



# LMA® Gastro™ Cuff Pilot™

## Instructions for use

### English Version

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

**WARNING:** LMA® Gastro™ Cuff Pilot™ is 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® Gastro™ 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® Gastro™ Cuff Pilot™ is 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® Gastro™ Cuff Pilot™ is not designed to be cleaned, disinfected, or re-sterilised.

## GENERAL INFORMATION

Unless otherwise stated, the reference to “device” stated on this IFU applies to LMA® Gastro™ Cuff Pilot™.

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

## DEVICE DESCRIPTION

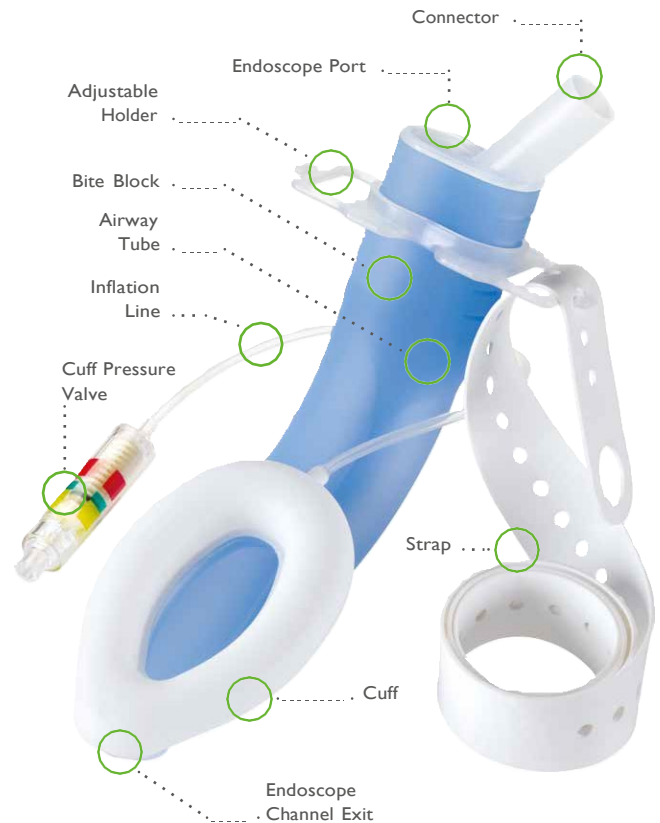
LMA® Gastro™ Cuff Pilot™ is not made with natural rubber latex and phthalates. It is supplied sterile (sterilised by Ethylene Oxide) for single use only.

The device provides access to, and functional separation of, the respiratory and digestive tracts. The anatomically shaped airway tube 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 a large bore endoscope channel which begins proximally and runs parallel along the airway tube. The endoscope channel ends at the cuff distal tip which communicates distally with the upper oesophageal sphincter (UES). A well lubricated endoscope (gastroscope or duodenoscope) may be passed through the endoscope port for upper gastrointestinal endoscopy procedures.

The device provides easy insertion with the patient in the left lateral position without the need for digital or introducer tool guidance. It has dynamic flexibility to permit the device

Figure 1. LMA® Gastro™ Cuff Pilot™ components



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 or endoscope in the event of biting.

The device’s adjustable holder and strap fixation system maintain the device in a neutral position during endoscope manipulation. If correctly used it allows the anaesthetist to be “hands free” of the device and enhances the seal of the cuff preventing leakage due to endoscope manipulation.

The inflation system of LMA® Gastro™ Cuff Pilot™ consists of an Inflation Line with Cuff Pilot™ Technology. Cuff Pilot™ Technology 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® Gastro™ Cuff Pilot™ is MR Safe. The term ‘MR Safe’ means that it poses no known hazards in all MR environments.

## INDICATION FOR USE

LMA® Gastro™ Cuff Pilot™ is indicated for use in achieving and maintaining control of the patient's airway while providing direct access to the oesophagus and upper gastrointestinal tract in patients undergoing endoscopic procedures. It can be used for either spontaneous respiration or positive pressure ventilation.

## RISK-BENEFIT INFORMATION

This device is intended for airway support and to improve endoscopic access during upper gastrointestinal endoscopy. The risk/benefit to individual patients must be individually weighed by the attending physician.

## 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.
- Patients who have not fasted, or patients whose fasting cannot be confirmed.
- 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.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, as such patients may be contraindicated for the device.

## WARNINGS

- 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.
- There is a theoretical risk of causing oedema or haematoma if suction is applied directly to the end of the endoscope channel.

- This device does not protect the trachea or lungs from the risk of aspiration. The benefits of establishing ventilation with this device during endoscopic procedures must be weighed against the small potential risk of aspiration in some situations including: symptomatic or untreated gastro-oesophageal reflux; pregnancy over 14 weeks; peritoneal infectious or inflammatory processes; conditions associated with delayed gastric emptying, such as the use of opiate medication in patients with acute injury.
- A water-soluble lubricant should be used to lubricate the device prior to insertion. Silicone-based lubricants can be used for the endoscope channel but it is not recommended to be used on other parts of the device. 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.
- This device does not allow tracheal intubation. Do not attempt tracheal intubation through the device.

