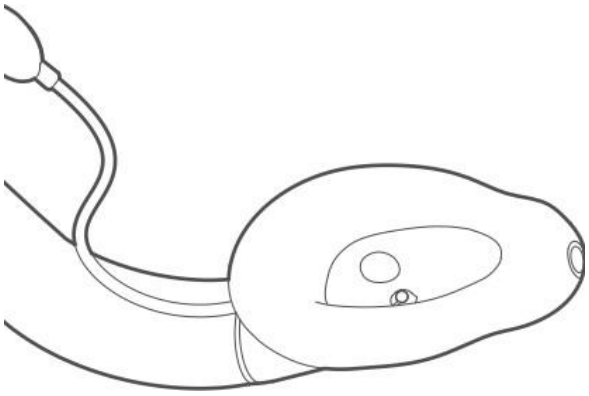


Instructions for Use

SourceMark Video Laryngeal Mask Airway

Date of issue: 2025-5-06

Revision: B/0

SourceMark, LLC

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

1. ⚠Cautions and warnings

1.1 Check the package before use and do not use the product if the package is broken or contaminated or the product is damaged.

1.2 The product is sterilized by ethylene oxide and is valid for 3 years after sterilization.

1.3 The product is disposable, please discard it after use.

1.4 Read the manual and perform pre-use test before use. Do not use the product if it fails in performance or it is expired.

1.5 The product shall be used by qualified healthcare professionals.

1.6 The anesthetic gas shall not leak out or contact the external surface of airway tube.

1.7 The product cannot rule out the possibility of trachea or lung aspiration risk.

1.8 The patency of the airway should be reconfirmed for any movement of patient's head and neck.

1.9 Check the leakage of cuff by pilot balloon during operation, and inflate the cuff in time.

2. Contraindications

2.1 Patients with difficulty in opening mouth or oropharyngeal tumors which make it hard to insert the product.

2.2 Patients with allergy to silicone materials.

2.3 Use the product with caution in patients with the risk of reflux and aspiration.

2.4 Use the product with caution in patients who require positive pressure ventilation as a result of respiratory obstruction caused by throat diseases, reduced lung compliance, or high resistance in respiratory tract.

2.5 Use the product with caution in patients with masses, injuries, infections, or other pathological changes in the throat.

3. Product description

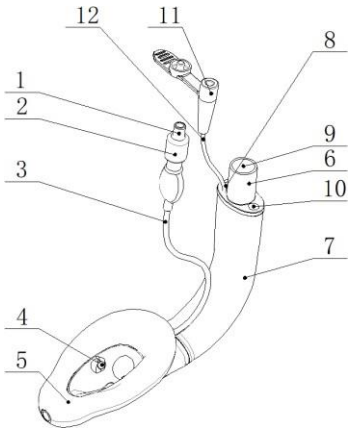
Product name: SourceMark Video Laryngeal Mask Airway

Product materials:

Masks are made primarily of medical-grade silicone.

4. Structure and components

1 Table 1

Models		Structure	Components
MLMXXC series	MLM10C MLM15C MLM20C MLM25C MLM30C MLM40C MLM50C MLM60C		1. Inflation valve 2. Pilot balloon 3. Inflation tube 4. Observation window 5. Cuff 6. Connector 7. Airway tube 8. Observation channel 9. Airway channel 10. Gastric channel 11. Cleaning connector 12. Cleaning tube

5. COMPATIBILITY WITH OTHER DEVICES

Disposable Laryngeal Mask can be used in conjunction with:

- Ventilation equipment: 15 mm conical connectors in compliance with ISO 5356-1.
- Airway management devices: Observation device, ET-Tubes, Gastric tubes.
- Other accessories: Standard 6 % conical Luer syringe in compliance with ISO 80369-7, Water-based lubricant.

6. Intended purpose

The SourceMark Video Laryngeal Mask Airway is intended to open and seal the supralaryngeal area to provide an unobstructed airway in patients during spontaneous, assisted, or controlled ventilation.

7. Indications for use

Routine, difficult, or emergent airway ventilation;

Facilitate tracheal intubation and extubation;

Clinical multidisciplinary emergency resuscitation ventilation.

8. Intended patient population

The SourceMark Video Laryngeal Mask Airway is intended for use in patients who need airway ventilation.

9. Intended users

The SourceMark Video Laryngeal Mask Airway shall be used by qualified healthcare professionals.

10. Intended clinical benefit

10.1 Establish reliable airway ventilation;

10.2 Facilitate intubation and extubation;

10.3 Minimize the risk of reflux and aspiration by gastric drainage;

10.4 Rule out the possibility of cross infection by single use design.

11. Side effects

Please refer to standard textbooks and published literature for the detailed information about the undesirable side effects with the use of laryngeal mask.

12. Instructions before use

12.1 Select suitable laryngeal mask in accordance with Table 3, or the operator's experience or the clinical condition of patient.

12.2 First confirm the package is intact, do not use if package is damaged.

12.3 Tear the package, take out laryngeal mask, inflate the cuff moderately to check the integrity.

12.4 Completely deflate the cuff with a syringe. Visual stylet or Embed camera can be used to facilitate the placement of laryngeal mask. After placement, inflate the cuff to the extent of clinical or standard requirements, then connect laryngeal mask

with ventilation device. The connector of ventilation device shall meet the requirements of that of the 15mm specified in ISO 5356-1:2015.

