






















# IFU

## Laryngeal Masks

Manufacture: Tianjin Medis Medical Device Co., Ltd.

Data: 2025-11-27

## Laryngeal Masks

	Do not re-use		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorized representative in the European Community
	Sterilized using ethylene oxide		Keep away from sunlight
	Do not use if package is damaged		Keep dry
	Consult instructions for use		Catalogue number
	Caution		Doesn't contain DEHP
	CE marking of conformity		Latex free
	This way up		Fragile, Handle with care
	Temperature limit		MR Safe
	MR unsafe		MR Conditional
	Medical device		

## GENERAL INFORMATION

Unless otherwise stated, the reference to “device” stated on this IFU applies to all versions of laryngeal mask. The device is not implanted device and dose not incorporate electronic programmable systems or accessories. And no installation required.

## DESCRIPTION

Laryngeal mask is supraglottic airway device. It can be used as a temporary method to maintain an open airway during the administration of anesthesia or as an immediate life-saving measure in a patient with a difficult or failed airway.

## CLINICAL BENEFIT

Using this product can help medical staff quickly establish artificial airway for patients.

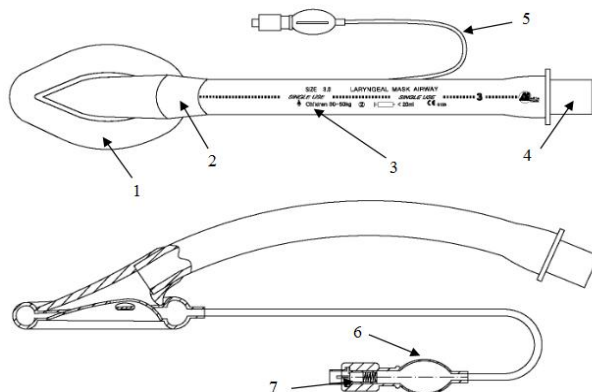
## TYPE AND SIZE

Categories	model code	model name	Size (ID)
100% Silicone Laryngeal mask	LM-PC	100% Silicone Laryngeal mask, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-PA	100% Silicone Laryngeal mask, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
Reinforced Laryngeal Mask	LM-JC	Reinforced Laryngeal Mask, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-JA	Reinforced Laryngeal Mask, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-JGC	Flowguard Flexy Laryngeal Mask, single use	1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-JGA	Flowguard Flexy Laryngeal Mask, with AccuCuff	1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-JPC	FlexyCurve Laryngeal mask, Single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-JPA	FlexyCurve Laryngeal mask, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
Laryngeal mask, Silicone/PVC	LM-SC	Laryngeal mask, Silicone/PVC, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-SA	Laryngeal mask, Silicone/PVC, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
Flowguard Laryngeal Mask	LM-GC	Flowguard Laryngeal Mask,single use	2.0#,3.0#,4.0#,5.0#
	LM-GA	Flowguard Laryngeal Mask , with AccuCuff	2.0#,3.0#,4.0#,5.0#
WydeGlyde laryngeal Mask	LM-WC	WydeGlyde laryngeal Mask, single use	3.0#,4.0#,5.0#
	LM-WA	WydeGlyde laryngeal Mask with AccuCuff	3.0#,4.0#,5.0#
Precurved Laryngeal Mask	LM-YC	Precurved Laryngeal Mask,single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LM-YA	Precurved Laryngeal Mask,with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#

DuoFit Laryngeal Mask	LM-DG	Dual-Cuff Laryngeal Mask	2.5/3#, 4/5#
-----------------------	-------	--------------------------	--------------

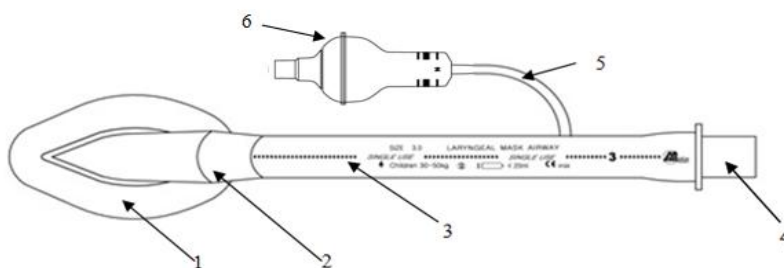
## STRUCTURE

The structure composition of the laryngeal mask is as follows:



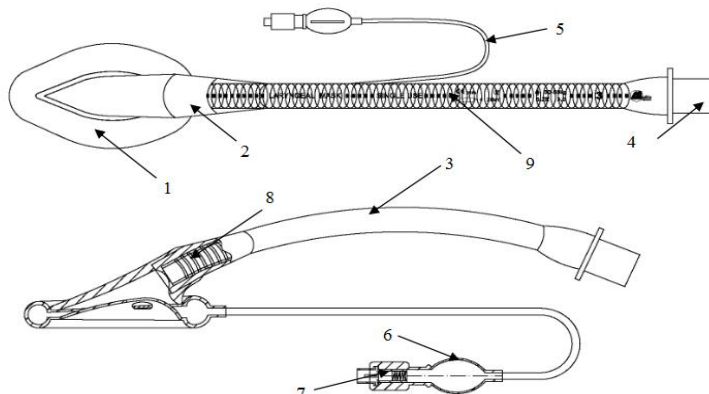
1 cuff, 2 linker piece, 3 airway tube, 4 machine-end connector, 5 inflating tube, 6 pilot balloon, 7 one-way valve

Figure 1 100% Silicone Laryngeal mask, single use



1 cuff, 2 linker piece, 3 airway tube, 4 machine-end connector, 5 inflating tube, 6 pressure indicator

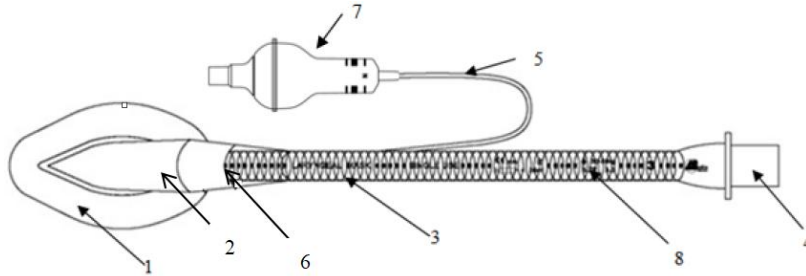
Figure 2 100% Silicone Laryngeal mask, with AccuCuff



1 cuff, 2 linker piece, 3 reinforced airway tube, 4 machine-end connector, 5 inflating tube, 6 pilot balloon,

7 one-way valve, 8 connector, 9 stainless steel wire

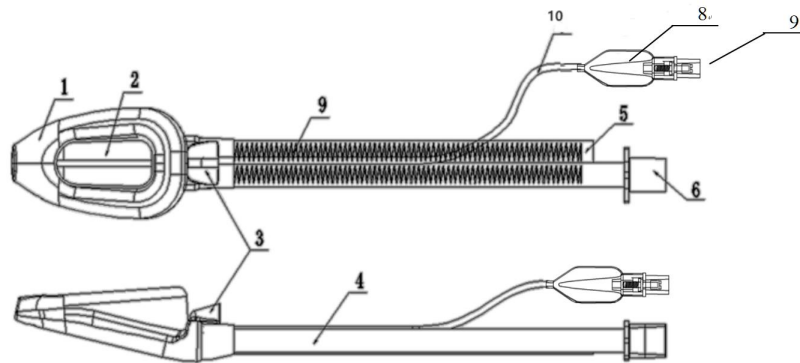
Figure 3 Reinforced Laryngeal Mask, single use



