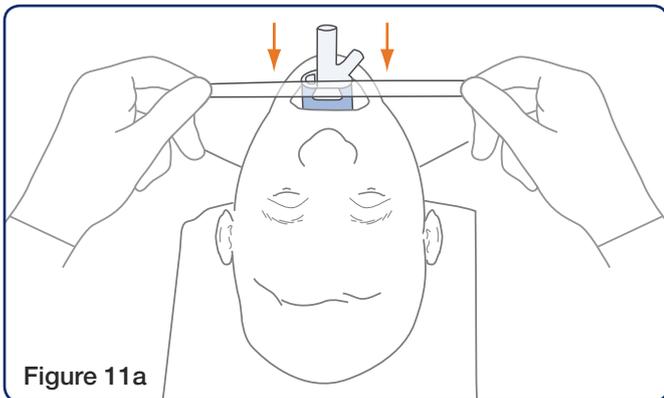


Figure 11a

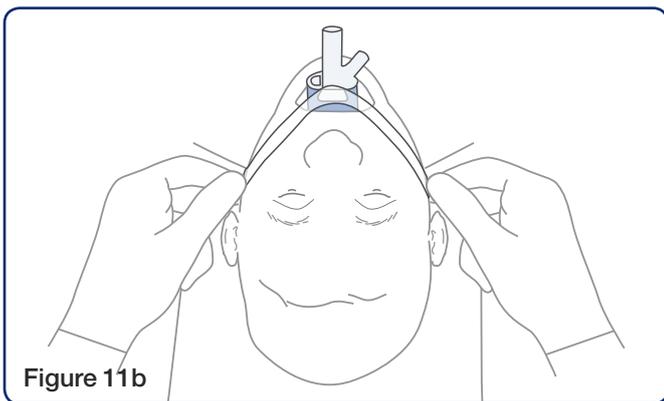


Figure 11b

**Figure 11:** Fix the device in place using adhesive tape. Stretch the adhesive tape as shown (See Figure 11a) to ensure that the middle of the tape is pressed vertically downwards over the tab (Figure 11b).

## INFLATION OF LMA PROTECTOR™

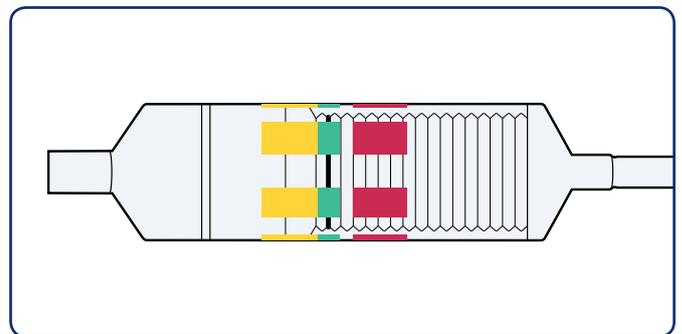
The cuff should be inflated with sufficient air to prevent a leak with positive pressure ventilation, but it must not exceed either a pressure of 60 cm H<sub>2</sub>O or the specific device cuff volume maxima. If no manometer is available, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

**Table 2:** LMA Protector™ and LMA Protector™ Cuff Pilot™ selection guide

Airway Size	Patient Weight	Max. Size OG Tube	Max. Size ETT	Maximum Intra-Cuff Pressure
3	30-50 kg	16 Fr	6.5	60 cm H <sub>2</sub> O
4	50-70 kg	18 Fr	7.5	60 cm H <sub>2</sub> O
5	70-100 kg	18 Fr	7.5	60 cm H <sub>2</sub> O

## INFLATION SYSTEM OF LMA PROTECTOR™ CUFF PILOT™

1. The LMA Protector™ 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 cm H<sub>2</sub>O. Air is introduced into the cuff until the black line is within this zone and a seal has been obtained.



**Figure 12a:** Cuff Pilot Valve in Green Zone

3. The Yellow Zone indicates a pressure of less than 40cm H<sub>2</sub>O. 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.

