**English**

**Instructions For Use – LMA Classic Excel™**

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 H₂O. 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 elevator 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 conduct 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.

The LMA Classic Excel™ airway incorporates the following features:

- **A** durable airway tube with a removable 15 mm connector. The tube is wide enough to accept up to a 7.0 cuffed endotracheal tube and short enough to facilitate the use of the ETT cuff beyond the cords. (see Table 5 for ETT compatibility)
- **An** inflatable cuff designed to conform to the contours of the hypopharynx with its lumen facing the laryngeal opening.
- **An** epiglottic elevator 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 ETT cuff of the LMA Classic Excel™ occludes the upper epiglottal sphincter. Its sides face into the perioval fossae and the upper border rests against the base of the tongue (Figure 2).

![Figure 2: The components of the LMA Classic Excel™ airway.](image)

**2 INDICATIONS**

The LMA Classic Excel™ is indicated for use as an alternative to the face mask with the following patient groups:

- Patients with fixed or acquired airway obstruction, such as patients with pulmonary fibrosis, because the airway forms a low pressure seal around the pharynx.
- Patients when the patient’s respiratory pressures are anticipated to exceed 20 cm H₂O.
- Adult patients who are unable to understand instructions or cannot answer questions regarding their medical history, since such patients may be contraindicated for LMA™ airway use.

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 airway must be inserted rapidly and aspiration must be weighed against the potential benefit of establishing an airway. The LMA Classic Excel™ should also be used in the resuscitation or emergency situation in patients who are profoundly unconscious and who may resist LMA™ airway insertion. Caution: Intubation through the LMA Classic Excel™ is contraindicated in the presence of malignancy or pharyngeal pathology.

**4 WARNINGS**

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

- **Preparation for use**
  - The LMA Classic Excel™ is delivered non-sterile and must be cleaned and sterilized prior to 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 disinfect the reusable 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 residues or inadequate sterilization.
  - All of the non-clinical tests described in this manual must be conducted on all of the reusable LMA Classic Excel™ airway. Failure of any one test indicates that the device has passed its useful life and cannot be reused.
  - 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.

- **Insertion**
  - Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.
  - To avoid trauma, force should not be used at any time during an insertion of the LMA Classic Excel™.
  - Never overinflate the cuff after insertion.
  - Excessive intra cuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nausea.
  - Use of a bite-block reduces the possibility of the device becoming dislodged. A bite-block should be used with the LMA Classic Excel™ and kept in place until the airway is removed.
  - An incorrectly placed mask may result in an unreliable or obstructed airway. Always check for proper placement after insertion.

- **Use**
  - 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 retched gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be considered. Examples of conditions where fasted patients may be at risk of retched gastric contents include, but are not limited to: hiatal hernia and moderate obesity.
  - Do not use the LMA Classic Excel™ in the presence of uncorrected hypoxia.
  - Always ensure the connector is securely seated in the breathing circuit to prevent disconnection during use.

**5 PRECAUTIONS**

This manual contains numerous precautionary statements regarding the special care to be exercised for the safe and effective use of the LMA Classic Excel™.

- Prevention for use
  - The LMA Classic Excel™ is not used to treat or relieve pain or infection.
  - Gloves should be worn during preparation and insertion to minimize contamination of the device.
  - When using a fiberoptic bronchoscope (FOB), it should not be passed through the LMA Classic Excel™ aperture unless protected by Cuff Deflater™ may be damaged by contact with the epiglottic elevator bar.
  - Always ensure the connector is securely seated in the breathing circuit to prevent disconnection during use.

**6 ADVERSE EFFECTS**

Both minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration) following use of the LMA™ airway have been reported in the literature. Following the use of the LMA™ airway, the incidence of aspiration with the LMA™ airway is low (0.012%), with the major adverse effects including inappropriate patient selection and inadequate depth of anesthesia.

The incidence of sore throat following LMA™ airway use is approximately 1.3%, and is usually mild and short lived; however, severe or prolonged sore throat that sometimes accompanied by dysphagia and tissue burns, has been reported in patients in whom an improperly cleaned or sterilized reusable mask has been used.

Infrequent neuromuscular events reported with LMA™ airway use include aspiration, laryngospasm, hypoxia secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, recurrent laryngeal nerve injury, and vocal cord paralysis. These complications are most likely the result of malposition or excessive intra cuff pressure, causing compression of nerves and/or blood vessels. Cuff malposition or failure to properly clean or sterilize the LMA™ airway may be implicated.

**7 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 LMA Classic Excel™ airway will help ensure continued safety of the device.

**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 after autoclaving.

**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™ should be cleaned and sterilized in the same manner as the airway.

**7.1 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 30 cups of water.

**WARNING:**

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

**7.1.1 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 elevator 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.