1 cuff, 2 linker piece, 3 reinforced airway tube, 4 machine-end connector, 5 inflating tube, 6 connector,

7 pressure indicator, 8 stainless steel wire

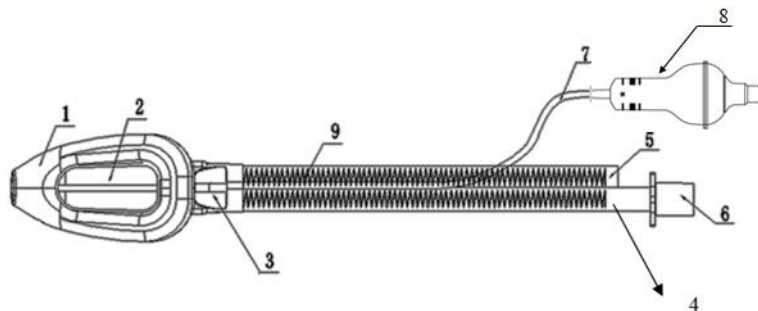
Figure 4 Reinforced Laryngeal Mask, with AccuCuff



1 cuff, 2 support piece, 3 finger stall, 4 reinforced airway tube, 5 reinforced drainage tube, 6 machine-end

connector, 7 inflating tube, 8 pilot balloon, 9 one-way valve

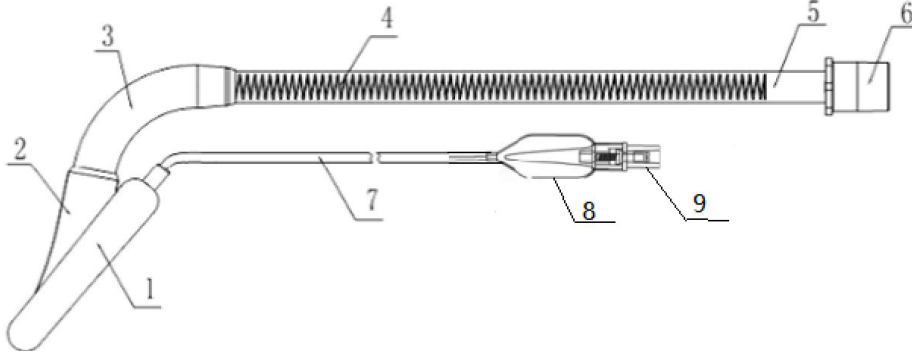
Figure 5 Flowguard Flexy Laryngeal Mask, single use



1 cuff, 2 support piece, 3 finger stall, 4 reinforced airway tube, 5 reinforced drainage tube, 6 machine-end

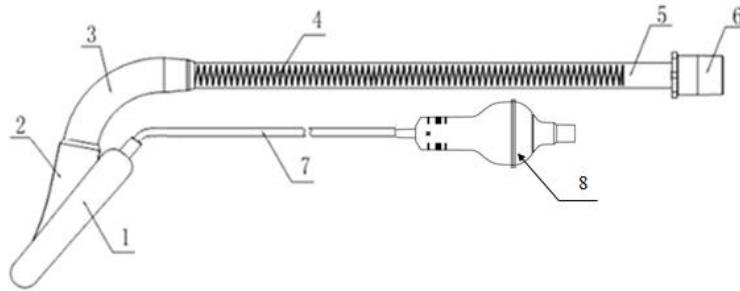
connector, 7 inflating tube, 8 pressure indicator, 9 stainless steel wire

Figure 6 Flowguard Flexy Laryngeal Mask, with AccuCuff



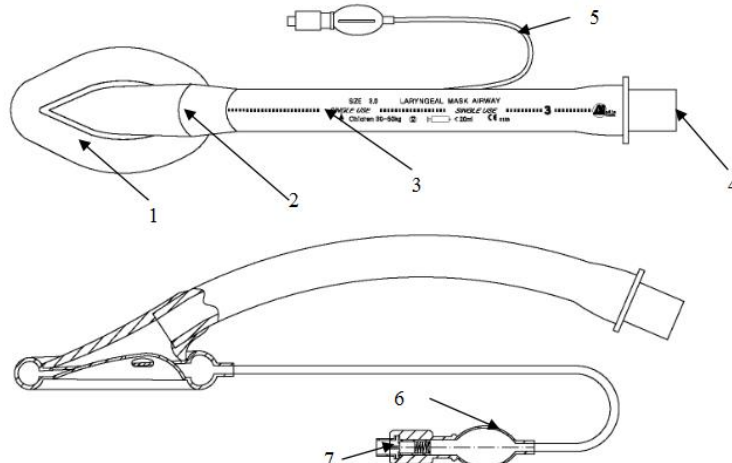
1 cuff, 2 linker piece, 3 improved reinforced airway tube connector, 4 stainless steel wire, 5 reinforced airway tube, 6 machine-end connector, 7 inflating tube, 8 pilot balloon, 9 one-way valve

Figure 7 FlexyCurve Laryngeal mask, Single use



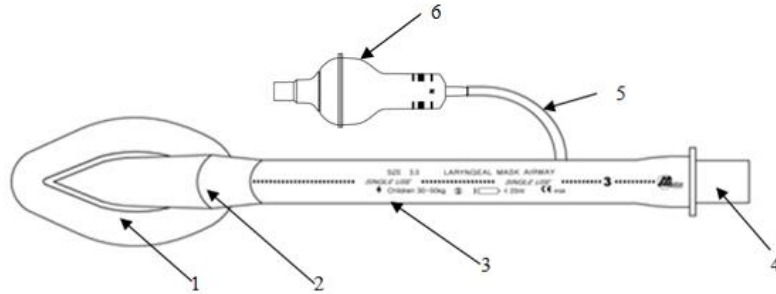
1 cuff, 2 linker piece, 3 improved reinforced airway tube connector, 4 stainless steel wire, 5 reinforced airway tube, 6 machine-end connector, 7 inflating tube, 8 pressure indicator

Figure 8 FlexyCurve Laryngeal mask, with AccuCuff



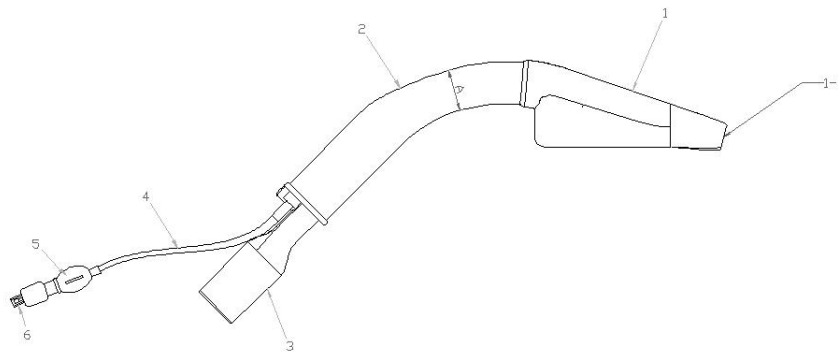
1 cuff, 2 linker piece, 3 PVC airway tube, 4 machine-end connector, 5 inflating tube, 6 pilot balloon, 7 one-way valve