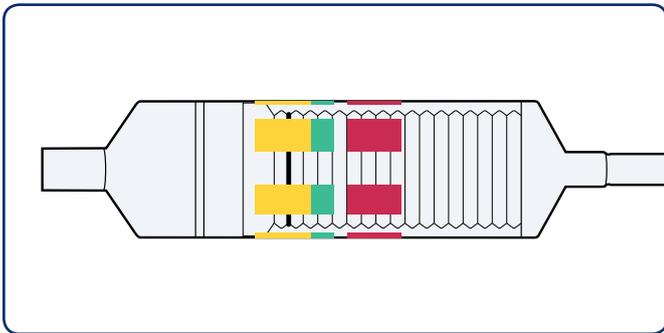


Figure 12b: Cuff Pilot Valve in Yellow Zone

- The Red Zone indicates a pressure of more than 70 cm H<sub>2</sub>O. 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.

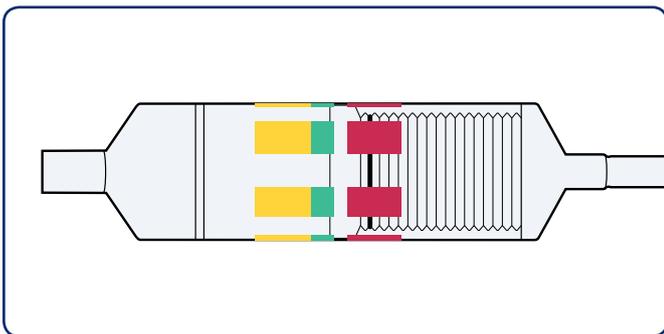


Figure 12c: Cuff Pilot Valve in Red Zone

**Warning:** Never overinflate the cuff.

## CORRECT POSITION

Correct placement should produce a leak-free seal against the glottis with the mask tip at the upper oesophageal sphincter. The integral bite block should lie between the teeth.

To discover whether the mask has been positioned correctly, place a small bolus (1-2ml) of suitably viscous, water-soluble lubricant in the proximal end of the male suction port and cover the female drainage port with a thumb. In a properly placed mask, there should be a slight up-down meniscus movement of the lubricant following the application and release of gentle pressure in the suprasternal notch. Such a movement indicates that the distal end of the drainage channel is correctly placed so that it seals around the upper oesophageal sphincter (the 'suprasternal notch test'). A similar movement may also be seen when gentle manual positive pressure is applied to the airway through the device.

## GASTRIC DRAINAGE

The drainage channels facilitate the channeling of fluids and gases emerging from the stomach. To facilitate gastric drainage, a gastric tube may be passed through the female drainage port into the stomach at any time during the anaesthetic procedure. Refer to Table 2 for maximum gastric tube sizes. The gastric tube should be well lubricated and inserted slowly and carefully. Suction should not be performed until the gastric tube has reached the stomach. It should not be applied directly to the end of the drainage channel as this may cause the drainage channel to collapse, which may, theoretically, cause injury to the upper oesophageal sphincter.

## ANAESTHESIA MAINTENANCE

This device 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 over-inflated.

During Positive Pressure Ventilation 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.

If leaks occur during PPV, this may be due to: light anaesthesia causing a degree of glottic closure; severe reduction in lung compliance related to the procedure or patient factors; or displacement, or migration, of the cuff by head turning or traction in an inadequately fixed mask.

## USE OF THE DRAINAGE CHANNEL

**Warning:** Do not attempt to pass a gastric tube through this device drainage channel if there is gas leaking through the latter, or if there is known, or suspected, oesophageal pathology or damage.

