IFU

Laryngeal Masks

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

GENARAL INFORMATION

Unless otherwise stated, the reference to "device" stated on this IFU applies to both 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	LMA-PC	100% Silicone Laryngeal mask, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-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	LMA-JC	Reinforced Laryngeal Mask, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-JGC	Flowguard Flexy Laryngeal Mask, single use	1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-JPC	FlexyPlus Laryngeal mask, Single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-JA	Reinforced Laryngeal Mask, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-JGA	Flowguard Flexy Laryngeal Mask, with AccuCuff	1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-JPA	FlexyPlus Laryngeal mask, with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
Laryngeal mask, Silicone/PVC	LMA-SC	Laryngeal mask, Silicone/PVC, single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-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	LMA-GC	Flowguard Laryngeal Mask， single use	2.0#,3.0#,4.0#,5.0#
	LMA-GA	Flowguard Laryngeal Mask , with AccuCuff	2.0#,3.0#,4.0#,5.0#
WydeGlyde laryngeal Mask	LMA-WC	WydeGlyde laryngeal Mask, single use	3.0#,4.0#,5.0#
	LMA-WA	WydeGlyde laryngeal Mask with AccuCuff	3.0#,4.0#,5.0#
Precurved Laryngeal Mask	LMA-YC	Precurved Laryngeal Mask， single use	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#
	LMA-YA	Precurved Laryngeal Mask， with AccuCuff	1.0#,1.5#,2.0#,2.5#,3.0#,4.0#,5.0#,6.0#

INTENDED USE

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, children, teenager and adults.

INTENDED USERS

Professionally trained doctors, anesthesiologist and midwife.

INDICATIONS

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

CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do not use the laryngeal mask as a substitute for an laryngeal mask 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 laryngeal mask is also contraindicated in:

3 ） Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the airway forms a low‐pressure seal around the pharynx.

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 laryngeal mask use.

5）Patients who are not profoundly unconscious and who may resist device insertion.

6）Intubation through the Intubation type laryngeal mask is contraindicated in the presence of oesophageal or pharyngeal pathology.

7）Patients whose head needs to be turned to the side during the case.

8）Patients in the prone position

COMPLICATONS/ ADVERSE EFFECTS

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

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 tubegastric tube is inserted into the esophagus of the patient through the drainage cavity of the ariway tube to the stomach for gastric fluid suction.	YY/T0031-2008 Silicone tubes and elastomeric pars 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 an 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 dose 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 dose 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.

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.

WARNING/PRECAUTIONS

1) Sterile product. Sterilized by Ethylene Oxide.
2) This product is only for one time use by a single patient. It is strictly prohibited to use it repeatedly. Reuse can cause infection or cross-infection which will lead to fever, respiratory failure, coma, endanger the patients life in severe cases.
3) Do not use if the package is damaged or exceed the shelf life.
4) 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.
5) 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.
6) 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.
7) 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.
8) 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).

9) 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.

10) 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.

11) 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 (HCI).

12) The supralaryngeal airway should be reconfirmed after any change in the patient's head or neck position .

PRE-USE CHECKS:

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

b. 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.

c. Check the interior of the airway tube, if there is blockage or loose particles discard the device.

d. Filling the cuff to observe for leaks. It is strictly forbidden to use if there is air leakage.

e. Discard the device if the connector is loose.

f. If the color of airway tube changed, the visubility will be affected.

g. If the pre-use inspection fails, please do not use the product and return the product to the supplier for inspection.

