EN- English

INSTRUCTIONS FOR USE – LMA® Flexible™

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

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

WARNING: Read all Instructions for Use warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

DEVICE DESCRIPTION:

LMA® Flexible™ is differentiated from other LMA airways by having a flexible wire-reinforced airway tube that allows it to be positioned away from the surgical field.

It may be particularly useful in procedures where the surgeon and anesthesiologist are working in the same area, such as procedures involving the head or neck.

The flexibility of the airway tube provides an easy connection at any angle from the mouth and allows the tube to be repositioned from the side during the surgical procedure without loss of seal of the cuff against the larynx.

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

The LMA® Flexible should not be reused more than 40 times. 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.

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

INDICATIONS FOR USE:

It is indicated for use in achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted 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 glossopharyngeal and laryngeal reflexes requiring artificial ventilation. In these cases, LMA® Flexible™ should be used only when tracheal intubation is not possible.

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.

CONTRAINDICATIONS:

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

1. Patients who have not fasted, including patients whose fasting cannot be confirmed.

2. Patients who are grossly or morbidly obese, more than 14 weeks pregnant or emergency and resuscitation situations or any condition associated with delayed gastric emptying or using opiate medication prior to fasting.

The LMA® Flexible™ is also contraindicated in:

3. Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 20 cm H_2O, because the device forms a low-pressure seal (approximately 20 cm H_2O) around the larynx.

4. 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® Flexible™ use.

5. The LMA® Flexible™ 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:

There are reported adverse reactions associated with the use of laryngeal mask airways. Potential side effects may include airway trauma, dysphagia, sore throat, dysphonia, laryngospasm, obstruction, stridor, bronchospasm, hoarseness, nausea and vomit, regurgitation, aspiration, gastric distension, patient intolerance e.g. coughing, and mouth, lip or tongue injury.

WARNINGS:

1. To avoid trauma, excessive force should not be used at any time when using the devices. Excessive force must be avoided at all times.

2. Do not use a device if it is damaged.

3. Never over-inflate the cuff of the device over 60cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.

4. Do not immerse or soak the device in liquid prior to use.

5. It is most important that pre-use checks are carried out on the LMA® Flexible™ prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.

6. When applying lubricant avoid blockage of the airway aperture with the lubricant.

7. A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the LMA® Flexible™ 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.

8. Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaning agents, iodine-containing cleaning agents or quaternary ammonium compounds to clean or sterilise LMA® Flexible™. 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. The cleaning agent must not contain skin or mucous membrane irritants.

9. Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or inadequate sterilisation.

10. 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.

11. 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.

12. The LMA® Flexible™ does not prevent regurgitation or aspiration. Its use in anaesthetised patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. **Do not use the device without taking appropriate precautions to ensure the stomach is empty.**

13. Refer to MRI information section prior to using the devices in MRI environment.

CAUTIONS:

1. Laryngeal spasm may occur if the patient becomes too lightly anaesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anaesthesia. If laryngeal spasm occurs, treat the cause. Only remove the device when airway protective reflexes are fully competent.

2. 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.

3. Only use a syringe with standard luer taper tip for inflation or deflation.

4. Careful handling is essential. Avoid contact with sharp or pointed objects at all times to prevent tearing or perforation of the device. Do not insert the device unless the cuffs are fully deflated as described in the instructions for insertion.

5. If airway problems persist or ventilation is inadequate, the device should be removed and an airway established by some other means.

6. Store the device in a dark cool environment, avoiding direct sunlight or extremes of temperatures.

7. Used device shall follow a handling and elimination process for bio-hazard products, in accordance with all local and national regulations.

8. Gloves should be worn during preparation and insertion to minimize contamination of the device.

9. Ensure all removable denture work is removed before inserting the device.

10. An unreliable or obstructed airway may result in cases where the device has been incorrectly inserted.

11. Only use with the recommended manoeuvres described in the instructions for use.

Note: For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website':
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

PREPARATION FOR USE:

Choose the correct size of LMA® Flexible™
Patient Weight/Size

Size 2 : 10k-20kg	**Size 4: 50kg-70kg**
Size 2½: 20kg-30kg	**Size 5: 70kg-100kg**
Size 3 : 30kg-50kg	**Size 6: >100kg**

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

PRE-USE CHECKS:

Warning: It is most important that pre-use checks are carried out on LMA® Flexible™ prior to use, in order to establish whether it is 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 indentations be found, 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. Reinflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 2	**15ml**	**Size 4**	**45ml**
Size 2½	**21ml**	**Size 5**	**60ml**
Size 3	**30ml**	**Size 6**	**75ml**

Examine the cuff for leaks, herniations and uneven bulging. If any indication of these, discard the device. A herniating mask may cause obstruction during use. Then deflate the mask again. While the device remains 50% over-inflated, examine the blue inflation pilot balloon. The balloon shape should be elliptical, not spherical.
4. Examine the airway connector. It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
5. Discoloration. Discoloration affects visibility of fluid in the airway tube.
6. Gently pull the inflation line to ensure it is securely attached to both the cuff and balloon.
7. Examine the aperture in the mask. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. If the aperture bars are not intact, the epiglottis may obstruct the airway. Do not use if the aperture bar is damaged.

PRE-INSERTION PREPARATION:

Completely deflate the cuff of the LMA® Flexible™ to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold back away from the aperture bars. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in blockage of aperture bar or aspiration of lubricant.

Warning: A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the LMA® Flexible™ 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.

Caution: Ensure all removable denture work is removed before inserting the device.

INSERTION:

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

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

Standard Insertion Method:

1. Anaesthesia must be deep enough to permit insertion
Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given.
2. Position the head and neck as for normal tracheal intubation.
Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand **(Fig.1).**
3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube **(Fig.1).** Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.
4. Using the index finger, push the mask backwards **still maintaining pressure against the palate (Fig.2).**
5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion **(Fig.3).** Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. **(Fig.3).**

AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.

When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth **(Fig.4).**
6. Check that the black line on the tube faces the upper lip.
Now immediately inflate the cuff **without holding the tube.**
Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. During cuff inflation, do not hold the tube as this prevents the device from settling into its correct location.

Warning: NEVER OVERINFLATE THE CUFF.

Maximum inflation volumes (ml)

Size 2	**10ml**	**Size 4**	**30ml**
Size 2½	**14ml**	**Size 5**	**40ml**
Size 3	**20ml**	**Size 6**	**50ml**

7. Connect to the gas supply, holding the tube, to prevent displacement. **Gently** inflate the lungs to confirm correct placement. Insert a roll of gauze as a bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the device, it is important to remember to insert a bite block at the end of the procedure.

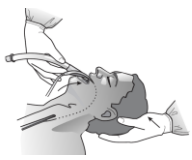
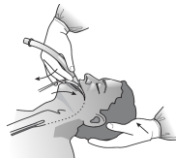


Figure 1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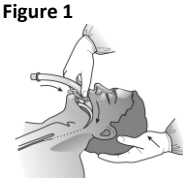
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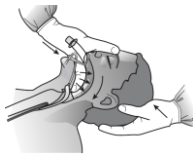
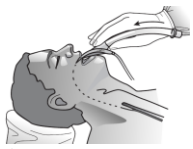


Figure 4

Thumb Insertion Method:

This technique is suitable for patients in whom access to the head from behind is difficult or impossible and during cardiopulmonary resuscitation. The LMA® Flexible™ is held with the thumb in the position occupied by the index finger in the standard technique (**Fig.5**). The tip of the mask is pressed against the front teeth and the mask is pressed posteriorly along the palate with the thumb. As the thumb nears the mouth, the fingers are stretched forward over the patient's face (**Fig.6**). Advance the thumb to its fullest extent (**Fig.7**). The pushing action of the thumb against the hard palate also serves to press the head into extension. Neck flexion may be maintained with a head support. Before removing the thumb, push the tube into its final position using the other hand (**Fig.8**).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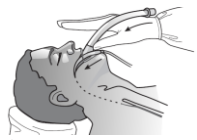
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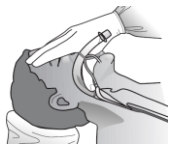
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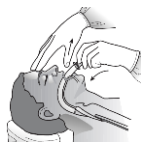
Figure 8

MAINTAINING THE AIRWAY:

1. Obstruction can occur if the device becomes dislodged or is incorrectly inserted. The epiglottis may be pushed down with poor insertion technique. Check by auscultation of the neck and correct by re-insertion or elevation of the epiglottis using a laryngoscope.
2. Malposition of mask tip into the glottis may mimic bronchospasm.
3. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.
4. Keep the bite-block in place until the device is removed.
5. Do not deflate the cuff until reflexes have fully returned.
6. Air may be withdrawn from the cuff during anaesthesia to maintain a constant intracuff pressure (always less than 60cm H_2O).

