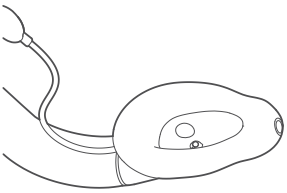


Disposable Medical Laryngeal Masks

Instructions for Use



CE 0197

Version: A/1

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

This device must not be used in the case of the following:

- 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 and PVC materials.
- 2.3 Patients who have had radiotherapy to the neck involving the hypopharynx as there is risk of trauma and/or a potential failure to seal effectively.
- 2.4 Patients with inadequate mouth opening to permit insertion.
- 2.5 Patients presenting for emergency surgery who are at risk of massive reflux due to such conditions as acute intestinal obstruction or ileus, or patients who have been injured shortly after ingesting a substantial meal.
- 2.6 Patients requiring head or neck surgery where the surgeon will be unable to gain adequate access due to the presence of the device.
- 2.7 Patients undergoing CPR who are responsive with an intact gag reflex.
- 2.8 Patients who have ingested caustic substances

3. Product description

Disposable Medical Laryngeal Mask is a sterile, single-use device consisting of a curved airway tube with an inflatable cuff at the distal end. The cuff can be inflated through the inflation valve allowing the pilot balloon to indicate the inflation/deflation status. The cuff conforms to the contours of the hypopharynx and with its lumen facing the laryngeal opening of the patient. It is intended to open and seal the supralaryngeal area to provide an unobstructed airway in patient.

Primary materials	Models
Silicone	DLM10, DLM15, DLM20, DLM25, DLM30, DLM40, DLM50, DLM60
	MLM10, MLM15, MLM20, MLM25, MLM30, MLM40, MLM50, MLM60
	MLM10C, MLM15C, MLM20C, MLM25C, MLM30C, MLM40C, MLM50C, MLM60C

4. Intended purpose

The Disposable Medical Laryngeal Masks is intended to open and seal the supralaryngeal area to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation.

5. Indications for use

Routine, difficult or emergent airway ventilation;
Facilitate tracheal intubation and extubation;
Clinical multidisciplinary emergency resuscitation ventilation.

6. Intended patient population

The Disposable Medical Laryngeal Mask is designed for use in adult and pediatric patients.

7. Intended users

The Disposable Medical Laryngeal Masks shall be used by qualified healthcare professionals.

8. Intended clinical benefit

- 8.1 Establish reliable airway ventilation
- 8.2 Facilitate intubation and extubation
- 8.3 Minimize the risk of reflux and aspiration by gastric drainage
- 8.4 Rule out the possibility of cross infection by single use design

9. 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.

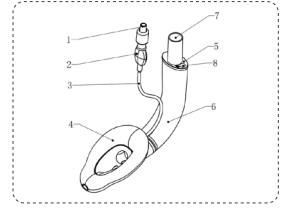
10. Structure and components

Table 1

Models
DLM10, DLM15, DLM20, DLM25, DLM30, DLM40, DLM50, DLM60

01 DLM series

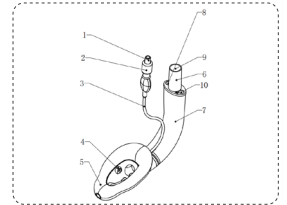
- 1-Inflation Valve
- 2-Pilot Balloon
- 3-Inflation tube
- 4-Cuff
- 5-Connector
- 6-Airway tube
- 7-Airway channel
- 8-Gastric channel



Models
MLM10, MLM15, MLM20, MLM25, MLM30, MLM40, MLM50, MLM60

02 MLM series

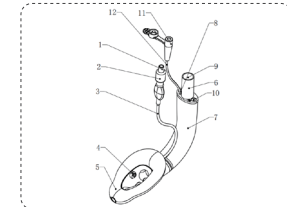
- 1-Inflation valve
- 2-Pilot balloon
- 3-Inflation tube
- 4-Observation window
- 5-Cuff
- 6-Connector
- 7-Airway tube
- 8-Observation channel
- 9-Airway channel
- 10-Gastric channel



Models
MLM10C, MLM15C, MLM20C, MLM25C, MLM30C, MLM40C, MLM50C, MLM60C

03 MLMxC series

- 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



11. Compatibility with other devices

Disposable Medical Laryngeal Masks can be used in conjunction with:

- Ventilation equipment: 15 mm conical connectors in compliance with ISO 5356-1.
- Airway management devices: Observation device, ETT-tubes, Drainage tubes
- Other accessories: Standard 6% conical Luer syringe in compliance with ISO 594-1986, Water-based lubricant, suction catheter.

