(For US only)

EN – English

Instructions For Use – LMA Classic Excel™

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

WARNING: LMA Classic Excel™ is supplied non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

1.DEVICE DESCRIPTION:

The LMA Classic Excel™ is an advanced supraglottic airway device used to ventilate spontaneously breathing patients as well as assist controlled ventilation up to 20 cm H_2O. It is also designed to facilitate tracheal intubation with an endotracheal tube (ETT) with the aid of a fiberoptic bronchoscope. The LMA Classic Excel™ is an enhanced version of the LMA Classic airway, designed with an epiglottic elevating bar and a removable airway connector, facilitating patient intubation at any time during the procedure. Because it is intended to be used as an airway device primarily, ventilatory control and patient oxygenation may be continuous during intubation attempts, lessening the likelihood of desaturation.

WARNING: *In an anticipated difficult airway situation where an LMA™ airway will be used as a conduit for intubation, the LMA Fastrach™ is recommended. In an unanticipated situation, intubation through the LMA Classic Excel™ should be attempted only under direct visualization with a Fiberoptic Bronchoscope (FOB).*

The LMA Classic Excel™ airway incorporates the following features (Figure 1):

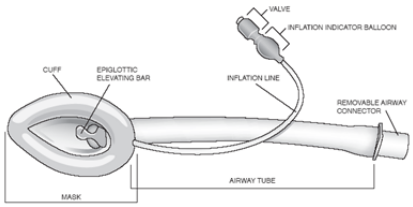

Figure 1: The components of the LMA Classic Excel™ airway.

- A durable airway tube with a removable 15 mm connector. The tube is wide enough to accept up to a 7.0 mm cuffed endotracheal tube and short enough to ensure passage of the ETT cuff beyond the cords. (see Table 5 for ETT compatibility).
- An inflatable cuffed mask designed to conform to the contours of the hypopharynx with its lumen facing the laryngeal opening.
- An epiglottic elevating bar (EEB) in the mask aperture. The caudal end of the EEB is not fixed, allowing it to elevate the epiglottis when an ETT is passed through the aperture.

The LMA Classic Excel™ is designed to be a minimally stimulating device. When fully inserted using the recommended insertion technique, the distal tip of the LMA Classic Excel™ cuff presses against the upper esophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue (Figure 2).

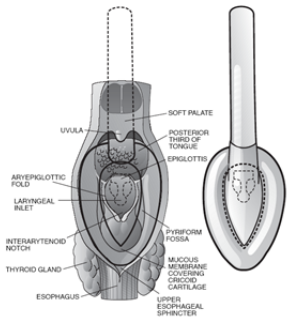

Figure 2: Dorsal view of the LMA Classic Excel™ cuff showing position in relation to the pharyngeal anatomy.

The LMA Classic Excel™ is a reusable device, made primarily of medical-grade silicone. It is not made with natural rubber latex.

Teleflex Medical recommends that the reusable LMA Classic Excel™ be used a maximum of 60 times before being discarded. Continued use beyond the maximum times is not recommended as degradation of the components may result in impaired performance or abrupt failure of the device. Steam autoclave is the only recommended method for sterilization.

This device is only for use by medical professionals trained in airway management.

2. INDICATIONS FOR USE:

The LMA Classic Excel™ is indicated for use as an alternative to the face mask for achieving and maintaining control of the airway during routine and emergency anesthetic procedures.

The LMA Classic Excel™ is not indicated for use as a replacement for the Endotracheal tube, and is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

The LMA Classic Excel™ is also indicated in a known or unexpected difficult airway situation.

The LMA Classic Excel™ is also indicated as a method of establishing a clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation. In these cases, the LMA Classic Excel™ should only be used when tracheal intubation is not possible.

3. 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.

4. CONTRAINDICATIONS:

Due to potential risk of regurgitation and aspiration, do not use the LMA Classic Excel™ as a substitute for an Endotracheal tube in the following elective or difficult airway patients on a non-emergency pathway:

- Patients who have not fasted, including patients whose fasting cannot be confirmed.
- Patients who are grossly or morbidly obese, more than 14 weeks pregnant or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The LMA Classic Excel™ is also contraindicated in:

- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the airway forms a low-pressure seal around the pharynx.
- Patients where the peak airway inspiratory pressures are anticipated to exceed 20 cm H_2O.
- 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™ airway use.

The LMA Classic Excel™ should not be used in the resuscitation or emergency situation in patients who are profoundly unconscious and who may resist LMA™ airway insertion.

CAUTION: *Intubation through LMA Classic Excel™ is contraindicated in the presence of esophageal or pharyngeal pathology.*

5. WARNINGS:

Throughout this instruction manual, appropriate warnings are given describing potential safety hazards associated with use of the LMA Classic Excel™ airway, limitations during use, and steps that should be taken should they occur. The user should be familiar with the following warnings prior to use of the LMA Classic Excel™.

For detailed instructions on the use of an ETT, please refer to the relevant manufacturer's instructions for use.