SIZE SELECTION

1. 100% Silicone Laryngeal mask, single use

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 adults*	*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

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 adults*	*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. Laryngeal mask, Silicone/PVC, single use

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 adults*	*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*

4. 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 adults*	*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. 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 adults*	*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. 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 adults	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

7. 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 adults
Patient weight (KG)	10-20	30-50	50-70	70-100
Maximum Inflation Volume (ml)	10	20	30	40

8. 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 adults
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

9. FlexyPlus Laryngeal mask, Single use； FlexyPlus Laryngeal mask, with AccuCuff

Sizes	1#	1.5#	2#	2.5#	3#	4#	5#	6#
Intended patient population	Neonate	Infant	Child	Child	Teenager	Ordinary adult	Heavier adults	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

10. WydeGlyde laryngeal Mask, single use；WydeGlyde laryngeal Mask with AccuCuff

Sizes	3#	4#	5#
Intended patient population	Teenager	Ordinary adult	Heavier adults
Patient weight (KG)	30-50	50-70	70-100

Maximum Inflation Volume（ml）	*20*	*30*	*40*

11. Precurved Laryngeal Mask，single use；

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 adults*	*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*

12. 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 adults*	*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*

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； FlexyPlus Laryngeal mask；Laryngeal mask, Silicone/PVC and Precurved Laryngeal Mask**

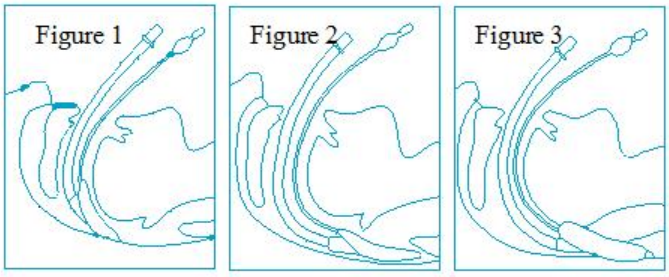


Figure A

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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 .

8) 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)

9) 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)

10) 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.

11) 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).

12) Make sure the airway is unobstructed.

13) Ensure that the device is stabilized to prevent unnecessary movement..

14) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.

15) 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.

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.

17) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by the hospital, also destroyed by the hospital.

➢ **Flowguard Laryngeal Mask and Flowguard Flexy Laryngeal Mask**

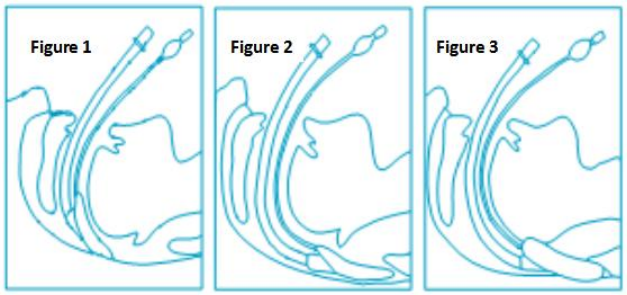


Figure-B

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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 B-2)

8) Completely inflate the syringe.

9) 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 B-3).

10) After making sure that the thorax undulates well and the laryngeal mask does not leak air, inject lubricant into the drainage tube. Insert a 14G gastric tube into the the drainage tube, and open the gastric tube after actively attracting the gastric tube.

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) 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.

15) 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.

16) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by the hospital, also destroyed by the hospital.

➢ **WydeGlyde laryngeal Mask**

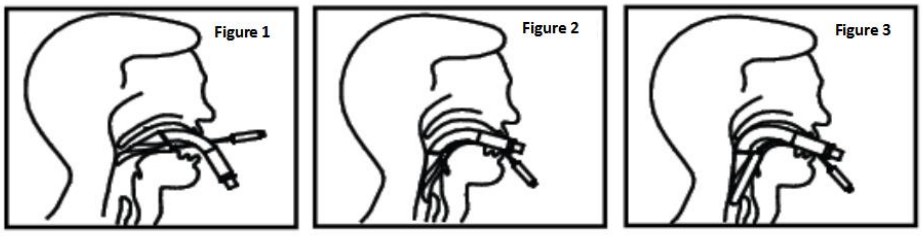


Figure C

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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 C-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.

8) Completely inflate the syringe.

9) 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).

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 (5 # 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.

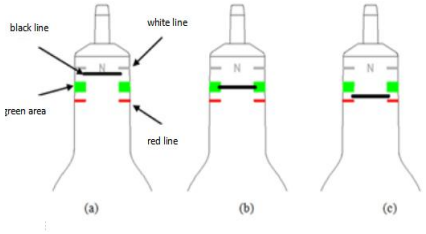
11) When the cannula is inserted into the proper depth, inflate the cuff with a syringe and connect the ventilation loop for trial ventilation.