Figure 9 Laryngeal mask, Silicone/PVC, single use



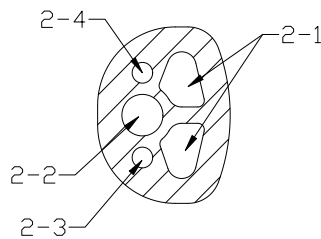
1 cuff, 2 linker piece, 3 PVC airway tube, 4 machine-end connector, 5 inflating tube, 6 pressure indicator

Figure 10 Laryngeal mask, Silicone/PVC, with AccuCuff



(A) Side view

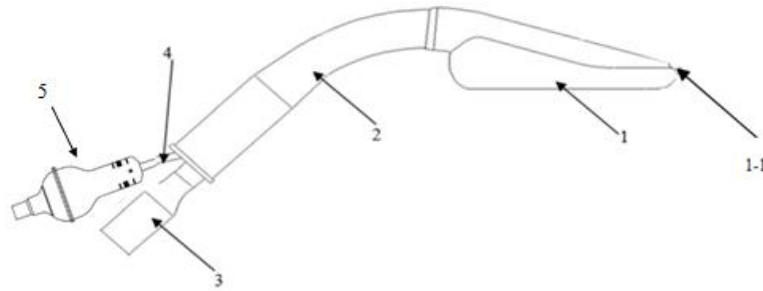
1 cuff, 2 airway tube, 3 machine-end connector, 4 inflating tube, 5 pilot balloon, 6 one-way valve, 1-1 drainage hole



(B) Cross-sectional view of inflating tube A-A

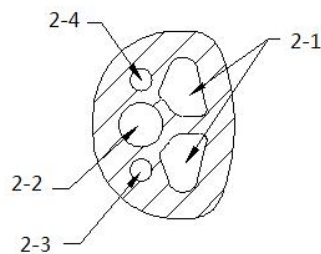
2-1 ventilation chamber 2-2 drainage chamber 2-3 inflating chamber 2-4 pressure-relief chamber

Figure 11 Flowguard Laryngeal Mask, single use



(A) Side view

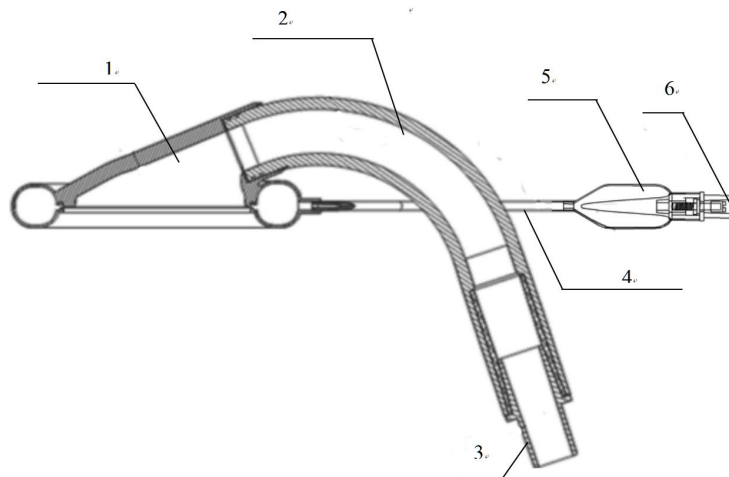
1 cuff, 2 airway tube, 3 machine-end connector, 4 inflating tube, 5 pressure indicator, 1-1 drainage hole



(B) Cross-sectional view of inflating tube A-A

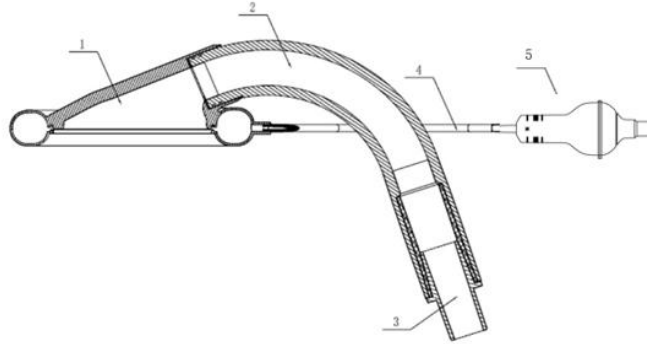
2-1 ventilation chamber 2-2 drainage chamber 2-3 inflating chamber 2-4 pressure-relief chamber

Figure 12 Flowguard Laryngeal Mask , with AccuCuff



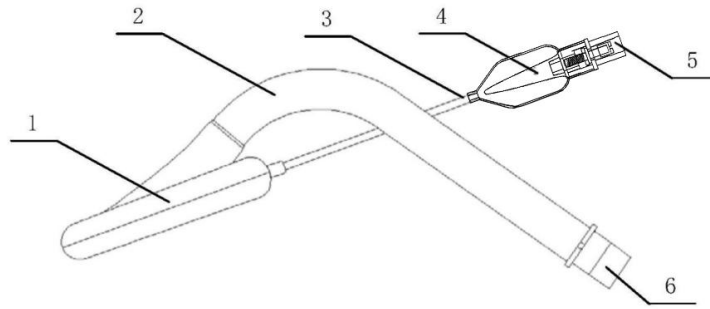
1 cuff, 2 airway tube, 3 machine-end connector, 4 inflating tube, 5 pilot balloon, 6 one-way valve

Figure 13 WydeGlyde laryngeal Mask, single use



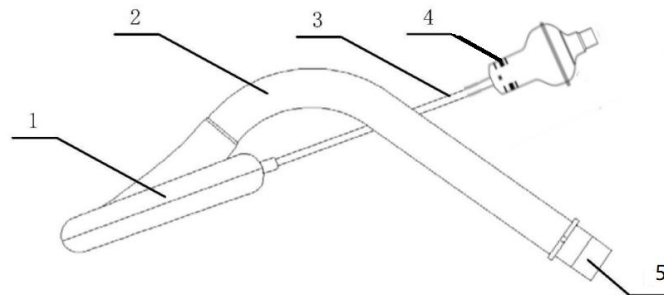
1 cuff, 2 airway tube, 3 machine-end connector, 4 inflating tube, 5 pressure indicator

Figure 14 WydeGlyde laryngeal Mask with AccuCuff



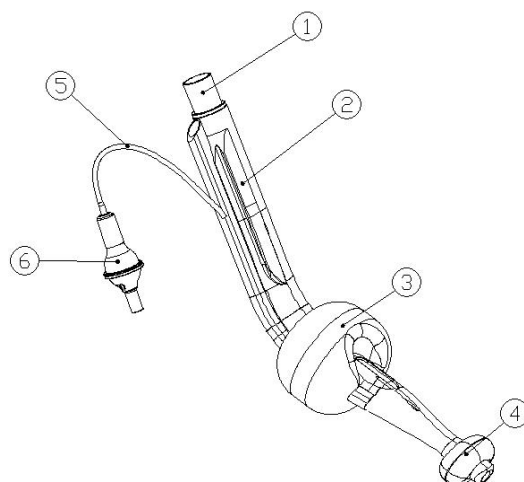
1 machine-end connector, 2 airway tube, 3 inflating tube, 4 pilot balloon, 5 one-way valve, 6 machine-end connector

Figure 15 Precurved Laryngeal Mask, single use



1 machine-end connector, 2 airway tube, 3 inflating tube, 4 pressure indicator, 5 machine-end connector