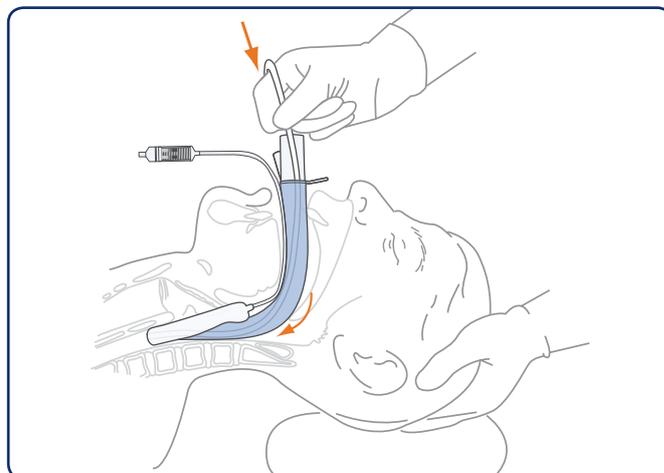
If it is clinically indicated to pass a gastric tube into the stomach, suction should not be performed until the tube has reached the stomach.

**Warning:** Suction should not be applied directly to the end of the drainage channel, as this may cause it to collapse. This could cause injury to the upper oesophageal sphincter.

The primary function of the drainage channel 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. Refer to Table 2 for maximum gastric tube sizes.

**WARNING:** Orogastric tubes which have been stiffened by refrigeration must not be used. Always ensure that the tube is at, or above, room temperature.

Upon insertion (Figure 13), some resistance is often detected when the tip of the catheter is pressed gently against the upper sphincter. Do not use excessive force. If a tube of appropriate size fails to pass, this may be because the mask is kinked or wrongly positioned. In these cases, the mask should be removed and reinserted. Clinical judgement should



**Figure 13:** Passage of an oro-gastric tube through the LMA Protector™ into the upper oesophageal sphincter

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 this device drainage channel.

## ADVICE AFTER INSERTION

### Inadequate level of anaesthesia

The most common problem following insertion is failure to maintain an adequate level of anaesthesia. If this occurs, anaesthesia should be deepened immediately with inhalational or intravenous agents, and manual ventilation should be instituted.

### Poor airway seal/Air leak

Should signs of a poor airway seal or air leak occur at the beginning of, or during, a case, one or more of the following measures may be taken:

- Verify that the depth of anaesthesia is adequate and deepen it if necessary.
- Check cuff pressures at the start of, and periodically during, a case, especially if using nitrous oxide.
- Ensure intra-cuff pressures are not >60 cm H<sub>2</sub>O. Reduce intra-cuff 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 oesophageal sphincter.

- Ensure proper fixation by applying palatal pressure while taping the device in place.
- Always confirm cuff integrity prior to placement.

### Incorrect positioning of an airway product

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.

Migration/rotation of this device during use may occur due to over-inflation 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 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.

## RECOVERY

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Removal should only be carried out by appropriately trained and equipped personnel. This device will usually be removed in the operating theatre, although its low invasivity makes it a good device to maintain the airway during recovery in the Post Anaesthetic Care Unit (PACU). Because recovery involves an increase in pharyngeal tone, it makes sense to reduce the volume of air in the cuff before sending the patient to the PACU, however, the cuff must never be fully deflated at this point.

Fully deflate the cuff and simultaneously remove the device **ONLY** when the patient can open their mouth on command. If the cuff is **FULLY** deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm.

Patient monitoring should continue throughout the recovery stage. Where appropriate, oxygen may be continuously administered through the anaesthetic circuit or via a T-piece attached to the proximal end of the airway device.

## USE WITH MAGNETIC RESONANCE IMAGING (MRI)

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LMA Protector™ with Metallic Spring is MR Conditional.

Non-clinical testing demonstrated that this product is MR Conditional. A patient with this device can be scanned safely, immediately after placement under 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 18,000-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Mode of operation for the MR system) for 15 minutes of scanning (per pulse sequence)

### MRI-Related Heating

Under the scan conditions defined above, the LMA Protector™ is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

### Artifact Information

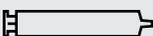
The maximum artifact size as seen on a gradient echo pulse sequence and a 3-Tesla MR system extends approximately 25 mm relative to the size and shape of the LMA Protector™ with Metallic Spring.