12) After ventilation test, remove the connector and completely deflate the cuff. 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.

13) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by

the hospital, also destroyed by the hospital.

- **100% Silicone Laryngeal mask,with AccuCuff; Reinforced Laryngeal Mask, with AccuCuff; FlexyPlus Laryngeal mask, with AccuCuff; Laryngeal mask, Silicone/PVC, with AccuCuff ; Precurved Laryngeal Mask，with AccuCuff**



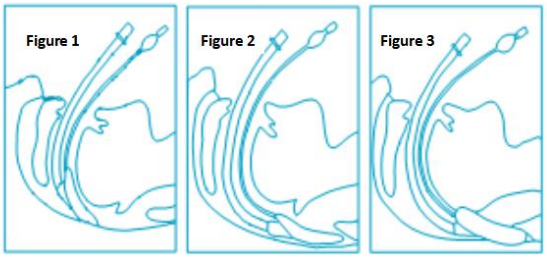


Figure D

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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 .

8) 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 D-1)

9) 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 D-2)

10) 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.

11) Completely inflate the syringe.

12) 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 40-60CMH2O. And the position of the laryngeal mask is shown in Figure D-3.

13) 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 (40-60CMH2O), as shown in Figure P(b).

14) 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 P(a).

15) 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 FigureP(c) above.

16) Make sure the airway is unobstructed.

17) Ensure that the device is stabilized to prevent unnecessary movement.. Connect the breathing device to the machine end connector of the laryngeal mask and start using it.

18) 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.

19) 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.

20) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by the hospital, also destroyed by the hospital.

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

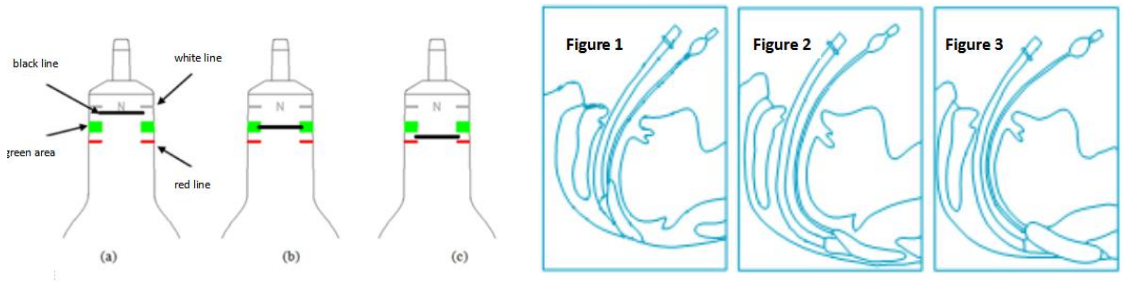


Figure E

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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 ariway 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 E-2)

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 in 40-60CMH2O. And the position of the laryngeal mask is shown in Figure E-3.

10) After making sure that the thorax undulates well and the laryngeal mask does not leak air, inject lubricant into the drainage tube. Insert a 14G gastric tube into the the drainage tube, and open the

gastric tube after actively attracting the gastric tube.

11) 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 (40-60CMH2O), as shown in Figure E(b).

12) 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 E(a).

13) 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 E (c) above.

14) Make sure the airway is unobstructed.

15) Ensure that the device is stabilized to prevent unnecessary movement..

16) Connect the breathing device to the machine end connector of the laryngeal mask and start using it.

17) 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.

18) 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.

19) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by the hospital, also destroyed by the hospital.