## 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 the endoscope through the endoscope channel.
- The endoscopist should NOT flex the endoscope during insertion in anticipation of entering the endoscope port. It only requires insertion and gentle advancement and will naturally follow the curve of the endoscope channel. The endoscopist will feel slight resistance as the scope passes through and exits the endoscope channel as it enters the oesophagus directly.
- Never overinflate the cuff after insertion. The maximum intra-cuff pressure is listed in **Table I** below and it 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.

- The correctly seated airway should be tested to 20 cm H<sub>2</sub>O ventilation seal pressure. If airway problems persist or ventilation is inadequate, the device should be repositioned and size checked. If airway problem persists further then the 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.
- Standard infection control procedures should be observed during 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.
- The intra-cuff pressure may rise slightly after the endoscope has been inserted due to pressure applied internally on the cuff. The intra-cuff pressure should be monitored to ensure that it does not exceed the maximum cuff pressure listed in **Table 1** below.
- The holder should be level, have engaged both sides of the grooves and be locked before tension is applied to the strap.
- The holder should be level to the patient's lips. The tension on the strap should not be so tight that the holder is pressing into the patient's lips.
- The patency of the 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. Standard textbooks and published literature should be consulted for specific information.

**Table 1. Specification for LMA® Gastro™ Cuff Pilot™**

	SIZE 3	SIZE 4	SIZE 5
Airway connector	15 mm male (ISO 5356-1)		
Inflation valve	Luer cone (ISO 594-1)		
Internal volume of ventilatory pathway	15 ml	15 ml	20 ml
Nominal length of the Internal ventilatory pathway	16 cm	17 cm	18 cm
Nominal length of the Internal endoscope pathway	18 cm	20 cm	22 cm
Pressure drop	<1.5 cm H <sub>2</sub> O at 60 l/min	<1.5 cm H <sub>2</sub> O at 60 l/min	<0.6 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	24 mm	28 mm	28 mm
Max. endoscope size (OD)	14 mm	14 mm	14 mm

LMA® Gastro™ Cuff Pilot™ is 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 is available on request.