Preparation for Use

- The LMA Classic Excel™ is delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The manufacturer recommends that the LMA Classic Excel™ be used a maximum of 60 times before being discarded. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.
- Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize the airway. Such substances are absorbed by the LMA Classic Excel™, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use LMA Classic Excel™ airway that has been exposed to any of these substances.
- Failure to properly clean, rinse, and dry the LMA Classic Excel™ airway may result in retention of potentially hazardous residue or inadequate sterilization.
- All of the non-clinical tests described in this manual must be conducted before each use of any LMA Classic Excel™ airway. Failure of any one test indicates that the device has passed its useful life and should be replaced.
- Do not use the LMA Classic Excel™ airway or any of the accessories if they are damaged in any way.
- Do not use the LMA Classic Excel™ if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.
- When using the device in special environmental conditions, such as enriched oxygen, ensure that all necessary preparation and precautions have been taken, especially with regard to fire hazards and prevention. The device may be flammable in the presence of lasers and electrocautery equipment.
- Refer to MRI information section prior to using the devices in MRI environment.

Insertion

- Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.
- A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as

they degrade the device components. Lubricants containing Lidocaine are not recommended for use with the device. Lidocaine can delay the return of the patient's protective reflexes expected prior to removal of the device, may possibly provoke an allergic reaction, or may affect the surrounding structures, including the vocal cords.

- Do not immerse or soak the device in liquid prior to use.
- To avoid trauma, force should not be used at any time during insertion of the LMA Classic Excel™.
- Never overinflate the cuff after insertion.
- Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.
- Use of a bite-block reduces the possibility of the danger of airway obstruction or tube damage. A bite-block should be used with the LMA Classic Excel™ and kept in place until the airway is removed.

Usage

- The LMA Classic Excel™ does not protect the patient from aspiration.
- Should the LMA Classic Excel™ airway be used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.
- Do not use force under any circumstances.
- Always ensure the connector is securely seated in the breathing circuit to prevent disconnection during use.
- Never over-inflate the cuff of the device over 60 cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.
- Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. In order to ensure that cuff pressures do not become excessive, cuff pressure should be measured regularly during a case with a cuff pressure monitor.

6. CAUTIONS:

This manual contains numerous cautionary statements regarding the special care to be exercised for the safe and effective use of the LMA Classic Excel™. The user and others involved in the preparation for use of the device should be familiar with and adhere to these instructions.

- Laryngeal spasm may occur if the patient becomes too lightly anesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, treat the cause. Only remove the device when airway protective reflexes are fully competent.
- Ensure all removable denture work is removed before inserting the device.
- Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
- Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.
- Only use a syringe with standard luer taper tip for inflation or deflation.
- 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.
- An incorrectly placed mask may result in an unreliable or obstructed airway. Always check for proper placement after insertion.
- Only use with the recommended maneuvers described in the instructions for use.

Preparation for use

- Careful handling is essential. The LMA Classic Excel™ is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.
- Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it could cause premature valve failure.
- Any air or moisture left in the cuff of the LMA Classic Excel™ will expand at high temperatures and the low pressures of the autoclave, causing irreparable damage (herniation and/ or rupture) to the cuff and/ or inflation balloon.
- The integrity of the reusable LMA™ airway materials will be adversely affected by exceeding sterilization temperatures of 275º F or 135º C.
- Gloves should be worn during preparation and insertion to minimize contamination of the device.
- When passing a fiberoptic bronchoscope (FOB), it should not be passed through the LMA Classic Excel™ aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottic elevating bar.
- Always ensure the connector is securely seated in the breathing circuit to prevent disconnection during use.

7. ADVERSE EFFECTS:

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks and published literature should be consulted for specific information.

8. PREPARATION FOR USE:

With proper cleaning, sterilization, and handling, the LMA Classic Excel™ can be used a maximum of 60 times. Proper cleaning and sterilization of the airway is essential to ensure continued safe usage up to 60 times.

WARNING: *The LMA Classic Excel™ is delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.*

CAUTION: *Careful handling is essential. The LMA Classic Excel™ is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.*

The LMA Classic Excel™ accessories, i.e. the LMA Cuff-Deflator, should be cleaned and sterilized in the same manner as the airway.

8.1 Cleaning the reusable airway

Thoroughly wash the device in warm water using a dilute (8-10% v/v) sodium bicarbonate/ water solution until all visible foreign matter is removed. A 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. The cleaners must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Enzodime® (Ruhof, Valley Stream, NY).

WARNING*: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize the LMA Classic Excel™ airway. Such substances are absorbed by the materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an LMA™ airway that has been exposed to any of these substances.*

CAUTION: *Do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure. If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm flowing tap water.* If moisture is noticed in the valve, tap against a towel to remove excess moisture.

8.1.1 Cleaning the LMA Classic Excel™

Clean the airway tube using a small soft bristle brush approximately ½ inch in diameter. Gently insert the brush through the connector end of the airway tube taking care not to damage the epiglottic elevating bar (EEB).

Thoroughly rinse the cuff and the tube in warm running tap water to remove cleaning residues. Carefully inspect to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

WARNING*: Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or in inadequate sterilization.*

8.2 Sterilization of the LMA Classic Excel™

Steam autoclaving is the only recommended method for sterilization. Adherence to the following procedure is essential to ensure sterilization without damage to the LMA Classic Excel™.

