LMA ProSeal™ 40-use guide
Why is 40-use important?

The 40-use specification is to alert the practitioner that although the reusable LMA™ airway is very durable, like all materials, it degrades with use and should not be re-used to the point of abrupt failure. Over the past several years, there has been an increased amount of data available regarding the possible ways that LMA™ airways may fail, and the average number of uses to reach failure.

Mechanical testing of LMA™ airway components found that as the number of uses increased, there were reductions in tear strength, tensile strength, and elongation, and an increase in stiffness (see charts below). Due to this material degradation, the manufacturer recommends that an LMA™ airway be used up to 40 times and only if the device passes the pre-use performance checks specified in the instructions before each use.

The following charts illustrate the degradation of materials associated with LMA™ airways after 40-uses.

### Results of Airway Tube Testing

<table>
<thead>
<tr>
<th>Effect</th>
<th>% Change after 40-uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tear Strength</td>
<td>-35%</td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>-30%</td>
</tr>
<tr>
<td>Elongation</td>
<td>-25%</td>
</tr>
<tr>
<td>Stiffness</td>
<td>-20%</td>
</tr>
</tbody>
</table>

- at 40-uses (manufacturer’s recommended maximum number of uses)

### Results of Cuff Testing

<table>
<thead>
<tr>
<th>Effect</th>
<th>% Change after 40-uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tear Strength</td>
<td>-40%</td>
</tr>
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<td>Tensile Strength</td>
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<td>Stiffness</td>
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</tbody>
</table>

- at 40-uses (manufacturer’s recommended maximum number of uses)
Best practice for reusable LMA™ airways

Compliance with the following guidelines is recommended for all institutions using reusable LMA™ airways.

1. Track the number of times each LMA™ airway has been used and autoclaved, and limit the number to the recommended 40-uses. Each reusable LMA airway has a unique serial number located at the proximal end of the airway tube. You can use this number or your own identification system.

2. Perform the pre-use tests prior to each use (see ‘LMA ProSeal™ pre-use performance tests’ for further guidance).

3. Use the standard insertion and fixation technique. Use of a rotational insertion technique or failure to secure the airway in place may result in significant torque on the airway tube. Refer to the IFU for more information at www.lmaco.com

4. Ensure all personnel (i.e. permanent or temporary, operating room, or central processing) who will clean and sterilise the LMA™ airways are trained in the proper cleaning and sterilisation techniques.

A 40-Use record card is supplied with every device to record the number and date of usage. Completion of the record card validates the warranty of the device.
Why is proper cleaning and sterilisation important?

Residual and harmful cleaning agents

**Clinical Consequences:** There have been numerous reports of severe sore throats and dysphagia associated with use of LMA™ airways that have been exposed to germicides, disinfectants, or chemical agents, such as phenols, glutaraldehyde, and ethylene oxide.

These substances can be absorbed by the silicone materials, and later leach out while in use. In some instances, tissue sloughing and ulcerations have resulted.

Once the silicone materials have been exposed to these chemical agents, there is no reliable method to remove these agents or to determine if potentially hazardous residue remains.

Therefore, devices that have been exposed to improper cleaning and sterilisation agents must be discarded.

Infection control

The basic principle of infection prevention and control is good hygiene practices. Adherence to correct cleaning and sterilisation guidelines is essential in preventing disease transmission and maximising the longevity of the LMA ProSeal™. The main problems arising from ineffective cleaning and sterilisation practices are damage to the device, local or systemic toxicity from chemicals, and disease transmission.

The LMA ProSeal™ is supplied unsterile and must be cleaned and sterilised prior to first use, and prior to each subsequent use in accordance with our instructions for use. Adhering to these protocols will ensure best practice with regards to infection control.

Use of cleaning agents

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 ProSeal™ use is Endozime® (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 sterilise the 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 airway that has been exposed to any of these substances.