REMOVAL:

1. The LMA® Flexible™, together with the recommended bite-block, should be left in place until the return of consciousness. Oxygen should be administered using a "T" piece system and standard monitoring should be in place. Before attempting to remove or deflate the device, **it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.**
2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary

to perform suction because the correctly used LMA® Flexible™ protects the larynx from oral secretions. Patients will swallow secretions on removal. **Suction equipment should always however be available .**
3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

REPROCESSING:

General Warnings, Precautions and Restrictions

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard to hospital hygiene and sterilization technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilization is performed using appropriate equipment, materials, and personnel to achieve the desired result.
Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

The equipment used during reprocessing should be validated for effectiveness according to internationally recognized standards:

- Washers-disinfectors meeting the requirements of ISO 15883 series and /or ANSI / AAMI ST15883 Series
- Steam sterilizers meeting the requirements of EN 13060/EN 285 in conjunction with ISO 17665 and / or ANSI AAMI ST8, ANSI AAMI ST79.

The World Health Organization (WHO) guidelines and published literature indicate that the LMA® Flexible™ cleaning and sterilization procedures outlined below 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 the LMA® Flexible™ after use.

Warning:
Before initial use and any subsequent use, all devices must be subjected to reprocessing as described in the following sections.
Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

Careful handling is essential. The LMA® Flexible™ is made of medical grade silicone which can be torn or perforated. Always avoid contact with sharp or pointed objects.

With proper cleaning, sterilization, and handling, the LMA® Flexible™ can be used a maximum of 40 times. Proper cleaning and sterilization of the airway is essential to ensure continued safe usage up to 40 times. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilisation.

REPROCESSING PRIOR TO FIRST AND ANY SUBSEQUENT USE

Preparation at the point of use prior to processing
Remove all traces of contamination immediately after use to avoid incrustation. Do not use fixative agents or hot water (>40°C/104°F). Storage and transport of the devices to the reprocessing location must be ensured in a sealed container.

CLEANING:

Warnings and Precautions

Warning: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (e.g. Cidex®), ethylene oxide, phenol-based cleaning agents or iodine-containing cleaning agents to clean or sterilise the LMA® Flexible™. 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. The cleaning agent must not contain skin or mucous membrane irritants.
If recommended cleaning agents / detergents that are indicated in the cleaning section are not available, mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. Please note that any deviation from these instructions, including the use of cleaning agents / detergents not specifically indicated in these instructions will require an evaluation of device-specific efficacy and suitability of the cleaning process. Respective evaluation usually requires equipment qualification and device specific performance qualification / Validation.

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

Freshly prepared purified water/ highly purified water or sterile water for final rinsing purposes is highly recommended.

Manual Cleaning

Always use a freshly prepared cleaning bath. Observe the cleaning agent manufacturer's instructions in regard to recommended temperatures, concentration and holding times.

Manual cleaning instructions have been validated using the following equipment / cleaning agents:

Cleaning Brush:
An appropriate size soft bristle brush.

Cleaning Agent/ Cleaning Process:
A) Endozime® Dual Enzymatic Detergent, Ruhof Healthcare (concentration: 0.8%).

Cleaning Process using cleaning agent A above:

1. Place the LMA® Flexible™ devices in a freshly prepared cleaning solution at 36°C to 40°C (97 °F to 104°F) and thoroughly clean the devices until all visible contamination is removed.
2. Clean the airway tubes by gently inserting the brush and stroking in and out
3. Gently insert the brush through the aperture bars into the airway tubes, taking care not to damage the bars.
4. Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
5. Carefully inspect all components for residual contamination.
6. If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Dry adequately at room temperature or in a drying cabinet with circulating air.

