Pre-Use Checks
It is most important that pre-use checks are carried out on LMA™ airways prior to use, in order to establish whether they are safe for use.

Warning: Failure of any one test indicates the device should not be used.

These tests should be carried out as follows:
1. Examine the interior of the airway tube to ensure it is free from blockage or loose particles. Examine the tube throughout its length. Should any cuts or inclusions be noted, discard the device.
2. Holding at each end flex the airway tube to increase its curvature up to but not beyond 180°. Should the tube kink during this procedure, discard the device.
3. Deflate the cuff fully. Reflate the device with a volume of air 50% greater than the maximum inflation value for each size.

General Information:
LMA Classic™ and LMA Flexi™ are latex free.

LMA Laryngeal Mask Airway (LMA) is a modification of the Laryngeal Mask Airway (LMA) formerly marketed as Laryngeal Mask Classic (LMC). LMC recommends LMA Classic™ and the LMA Flexi™ be used a maximum of 40 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.

LMA Unique™ and LMA Flexi™ SU are latex free and they are supplied sterile (sterilized by Ethylene Oxide) for single use only.

Warning:
It is indicated for use in achieving and maintaining control of the airway during most anesthetic procedures in fasted or lightly sedated patients using either spontaneous or Positive Pressure Ventilation (PPV).

It is also indicated for securing the immediate airway in known or unexpected difficult airway situations. It is best suited for use in elective surgical procedures where tracheal intubation is not necessary. It may be used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glottis/pharyngeal and laryngeal reflexes requiring artificial ventilation. In these cases, LMA™ airway should be used only when tracheal intubation is not possible.

When used in the profoundly unconscious patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e., “cannot intubate, cannot ventilate”), the risk of aspiration and resuscitation must be weighed against the potential benefit of establishing an airway.

Contraindications:
Due to the risk of regurgitation and aspiration, do not use the LMA™ airway as a substitute for an endotracheal tube in the following elective or difficult airway patients on a non-emergency pathway:
1. Patients who are not fasted, including patients whose fasting cannot be confirmed.
2. Patients who are grossly or morbidly obese, more than 14 weeks pregnant or emergently resuscitation situations or any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The LMA™ airway is also contraindicated in:
3. Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 20 cm H₂O, because the device forms a low-pressure seal (approximately 20 cm H₂O) around the larynx.
4. Adult patients who are unable to understand instructions or cannot adequately follow those instructions; their medical history should in such patients may be contraindicated for LMA™ airway use.

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

Adverse Effects:
Such minor adverse effects (e.g. sone throat) and major adverse effects (e.g. aspiration) following LMA™ airway use have been reported in the published literature. There have been no reports of death directly attributable to the LMA™ airway in over 100 million uses of the device worldwide.

A review of published literature suggests that the incidence of aspiration is low (2/10,000) and is comparable to the incidence of aspiration associated with out-of-hospital general anaesthesia with the face mask or endotracheal tube. There have been no published reports of long term morbidity or mortality associated with the LMA™ airway subsequent to aspiration.

The incidence of sore throat following LMA™ airway use is approximately 10% (range 0-70%) and is usually mild and short-lived. Severe or prolonged sore throat, sometimes accompanied by dysphagia, has been reported in patients in whom an improperly cleaned or sterilised mask has been used.

Unusual neurovascular events reported with LMA™ airway use include rashes of hypoglycaemic neuropathy, transient tongue numbness, secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, and vocal cord paralysis. These complications are probably the result of airway suction techniques or excessive cuff pressure. However, a clear relationship to the use of the device has not been established.

Immediate Action:

Choose the correct size of LMA™ airway

<table>
<thead>
<tr>
<th>Patient Weight/Size</th>
<th>Size 1</th>
<th>Size 2</th>
<th>Size 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>65 kg - 70 kg adult</td>
<td>30 ml</td>
<td>40 ml</td>
<td>50 ml</td>
</tr>
<tr>
<td>50 kg - 90 kg adult</td>
<td>25 ml</td>
<td>35 ml</td>
<td>45 ml</td>
</tr>
<tr>
<td>20 kg - 60 kg adult</td>
<td>15 ml</td>
<td>25 ml</td>
<td>35 ml</td>
</tr>
</tbody>
</table>

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

Choosing the optimal size requires the following considerations:

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7
Warning:
1. Store device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.
2. Excessive force must be avoided at all times.
3. Used reusable devices (LMA Classic™ & LMA Flexi™) shall be decontaminated first in accordance with local hospital procedures for handling of bio-hazard products and subsequently disposed of by incineration or landfill in accordance with all local and national regulations.
4. Single use devices (LMA Flexible™ SU & LMA Unique™) contain Di (2-ethylhexyl) phthalate (DEHP). However, both devices are not meant for long term use in patients and shall not pose any known risk to the patient. There is no concern and/ or known risk for use of these devices on children or nursing/ pregnant women. The risk and benefits of using these devices shall be carefully evaluated by clinician on a case by case basis.
5. Do not use if the device is damaged or the unit packaging for LMA Flexible™ SU & LMA Unique™ is damaged or opened.