**7.2 Sterilization of the LMA Classic Excel™**

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

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

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For complete deflation, it is recommended that the LMA™ Cuff Deflator be used to ensure that both syringes are free and that 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 higher temperature and low pressure environment of the autoclave, causing irreparable damage (hermiation and/or rupture) to the cuff and/or to the inflation balloons.

7.2.1 Autoclave Settings
Steam autoclaves: LMA Classic Excel™ follows the autoclave manufacturer’s recommendations and applicable institution and industry guidelines for time and temperature. Ensure that the autoclave 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 275°F (135°C). (Table 1).

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

Table 1: Minimum Exposure Times

<table>
<thead>
<tr>
<th>Method</th>
<th>Minimum Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Sterilization</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Autoclave</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>

WARNING: Do not use the LMA Classic Excel™ airway if the inflation balloon is broken or otherwise damaged, or if the free end does not lie in contact with the mask.

Deflator
Lubrication of the posterior surface of the cuff should be performed just prior to insertion, the insertion finger must press the tube upwards (cranially) through the insertion maneuver.

Index Finger Insertion Technique

Hold the LMA Classic Excel™ airway 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 coaption of the mouth makes it easier to verify the position of the mask. Push the jaw downward with your middle finger or an assistant to pull the lower jaw downward. Resistance to further entry suggests that the mask is not fit properly.

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 fingers 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 without the event that this moving could not be achieved by the index finger. At this point the airway should be correctly located with its tip pressed up against the upper esophageal sphincter.

Figure 3: Airway link test

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 surface of the cuff before insertion to prevent drying of the lubricant. Lubricate 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 cuff. Lubricants containing iodine are not recommended for use as it may delay the return of the protective reflexes, provoke an allergic reaction, or affect survival of the patient.

8.2 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 uninflated or obstructed airway may be obtained. Always check for proper placement after insertion (see Sections 8.4 and 8.5).

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 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. Insertion is similar to that using the index finger. As the thumb nears the position occupied by the index finger, i.e., cuff/tube, the index finger should be removed. It also permits completion of insertion even if this movement could not be achieved by the index finger.
9 ANESTHESIA MAINTENANCE AND RECOVERY

As with other methods of airway management, the use of pulse oximetry and capnometry is important. Using the LMA Classic™ airway. The LMA Classic™ may be used for either spontaneous or controlled ventilation.

9.1 spontaneous ventilation

The LMA Classic™ 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, breathing, 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 intravenous giving of the different sizes such as the surgically but not when turning the patient when the level of anesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

9.2 Positive Pressure Ventilation (PPV)

The LMA Classic™ can be used with PPV. When a relaxation technique is chosen, the relaxant drug may be given either before or after intubation. Although this is routine 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™ with anesthesia

- Tidal volumes should not exceed 8 mL/kg, and peak inspiratory pressure should be kept within the maximum arterial seal pressure, which will be found to vary between individual patients, but is, on average, up to 20 cm H2O for the LMA Classic™.
- If leaks occur during PPV, this may be due to:
  - Light anesthesia causing a degree of surgical closure, inadequate neuromuscular blockade
  - Reduction in lung compliance related to the procedure or patient
  - 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 increase the airway pressure and may make the leak worse by adding tension to the normally soft cuff, pushing it away from the larynx.

9.3 Potential problems after insertion

Inadequate positioning of the LMA Classic™

The most common problem following insertion is failure to maintain an adequate level of anesthesia. Administer an additional bolus of induction agent and/or an increase in 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. Storing the cuff at room temperature prior to use will reduce the recommended inflation volumes. Frequently, only the maximum volumes are sufficient to obtain a seal and/or achieve 60 cm H2O intracuff pressure. Never overinflate the cuff. Avoid intraocular pressures greater than 60 cm H2O.

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

9.4 Emergence from anesthesia and cuff removal

If regurgitation occurs, provided that the oxygen saturation remains at acceptable levels, the LMA Classic™ should be left in place. 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 remains deep and intubation occurs. Separate the device to ensure the distal end is lying against the upper esophageal sphincter and close the plies securely. The gastric tube should be clamped until the device is removed.

Suction then should 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 suitable antibiotic therapy as appropriate, with antibiotics, physiotherapy, and tracheal suction.

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

9.5 Fiberoptic intubation through the LMA Classic™

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

WARNING: In an anticipated difficult airway situation where an LMA™ airway will be used as a conduit for intubation, the LMA Fastair™ is recommended. In an unexpected situation, intubation through the LMA Classic™ should be attempted only under direct visualisation with a FOB.

In order to achieve optimal intubation success with the LMA Classic™ 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™ aperture unless protected by the ETT. Otherwise, the FOB may damage the device.

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

Table 5 in the back of the mask shows the internal diameters and tube lengths of the different sizes of LMA Classic™ airways. Table 5 shows the maximum fiberoptic bronchoscopic and endotracheal tube sizes that can be passed through the LMA Classic™ airway tube.