Immediately prior to steam autoclaving, deflate the cuff completely, pulling the syringe backward to obtain a vacuum of the cuff.

For complete deflation, it is recommended that the LMA™ Cuff-Deflator be used for this purpose. Ensure that both the syringe used to deflate the cuff and the valve are dry.

Do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving to avoid damage to the valve.

If the cuff of a deflated LMA Classic Excel™ immediately and spontaneously re-inflates after the syringe has been removed, do not autoclave or reuse the mask. This indicates the presence of a defective device. It is normal, however, for the cuff to re-inflate slowly over a period of several hours as the silicone rubber material is gas permeable.

CAUTION: *Any air or moisture left in the cuff of the airway will expand at the high temperatures and low pressure environment of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or the inflation balloon.*

8.2.1 Autoclave Settings

Steam autoclave the LMA Classic Excel™ following the autoclave manufacturer's recommendations and applicable institution and industry guidelines for temperature and time. Ensure that the airway connector is securely in place before beginning the autoclave. All steam autoclave cycles typically used for porous items are acceptable, provided the maximum temperature does not exceed 275º F (135º C) (Table 1).

CAUTION*: The integrity of the LMA Classic Excel™ materials may be adversely affected by autoclave temperature exceeding 275º F or 135º C.*
Steam Sterilization 270º - 275º F (132º - 135º C)

AUTOCLAVE	WRAPPED	UNWRAPPED (FLASH)
Gravity	10 - 15 minutes	10 minutes*
Prevaccuum	3 - 4 minutes	4 minutes*

Table 1: Minimum Exposure Times

**Mixed porous and non-porous items*
Reference: AAMI Standards and Recommended Practices.

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare facility personnel are responsible for adhering to the processes specified and validated in their facility and for maintaining process control. Failure to do so may invalidate the healthcare facility's sterilization process.

After autoclaving allow the LMA™ airway to cool to room temperature before use.

8.3 Special Considerations

The World Health Organization (WHO) guidelines and published literature indicate that the LMA Classic Excel™ cleaning and sterilization procedures outlined above are sufficient for inactivation of conventional pathogens (i.e., bacteria, fungi, and viruses). In patients known or suspected to have transmissible spongiform encephalopathy, it is recommended that the institutions follow WHO guidelines by destroying rather than reusing LMA Classic Excel™ after use.

The WHO also provides guidelines for institutions wishing to follow high level decontamination protocols for reusable medical devices. Testing has been performed to validate that the LMA Classic Excel™ can withstand 60 autoclave cycles with up to a 20 minute exposure time. Note that all cautions and warnings regarding cleaning solutions must be followed (e.g., do not clean with chemical agents).

8.4 Performance tests

All of the non-clinical tests described below must be conducted before each use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimizes contamination of the LMA Classic Excel™ before insertion.

WARNING: *Do not use the LMA Classic Excel™ or any of the airway accessories if damaged in any way.*

WARNING: *Failure of any of the test indicates that the device has passed its useful life and should be replaced.*

CAUTION: *Gloves should be worn during the preparation and insertion of the airway to minimize contamination of the device.*

Performance test 1: Visual inspection

Airway Tube and Connector

- Examine the surface of the LMA Classic Excel™ airway tube for damage, including cuts, tears or scratches.
- Examine the interior of the LMA Classic Excel™ airway tube to ensure that it is free from blockages or loose particles. Any particles present in the tubes should be removed.
- Examine the transparency of the tubes. LMA Classic Excel™ airway tube will gradually discolor with age and re-use.

WARNING: *Do not use the LMA Classic Excel™ airway if the tubes are discolored, as this impairs the ability to see and effectively remove foreign particles during cleaning or to see regurgitated fluids during use.*

WARNING: *Do not use the LMA Classic Excel™ airway if it is damaged or if visible particles cannot be removed from inside the airway tube as they may be inhaled by the patient after insertion.*

- Flex the LMA Classic Excel™ airway tube up to, but not beyond 180º, pressing at the points and in the direction shown by the arrows (Figure 3). Should the tube kink, discard the airway.

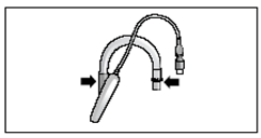

Figure 3*:* Airway kink test

WARNING: *Do not use the LMA Classic Excel™ airway if the airway tube kinks when flexed through 180º, as such an airway may become obstructed during use.*

- Examine the 15mm connector. Ensure the removable connector is inserted into the end of the airway tube. It should fit snugly into the outer end of the airway tube and can be removed by squeezing the end of the airway tube and twisting while gently pulling the connector out. It is a good idea to test this during the preparation process to make sure if the need to intubate occurs during the procedure, that the connector will be easily removed. It should also be ensured that the connector is not too loose when inserted as this may pose the risk of accidental disconnection during anesthesia.