Cleaning (for LMA Classic™ & LMA Flexi™ only):

Thoroughly wash the cuff and airway tube in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer’s instructions and at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is EnduraPrep® (Fluhof, Valley Stream, NY).

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, peracetic acid, or iodine-containing cleaners to clean or sterilize the LMA™ airway. Such substances are absorbed by the device materials, resulting in exposure of the patient to unnecessary risk and possible deterioration of the device. Do not use a device 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, remove excess moisture, and allow it to dry. If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Clean the device using a small soft bristle toothbrush (approximately 1/2 inch or 12.5 mm in diameter). Gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars. Thoroughly rinse the cuff area and airway tube in warm flowing rinse water to remove cleaning residues. Carefully inspect the device 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 inadequate sterilization.

Sterilisation (for LMA Classic™ & LMA Flexi™ only):

Immediately prior to steam autoclaving, deflate the cuff completely. Ensure that both the syringe used to deflate the cuff and the valve is dry.

Caution: Any air or moisture left in the cuff will expand at the high temperatures and low pressures of the autoclave, causing damage (hermiation and/or rupture) to the cuff and/or inflation balloon. To avoid damage to the valve, do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port after deflation.

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

Steam autoclave the device following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable for sterilisation of the LMA™ airway. Provided the maximum autoclave temperature does not exceed 137°C or 278°F. One steam sterilisation cycle that is suitable for reusable device is to expose the device to steam at 134°C with a hold time of at least 10 minutes.

Caution: The integrity of the reusable LMA™ airway materials may be adversely affected by exceeding sterilisation temperatures of 278.6°F or 137°C.

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

Healthcare personnel are responsible for adhering to the appropriate sterilisation processes which have been specified. Failure to do so may invalidate the sterilisation process of the healthcare facility.

After autoclaving allow the device to cool to room temperature before use.

Use with Magnetic Resonance Imaging (MRI)

Caution: Testing has been performed to determine the compatibility of the LMA Classic™, LMA Flexi™, LMA Flexi™ SU and LMA Unique™ with MRI. The user should carefully compare the equipment and test conditions described with those planned for use in the actual clinical environment. Refer to the below for detailed results of device testing in the MRI environment. The LMA Classic™, LMA Flexi™, LMA Flexi™ SU & LMA Unique™ were determined to be MRI-conditional. Non-clinical testing demonstrated that these devices are MRI-conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field:
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- If LMA Flexible™ & LMA Flexi™ display magnetic field interactions in the MRI environment. However, during the intended use of these products, it is “fixed” in place using adhesive tape. The appropriate “fixation” of these products is required to prevent possible issues in the MRI environment because it will effectively prevent this object from being moved due to magnetic field interactions.

MRI-Related Heating

In non-clinical testing, the device produced the following temperature rise during MRI performed for 85-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14K.5M, General Electric Healthcare, Milwaukee, WI) MRI system:

- Highest temperature change +1.6°C (LMA Classic™ & LMA Unique™)
- Highest temperature change +1.7°C (LMA Flexible™ & LMA Flexi™ SU)

Therefore, the MRI-related heating experiments for the device at 3-Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C (LMA Classic™ & LMA Unique™) and +1.7°C (LMA Flexible™ & LMA Flexi™ SU).

Artifactual 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 device. Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.

LMA Classic™:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
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</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>5,481 mm²</td>
<td>3,400 mm²</td>
<td>12,343 mm²</td>
<td>7,394 mm²</td>
</tr>
<tr>
<td>Plane Orientation</td>
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<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
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LMA Flexible™:

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<tr>
<td>Signal Void Size</td>
<td>10,296 mm²</td>
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<td>44,445 mm²</td>
<td>25,837 mm²</td>
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<tr>
<td>Plane Orientation</td>
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<td>Perpendicular</td>
<td>Parallel</td>
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LMA Unique™:

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LMA Flexi™ SU:

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</tr>
</tbody>
</table>

**Symbol Definition:**

- **MR**
- **MR Conditional**
- **MRE**
- **MRE Conditioned**
- **Read Instruction before use**
- **Latex Free**
- **Fragile, handle with care**
- **Keep away from sunlight**
- **Keep dry**
- **This way up**
- **Product Code**
- **Lot Number**
- **CE Mark**
- **Serial Number**
- **Do not re-use**
- **Do not re-use more than 40 times**
- **Non-sterile**
- **Contains or Presence of Phthalates: Bis(2-ethylhexyl) phthalate (DEHP)**
- **STERILISED BY**
- **Sterilised by Ethylene Oxide**
- **Use By**
- **Do not use if package is damaged**

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

**Manufacturer’s Warranty:**

The LMA Classic™ and LMA Flexi™ are reusable and warranted against manufacturing defects for forty (40) uses or a period of one (1) year from date of purchase (whichever is the earlier), subject to certain conditions. The completed record card must accompany any product returned for evaluation.

The LMA Unique™ and LMA Flexi™ Single Use are designed for single patient use and warranted against manufacturing defects at the time of delivery.

Warranty is applicable only if purchased from an authorized distributor.

**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.

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