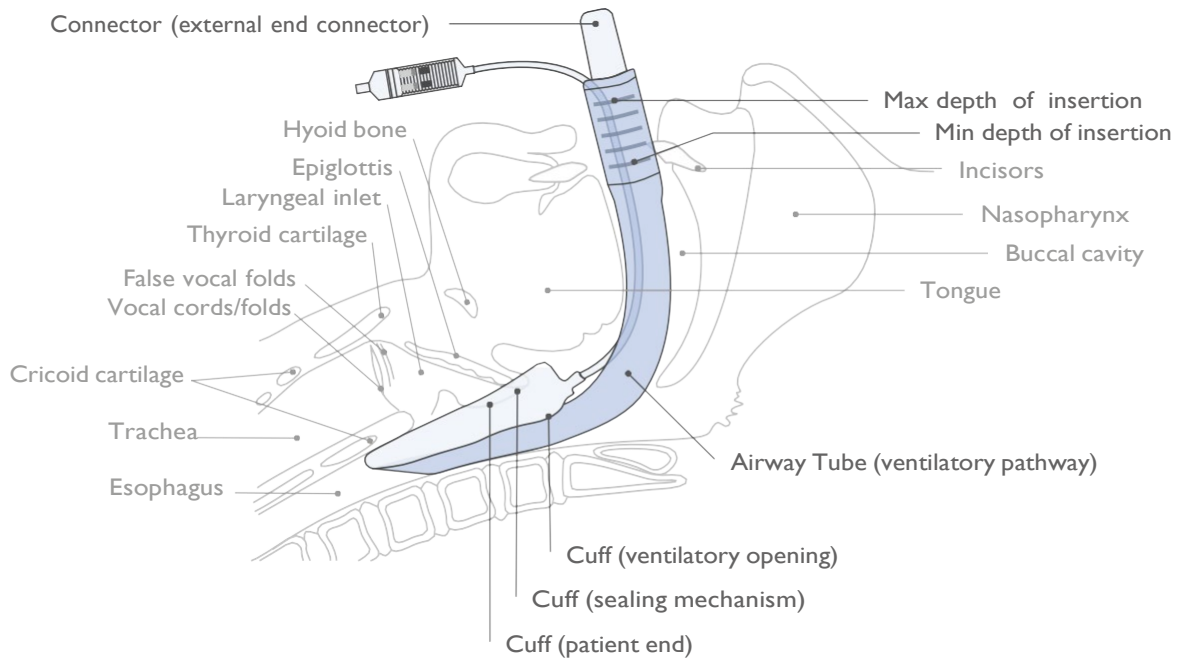


Figure 2a. Intended position of LMA® Gastro™ Cuff Pilot™ with anatomic landmarks

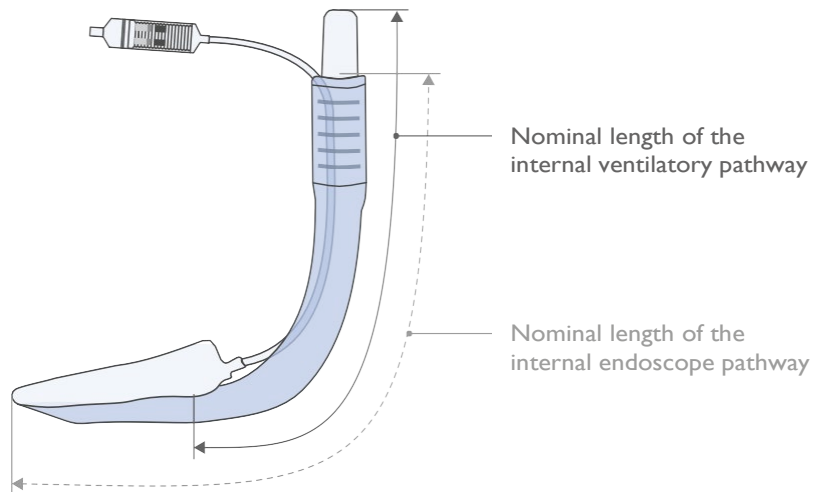


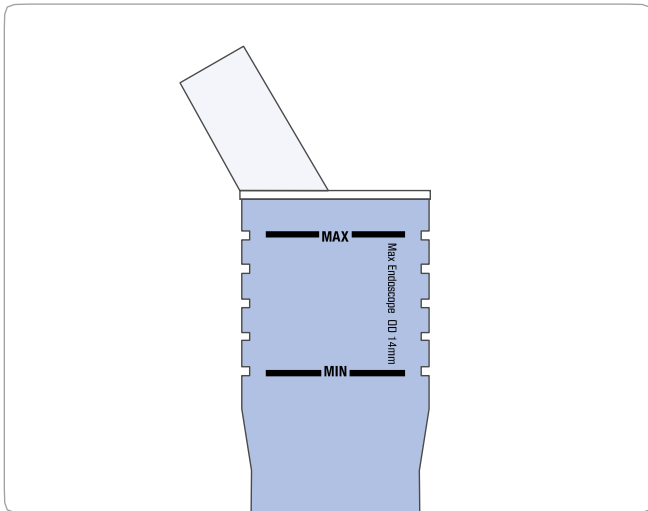
Figure 2b. Nominal length of internal pathways

### SIZE SELECTION

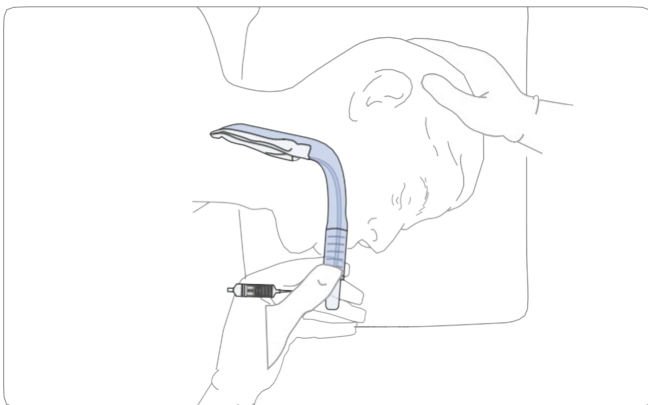
See **Table 2** below for selection guidelines based on patient weight. After inserting, fixing the device in place, and then inflating to the recommended pressure, the holder underside should be flush against, but not pressing into the patient's lips as shown in **Figure 5**, with the holder engaged to one pair of the grooves along the maximum to minimum marking on the bite block.

**Table 2. Size selection guidelines for LMA® Gastro™ Cuff Pilot™ based on patient's weight**

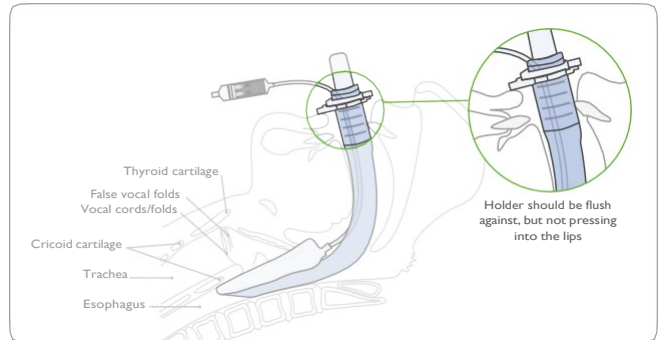
	SIZE 3	SIZE 4	SIZE 5
Patient Weight (KG)	30 – 50	50 – 70	70 – 100