WARNING*: Do not use the LMA Classic Excel™ if the mask connector does not fit snugly into the outer end of the airway tube.*

Cuff and Bowl of Mask

- Examine the surface of the cuff for damage, including cuts, tears and scratches.
- Examine the interior of the mask bowl to ensure it is free from blockages or loose particles. Any particles should be removed.
- Examine the distal aperture of the mask. Gently probe the flexible epiglottic elevating bar traversing the mask aperture to ensure it is not damaged. The free end of the bar should lie in contact with the floor of the mask. If it does not, it may fail to engage correctly with the epiglottis. Do not attempt to repair a broken or otherwise damaged bar. Do not remove the bar.

WARNING*: Do not use the LMA Classic Excel™ if the epiglottic elevating bar (EEB) is broken or otherwise damaged, or if the free end does not lie in contact with the mask.*

Performance test 2: Inflation and deflation

- Carefully insert a syringe into the valve port and fully deflate the device so that the cuff walls are tightly flattened against each other. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other. If the mask spontaneously reinflates, this may indicate damage to the mask or the valve.

WARNING: *Do not use the LMA Classic Excel™ if the cuff walls reinflate immediately and spontaneously, even if only slightly.*

- Inflate the cuff with 50% more air than the recommended maximum clinical inflation volume (see Table 2). Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes. Examine the symmetry of the inflated cuff. There should be no uneven bulging at either end or sides.

LMA Classic Excel™	Air Volume
Size 3	30 mL
Size 4	45 mL
Size 5	60 mL

Table 2: Test cuff Over-Inflation Volumes

WARNING: *Do not use the airway if cuff leakage is present or if there is uneven bulging of the cuff.*

- While the device remains 50% overinflated, examine the inflation balloon. The balloon shape should be a thin, slightly flattened elliptical shape, not spherical.

WARNING: *Do not use the LMA Classic Excel™ if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.*

9. INSERTION:

CAUTION: *The patency of the airway should be reconfirmed after any change in the patient's head and neck position.*

9.1 Pre-insertion preparation

Prior to insertion of the LMA Classic Excel™ the cuff should be tightly deflated so that it forms a smooth wedge shape without any wrinkles. This can be accomplished by pressing the mask with its aperture side down on a flat surface (Figure 4). The fingers may be used to form the cuff into the desired shape. Alternatively, an LMA™ Cuff-Deflator (available at LMA North America, Inc.) may be used to deflate the cuff. While deflating, pull back gently on the inflation line to obtain the correct shape for insertion.

A completely deflated mask, with a smooth leading edge facilitates insertion, avoids deflection of the epiglottis, or entry of the tip into the glottis. Optimal deflation facilitates complete insertion of the LMA Classic Excel™ airway and correct positioning of the airway (Figure 4).

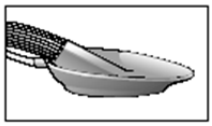

Figure 4*:* LMA Classic Excel™ cuff properly deflated for insertion

Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. Apply a bolus of lubricant to the posterior tip of the deflated cuff. It is not necessary to spread the lubricant over the mask surface.

WARNING: *Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.*

A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the silicone components. Lubricants containing lidocaine are not recommended for use as it may delay the return of the protective reflexes, provoke an allergic reaction, or affect surrounding structures, including the vocal cords.

9.2 Introduction

Before using the LMA Classic Excel™ airway, the user should be familiar with the instructions contained in this manual. If the device is inserted incorrectly, an unreliable or obstructed airway may be obtained. Always check for proper placement after insertion (see Sections 9.4 and 9.5).

***CAUTION**: An incorrectly placed mask may result in an unreliable or obstructed airway. Always check for proper placement after insertion.*

Before insertion it is important to note the following points:

- Check that the size of the device is appropriate for the patient (see Table 4 in back of manual). The ranges are approximate and clinical judgment should be used in selecting an appropriate size.
- The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.
- Check the shape of the cuff and its lubrication, as described previously.
- Have a spare, sterile LMA™ airway ready and prepared for immediate use. Where possible, an alternative size LMA™ airway should also be available.
- Pre-oxygenate and implement standard monitoring procedures.
- Achieve an adequate level of anesthesia before attempting insertion. Resistance or swallowing indicates inadequate anesthesia. Retching indicates inadequate anesthesia and/or inappropriate technique. Inexperienced users should choose a deeper level of anesthesia.
- The ideal head position is extension of the head with flexion of the neck in the position normally used for tracheal intubation ("the sniffing position"). This can be achieved by pushing the head from behind with the non-dominant hand during the process of insertion. A pillow can also be used to keep the neck flexed.
- Excessive force must be avoided at all times.

9.3 Insertion Methods

The LMA Classic Excel™ may be inserted using the standard finger technique or the thumb technique, depending on access to the patient.

Both techniques follow the same principles. To position the LMA Classic Excel™ correctly, the cuff tip must avoid entering the vallaculae or the glottic opening and must not become caught against the epiglottis or the arytenoids. The cuff must be deflated in the correct wedge shape (Figure 4) and should be kept pressed against the patient's posterior pharyngeal wall. To avoid contact with anterior structures during insertion, the insertion finger must press the tube upwards (cranially) through the insertion maneuver.

Index Finger Insertion Technique

Hold the LMA Classic Excel™ like a pen, with the index finger placed at the junction of the cuff and the airway tube (Figure 5).