Listed below are SOME products known to contain the above or other ingredients that should **NOT** be used.

**WARNING:** Failure to properly clean, rinse and dry an LMA™ airway may result in retention of potentially hazardous residue or inadequate sterilisation.

**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.

<table>
<thead>
<tr>
<th>Cleaner Name</th>
<th>Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amerse®</td>
<td>Quaternary ammonium</td>
</tr>
<tr>
<td>Beaucoup® Phenols</td>
<td>Phenols</td>
</tr>
<tr>
<td>Betadine® Phenols</td>
<td>Phenols</td>
</tr>
<tr>
<td>Cidex® Glutaraldehyde</td>
<td></td>
</tr>
<tr>
<td>Cidex OPA® Ortho-phthalaldehyde</td>
<td></td>
</tr>
<tr>
<td>CIDA-FOAM™ Quaternary ammonium</td>
<td></td>
</tr>
<tr>
<td>Coverage® Plus Quaternary ammonium</td>
<td></td>
</tr>
<tr>
<td>Instra-Clean Sulphur dioxide</td>
<td></td>
</tr>
<tr>
<td>LpH®se Phenols</td>
<td>Phenols</td>
</tr>
<tr>
<td>LysoMIC Phenols</td>
<td>Phenols</td>
</tr>
<tr>
<td>Matar® Phenols</td>
<td>Phenols</td>
</tr>
<tr>
<td>Powder Keg® Quaternary ammonium</td>
<td></td>
</tr>
<tr>
<td>T.B.Q® Quaternary ammonium</td>
<td></td>
</tr>
<tr>
<td>Vesta-Syde® Phenols</td>
<td></td>
</tr>
<tr>
<td>Vesphene II® se Phenols</td>
<td></td>
</tr>
<tr>
<td>Wavicide® Glutaraldehyde</td>
<td></td>
</tr>
</tbody>
</table>

For more information please refer to the IFU available at www.lmaco.com
LMA ProSeal™ device overview

It is important for any personnel involved in the process of cleaning, sterilisation and preparation for use of LMA ProSeal™ devices to be familiar with the components.

Please note: The LMA ProSeal™ size 1 does not have a bite block.
How to clean the LMA ProSeal™

Before you start

With proper cleaning, sterilisation and handling, the LMA ProSeal™ can be safely used 40 times. Continued use beyond 40-uses is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device. The manufacturer can accept no liability for failure beyond 40-uses.

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

CAUTION: Use only syringe with standard luer taper tip for inflation or deflation.

CAUTION: Gloves should be worn to minimise contamination of the device.

Cleaning procedure

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

CAUTION: Make sure the red plug is closed during cleaning to prevent exposure of the valve to any cleaning solution. If moisture is noticed, the red plug should be opened and tapped against a towel to remove the excess moisture.

Ensure the areas behind the Introducer strap and under the internal drain tube are clean using a small soft bristle brush (approximately 1/4 inch or 6mm in diameter for adult size devices). Gently insert the brush through the proximal (outer) end of the drain tube, taking care not to damage the drain tube.

2. Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues.

3. Carefully inspect the LMA ProSeal™ to ensure that all visible foreign matter has been removed.

4. Repeat steps 1, 2 and 3 as necessary.

For more information please refer to the IFU available at www.lmaco.com
How to sterilise the LMA ProSeal™

Before you start

With proper cleaning, sterilisation and handling, the LMA ProSeal™ can be safely used 40 times. Continued use beyond 40-uses is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device. The manufacturer can accept no liability for failure beyond 40-uses.

**WARNING:** Steam autoclaving is the only recommended method for sterilisation. Adherence to the following procedure is essential to ensure sterilisation without damage.

**IMPORTANT INFORMATION:** 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.

Sterilisation procedure

1. **CAUTION:** Make sure the LMA ProSeal™ manual vent is open during sterilisation to prevent herniation of the cuff.

