尺寸：210x290mm（双面印刷，中间对折） BLACK

Instruction For Use

ResGuard REUSABLE LARYNGEAL MASK AIRWAY SILICONE

Type:
Reusable Silicone Laryngeal Mask Airway

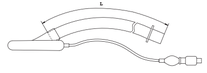
DESCRIPTION

The Laryngeal Mask Airway is a type of supraglottic airway device that provides an alternative to endotracheal intubation and standard mask anaesthesia in general anaesthesia. It is inserted into the hypopharynx to form a seal around the larynx to allow spontaneous or positive pressure ventilation without the need for intubating the larynx.

Laryngeal Mask Airway is used in anesthesia and in emergency medicine for airway management. It consists of a tube with an inflatable cuff that is inserted into the pharynx. It causes less pain or coughing than Endotracheal Tubes, and is much easier to insert.
The Reusable Silicone Laryngeal Mask Airway is recommended to be used a maximum of 40 times before being discarded.

The product can be used on neonate, infant, pediatric, adult patients.

Figure 1. Reusable Silicone Laryngeal Mask Airway



Size	Pressure drop cmH_2O	Capacity ml	Distance from connector machine end to the ventilator opening, L mm	Maximum outer diameter of device passing the Laryngeal Mask mm	Applicable Patient Weight kg
1#	5	4	98	3.35	⩽5
1.5#	2	6	110	3.35	5-10
2#	3	8	131	4.75	10-20
2.5#	2	12	139	6.05	20-30
3#	3	19	181	6.75	30-50
4#	3	19	181	6.75	50-70
5#	2	25	200	7.35	70-100
6#	2	25	200	7.35	>100

FEATURES

- Suitable for pharynx anatomy structure and can provide good seal.
- Soft cuff for easy insertion
- Various size available
- Reusable device

INTENDED USE / INDICATIONS

Laryngeal Mask Airway is designed to sit in the hypopharynx covering the supraglottic structures, and is indicated to maintain upper airway patency and facilitate positive pressure ventilation.

CONTRAINDICATIONS

- Patients who cannot open mouth or have complete upper airway obstruction are not recommended to use the Laryngeal Mask.
- Do not substitute Laryngeal Mask for an Endotracheal Tube due to the potential risk of aspiration and regurgitation.
- Laryngeal Mask cannot use on morbidly obese patients, patients who have not adequate fasting times, patients who are 14 weeks pregnant or more, patients who have acute or thoracic injuries.
- Laryngeal Mask cannot use on patients who have pulmonary compliance problems, such as fibrosis of the lungs and whose peak inspiratory airway pressures are expected to exceed 20 cm H^2O.

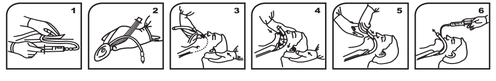
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ADVERSE REACTIONS

- Aspiration pneumonia
- Airway obstruction
- Laryngospasm
- Sore throat
- Dryness of the throat and/or mucosa
- Laryngeal nerve injury and vocal cord paralysis
- A diminished sense of taste
- Side effects due to improper placement vary based on the nature of the placement.

DIRECTIONS FOR USE

- Test cuff by inflation prior to use.
- Deflate cuff completely before intubation.
- The index finger is placed at the junction of the cuff and the tube.
- With the head extended and the neck flexed, carefully flatten the Laryngeal Mask Airway tip against the hard palate.
- To facilitate Laryngeal Mask Airway introduction into the oral cavity, gently press the middle finger down on the jaw.
- The index finger pushes the Laryngeal Mask Airway in a cranial direction following the contours of the hard and soft palates.
- Maintaining pressure with the finger on the tube in the cranial direction, advance the mask until definite resistance is felt at the base of the hypopharynx. Note the flexion of the wrist.
- Inflate the cuff with enough air to obtain an Airway Pressure at 18-20 cmH^2O. Do not exceed the maximum volume recommended for the cuff.
- Finally, secure the tube. Suggest inserting a bite block. And then connect to the ventilation equipment.
- Gently maintain cranial pressure with the non-dominant hand while removing the index finger.
- Inflation without holding the tube and allows the mask to seal itself optimally.
- The device placement should be confirmed again if the patient's body position is changed.



CLEANING GUIDE

- Wash the tube with soap, distilled water or $NaHCO^3$ (saleratus).
- Brush gently the airway tube.
- Make sure tube is dry.
- Deflate all the air from the tube before steam autoclave.
- Steam autoclave 4-6 minutes at 132℃-135℃.

WARNINGS / PRECAUTIONS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- This device can only be used by trained professionals.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use if it's damaged or irregularly shaped.
- Do not use after the expiry date.
- Not compatible with MRI
- If moisture or water is noticed in the inlet of the valve. Use a towel to remove excess moisture.
- Ensure that both the valve and the syringe used to deflate the cuff are dry.
- Any air or moisture left in the cuff will expand in the high temperature and low pressure environment of the autoclave, causing irreparable damage to the cuff and/or inflation pilot balloon.
- When applying lubricant, prevent blocking the airway

Instruction For Use

- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Be care for the risk of inflammable if use any laser device.
- It is recommended that the Reusable Silicone Laryngeal Mask Airway can be used maximum of 40 times.
- Steam autoclaving is the only recommended method to re-sterilize the Reusable Silicone Laryngeal Mask Airway.
- Suggest maximum cuff pressure 60 cm H^2O
- Diffusion of nitrous oxide (N^2O) mixture, oxygen or air from a surrounding gas mixture may either increase or decrease cuff volume and pressure.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

STORAGE CONDITIONS

- Store in a dark, cool and dry place.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

MEANING OF SYMBOLS ON PACKAGE

	Date of manufacture		**Use-by date**	LOT	**Batch code**
STERILE EO	**Sterilized using ethylene oxide**		**Consult instructions for use**		**Do not use if package is damaged**
MD	**Medical Device**		**Manufacturer**		**Keep dry**
	Single sterile barrier system	REF	**Catalogue number**	49℃ -15℃	**Temperature limits: -15℃~49℃**

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