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. Note the position of the hand and wrist (Figure 6). A high arched palate may require a slightly lateral approach. Look carefully in the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding. Further opening of the mouth makes it easier to verify the position of the mask. Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

As the index finger passes further into the mouth, the finger joint begins to extend (Figure 7). The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask.

Using the index finger, press backward toward the other hand, which exerts counter pressure (Figure 7). Do not use excessive force. Advance the device into the hypopharynx until a definite resistance is felt.

Depending on patient size, the finger may be inserted to its fullest extent into the oral cavity before resistance is encountered. Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube (Figure 8). This prevents the airway from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the airway should be correctly located with its tip pressed up against the upper esophageal sphincter.

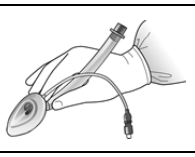

Figure 5*:* Hold the LMA Classic Excel™ with the index finger at the cuff/tube junction.

Figure 6: Press the mask up against the hard palate. Note the flexed wrist.

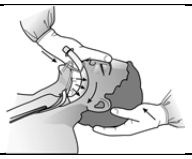

Figure 7: Slide the mask inward, extending the index finger. Press the finger towards the other hand, which exerts counter-pressure.

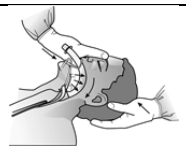

Figure 8*:* Hold the outer end of the airway tube while removing the index finger.

Thumb Insertion Technique

The thumb insertion technique is useful if it is difficult to access the patient from behind. The LMA Classic Excel™ is held with the thumb in the position occupied by the index finger, i.e., cuff/ tube junction. Insertion is similar to that using the index finger. As the thumb nears the mouth, the fingers are stretched forward over the patient's face. The thumb is advanced to its fullest extent. The pushing action of the thumb against the hard palate also serves to press the head into extension.

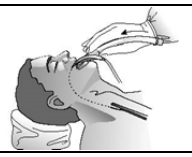

Figure 9: Hold the LMA Classic Excel™ with the thumb at the base of the mask. Place the mask against the hard palate.

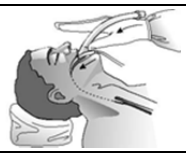

Figure 10: With the fingers extended, press the thumb along the posterior pharynx.

Figure 11: Advance the thumb to its fullest extent.

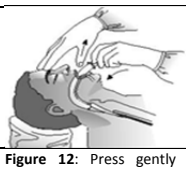

Figure 12: Press gently into place with the non-dominant hand while removing the thumb.

9.4 Insertion Problems

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

If the patient's mouth cannot be opened sufficiently to insert the mask, first ensure that the patient is adequately anesthetized. An assistant can be asked to pull the jaw downward. This maneuver makes it easier to see into the mouth and verify the position of the mask. However, do not maintain downward jaw traction once the mask has been passed beyond the teeth.

The inserting finger must press the tube against the palate throughout the insertion maneuver, 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.

If difficulty persists with the chosen technique, one of the other techniques described above should be used.

***WARNING:** To avoid trauma, force should not be used at any time during insertion of the LMA Classic Excel™ airway.*

9.5 Inflation

After insertion, the airway tube should emerge from the mouth directed caudally. Without holding the tube, inflate the cuff with just enough air to achieve an intracuff pressure of 60 cm H_2O (Figure 13). Note: The inflation amounts printed in Table 4 in the back of the manual and directly onto the airway tube are the MAXIMUM clinical inflation volumes and should not automatically be considered the recommended inflation volumes. Frequently, only half the maximum volumes are sufficient to obtain a seal and/ or achieve 60 cm H_2O intracuff pressure. Never overinflate the cuff. Avoid intracuff pressures greater than 60 cm H_2O.

***WARNING:** Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.*

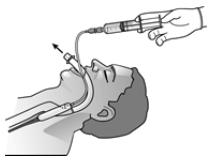

Figure 13*:* Inflate the LMA Classic Excel™ cuff, do not exceed 60 cm H_2O.

The initial cuff volume will vary according to the patient, size of the device, head position, and anesthetic depth. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location. A small outward movement of the tube is sometimes noted as the device seats itself in the hypopharynx. The signs of correct placement may include one or more of the following: the slight outward movement of the tube upon inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.

***WARNING**: Never over-inflate the cuff after insertion.*

9.6 Connecting to the anesthesia system

Taking care of avoid dislodgement, connect to the anesthesia circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. Auscultation and capnography should be used to confirm adequate gas exchange. Auscultate in the anterolateral neck region to check for abnormal sounds that might indicate mild laryngeal spasm or light anesthesia.

9.7 Fixation

A bite-block must be inserted before taping the LMA Classic Excel™ into place. The bite-block can be fabricated from three or four 4 x 4 gauze pads tightly rolled and taped into a cylindrical pad. Do not use an oral Guedel airway as a bite-block. The gauze bite-block should be at least 3 cm thick for adults and at least 2 cm thick for children. This is twisted in place alongside the airway tube. The device should then be fixed in place using adhesive tape. Apply gentle pressure to the outer end of the airway tube as it is fixed. This ensures that the tip of the mask is pressed

securely against the upper esophageal sphincter. The use of the bite block and correct taping procedures stabilizes the LMA Classic Excel™ airway and prevents potential occlusion of the tube. Keep the bite block in place until the airway is removed.