Or,
B) Dilute (8-10% v/v) sodium bicarbonate solution. 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water

Cleaning Process using cleaning agent B above: -

1. Place the LMA® Flexible™ devices in a freshly prepared cleaning solution at 36°C to 40°C (97 °F to 104°F) and thoroughly clean the devices until all visible contamination is removed.
2. Prepare a second freshly prepared cleaning solution as described above and thoroughly clean the devices using appropriate soft bristle brush.
3. Clean the airway tubes by gently inserting the brush and stroking in and out.
4. Gently insert the brush through the aperture bars into the airway tube, taking care not to damage the bars.
5. Thoroughly rinse all components under flowing tap water. (Note: Pay special attention to inner check valve to avoid contact with cleaning solution. If the valve is exposed to a cleaning solution, rinse thoroughly under flowing tap water to remove cleaning residues as it may cause premature valve failure.)
6. Carefully inspect all components for residual contamination.
7. If residual contamination is detected, repeat the complete cleaning procedure.

If moisture is noticed in the valve, tap against a towel to remove excess moisture.

Dry adequately at room temperature or in a drying cabinet with circulating air.

Automated Cleaning:

Automated cleaning instructions have been validated using the following equipment:

Washer: Miele Type G7735 CD, Miele Standard rack with rinse ports

Cleaning agents:
Deconex® PowerZyme, Borer Chemie AG

Thoroughly deflate all cuffs. Place the devices in the instrument rack. Ensure adequate placement of all devices in a way that all internal and external areas of the devices are accessible. Connect the lumens of the airways with the rinse ports.

Start washing process:
Miele G 7735 CD washer-disinfector, Vario TD programme :

1. 2 min pre-cleaning with cold water (≤ 35°C/ 95 °F).
2. Drain
3. 5 min cleaning with Deconex® PowerZyme, 0.5% at 55°C/ 131 °F.
4. Drain
5. 3 min neutralization with cold water (≤ 35°C/ 95 °F).
6. Drain
7. 2 min rinsing with cold water (≤ 35°C/ 95 °F).
8. Optional thermal disinfection following automated cleaning.
   5 min thermal disinfection at 90°C/194°F.

***Disinfection**
Thermal disinfection may be performed as part of the automated cleaning process as in step no. 8 above for Vario TD programme.

Ensure adequate drying (e.g. circulating air 70°C/ 158 °F, 1 hour).

INSPECTION, MAINTENANCE AND TESTING

Perform device inspection and functionality checks as described in section "Pre-Use Checks"

All of the functional tests and inspections described in this manual must be conducted as part of every reprocessing procedure prior to sterilization of the LMA® Flexible™. Failure in any of respective testing indicates that the device has passed its useful life and should be replaced.

PACKAGING

The selected packaging for thermal sterilization must comply to requirements according to ISO/ANSI AAMI ISO 11607. For USA: Use FDA-cleared sterilization wraps.

Visually check for residual moisture prior to packaging into sterilization wrap.

STERILISATION:

Warnings and Precautions
Adherence to the following procedure is essential to ensure sterilization without damage to the LMA® Flexible™.

Caution: The integrity of the reusable LMA® Flexible™ materials may be adversely affected by exceeding sterilization cycle of 134°C or 273°F.

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 the process control. Failure to do so may invalidate the sterilization process of the healthcare facility.

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 environment of the autoclave, causing irreparable damage (herniation 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 the cuff of a deflated LMA® Flexible™ 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.

STERILISATION SETTING
Steam sterilization is recommended either via pre-vacuum or gravity displacement process. Each of the following cycles has been validated in accordance with internationally harmonized standards to reach a sterility assurance level (SAL) that is appropriate for the intended use of the devices and in compliance with internationally recognized standards and guidelines.

Type	Temperature	Holding Time	Minimum Drying Time
Prevac Cycle	134°C (273°F)	3 Minutes	16 Minutes
Gravity Displacement	132°C (270°F)	10 Minutes	1 Minute

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

STORAGE

Store the sterilized devices at room temperature in a dry and dust-free place, protected from direct sunlight.

Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

USE WITH MAGNETIC RESONANCE IMAGING (MRI):

MR Conditional

The LMA® Flexible™ 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® Flexible™ is expected to produce a maximum temperature rise of 2.3°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 50-mm relative to the size and shape of the LMA® Flexible™, Size 6.

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
REF	Product Code
LOT	Lot Number
CE 2797	CE Mark
SN	Serial Number
	Do not reuse more than 40 times
NON STERILE	Non-sterile
MR	MR Conditional
Rx only	Prescribed only

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The LMA® Flexible™ is 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.

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