**Figure 3. Maximum and Minimum marking on LMA® Gastro™ Cuff Pilot™ Biteblock**

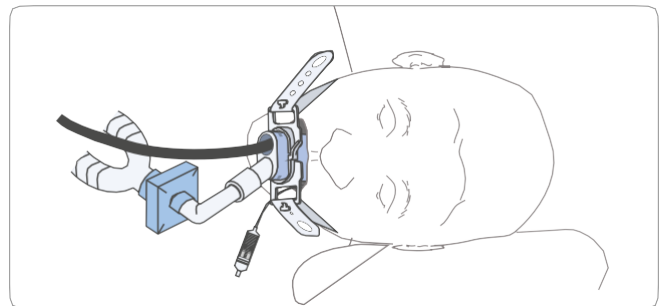


**Figure 4. LMA® Gastro™ Cuff Pilot™ sizing (method 1)**

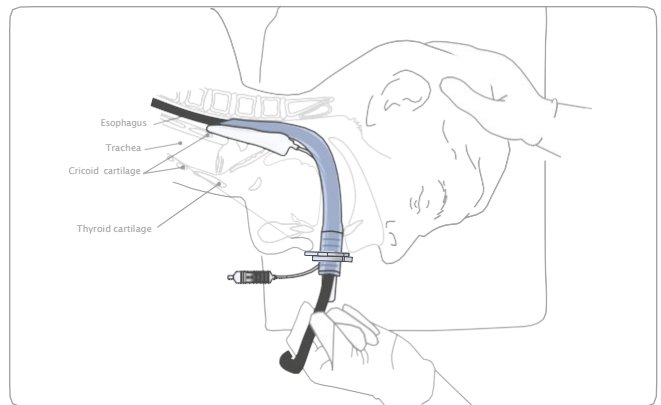


**Figure 5. LMA® Gastro™ Cuff Pilot™ sizing (method 2)**

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 prevent a leak with positive pressure ventilation but which does not exceed the maximum intra-cuff pressure listed in **Table 1** above. 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 also be made by holding each device against the side of the patient's face in the position corresponding to that shown in **Figure 4**.



**Figure 6a. Placement of Endoscope for LMA® Gastro™ Cuff Pilot™**



**Figure 6b. Placement of Endoscope for LMA® Gastro™ Cuff Pilot™**

## 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, which will minimise the likelihood of 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 the 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.

## PRE-USE PREPARATIONS

Prior to inserting the device into the patient, the device endoscope channel needs to be prepared.

1. It is recommended that medical-grade silicone spray is used to lubricate the inside of the endoscope channel.
2. The endoscope should then be inserted through the lubricated channel on the device and passing it backwards and forward to confirm smooth and free movement before use.
3. Remove the endoscope completely out of the device.
4. The device endoscope channel is prepared.

## DEFLATING THE DEVICE PRIOR TO INSERTION

1. After firmly connecting a syringe of at least 50 ml to the inflation port, hold the syringe and this device exactly as shown in **Figure 7**. Move the connected syringe away from the device until the inflation line is slightly stretched as shown. With a gloved hand, 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 7**.

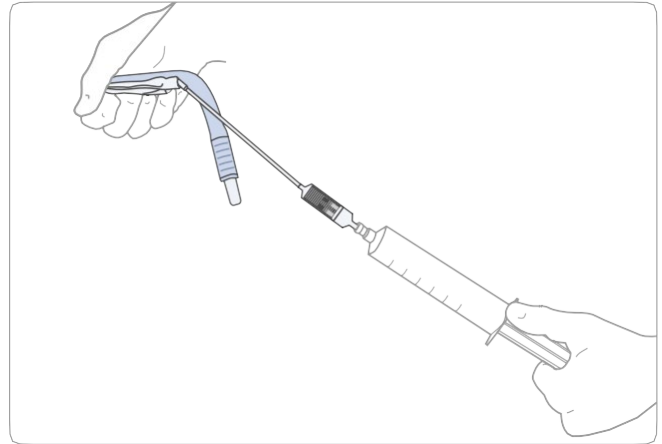


Figure 7. LMA® Gastro™ Cuff Pilot™ deflation

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 8**.