WARNING: *Use of a bite-block reduces the possibility of the danger of airway obstruction or tube damage. A bite-block should be used with the LMA Classic Excel™ airway and kept in place until airway removal.*

10. ANESTHESIA MAINTENANCE AND RECOVERY:

As with other methods of airway management, the use of pulse oximetry and capnography is recommended when using the LMA Classic Excel™ airway. The LMA Classic Excel™ may be used for either spontaneous or controlled ventilation.

10.1 Spontaneous ventilation

The LMA Classic Excel™ is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anesthesia provided anesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.

Coughing, breathholding, or movement may result if the induction agent is allowed to wear off before adequate levels of anesthesia for maintenance have been obtained. This is particularly likely to occur following the introduction of an external stimulus such as surgery or turning the patient when the level of anesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

10.2 Positive Pressure Ventilation (PPV)

The LMA Classic Excel™ may be used with PPV. When a relaxant technique is chosen, the relaxant drug may be given either before or after insertion. Alternatively, if a change in the surgical or diagnostic procedure requires conversion to a relaxant technique, a muscle relaxant can be given at any time.

The following points should be observed when using the LMA Classic Excel™ with PPV:

- Tidal volumes should not exceed 8 ml/ kg, and peak inspiratory pressure should be kept within the maximum airway seal pressure, which will be found to vary between individual patients, but is, on average, up to 20 cm H_2O for the LMA Classic Excel™.
- If leaks occur during PPV, this may be due to:
  - Light anesthesia causing a degree of glottic closure,
  - Inadequate neuromuscular blockade,
  - Reduction in lung compliance related to the procedure or patient factors, or
  - Displacement or migration of the cuff by head turning or traction.

In the event of a leak around the cuff, do not simply add more air to the cuff. This will not necessarily improve the seal pressure and may make the leak worse by adding tension to the normally soft cuff, pushing it away from the larynx.

10.3 Potential problems after insertion

Inadequate level of anesthesia

The most common problem following insertion is failure to maintain an adequate level of anesthesia. Administer an additional bolus of induction agent and/ or increase the concentration of volatile agent, while gently assisting ventilation.

Nitrous oxide diffusion

Nitrous oxide diffuses into the silicone cuff causing a rise in intracuff pressure. Studies have shown that use of nitrous oxide can increase LMA Classic Excel™ cuff pressure by as much as 1 mm Hg per minute.

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, the percentage of nitrous oxide in the inhaled mixture, and the size of the device.

The incidence of post-operative sore throat may increase if intracuff pressure becomes excessive. To reduce the risk of a sore throat or possible neurovascular injury, the cuff pressure should be periodically checked and gas intermittently withdrawn to maintain the 60 cm H_2O intracuff pressure or the minimal "just seal" pressure.

This can be achieved in several different ways. First, a pressure monitor or pressure transducer may be used. Pressure manometers are commercially available from Posey, Mallinckrodt, Portex, and VBM-Medical. Secondly, simply feeling the inflation indicator balloon can be performed. At intracuff pressure of 60 cm H_2O, the inflation balloon should feel very compliant. If the inflation indicator balloon becomes stiff or olive-shaped, this indicates excessive pressure. Finally, gas can be withdrawn until there is a slight leak, and then 1-2 ml added.

WARNING: *Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.*

Poor airway seal/ Air leak

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

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Check cuff pressures at start and periodically during a case, especially if using nitrous oxide.
- Ensure intracuff pressures are not >60 cm H_2O; reduce intracuff 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 esophageal sphincter.
- Ensure proper fixation by applying palatal pressure while taping in place.
- Always confirm cuff integrity prior to placement.

Malposition of the LMA Classic Excel™

In general, malposition of the airway can be assessed by capnography or by observation of changes in tidal volume, e.g., a reduced expired tidal volume. If malposition 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 malposition is suspected, the airway may be removed and reinserted once anesthetic depth is adequate for reinsertion.

Unexpected regurgitation

Even in fasted patients, regurgitation may occur for a variety of reasons (for example, if anesthesia becomes inadequate), resulting in fluid emerging from the airway tube.

If regurgitation occurs, provided that the oxygen saturation remains at acceptable levels, the LMA Classic Excel™ should not be removed. The patient should immediately be tilted head-down. Momentarily disconnect the anesthetic circuit so that the gastric contents are not forced into the lungs. Verify that the depth of anesthesia is adequate and deepen intravenously, if appropriate. Reposition the device to ensure the distal end is lying against the upper esophageal sphincter and secure it in place using the fixation method described earlier.
Suction should then be applied through the airway tube. Suction of the tracheobronchial tree using a fiber optic bronchoscope through the airway tube may be employed if the airway reflexes are adequately obtunded.

If clinically indicated, commence preparation for immediate tracheal intubation of the patient. If aspiration has occurred, the patient should receive a chest X-ray and be treated, as clinically appropriate, with antibiotics, physiotherapy, and tracheal suction.

A gastric tube may be inserted behind the LMA Classic Excel™ airway to complete drainage if the presence of further gastric contents is suspected.