Figure 16 Precurved Laryngeal Mask, with AccuCuff



1 machine-end connector, 2 airway tube, 3 large balloon , 4 small balloon, 5 inflating tube, 6 pressure indicator

Figure 17 Dual-Cuff Laryngeal Mask

## SIZE SELECTION

### 1. 100% Silicone Laryngeal mask, single use; 100% Silicone Laryngeal mask, with AccuCuff

Sizes	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult	Overweight adult
Patient weight (KG)	<5	5-10	10-20	20-30	30-50	50-70	70-100	>100
Maximum Inflation Volume (ml)	4	7	10	14	20	30	40	50

### 2. Reinforced Laryngeal Mask, single use; Reinforced Laryngeal Mask, with AccuCuff

Sizes	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult	Overweight adult
Patient weight (KG)	<5	5-10	10-20	20-30	30-50	50-70	70-100	>100
Maximum Inflation Volume (ml)	4	7	10	14	20	30	40	50

### 3. Flowguard Flexy Laryngeal Mask, single use; Flowguard Flexy Laryngeal Mask, with AccuCuff

Sizes	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#
Intended patient population	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult
Patient weight (KG)	5-10	10-20	20-30	30-50	50-70	70-100
Maximum Inflation Volume (ml)	7	10	14	20	30	40

Maximum OG Tube (Fr)	14Fr	14Fr	16Fr	20Fr	20Fr	20Fr
----------------------	------	------	------	------	------	------

#### 4. FlexyCurve Laryngeal mask, Single use; FlexyCurve Laryngeal mask, with AccuCuff

Sizes	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult	Overweight adult
Patient weight (KG)	<5	5—10	10-20	20-30	30-50	50-70	70-100	>100
Maximum Inflation Volume (ml)	4	7	10	14	20	30	40	50

#### 5. Laryngeal mask, Silicone/PVC, single use; Laryngeal mask, Silicone/PVC, with AccuCuff

Sizes	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult	Overweight adult
Patient weight (KG)	<5	5—10	10-20	20-30	30-50	50-70	70-100	>100
Maximum Inflation Volume (ml)	4	7	10	14	20	30	40	50

#### 6. Flowguard Laryngeal Mask, single use; Flowguard Laryngeal Mask, with AccuCuff

Sizes	2.0#	3.0#	4.0#	5.0#
Intended patient population	Child	Teenager	Ordinary adult	Heavier adult
Patient weight (KG)	10-20	30-50	50-70	70-100
Maximum Inflation Volume (ml)	10	20	30	40
Maximum OG Tube (Fr)	12Fr	15Fr	15Fr	18Fr

#### 7. WydeGlyde laryngeal Mask, single use; WydeGlyde laryngeal Mask with AccuCuff

Sizes	3.0#	4.0#	5.0#
Intended patient population	Teenager	Ordinary adult	Heavier adult
Patient weight (KG)	30-50	50-70	70-100
Maximum Inflation Volume (ml)	20	30	40
Maximum OETT(size)	7.0	8.0	10.0

#### 8. Precurved Laryngeal Mask, single use; Precurved Laryngeal Mask, with AccuCuff

Sizes	1.0#	1.5#	2.0#	2.5#	3.0#	4.0#	5.0#	6.0#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adult	Overweight adult
Patient weight (KG)	<5	5—10	10-20	20-30	30-50	50-70	70-100	>100
Maximum Inflation Volume (ml)	4	7	10	14	20	30	40	50

## 9. Dual-Cuff Laryngeal Mask

Sizes	2.5/3.0#	4.0/5.0#
Intended patient population	Teenager	Adult
Patient height(cm)	125-155	≥ 155
Maximum Inflation Volume (ml)	65	100
Maximum OETT(size)	6.5	8.0
Maximum OG Tube (Fr)	16Fr	18Fr

## INTENDED USE

Laryngeal mask is used for emergency resuscitation; anesthesia for surgeries that the operation time is short; difficult airway intubation and tracheal intubation performed during general anesthesia.

## INDICATIONS

- 1) indicated for use as a guide for intubation of the trachea.
- 2) indicated for achieving and maintaining control of the airway during routine and emergency situations, including anticipated or unexpected difficult airways.
- 3) indicated as a method of establishing an airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

## PATIENT GROUPS

Neonate, infant, children, teenager and adults.

## INTENDED USERS

Professionally trained doctors, anesthesiologist and midwife.

## **CONTRAINDICATIONS**

1. This product is contraindicated in patients with tracheal compression and softening who experience airway obstruction after anesthesia.
2. Patients in upper abdominal surgeries.
3. The following conditions are contraindicated: full stomach, pyloric obstruction, intestinal obstruction, laryngeal obstruction, failure to fast, acute abdomen, abdominal trauma, drug poisoning, and gastrointestinal bleeding.
4. Due to the potential risk of regurgitation and aspiration, do not use this product as a substitute for endotracheal tube for the following elective or difficult airway patients who are not in the emergency channel:
  - 1) Patients with severe obesity or morbid obesity;
  - 2) Patients who are pregnant for more than 14 weeks;
  - 3) Any condition related to delayed gastric emptying, or those who have used opioid drugs before fasting.
  - 4) Patients with fixed lung compliance reduction, such as those with pulmonary fibrosis.
  - 5) Patients who are not in a deep coma and may resist the insertion of medical devices.
  - 6) Patients whose heads need to be turned during the examination.
  - 7) Patients in the prone position.
5. Those with throat lesions causing obstruction of the respiratory tract or high respiratory resistance should use it with caution.
6. Patients with laryngeal edema, acute inflammation of the respiratory tract, and throat abscess should use it with caution.

## **COMPLICATONS/ ADVERSE EFFECTS**

Sore throat, hoarseness, dysphagia, dysphonia, laryngospasm and bronchospasm.

## **SERIOUS INCIDENT**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## COMBINATIONS

Combination devices used in surgery: syringe, gloves, suction tube, esophagus gastric suction tube,ETT

SN	Combination device	Safety and performance of the combination	Regulatory references/evidences
1	syringe	Insert the the laryngeal mask in a proper position in the patient's airway. And then take a syringe which is in accordance with the requirements of ISO 7886-1:2017. Connect the conical fitting of the syringe (the male conical fitting shall satisfy the requirement of ISO 80369-7:2021) with the check valve(with pilot balloon) or cuff pressure of the the laryngeal mask. Inflate the cuff of the the laryngeal mask, so as to close the patient's respiratory airway and avoid accidental inhalation.	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
2	gloves	In the process of inserting the laryngeal mask into the patient's airway, wear gloves throughout the process to isolate bacteria.	ISO 10282:2023 Single-use sterile rubber surgical gloves — Specification
3	suction tube	The prepared suction tube is inserted into the patient's airway through the laryngeal mask airway tube. During the process, the suction tube needs to be gradually rotated to gradually suck out the secretions in the respiratory tract, thereby reducing the respiratory obstruction of the patient and ensuring the smooth breathing.	ISO 8836:2019 Suction catheters for use in the respiratory tract
4	ETT	For laryngeal masks that need to be used in combination with ETT, the ETT is inserted into the patient's airway through the laryngeal mask airway tube for mechanical ventilation.	ISO 5361:2023 Anaesthetic and respiratory equipment — Tracheal tubes and connectors

5	esophagus gastric suction tube	For the drainage laryngeal mask, the esophagus gastric suction tube is inserted into the esophagus of the patient through the drainage cavity of the airway tube to the stomach for gastric fluid suction.	YY/T0031-2008 Silicone tubes and elastomeric parts for infusion and transfusion
---	--------------------------------	--	--

Combination devices used during ventilating: anesthesia machine and breathing machine.