➢ **WydeGlyde laryngeal Mask with AccuCuff**

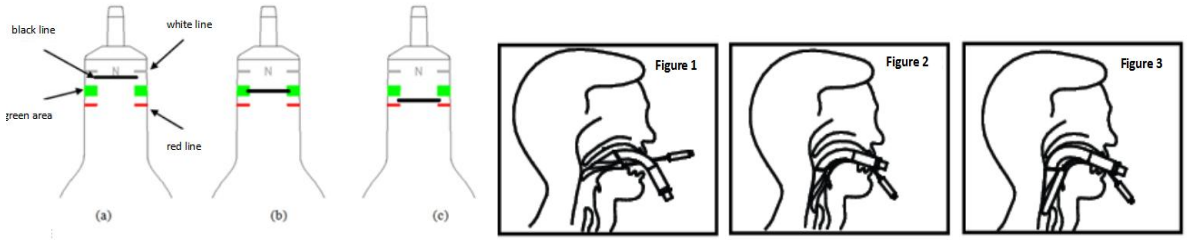


Figure F

1) The product should be handled by a trained doctor or clinical nurse.

2) Disposable medical gloves should be worn during the insertion process, and the gloves should be discarded after insertion to prevent cross-infection.

3) Before use, a doctor or nurse should inspect the package for any damage, then open the package and

take out the device to ensure there is no cut, indentations or leakage. Do not use if the package or product has been damaged.

4) 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.

5) Distribute the water-soluble lubricant on the back of the laryngeal mask prior to insertion.

6) 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.

7) 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.

8) Completely inflate the syringe. Insert the head of the pressure indicator by rotating 90 degrees forward and right.

9) 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 40-60CMH2O. And the position of the laryngeal mask is shown in Figure F-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 (40-60CMH2O), as shown in Figure F(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 F(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 F(c) above.

13) 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 (5 # 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.

14) When the tube is inserted into the proper depth, inflate the cuff with a syringe and connect the ventilation loop for trial ventilation.

15) After ventilation test, remove the connector and completely deflate the cuff. 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.

16) This product is a disposable product. After use, cut off the cuff and the inflating tube to make them completely scrapped and unable to be reused. Put into the disposable product waste designated by the hospital, also destroyed by the hospital.

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	conditional	
	100% Silicone Laryngeal mask, with AccuCuff	safe	
	Reinforced Laryngeal Mask, single use	unsafe	
	Reinforced Laryngeal Mask, with AccuCuff	unsafe	
	FlexyPlus Laryngeal mask, Single use	unsafe	
	FlexyPlus 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	conditional	
	Laryngeal mask, Silicone/PVC, with AccuCuff	safe	
	Precurved Laryngeal Mask，single use	conditional	
	Precurved Laryngeal Mask，with AccuCuff	safe	
	Flowguard Laryngeal Mask，single use	conditional	

	Flowguard Laryngeal Mask , with AccuCuff	safe	MR
	WydeGlyde laryngeal Mask, single use	conditional	MR
	WydeGlyde laryngeal Mask with AccuCuff	safe	MR

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 10–30^0 C.

Do not expose to direct sunlight or UV light.

RADIATION AND ELECTROMAGNETIC INTERFERENCE

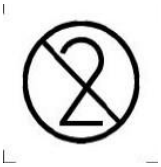
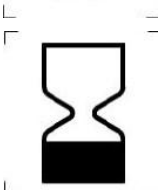
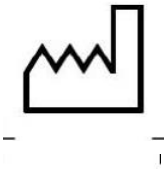
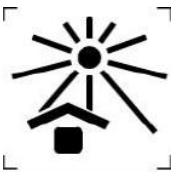
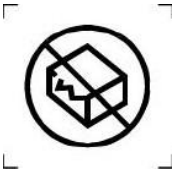
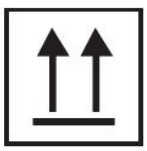
The device emits neither radiation nor electromagnetic interference.

Made in China

Release date:4/2/2021

Revision date:1/05/2024

MEANING OF SYMBOLS ON PACKAGE

	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

MR Safe

MR unsafe

MR Conditional

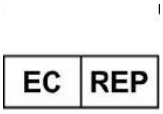
TIANJIN MEDIS MEDICAL DEVICE CO., LTD.

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



Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg ,Germany

Tel: +49-40-2513175

Fax:+49-40-255726