10.4 Fiberoptic intubation through the LMA Classic Excel™

The user should be familiar with complete ETT instructions issued by the relevant manufacturer prior to use.

In an anticipated difficult airway situation where an LMA™ airway will be used as a conduit for intubation, the LMA Fastrach™ is recommended. In an unanticipated situation, intubation through the LMA Classic Excel™ should be attempted only under direct visualization with a FOB.

In order to achieve optimal intubation success with the LMA Classic Excel™, fiberoptic assistance is highly recommended. A fiberoptic bronchoscope (FOB) should be used to verify the position of the larynx before and during intubation.

WARNING: *When passing an FOB, it should not be passed through the LMA Classic Excel™ aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the EEB.*

Since the bowl of the mask faces the opening of the larynx, the LMA Classic Excel™ can be used as a guide to fiber optic visualization of the larynx and trachea while ventilation is maintained.

Table 3 in the back of the manual shows the internal diameters and tube lengths of the different sizes of LMA Classic Excel™ airways. Table 5 shows the maximum fiberoptic bronchoscope and endotracheal tube sizes that can fit through the LMA Classic Excel™ airway tube.

The user should be familiar with complete ETT instructions issued by the relevant manufacturer prior to use.

Use the following steps when attempting fiberoptic intubation through the LMA Classic Excel™:

1. Load the ETT onto the fiberoptic bronchoscope (FOB) prior to insertion.
2. Orient the fiberoptic bronchoscope (FOB) so the tip flexes in the anteroposterior direction.
3. Pass the FOB without flexing it through the airway tube of the LMA Classic Excel™.
4. The epiglottis will usually be observed lying against the epiglottic elevating bar. If the epiglottis is deflected downwards, manipulate the tip of the FOB under the epiglottis until the vocal cords come into view. If the epiglottis is deflected downwards, an up-down maneuver is the recommended method to get it unfolded.

Alternatively, an ETT with a resealing adaptor may be inserted through the airway until the tip protrudes through the epiglottic elevating bar prior to insertion in the patient.

Table 5 in the back of the manual provides guidance for selecting the appropriate size ETT and FOB with use with the LMA Classic Excel™. The compatibility of the ETT and its adaptor should be tested before insertion, since the outer diameter of the endotracheal tubes may vary.

5. Administer oxygen throughout the intubation procedure and monitor the adequacy of ventilation by capnography and pulse oximetry.
6. Once the cords are visualized, pass the tip of the FOB into the trachea.
7. Thread the ETT downwards into the trachea over the FOB.
8. Inflate the ETT cuff and ventilate to check for correct position by auscultation and capnography.
9. Leave the LMA Classic Excel™ in place. If intubation has been performed, it is recommended that the cuff of the LMA Classic Excel™ be fully deflated.

WARNING: *After intubation, do not remove the LMA Classic Excel™ airway.*

Using a slightly longer endotracheal tube may be helpful in fiberoptic intubation through the LMA Classic Excel™. The microlaryngeal tracheal tube (Mallinckrodt, St. Louis, MO; Rüsch Inc., Duluth, GA) or nasal RAE® tube (Mallinckrodt) offer increased length, which allows the cuff of the ETT to be positioned below the vocal cords in large patients.

Removing the ETT through the LMA Classic Excel™, leaving the airway in place, under deep anesthesia

1. Without holding the tube, re-inflate the cuff of the LMA Classic Excel™ with an intracuff pressure no greater than 60 cm H_2O.
2. Deflate the cuff of the ETT and while holding the airway in place, slowly remove the ETT through the LMA Classic Excel™, taking care to avoid removal or misplacement of the airway.
3. Remove the LMA Classic Excel™ airway when protective reflexes have returned.

WARNING: *Removing the ETT through the LMA Classic Excel™ while the patient is under deep anesthesia allows the patient to emerge from anesthesia with an LMA™ airway, awaking when protective reflexes have returned.*

10.5 Emergence from anesthesia and removal

If applicable, reverse the neuromuscular block or allow the block to wear off before switching off the anesthesia agents at the end of the surgical or diagnostic procedure. With gentle assisted ventilation, the patient should be allowed to start breathing spontaneously. At this stage it is advisable to check the intracuff pressure.

The correctly placed LMA Classic Excel™ airway is well tolerated until the return of protective reflexes, provided that the intracuff pressures are kept around 60 cm H_2O. This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal should always be carried out in an area where suction equipment and the space for rapid tracheal intubation are present. The following procedure should be followed:

- Patient monitoring should continue throughout the recovery stage. Oxygen should be continuously administered through the anesthesia circuit or via a T-piece. If suction is required around the oral cavity or down the airway tube, it should be carried out prior to recovery of reflexes.
- Leave the patient undisturbed until reflexes are restored, except to administer oxygen and perform monitoring procedures. It is not advisable to move the patient from the supine to the lateral recumbent position unless there is urgent reason to do so, such as regurgitation or vomiting. If the patient needs to be awakened in the lateral position, the patient must be turned in this position under adequate anesthesia.
- Avoid suctioning of the airway tube with the LMA Classic Excel™ airway in place. The inflated cuff protects the larynx from oral secretions and suctioning is not likely to be required. Suctioning and physical stimulation may provoke laryngospasm if anesthesia is light.
- Watch for signs of swallowing. It is usually safe and convenient to remove adhesive tape when swallowing begins. However, the interval between the beginning of swallowing and the ability to open the mouth varies from patient to patient according to the length and type of anesthesia.
- Deflate the cuff and simultaneously remove the device only when the patient can open the mouth on command. If the cuff is deflated before the return of effective swallowing and coughing reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngospasm. Verify airway patency and respiratory depth. Oral suctioning may now be performed, if required.