- Breathing machine

The breathing machine is connected with a breathing tube which is a flexible tube used to convey gases and/or vapour in breathing system. The breathing tube is connected with an adapter. The adapter is a specialized connector which can establish functional continuity between disparate or incompatible components. One end of the adapter is connected with the breathing tube of the breathing machine and the other end of the adapter has a conical connector complied with ISO 5356-1, which can be connected with the machine-end connector of the laryngeal mask. So the oxygen can be conveyed to the patient through the laryngeal mask.

- Anesthesia machine

The anesthesia machine is connected with a breathing tube which is used to convey gases and /or vapour in the breathing system. The breathing tube is connected with an adapter. One end of the adapter is connected with the breathing tube of the anesthesia machine and the other end of the adapter has a conical connector complied with ISO 5356-1, which can be connected with the machine-end connector of the laryngeal mask. So the anesthetic gas can reach the patient's body through the laryngeal mask.

## CONTAINED SUBSTANCE AND CONSTITUENT SUBSTANCE

a) The device does not contain medicinal substance, tissues or cells, their derivatives, of human origin, or tissues or cells of animal origin, or their derivatives as referred to in Regulation (EU) No 722/2012.

b) Where devices, parts thereof or materials used therein do not include medicinal substance and biological material or include substances which are carcinogenic, mutagenic or toxic to reproduction or substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health.

c) The devices are not composed of substances or of combinations of substances that are intended to be

---

introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.

## **WARNING/PRECAUTIONS**

- 1) Sterile product. Sterilized by Ethylene Oxide.
- 2) The product should be operated and used by professionally trained doctors or clinical nurses.
- 3) This product is only for one time use by a single patient. It is strictly prohibited to reuse or use after secondary sterilization. Reuse can cause infection or cross-infection which will lead to fever, respiratory failure, coma, endanger the patients life in severe cases.
- 4) Do not use if the package is damaged or exceed the shelf life.
- 5) After use, the products should be completely scrapped, and put into the disposable product waste designated by the hospital, which will be treated by the hospital in accordance with local laws and regulations.
- 6) According to the patients' condition, ensure anaesthesia level is adequate and use of a bite block to prevent to prevent the patient's gums from occluding and causing damage to the laryngeal mask.
- 7) Wear disposable medical gloves during the insertion process of the product. After the product is inserted, discard the gloves to prevent cross-infection.
- 8) The laryngeal mask is a short-term device which is contact with the tracheal mucous membrane, and the duration of use should not exceed 24 hours.
- 9) This product is mainly made of silicone material. People who are allergic to this material should avoid using it.
- 10) The supralaryngeal airway should be reconfirmed after any change in the patient's head or neck position .
- 11) For neonates and infants, in addition to the weight selection criteria on the IFU, the model selection should also meet the practical clinical situation.
- 12) Do not use a laser near the Laryngeal Mask as this may cause combustion and injury. (Note: Contact of the beam or electrode with the Laryngeal Mask, especially in the presence of oxygen-enriched or nitrous oxide containing mixtures could result in the rapid combustion of the airway with harmful thermal effects and with emission of corrosive and toxic combustion products including hydrochloric acid (HCl).

- 13) For the cuffed products, monitor the intracuff pressure per hour. In addition, for products without a cuff pressure indicator, a pressure gauge should be used to monitor the intracuff pressure to prevent excessive cuff pressure and related complications, such as sore throat, vocal cord paralysis, arytenoid cartilage dislocation, recurrent laryngeal nerve injury and hypoglossal nerve injury.
- 14) Non-routine deflating or adjusting the cuff pressure can be carried out according to the condition to prevent the cuff from pressing the tracheal wall for a long time and causing mucosal injury.
- 15) Syringes, 3-way stopcocks or other lure tip devices should not remain in the cuff pressure indicator or one-way valve for extended periods of time for the resulting stress could crack the valve housing and the leakage of cuff.
- 16) The one-way valve of Laryngeal Mask is one of the key components. During use, the operator shall not insert the syringe into the one-way valve with excessive force.
- 17) Do not use reinforced Laryngeal Mask during MRI examination (Note: Intubation with metal components can produce displacement, artifact, heat generation, and magnetic torsion forces under MRI, which can be life-threatening in severe cases).

## PRE-USE CHECKS:

Do not use this product unless these checks are completely qualified.

- a. Check the expiration date. Products exceeding expiration date, packaging damage, air leakage, herniations, uneven bulging or packaging containing foreign matter are strictly prohibited to use.
- b. Open the packaging bag, take out the product, check if there are any cuts, tears or scratches on the surface of the product, and check the interior of the product for any blockages or loose particles. Conduct an airtightness test to check its sealing performance. If the product is damaged, do not use it.
- c. Discard the device if the connector is loose.
- d. If the color of airway tube changed, the visibility will be affected.

## DIRECTION FOR USE

These directions are general guidelines intended for use by qualified medical personnel. Any instructions, indications and contraindications given are not exhaustive and it is the clinician's responsibility to ensure the safe, correct use of this product.

- **100% Silicone Laryngeal mask ; Reinforced Laryngeal Mask ; FlexyCurve Laryngeal mask ; Laryngeal mask, Silicone/PVC and Precurved Laryngeal Mask**

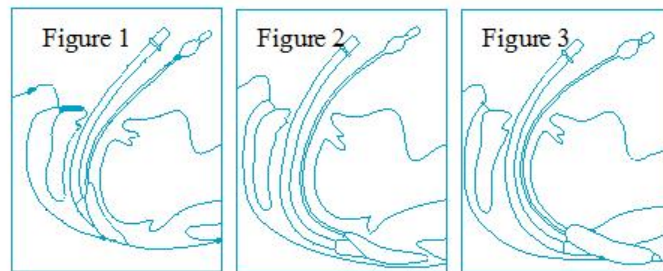


Figure A

- 1) Before inserting the laryngeal mask airway, insert the syringe from the one-way valve and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head and expose the path of the back of the mouth.
- 4) Hold the junction of the cuff and the airway tube within the index finger and thumb, and press the tip of the mask and verify it lies flat against the hard palate. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Gently push the jaw, and insert the index finger fully into the mouth to move the mask downwards .
- 5) Keep the neck bent and the head extended, press the cuff to move it along the velopharyngeal curve. Press the cuff of laryngeal mask and move along the posterior pharyngeal curve to the oropharynx with the index finger. The cuff must be kept flat and close to the velopharyngeal curve to avoid embedding into the tongue, epiglottis and glottis. (Figure A-1)
- 6) Continue to move the capsule with index finger until it reaches the proper position. Don't use force . The resistance is felt when the tip of the cuff enters the hypopharynx. The finger should have been inserted into the mouth as deep as possible, before encountering resistance to move the laryngeal mask forward. Once the cuff ring surrounds the oropharyngeal entrance, the laryngeal mask has reached the final position. (Figure A-2)
- 7) Check the black line at the back of the airway tube so that it faces the upper lip. Hold the airway tube and gently press it down to ensure that the laryngeal mask is fully inserted.
- 8) Insert the syringe at the one-way valve. Inflate the device with a volume of air 50% greater than the maximum inflation value for each size. Adjust as required. Do not overinflate. ( Figure A-3 ).
- 9) Make sure the airway is unobstructed.