2. **CAUTION:** The integrity of the device material may be adversely affected by exceeding sterilisation temperatures of 275°F or 135°C.

   - 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.

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

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LMA ProSeal™ pre-use performance tests

Before you start

With proper cleaning, sterilisation and handling, the LMA ProSeal™ can be safely used 40 times. Continued use beyond 40-uses is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure of the device. The manufacturer can accept no liability for failure beyond 40-uses.

WARNING: All of the non-clinical tests described below must be conducted before each use of LMA ProSeal™. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimises contamination of the airway device before insertion. Failure of any one test indicates that the device has passed its useful life and should be replaced.

WARNING: Do not use the LMA™ airway or any of the accessories if they are damaged in any way.

Pre-use performance tests

Visual Inspection

1. a) Examine the surface of the airway tube, cuff and drain tube for damage, including cuts, tears, or scratches.
   
   b) Examine the interior of the airway tube, mask bowl and drain tube to ensure that they are free from blockages or loose particles. Any particles present in the tubes should be removed.
   
   c) Examine the transparency of the tubes. Reusable airway tubes will gradually discolor with age and re-use.
   
   d) Examine the 15 mm connector. It should fit tightly into the outer end of the airway tube. Ensure that it cannot easily be pulled off by hand using reasonable force. Do not use excessive force or twist the connector as this may break the seal.
   
   e) Ensure that the section of the LMA ProSeal™ drain tube lying within the bowl of the mask is not torn or perforated, and that there is no contamination between the tube and the mask.
   
   f) Examine the rear cuff of the LMA ProSeal™, if present, for wrinkles or folds suggesting herniation.

WARNING: Do not use if:

- The device is damaged or if visible particles cannot be removed from inside the airway tube as they may be inhaled by the patient after insertion.
- 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.
- The mask connector does not fit tightly into the outer end of the airway tube.
LMA ProSeal™ pre-use performance tests

Pre-use performance tests (continued)

**Inflation and deflation**

1. **a)** Insert a syringe into the valve port and fully deflate the device so that the cuff walls are tightly flattened against each other (make sure the red plug is closed). Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other.

   **WARNING:** Do not use the device if the cuff walls reinflate immediately and spontaneously, even if only slightly.

2. **b)** Examine the fully deflated mask for wrinkles or folds suggesting herniation. If obvious wrinkles are apparent, the rear cuff may be severely herniated and the LMA ProSeal™ should not be used.

3. **c)** Inflate the cuff with 50% more air than the recommended maximum clinical inflation volume. 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.

4. **d)** While the device remains 50% over-inflated, examine the inflation balloon. The balloon shape should be a thin, slightly flattened elliptical shape, not spherical.

5. **e)** While the device remains 50% over-inflated, inspect the interior of the drain tube from both ends of the mask. Ensure that the tube is not collapsed or perforated.

**Test cuff over-inflation volumes**

<table>
<thead>
<tr>
<th>LMA™ size</th>
<th>Air volume*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 ml</td>
</tr>
<tr>
<td>1.5</td>
<td>10 ml</td>
</tr>
<tr>
<td>2</td>
<td>15 ml</td>
</tr>
<tr>
<td>2.5</td>
<td>21 ml</td>
</tr>
<tr>
<td>3</td>
<td>30 ml</td>
</tr>
<tr>
<td>4</td>
<td>45 ml</td>
</tr>
<tr>
<td>5</td>
<td>60 ml</td>
</tr>
<tr>
<td>6</td>
<td>75 ml</td>
</tr>
</tbody>
</table>

* Inflate the cuff with these volumes for testing only

**WARNING:** Do not use if:

- Cuff leakage is present or if there is uneven bulging of the cuff.
- The inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.

**WARNING:** Use of an LMA ProSeal™ with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the LMA ProSeal™ from being inflated or allow for escape of anesthetic gases.

For more information please refer to the IFU available at www.lmaco.com