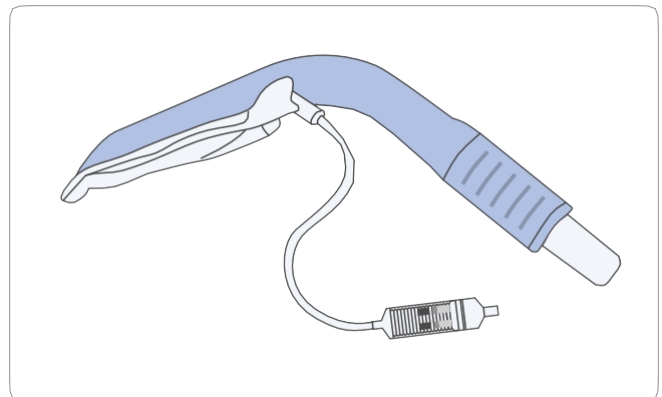


Figure 8. After achieving wedge shape cuff during deflation, disconnect the syringe from the inflation line

## INSERTION

1. Lubricate the posterior surface of the mask and airway tube with water based lubricant gel just prior to insertion.
2. For gastroscopy the patient is placed in the left lateral position prior to induction. Supine may be used during insertion, however, the patient may be required to be rolled to the left lateral position for the endoscopy.
3. Stand beside the patient's head.
4. Position the strap across the underneath of the patient's head.
5. Place the holder over the bite block section such that the flat surface of the flange is facing towards the patient and position the holder midway along the bite block **WITHOUT LOCKING** it as shown in **Figure 9**. For ease of use, it is recommended that the holder is orientated such that the clip of the holder is facing toward the patient's nose when inserted.
6. In the left lateral position keep the head in a neutral position.
7. Hold the device exactly as shown in **Figure 9**.
8. Press the distal tip against the inner aspect of the upper teeth or gums as shown in **Figure 10**.
9. Slide inwards using a slightly diagonal approach (direct the tip away from the mid-line) as shown in **Figure 11**.
10. Continue to slide inwards rotating the hand in a circular motion so that the device follows the curvature behind the tongue.
11. Slight resistance should be felt when the distal end of the device meets the upper oesophageal sphincter. The device is now fully inserted as shown in **Figure 12**.
12. If the holder's position needs to be adjusted, it can be adjusted using 2 fingers while holding onto the device.

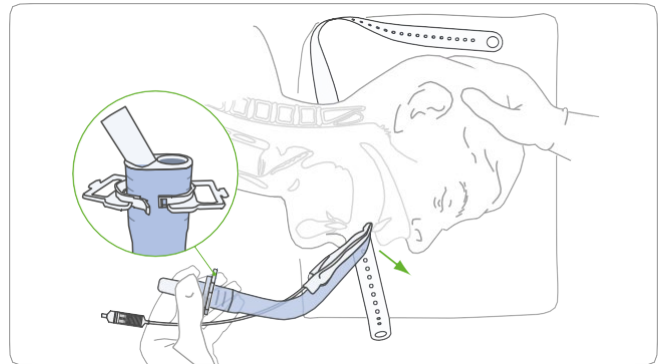


Figure 9. Press the tip of the mask against the hard palate

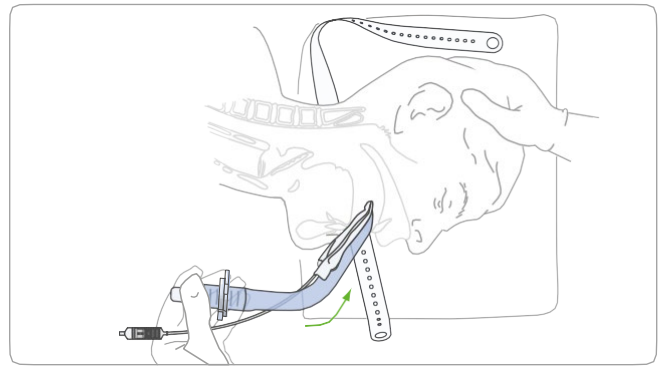


Figure 10. Press the cuff further into the mouth, maintaining pressure against the palate

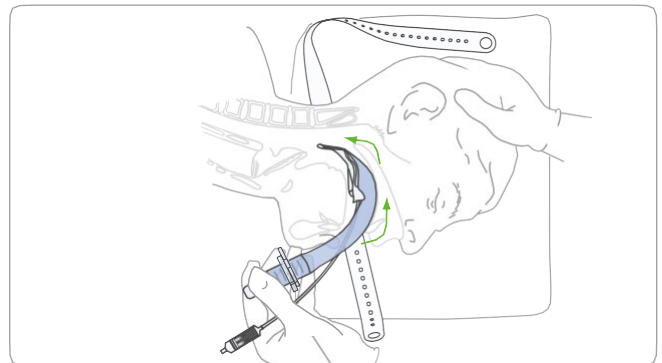


Figure 11. Slide the device inward with a circular motion, pressing against the contours of the hard and the soft palate