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

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

1. Pass the LMA Classic™ onto the fiberoptic bronchoscope (FOB) prior to insertion.
2. Orient the fiberoptic bronchoscope (FOB) so the tip is in line with the ETT.
3. Pass the FOB without flexing it through the airway tube of the LMA Classic™.
4. The user usually observes being seen against the epiglottic elevation. If the epiglottis is reflected downwards, manipulate the tip of the FOB under the epiglottis until the vocal cords come into view. If the LMA Classic™ is removed at this stage, manual manoeuvre is the recommended method to get it unfolded.

Alternatively, an ETT with a reassembling adaptor may be inserted through the airway tube of the LMA Classic™ 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™. The correct size of ETT and FOB for the LMA Classic™ should be selected, not the inner diameter of the endotracheal tube 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. Inflate the ETT and while holding the airway in place, ventilate to check for correct position by auscultation and capnography.
8. Leave the LMA Classic™ in place. If intubation has been performed, it is recommended that the cuff of the LMA Classic™ be fully deflated.

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

Using a slightly longer endotracheal tube may be helpful in fiberoptic intubation through the LMA Classic™. The microendotracheal tube (Malinckrodt, St. Louis, MO, Kohn Inc., Duluth, GA) or nasal RAE tube (Malinckrodt) offers 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™

Leaving the airway in place, under deep anesthesia

1. Without holding the tube, re-inflate the cuff of the LMA Classic™ with an intracuff pressure no greater than 60 cm H2O.
2. Deflate the cuff of the LMA Classic™. The airway is left to slowly remove the ETT through the LMA Classic™, taking care that no manipulation of the airway.
3. Remove the LMA Classic™ airway when protective reflexes have returned.

WARNING: Removing the ETT through the LMA Classic™ while the patient is under deep anesthesia leaves the patient exposed to emergence from anesthesia with an LMA™ airway, avoidance of regurgitation protects reflexes have returned.

9.5 Emergence from anesthesia and removal

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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™ airway is well tolerated until the return of protective reflexes, provided that the intracuff pressures are kept around 80 cm H2O. 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 adequate intubation are present. The following procedure should be followed:

1. Patient monitoring should continue throughout the recovery stage.
2. Oxygen should be continuously administered through the anesthesia circuit 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.
3. 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 until 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.
4. Avoid suctioning of the airway tube with the LMA Classic™ 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.
5. 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.
6. 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 be performed if required.

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

10 SPECIALIZED USES

10.1 Pediatric use

The smallest LMA Classic™ airway sizes have been shown to function effectively in children. It is recommended that LMA Classic™ airway use in children be performed by anesthetists 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™ airway insertion in children is carried out in the same way as described for adults following either intravenous or gas 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, resuscitation is likely to occur faster due to their higher oxygen consumption.8

LMA™ airway anesthesia in children is associated with maintenance of higher oxygen saturation compared to a face mask and Guedel airway9 and the ability to cough and cry while waking up. The LMA Classic™ 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

10.2 Gastric Drainage with the LMA Classic™

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

Gastric drainage through a gastric tube is compatible with the LMA Classic™ and does not interfere with its use against the larynx. The gastric tube is best placed 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.

10.3 Use with magnetic resonance imaging (MRI)

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

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

ARTIFACT INFORMATION

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the LMA Classic™. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Artifact Information

MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the LMA Classic™. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence

11SE 11SE GRET GRET

Signal Void Size

3.481 mm 3.400 mm 12.343 mm 3.734 mm

Plane Orientation

Parallel Perpendicular Parallel Perpendicular

14 APPENDIX B: SPECIFICATION

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

<table>
<thead>
<tr>
<th>LMA Classic™ Size</th>
<th>Internal Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>9.4</td>
<td>220</td>
</tr>
<tr>
<td>4</td>
<td>9.4</td>
<td>220</td>
</tr>
<tr>
<td>5</td>
<td>10.4</td>
<td>235</td>
</tr>
</tbody>
</table>

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Table 4: LMA Classic™ Airway Selection Guidelines

<table>
<thead>
<tr>
<th>Patient Size</th>
<th>Maximum Cuff Inflation Volumes (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 50 – 70 kg</td>
<td>30 mL</td>
</tr>
<tr>
<td>Adults 70 – 100 kg</td>
<td>40 mL</td>
</tr>
</tbody>
</table>

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

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

Manufacturer’s Warranty:

The Laryngeal Mask Company Limited warrants the LMA Classic™ airway products against faulty materials or manufacturing defects. The LMA Classic™ 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 card or log sheet recording uses and the LMA™ airway must accompany any return for evaluation of manufacturing defect.

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

CAUTION: Federal law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.

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