12.5 In case that tracheal intubation is needed, lubricate endotracheal tube and airway channel in advance, and insert the tube into the laryngeal mask airway channel to make pre-use test for later use.

12.6 It is recommended that the maximally continuous use time for laryngeal mask is 3 hours in routine procedure, and the respiratory secretions shall be cleaned away during use.

12.7 See the instruments matched with laryngeal masks in different sizes in Table 3

Table 3

Model	Size	Patient weight (kg)	Max. ETT (mm)	Max. drainage tube (Fr)	OD of observation device (mm)	OD of the instrument that can pass through airway channel	Max intracuff volume (ml)	Inner channel capacity (ml)
MLM10C	1.0#	<5	3.5	6	3.0	4.2	10	10
MLM15C	1.5#	5-10	4.0	8	3.0	4.2	15	13
MLM20C	2.0#	10-20	5.0	10	3.0	5.8	20	16
MLM25C	2.5#	20-30	5.5	10	3.0	5.8	25	18
MLM30C	3.0#	30-50	7.0	16	4.0	5.8	30	20
MLM40C	4.0#	50-70	7.5	16	4.0	5.8	40	23
MLM50C	5.0#	70-100	8.0	16	4.0	5.8	50	25
MLM60C	6.0#	＞100	8.0	16	4.0	5.8	60	28

12.8 Pressure drop of airway channel in airway tube

Table 4

Size	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Maximum pressure drop（kPa）	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.6

13. Directions for use

13.1 **Insertion**: Hold the laryngeal mask and insert it into the mouth of patient. Fix the connector once the laryngeal mask is inserted in place. Then inflate the cuff with a syringe and confirm the patency of airway. The laryngeal mask can also be inserted through direct observation: first insert the visual stylet into the observation channel of laryngeal mask, by which the circumstance in front of the mask can be clear viewed, then insert the laryngeal mask in place.

13.2 **Correct Position**: In case the laryngeal mask is not aligned well after insertion, the following adjustments can be adopted: Method A. deflate the cuff, tilt the patient's head back, hold the laryngeal mask by one hand, move it up and down for two or three times, and then push the laryngeal mask softly into the place. Method B. The laryngeal mask can also be moved up and down by one hand with an assistant supporting the mandible of patient, or the operator lifts the mandible of patient by two hands, meanwhile, hold the two upper corners of laryngeal mask by two thumbs, and move up and down to adjust the position. The position of a well-placed laryngeal mask is shown as below:

13.3 **Gastric Drainage**: Place the lubricated gastric tube into gastric channel of laryngeal mask. A well-placed laryngeal mask will make it smooth to suck away the gastric fluids.

13.4 Seal Pressure Test: After connecting with ventilator, switch off the APL valve, and manually and rapidly oxygenate the mask until the pressure indicator of the breathing machine exceeds 20cmH_2O, then stop the rapid oxygenation and make the oxygen flow exceed 6L/min. With the increasing of airway inner pressure, air leakage sound can be heard around the oral cavity and the airway pressure indicator stops rising. The value showed on the pressure indicator is the seal pressure. The test shall not exceed one minute. Turn on APL valve immediately after getting test result and return it to normal airway pressure.

13.5 Connect the syringe to the cleaning connector. If fog appears in front of observation view, clean the observation window with air by the syringe, which can effectively remove the fog.

14. Disposal after Use

SourceMark Video Laryngeal Mask Airway are designed for single use, please dispose of the used laryngeal masks in a safe manner according to local regulations.

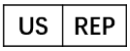
15. Condition for transportation and storage

15.1 No heavy pressure, direct sunlight or rain and snow immersion, so as not to damage the product.

15.2 Move the product with care to avoid fierce collision.

15.3 The product should be stored away from the fire hazards, with a temperature limit of -40-55 °C, relative humidity of no more than 93%, free of corrosive gases and in well-ventilated room.

16. Symbols Definition

Symbols	Indication	Symbols	Indication
	Sterilized using ethylene oxide Single sterile barrier system		Do not re-use
	Do not use if package is damaged		Date of manufacture
	Batch Code		Use-by date
	Manufacturer		Do not resterilize
	Not made with natural rubber latex		Not made with phathalates and DEHP
	Caution		Consult instructions for use
	Medical device		Keep away from sunlight
	Unique Device Identifier		Humidity limitation 93%
	Temperature limit (-40~55°C)		Stack limit by 5
	Keep dry		Fragile, handle with care
	This Way UP		Product code
	U.S. Agent	Rx only	Prescription Use Only

17. Date of manufacture and Use-by date

Date of manufacture: see product label for details.

Use-by date: see product label for details.

18. Customer Service

For additional information, contact your SourceMark, LLC Sales Representative or Customer Service.

Zhejiang UE Medical Corp.

No.8, Youyi Road, Baita Economic Development Zone, Xianju, Zhejiang 317300, China

Tel: +86-576-87788798

Fax: +86-576-87721129

Website: www.ueworld.com

E-mail: export@ueworld.com

US | REP

Importer：

SourceMark, LLC

Franklin, TN 37069 USA.

Version: B/0

Date of Issue: 2025/05/06