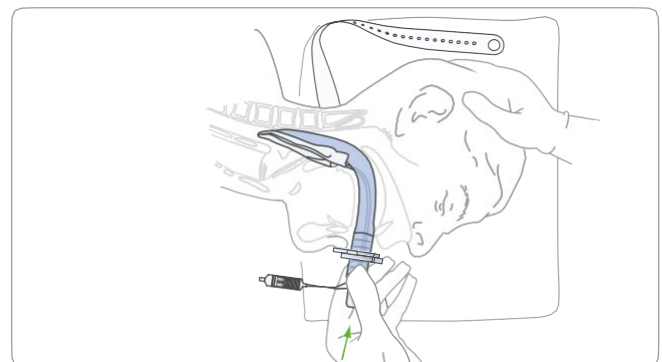


Figure 12. Advance the device into the hypopharynx until resistance is felt



## 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 necessary.

If the patient's mouth cannot be opened sufficiently to be able to insert the mask, first ensure that the patient is adequately anaesthetized, and then ask an assistant to gently pull the jaw downward.

This manoeuvre makes it easier to see into the mouth in order to verify the position of the mask. 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 the device to the patient's face using the adjustable holder and strap provided as follows:

With the device in the correct position, place the holder at one of the grooves such that the holder underside is flush against, but not pressing into the patient's lips. Lock the holder to engage it with the grooves on both sides as shown in **Figure 13**.

- In the left lateral position, secure one end of the strap to the left side of handle by looping the end of the strap through the wing of the holder and secure it to the hook on the outside. Bring the unsecured part of the strap behind and around the patient's head. Pull the strap through the right holder, apply sufficient tension to hold it in place and then secure it to the right handle of the holder as shown in **Figure 14**.

- The device should be secure in its natural position.
- Do not use a Guedel airway or any other bite block devices as the device has an integral bite block.

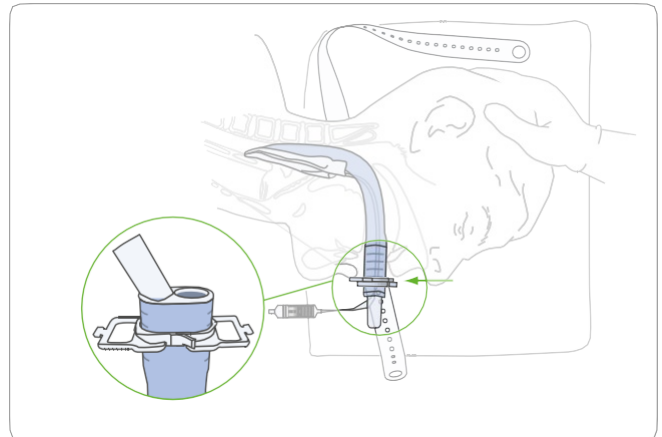


Figure 13. With the device in place, secure the adjustable holder at one of the grooves such that the holder underside is flush against, but not pressing into the patient's lips

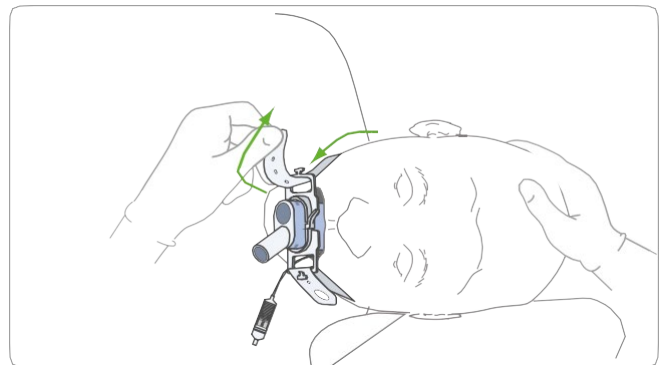


Figure 14. Bring the unsecured part of the strap behind and around the patient's head and secure it to the right handle of the holder

### INFLATION OF LMA® GASTRO™ CUFF PILOT™

The cuff should be inflated with sufficient air to prevent a leak with positive pressure ventilation, but it must not exceed the maximum cuff pressure indicated in **Table 1** above. If no manometer is available, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

### INFLATION SYSTEM OF LMA® GASTRO™ CUFF PILOT™

1. LMA® Gastro™ Cuff Pilot™ has a cuff pressure valve, which enables the end user to monitor the intra-cuff pressure of the mask through visual means while it is inserted in the patient's airway. There are three pressure zones on the cuff pressure 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.