### MR Safe



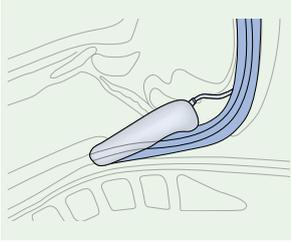
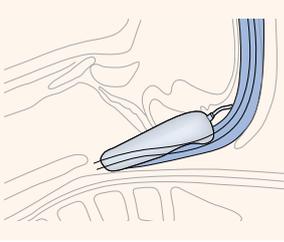
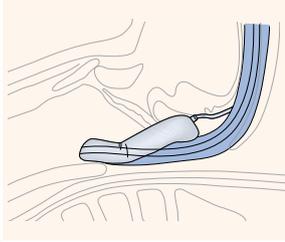
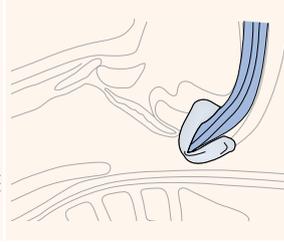
The LMA Protector™ *Cuff Pilot*™ is MR Safe (i.e., an item that poses no known hazards in all MR environments).

## SYMBOLS DEFINITION

	Manufacturer		Lot Number
	Consult IFU on this website: <a href="http://www.LMACO.com">www.LMACO.com</a>		CE Mark
	Air inflation volume/Intra-cuff pressure		MR Conditional
	Patient weight		MR Safe
	Read Instruction before use		Do not Re-use
	Not made with natural rubber latex		Do not Re-sterilise
	Fragile, handle with care		This product not made with phthalates
	Keep away from sunlight		Sterilised by Ethylene Oxide
	Keep dry		Use By
	This way up		Do not use if package is damaged
	Product Code		

## STEPS TO FACILITATE CORRECT MASK POSITION

- After insertion, inflate the cuff to no more than 60 cm H<sub>2</sub>O intracuff pressure.
- Connect to anesthesia circuit and check for leaks from the drain channels and airway tube.
- Verify position of bite block.
- Place a small bolus of lubricant gel on the proximal end of the male suction port, cover the female drainage port with a thumb 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 channel is patent.
- Once correctly positioned, apply palatal pressure to the airway tube while taping in place.

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

## ADVICE AFTER LMA PROTECTOR™ INSERTION

Problems after insertion	Possible cause(s)	Possible solution(s)
<b>Poor airway seal/air leak (audible air leak, poor ventilation)</b>	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 <sub>2</sub> O (adjust if necessary)
	Herniation of cuff	Confirm cuff integrity prior to use
<b>Gas leakage up to drain tube with or without PPV</b>	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
<b>Airway obstruction (difficult ventilation, phonation, stridor)</b>	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"> <li>– Ensure adequate anaesthesia and correct cuff inflation pressures,</li> <li>– Place patient's head/neck in sniffing position</li> <li>– Try PPV or add PEEP</li> </ul>
	Folding of cuff walls medially	<ul style="list-style-type: none"> <li>– Consider insertion of one size smaller LMA Protector™</li> <li>– Ensure correct cuff inflation pressures</li> </ul>
<b>Gastric insufflation</b>	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
<b>Migration/Rotation/ Mask popping out of mouth</b>	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not >60 cm H <sub>2</sub> 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
<b>Resistance to OG tube insertion</b>	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 <sub>2</sub> O

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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.

Always consult the instructions on indications, contraindications, warnings and precautions, or information on which LMA™ airways are best suited for different clinical applications.

**Manufacturer's Warranty:**

LMA Protector™ and LMA Protector™ *Cuff Pilot*™ are designed for single use, It is warranted against manufacturing defects at the time of delivery. Warranty is applicable only if purchased from an authorized distributor.

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