- 10) Ensure that the device is stabilized to prevent unnecessary movement..
  - 11) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.
  - 12) When the patient is return to consciousness, a professionally trained doctor or clinical nurse should insert a syringe at the one-way valve to completely deflate the cuff and pull out the laryngeal mask airway.
- **100% Silicone Laryngeal mask, with AccuCuff; Reinforced Laryngeal Mask, with AccuCuff; FlexyCurve Laryngeal mask, with AccuCuff; Laryngeal mask, Silicone/PVC, with AccuCuff ; Precurved Laryngeal Mask, with AccuCuff**

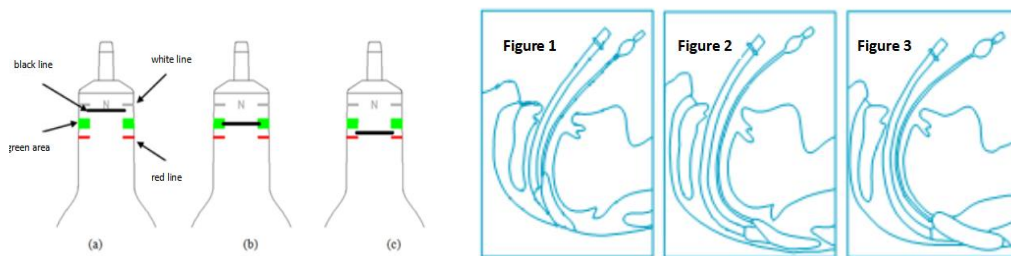


Figure B

- 1) Before insertion, insert the syringe at the syringe interface of cuff pressure indicator, and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head and expose the path of the back of the mouth.
- 4) Hold the junction of the cuff and the airway tube within the index finger and thumb, and press the tip of the mask and verify it lies flat against the hard palate. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Gently push the jaw, and insert the index finger fully into the mouth to move the mask downwards .
- 5) Keep the neck bent and the head extended, press the cuff to move it along the velopharyngeal curve. Press the cuff of laryngeal mask and move along the posterior pharyngeal curve to the oropharynx with the index finger. The cuff must be kept flat and close to the velopharyngeal curve to avoid embedding into the tongue, epiglottis and glottis. (Figure B-1)
- 6) Continue to move the capsule with index finger until it reaches the proper position. Don't use force . The resistance is felt when the tip of the cuff enters the hypopharynx. The finger should have been inserted into the mouth as deep as possible, before encountering resistance to move the laryngeal

mask forward. Once the cuff ring surrounds the oropharyngeal entrance, the laryngeal mask has reached the final position. (Figure B-2)

- 7) Check the black line at the back of the airway tube so that it faces the upper lip. Hold the airway tube and gently press it down to ensure that the laryngeal mask is fully inserted.
- 8) Completely inflate the syringe.
- 9) Rotate 90 degrees forward and right to push the syringe to inflate the cuff. At the same time, observe the position of the black line on the pressure indicator. When the black line is located in the green area, stop inflation and pull out the syringe. At this time, the intracuff pressure should be in 40-60CM H<sub>2</sub>O. And the position of the laryngeal mask is shown in Figure B-3.
- 10) During use, doctors can judge the intracuff pressure by the position of black line, and make corresponding treatment. Green area is safe area, and when black line is located in this area, it means that the pressure is within safe range (40-60CM H<sub>2</sub>O), as shown in Figure (b).
- 11) When the black line moves away from the green area and move towards to the white line, it indicates that the pressure is low and the doctor needs to inflate air, as shown in Figure (a).
- 12) When the black mark moves away from the green area and move towards the red line, it indicates that the pressure is too high and the doctor needs to deflate, as shown in Figure (c) above.
- 13) Make sure the airway is unobstructed.
- 14) Ensure that the device is stabilized to prevent unnecessary movement.
- 15) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.
- 16) When the patient is return to consciousness, a professionally trained doctor or clinical nurse should insert a syringe at the one-way valve to completely deflate the cuff and pull out the laryngeal mask airway.

➤ **Flowguard Laryngeal Mask and Flowguard Flexy Laryngeal Mask**

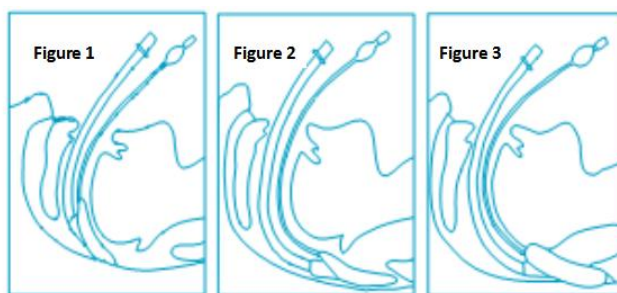


Figure-C

- 1) Before insertion, insert the syringe at the syringe interface of one-way valve ,and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head.
- 4) Hold the airway tube of laryngeal mask with the right hand. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Insert the mask into the mouth along the hard palate. When the mask completely enters the mouth, move the airway tube backward and downward to insert the laryngeal mask. When resistance is felt the the tip of the laryngeal mask should have entered the hypopharynx. ( Figure C-2)
- 5) Insert the syringe at the one-way valve. Inflate the device with a volume of air 50% greater than the maximum inflation value for each size. Adjust as required. Do not overinflate. ( Figure C-3 ).
- 6) After making sure that the thorax undulates well and the laryngeal mask does not leak air, inject lubricant into the drainage tube. Insert a drainage tube into the the drainage chamber, and open the drainage tube and actively attracting the gastric fluid.
- 7) Make sure the airway is unobstructed.
- 8) Ensure that the device is stabilized to prevent unnecessary movement..
- 9) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.
- 10) When the patient is return to consciousness, a professionally trained doctor or clinical nurse should insert a syringe at the one-way valve to completely deflate the cuff and pull out the laryngeal mask airway.

➤ **Flowguard Laryngeal Mask, with AccuCuff; Flowguard Flexy Laryngeal Mask, with AccuCuff**