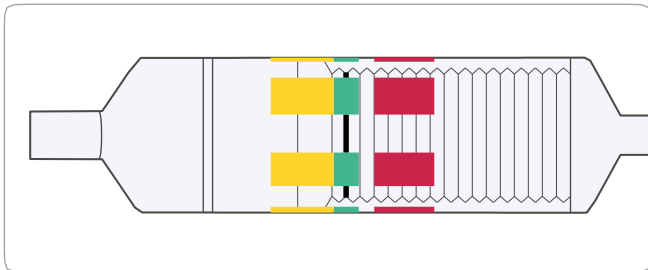


Figure 15a. Cuff Pilot™ Cuff Pressure Valve in Green Zone

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

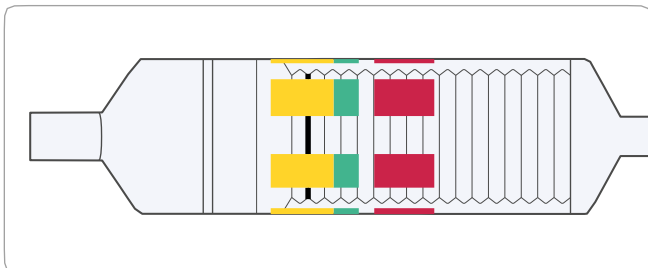


Figure 15b. Cuff Pilot™ Cuff Pressure Valve in Yellow Zone

4. 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 reduced until the black bellows line is back in the Green Zone.

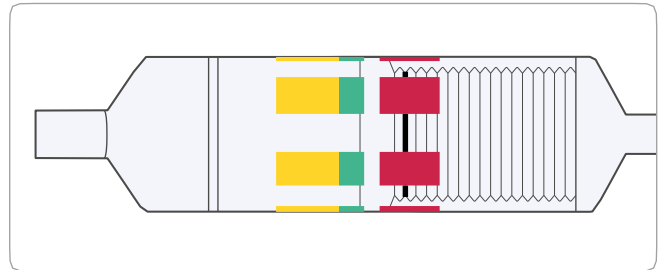


Figure 15c. Cuff Pilot™ Cuff Pressure Valve in Red Zone

**WARNING: Never overinflate the cuff.**

### CORRECT POSITION

Correct placement should produce a leak-free seal against the glottis with the mask tip in the upper oesophageal sphincter. The patient should be easily ventilated and seal pressure should be tested at 20 cm H<sub>2</sub>O, with the Cuff Pilot™ Cuff Pressure Valve in the Green. The holder underside should be flush against, but not pressing into the patient's lips, with the holder engaged to one pair of the grooves along the maximum to minimum marking on the bite block.

### ENDOSCOPE INSERTION

The endoscope channel facilitates the insertion of an endoscope to the upper esophageal sphincter without need for the endoscopist to use the maneuvering controls of the endoscope (i.e. the endoscope should NOT BE flexed for entry). For gastroscopy procedures, normal forward vision will show the device moving along the endoscope channel and entering the oesophagus directly. The oesophagus may appear to "occlude" the distal end of the port and with gentle advancement the endoscope will pass into the oesophagus under direct vision.

Refer to **Table 1** above for maximum endoscope sizes allowable for the device.

## ANAESTHESIA MAINTENANCE

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, and the cuff is not over-inflated.

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.

If leaks occur during PPV, this may be due to: malpositioning; light anaesthesia; severe reduction in lung compliance related to the procedure or patient factors; displacement; or migration of the cuff by head turning or traction in an inadequately fixed mask. Each of these may be rectified with taking the appropriate action described in the “ADVICE AFTER LMA® GASTRO™ CUFF PILOT™ INSERTION” section of the IFU.

## USE OF THE ENDOSCOPE CHANNEL

**CAUTION:** Caution should be exercised when the device is used in patients with suspected upper oesophageal inlet pathology.

For gastroscopy, it is recommended to pass the endoscope under vision through the device (this will not be possible with the duodenoscope).

The primary function of the endoscope channel is to allow an endoscope to be passed through the device.

The secondary function of the endoscope channel is to provide a separate conduit from and to the alimentary tract. It may direct gases or liquids from the patient. Refer to **Table I** above for maximum endoscope sizes.

Upon insertion as shown in **Figure 16**, some resistance is often detected as the endoscope is passed through the device. Do not use excessive force. If an endoscope of appropriate size fails to pass, this may be because the mask is kinked or wrongly positioned. Flexing of the device that may be too large for the patient will trap the endoscope as it is inserted. In these cases, the mask should be gently withdrawn a few mm or repositioned. Clinical judgement should be used in deciding when the endoscope should be removed.

The intra-cuff pressure may rise slightly after the endoscope has been passed due to pressure applied internally on the cuff. The intra-cuff pressure should be monitored to ensure that it does not exceed the maximum cuff pressure listed in **Table I** above.