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 can be used to facilitate the placement of laryngeal mask (applicable to MLM, MLMxC series only). 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

13. Storage, transportation and operating environment

Table 5

Storage and Transportation	
Recommended storage and transportation temperature (°C)	-40~55
Relative humidity (%)	≤93

Product Code	Product description	Model	Size	Patient type	Patient weight (kg)	Max. ETT (mm)	Max. gastric tube (Fr)	Max. bronchoscope size (mm)	Max. OD of the instrument that can pass through the observation channel (mm)	Max OD of the instrument that can pass through airway channel	Max intracuff volume (ml)	Inner channel capacity (ml)
AN036010	SaCoVLM™ Video Laryngeal Masks	MLM10C	1.0	Neonatal/infant	<5	3.5	6	2.8	3.0	4.2	10	10
AN036015	SaCoVLM™ Video Laryngeal Masks	MLM15C	1.5	Neonatal/infant	5-10	4.0	8	2.8	3.0	4.2	15	13
AN036020	SaCoVLM™ Video Laryngeal Masks	MLM20C	2.0	Paediatric	10-20	5.0	10	2.8	3.0	5.8	20	16
AN036025	SaCoVLM™ Video Laryngeal Masks	MLM25C	2.5	Paediatric	20-30	5.5	10	2.8	3.0	5.8	25	18
AN036030	SaCoVLM™ Video Laryngeal Masks	MLM30C	3.0	Adult	30-50	7.0	16	5.2	4.0	5.8	30	20
AN036040	SaCoVLM™ Video Laryngeal Masks	MLM40C	4.0	Adult	50-70	7.5	16	5.5	4.0	5.8	40	23
AN036050	SaCoVLM™ Video Laryngeal Masks	MLM50C	5.0	Adult	70-100	8.0	16	5.8	4.0	5.8	50	25
AN036060	SaCoVLM™ Video Laryngeal Masks	MLM60C	6.0	Obesity	>100	8.0	16	5.8	4.0	5.8	60	28

12.8 Pressure drop of airway channel in airway tube

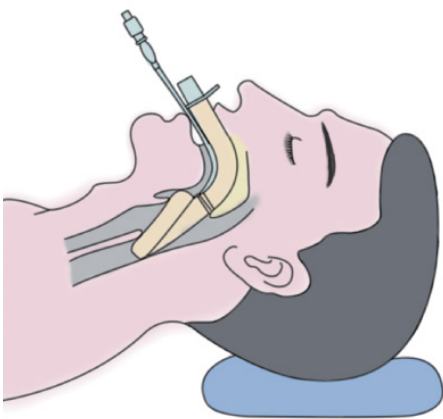
Table 4

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

14.Directions for use

14.1 Insertion: Hold the laryngeal mask like holding a pen 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. The laryngeal mask can also be inserted by means of direct observation: first insert the visual stylet into the observation channel of laryngeal mask, by which the circumstance before the mask can be clearly viewed, then insert the laryngeal mask in place like holding a pen.

14.2 Position adjustment: In case that the laryngeal mask is not aligned well after insertion, the following adjustments can be adopted manually: a) deflate the cuff, tilt the patient's head back, hold the laryngeal mask by one hand like holding a pen, move it up and down for two or three times, and then push the laryngeal mask softly into the place. 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 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.



14.3 Drainage tube insertion: Place the lubricated drainage tube into gastric channel of laryngeal mask. If it can be smoothly inserted and suck away gastric juice after entering gastric channel, it indicates that the laryngeal mask is well placed.

14.4 Seal pressure test: After several times of normal ventilation, close the APL valve, and manually and rapidly oxygenate until the airway pressure indicator of the anesthesia machine exceeds 20cmH2O, then stop the rapid oxygenation and make the oxygen flow over 6L/min. With the inflation of cuff and the increase of airway inner pressure, the sound of air leakage around the oral channel can be heard and the airway pressure indicator no longer continues to rise, then the pressure value displayed on the pressure indicator is the seal pressure of the laryngeal mask. The whole process shall not be over one minute. Open APL valve immediately after getting test result and return to normal airway pressure.

14.5 Connect syringe to the cleaning connector. If fog appears in front of observation view, clean the observation window with gas by the syringe, which can effectively remove the fog (applicable to MLMxC series only).

15. Disposal after Use

Disposable Medical Laryngeal Masks are designed for single use, please dispose of the used laryngeal masks in a safe manner according to local regulations.

16. Indications of medical device marks

	Sterilized using ethylene oxide Single sterile barrier system		Keep away from sunlight
	Authorized representative in the European Community		Not made with phthalates and DEHP
	Do not re-use		Keep dry
	Do not use if package is damaged		Temperature limit -40 - 55 °C
	Batch Code		Humidity limitation 93%
	Date of manufacture		Do not re-sterilize
	Use-by date		Caution
	Manufacturer		Consult instructions for use
	Fragile, handle with care		Stack limit by 5
	Medical device		CE marking of conformity, and Notified Body Code
	This Way UP		Unique Device Identifier
	Not made with natural rubber latex		Model number
	Sterilized using ethylene oxide Single sterile barrier system with protective packaging outside		

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 a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 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

For additional information, contact Zhejiang UE Medical Corp. Sales Representative or Customer Service.

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