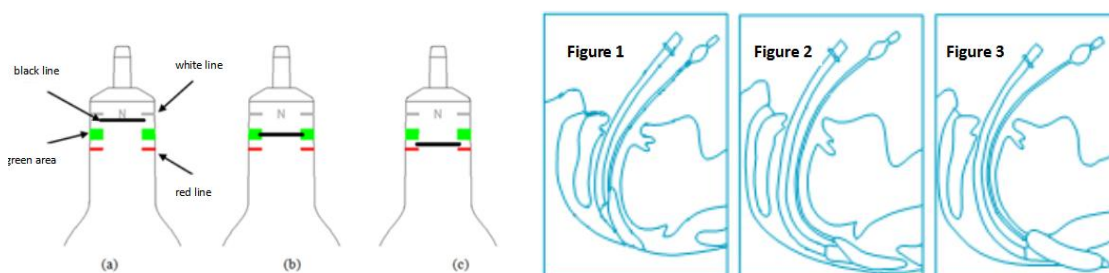


Figure D

- 1) Before insertion, insert the syringe at the syringe interface of cuff pressure indicator, and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head.
- 4) Hold the airway tube of laryngeal mask with the right hand. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Insert the mask into the mouth along the hard palate. When the mask completely enters the mouth, move the airway tube backward and downward to insert the laryngeal mask. When resistance is felt the tip of the laryngeal mask should have entered the hypopharynx. ( Figure D-2)
- 5) Completely inflate the syringe.
- 6) Rotate 90 degrees forward and right to push the syringe to inflate the cuff. At the same time, observe the position of the black line on the pressure indicator. When the black line is located in the green area, stop inflation and pull out the syringe. At this time, the intracuff pressure should be in 40-60CM H<sub>2</sub>O. And the position of the laryngeal mask is shown in Figure D-3.
- 7) After making sure that the thorax undulates well and the laryngeal mask does not leak air, inject lubricant into the drainage tube. Insert a gastric tube into the drainage tube, and open the gastric tube after actively attracting the gastric fluid.
- 8) During use, doctors can judge the intracuff pressure by the position of black line, and make corresponding treatment. Green area is safe area, and when black line is located in this area, it means that the pressure is within safe range (40-60CM H<sub>2</sub>O), as shown in Figure (b).
- 9) When the black line moves away from the green area and moves towards the white line, it indicates that the pressure is low and the doctor needs to inflate air, as shown in Figure (a).
- 10) When the black mark moves away from the green area and moves towards the red line, it indicates that the pressure is too high and the doctor needs to deflate, as shown in Figure (c) above.
- 11) Make sure the airway is unobstructed.
- 12) Ensure that the device is stabilized to prevent unnecessary movement..
- 13) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.

- 14) When the patient is return to consciousness, a professionally trained doctor or clinical nurse should insert a syringe at the one-way valve to completely deflate the cuff and pull out the laryngeal mask airway.

➤ **WydeGlyde laryngeal Mask**

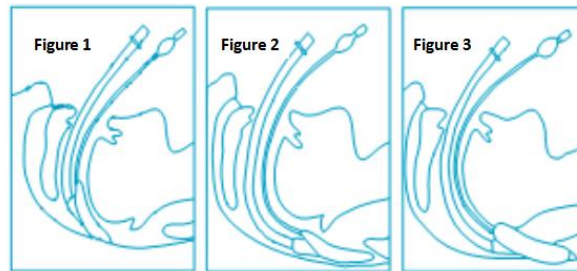


Figure E

- 1) Before insertion, insert the syringe at the syringe interface of one-way valve, and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head.
- 4) Hold the airway tube of laryngeal mask with the right hand. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Insert the mask into the mouth along the hard palate. ( Figure E-1) When the mask completely enters the mouth, move the airway tube backward and downward to insert the laryngeal mask. When resistance is felt the the tip of the laryngeal mask should have entered the hypopharynx, and the proximal end of the airway tube is located in the lips. Connect the breathing device to the machine end connector of the laryngeal mask.
- 5) Insert the syringe at the one-way valve. Inflate the device with a volume of air 50% greater than the maximum inflation value for each size. Adjust as required. Do not overinflate. ( Figure E-3 ).
- 6) After making sure that the thorax undulates well and the laryngeal mask does not leak air, apply lubricant to the outer wall of the tube, and then insert it into the airway of the laryngeal mask (pull out the machine end connector of the laryngeal mask before intubation), distribute the lubricant within the shaft by moving the tube up and down until it travels freely through the entire airway tube and gently move the tube until the depth of insertion beyond the 15 cm depth marker.

- 7) When the endotracheal tube is inserted into the proper depth, inflate the cuff with a syringe and connect the ventilation circle for trial ventilation.
- 8) After ventilation test, remove the connector and completely deflate the cuff of laryngeal mask. Hold the tube with one hand and make sure the tube is in place with the assistance of a stabilizing rod. And then completely withdraw the laryngeal mask from the mouth.

➤ **WydeGlyde laryngeal Mask with AccuCuff**

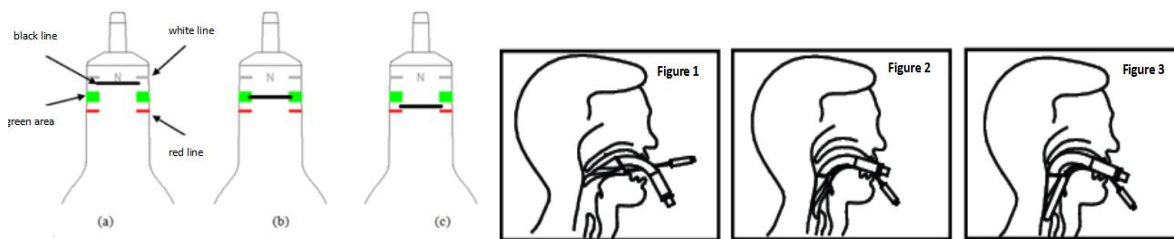


Figure F

- 1) Before insertion, insert the syringe at the syringe interface of cuff pressure indicator, and deflate the cuff fully. Ensure that the cuff wall is tightly flattened so as to easily enter the laryngeal cavity with a small volume.
- 2) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.
- 3) The patient takes the supine position, and the doctor stands on the side of the patient's head to slightly tilt back the patient's head.
- 4) Hold the airway tube of laryngeal mask with the right hand. The aperture of the cuff should face forward, and the black line at the back of the airway tube faces the upper lip. Insert the mask into the mouth along the hard palate. ( Figure F-1) When the mask completely enters the mouth, move the airway tube backward and downward to insert the laryngeal mask. When resistance is felt the the tip of the laryngeal mask should have entered the hypopharynx, and the proximal end of the airway tube is located in the lips. Connect the breathing device to the machine end connector of the laryngeal mask.
- 5) Completely inflate the syringe.
- 6) Rotate 90 degrees forward and right to push the syringe to inflate the cuff. At the same time, observe the position of the black line on the pressure indicator. When the black line is located in the green area, stop inflation and pull out the syringe. At this time, the intracuff pressure should in 40-60CM H<sub>2</sub>O. And the position of the laryngeal mask is shown in Figure F-3.
- 7) During use, doctors can judge the intracuff pressure by the position of black line, and make

corresponding treatment. Green area is safe area, and when black line is located in this area, it means that the pressure is within safe range (40-60CMH<sub>2</sub>O), as shown in Figure (b).

- 8) When the black line moves away from the green area and move towards to the white line, it indicates that the pressure is low and the doctor needs to inflate air, as shown in Figure (a).
- 9) When the black mark moves away from the green area and move towards the red line, it indicates that the pressure is too high and the doctor needs to deflate, as shown in Figure (c) above.
- 10) After making sure that the thorax undulates well and the laryngeal mask does not leak air, apply lubricant to the outer wall of the tube, and then insert it into the airway of the laryngeal mask (pull out the machine end connector of the laryngeal mask before intubation), distribute the lubricant within the shaft by moving the tube up and down until it travels freely through the entire airway tube and gently move the tube until the depth of insertion beyond the 15 cm depth marker.
- 11) When the endotracheal tube is inserted into the proper depth, inflate the cuff with a syringe and connect the ventilation circle for trial ventilation.
- 12) After ventilation test, remove the connector and completely deflate the cuff of laryngeal mask. Hold the tube with one hand and make sure the tube is in place with the assistance of a stabilizing rod. And then completely withdraw the laryngeal mask from the mouth.