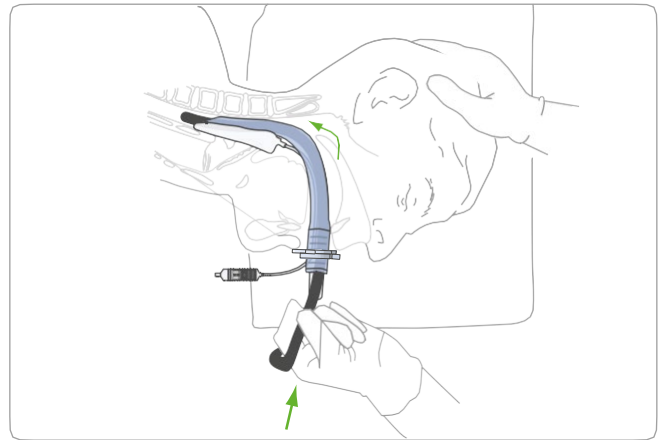


Figure 16. Passage of an endoscope through LMA® Gastro™ Cuff Pilot™ into the upper oesophageal sphincter

**WARNING:** To avoid trauma, excessive force should not be used at any time during insertion of an endoscope through the device's endoscope 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 if required, 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 securing the strap onto the adjustable holder.
- 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 of this device during use may occur due to movement of the endoscope, 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 or patient may be inadequately anaesthetised.

### RECOVERY

Removal should only be carried out by appropriately trained and equipped recovery personnel. The device will usually be removed in the operating theatre; however, as with other LMA® Airways, it is well tolerated and will maintain the airway during recovery in the Post Anaesthetic Care Unit (PACU). The cuff must never be fully deflated at this point. 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.

Remove the device in a “rolling” action when the patient can open their mouth on command, deflating the cuff sufficiently when in the mouth in order not to damage the patient’s dentition during removal. It is recommended that the cuff remains inflated when the device is being removed from the oesophagus as it may allow more secretions to be removed during removal.

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 device.

## USE WITH MAGNETIC RESONANCE IMAGING (MRI)




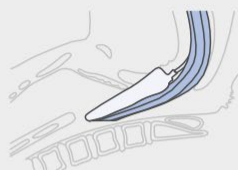


LMA® Gastro™ Cuff Pilot™ is MR Safe (i.e., an item that poses no known hazards in all MR environments).

### 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		Date of Manufacture
	Patient weight		MR Safe
	Caution (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		Quantity

### STEPS TO FACILITATE CORRECT MASK POSITION

- After insertion, inflate the cuff to no more than 60 cm H<sub>2</sub>O intra-cuff pressure.
- Connect to anesthesia circuit and check for leaks from the endoscope channel and airway tube.
- Verify position of bite block.
- Once correctly positioned, fix the device in place using the adjustable holder and strap.

	CorrECT pLAcEmEnt	InCorrECT pLAcEmEnt	InCorrECT pLAcEmEnt	InCorrECT pLAcEmEnt
				
	tip bEhInd arytenoid and CrIcoid CartIlagES	tip too high In thE pharynx	tip In thE laryngEal vEstIbuIE	tip foldEd baCkwardS
Gas leak from endoscope ports	No	Yes	Yes	No
Bite block	Approximately midway between teeth	Too high	Approximately midway between teeth	Too high
Additional verification	Passing endoscope to mask tip demonstrates that endoscope channel is patent	Pressing in further eliminates leak	Pressing in further increases obstruction	Difficulty passing endoscope indicates occluded endoscope channel

## ADVICE AFTER LMA® GASTRO™ CUFF PILOT™ INSERTION

problemS aftEr InSErtion	poSSibIE CauSE(S)	poSSibIE SoLution(S)
Poor airway seal/air leak (audible air leak, poor ventilation)	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes
	Inadequate anaesthesia	Deepen anaesthesia
	Poor fixation	Ensure palatal pressure and proper fixation
	Over inflation 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)
Gas leakage up to endoscope with or without PPV	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Open upper esophageal sphincter	Monitor
Airway obstruction (difficult ventilation, phonation, stridor)	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Distal tip of mask pressing on glottis inlet with mechanical closure of vocal cords	Ensure adequate anaesthesia and correct cuff inflation pressures
		Place patient's head/neck in sniffing position
		Try PPV or add PEEP
Folding of cuff walls medially	Consider insertion of one size smaller LMA® Gastro™ Cuff Pilot™	
	Ensure correct cuff inflation pressures	
Gastric insufflation	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes
Migration/Rotation/Mask popping out of mouth	Over inflation 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
	Accidental displacement	Ensure proper fixation
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Poor fixation	Ensure palatal pressure and proper fixation
Resistance to endoscope insertion	Insufficient lubrication	Add lubricant and re-attempt passing endoscope
	Mask seated too high in pharynx may crimp the endoscope	Advance mask in further and re-secure airway tubes
	Mask seated too low in pharynx may crimp the endoscope	Withdraw the mask a short distance and re-secure airway tubes
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Gross over inflation 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



1 DEVICE OVERVIEW

2 PREPARATION FOR USE

3 INSERTION

4 ANAESTHESIA MAINTENANCE AND RECOVERY

5 APPENDIX

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

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® Gastro™ Cuff Pilot™ is 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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Teleflex Medical  
IDA Business and Technology Park,  
Dublin Road, Athlone,  
Co. Westmeath, Ireland  
[www.lmaco.com](http://www.lmaco.com)



Issue: PBF-2100-000 Rev C UK