If the LMA Classic Excel™ is to be removed in a Post-Anesthesia Care Unit (PACU), recovery room staff should receive training in all aspects of LMA™ airway management. An anesthesiologist should always be readily available if the device is to be removed away from the operating room.

11. SPECIALIZED USES

11.1 Pediatric use

The smallest LMA Classic Excel™ airway sizes have been shown to function effectively in children. It is recommended that LMA Classic Excel™ airway use in children be performed by anesthesiologists familiar with pediatric patients and already experienced in adult LMA™ airway anesthesia.

Table 4 provides basic guidelines for sizing. In children at the transition weights, substitution of one size for another may be necessary.

LMA Classic Excel™ airway insertion in children is carried out in the same way as described for adults following either intravenous or gaseous induction, provided an adequate depth of anesthesia is achieved. Insertion should be successful at the same plane of anesthesia that would be suitable for tracheal intubation. The incidence of airway problems in children with the LMA™ airway seems to follow the same trends as in adults. However, as with any form of anesthesia and airway management in children where ventilation is inadequate, desaturation is likely to occur faster due to their higher oxygen consumption.[6]

LMA™ airway anesthesia in children is associated with maintenance of higher oxygen saturation compared to a face mask and Guedel airway[7] and the ability to cough and cry while waking up. The LMA Classic Excel™ airway is suitable for many short pediatric ambulatory surgical or diagnostic procedures and those where access to the head and neck would otherwise be limited by the use of a face mask. [7]

11.2 Gastric Drainage with the LMA Classic Excel™

WARNING: *Should the LMA Classic Excel™ be used in a fasted patient who is at risk or retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.*

Gastric drainage through a gastric tube is compatible with the LMA Classic Excel™ and does not interfere with its seal against the larynx. The gastric tube is best passed before airway insertion, but it is possible to pass it during anesthesia, if necessary, by slight deflation of the airway cuff. A Magill's forceps may be used to push the tip down behind the mask. The insertion of a gastric tube does not guarantee that the stomach can be drained completely.

WARNING: *The presence of a gastric tube does not rule out regurgitation and may even make regurgitation more likely because the tube may make the lower esophageal sphincter incompetent.*

11.3 Use with magnetic resonance imaging (MRI)

MR Conditional

The LMA Classic Excel™ 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 720 gauss/cm (7.2T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode of operation for the MRI system) for 15 min. of scanning (per pulse sequence).

MRI-Related Heating

Under the scan conditions defined above, LMA Classic Excel™ is expected to produce a maximum temperature rise of 2.2°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 MRI system extends approximately 20-mm relative to the size and shape of the LMA Supreme, Size 5 which is also applicable to the LMA Classic Excel™.

12. SYMBOL DEFINITION:

	Manufacturer
	Consult IFU on this website: www.LMACO.com
	Air inflation volume
	Patient weight
	Read Instructions before use
	Not made with natural rubber latex
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	This way up
	Product Code
	Lot number
	Serial Number
	Do not reuse more than 60 times
	Non-sterile
	MR Conditional

13. APPENDIX A: SPECIFICATION:

Table 3: Airway Tube Internal Diameters (mm) and Lengths (mm)

LMA Classic Excel™ Size	Internal Diameter	Length
3	9.4	220
4	9.4	220
5	10.4	235

Table 4: LMA Classic Excel™ Airway Selection Guidelines

LMA Classic Excel™ Size	Patient Size	Maximum Cuff Inflation Volumes (*air)
3	Children 30 – 50 kg	20 mL
4	Adults 50 – 70 kg	30 mL
5	Adults 70 – 100 kg	40 mL

Table 5: Maximum FOB and ETT Sizes (mm)

LMA Classic Excel™ Size	ETT	FOB
3	7.0*	5.0
4	7.0*	5.0
5	7.5*	5.5

***The LMA Reusable ET Tube has a larger outer diameter than the average ETT. Compatible sizes for the LMA Reusable ETT are: LMA Classic Excel™ size 3 – 6.5 mm ETT, LMA Classic Excel™ size 4 – 6.5 mm ETT, LMA Classic Excel™ size 5 – 7.0 mm ETT.**

Manufacturer's Warranty:
Teleflex Medical warrants the LMA Classic Excel™ airway products against faulty materials or manufacturing defects. The LMA Classic Excel™ airway products are warranted for sixty (60) uses or a period of one (1) year from date of invoice, whichever comes first, provided that the product is used in accordance with the procedures set forth in the instruction manual. A completed LMA™ airway record card or log sheet recording uses and the LMA™ airway must accompany any return for evaluation of a manufacturing defect.

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

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