### ➤ Dual-Cuff Laryngeal Mask

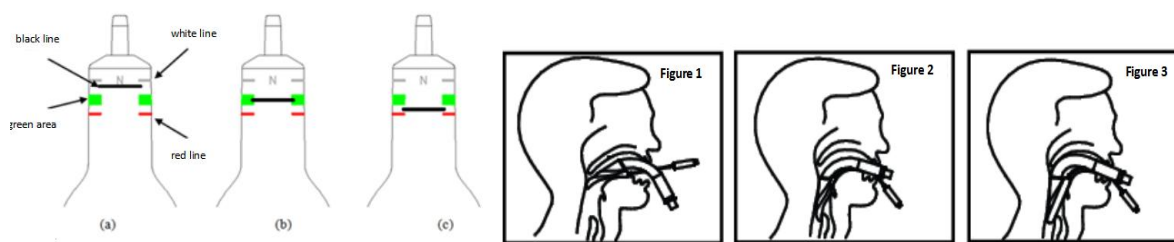


Figure G

- 1) Open the package. Before inserting the laryngeal tube, insert the syringe from the pressure indicator to completely deflate the large and small balloons, making the balloon walls adhere closely to each other, so that it can be easily inserted into the pharynx with a smaller volume.
- 2) Before insertion, apply water-soluble lubricant to the far tip and the rear part of the laryngeal tube. Be careful not to let the lubricant enter the ventilation port or the area near it.
- 3) Before insertion, the head should be in the sniffing position or the neutral position.
- 4) During the insertion of the laryngeal tube, lift the chin. During the process of inserting the laryngeal

---

tube into the mouth, the tongue should not fold backward. Do not use brute force.

- 5) When the large balloon passes through the front teeth, push the laryngeal tube along the base of the tongue towards the esophagus.
- 6) Insert the laryngeal tube until the upper teeth reach the depth mark.
- 7) Completely inflate the syringe.
- 8) Rotate 90 degrees forward and right to push the syringe to inflate the cuff. At the same time, observe the position of the black line on the pressure indicator. When the black line is located in the green area, stop inflation and pull out the syringe. At this time, the intracuff pressure should be in 40-60CM H<sub>2</sub>O. And the position of the laryngeal mask is shown in Figure G-3.
- 9) During use, doctors can judge the intracuff pressure by the position of black line, and make corresponding treatment. Green area is safe area, and when black line is located in this area, it means that the pressure is within safe range (40-60CM H<sub>2</sub>O), as shown in Figure G(b).
- 10) When the black line moves away from the green area and move towards to the white line, it indicates that the pressure is low and the doctor needs to inflate air, as shown in Figure G(a).
- 11) When the black mark moves away from the green area and move towards the red line, it indicates that the pressure is too high and the doctor needs to deflate, as shown in Figure G(c) above.
- 12) The drainage tube can be inserted into the drainage chamber of the laryngeal mask to aspirate gastric fluid and gas.
- 13) If the ventilation volume is insufficient, the following operations may be required:
  - a.If the drainage tube cannot be pushed down, it may be that the tip of the laryngeal mask is twisted at the incorrect position in the pyriform sinus. In this case, remove the laryngeal mask and reinsert it;
  - b.If it is inserted too deeply, pull out the laryngeal mask until normal ventilation is achieved;
  - c.If it is inserted too shallowly, remove the drainage tube, fully deflate the cuff, and then reinsert the laryngeal mask;
  - d.Check the pressure. The pressure should not exceed 60 cmH<sub>2</sub>O.
- 14) After several minutes of ventilation and suctioning, the cuff of the laryngeal mask deflates. Start the laryngoscopy using a video laryngoscope. The glottic structure can be seen.

## **The CLASSIFICATION of MR Marking**


















The laryngeal mask is divided into three types according to the MR environment-MR safe, MR unsafe and MR conditional.

MR Safe: The laryngeal mask is metal free.

MR Unsafe: The laryngeal mask has metal in it. There is a large reinforced metal (spring) in the Reinforced laryngeal mask which is used to improve the strength of the tube .

MR conditional: The laryngeal mask has metal in it. There is a small spring in the pilot balloon.

And the table of MR information is as follows:

Product	Model	MR information	Symbol
Laryngeal mask	100% Silicone Laryngeal mask, single use	safe	
	100% Silicone Laryngeal mask, with AccuCuff	safe	
	Reinforced Laryngeal Mask, single use	unsafe	
	Reinforced Laryngeal Mask, with AccuCuff	unsafe	
	FlexyCurve Laryngeal mask, Single use	unsafe	
	FlexyCurve Laryngeal mask, with AccuCuff	unsafe	
	Flowguard Flexy Laryngeal Mask, single use	unsafe	
	Flowguard Flexy Laryngeal Mask, with AccuCuff	unsafe	
	Laryngeal mask, Silicone/PVC, single use	safe	
	Laryngeal mask, Silicone/PVC, with AccuCuff	safe	
	Precurved Laryngeal Mask,single use	safe	
	Precurved Laryngeal Mask,with AccuCuff	safe	
	Flowguard Laryngeal Mask,single use	safe	
	Flowguard Laryngeal Mask, with AccuCuff	safe	
	WydeGlyde laryngeal Mask, single use	safe	
	WydeGlyde laryngeal Mask with AccuCuff	safe	
	Dual-Cuff Laryngeal Mask	safe	

## MANUFACTURE

### TIANJIN MEDIS MEDICAL DEVICE CO., LTD.

Add: No.15-A, Saida One Avenue, Xiqing Economic Development Area,  
300385 Tianjin, P.R. China

Tel: +86-22-83963862

Fax: +86-22-83988486

www.medis-medical.com



## **SHELF LIFE**

Five years

## **DURATION**

Less than 24 hours

## **STORAGE CONDITIONS**

Store product inside containers or outer boxes in a clean, dry area.

Storage should be within a temperature range of 10–30°C.

Do not expose to direct sunlight or UV light.

## **RADIATION AND ELECTROMAGNETIC INTERFERENCE**

The device emits neither radiation nor electromagnetic interference.

## **EUROPEAN AUTHORIZED REPRESENTATIVE**

**Shanghai International Holding Corp. GmbH (Europe)**

Add: Eiffestrasse 80, 20537 Hamburg ,Germany

Tel: +49-40-2513175

Fax:+49-40-255726



## **Made in China**

Release date:4/2/2021

Revision date:11/27/2025

## Editions

SN	Date	Description of Revision	Version	Editor	Approver
1	4/2/2021	Drafting	A/ 0	Ningning Wang	Yongzhi Wu
2	5/30/2023	1.provided all related drawing of each categories on updated; 2. Added the size selection rationale; 3.Update WARNING/PRECAUTIONS 2), 7), 12)	A/ 1	Fei Wang	Yongzhi Wu
3	1/05/2024	1. Supplement content according to the Guidance for MDR Technical Documentation Submissions: Annex A Add non-application statement Add description according the guidance 2.Update combination device	A/ 2	Fei Wang	Yongzhi Wu
4	7/18/2024	Update the warning for neonate and infant	A/ 3	Rui Li	Yongzhi Wu
5	1/9/2025	Add new product, update model name	A/4	Rui Li	Yongzhi Wu
6	10/16/2025	Reformatting, update Europe representative label.	A/5	Rui Li	Yongzhi Wu
7	11/27/2025	1. Update the model code from 'LMA' to 'LM' for the laryngeal mask. 2. Change classification of MR Marking	A/6	Yanan Ge	Yongzhi Wu