INTERSURGICAL®

IFU

Laryngeal Masks

GENARAL 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

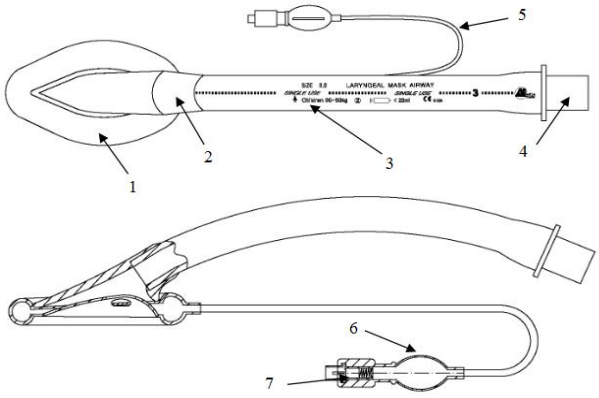
ISG Product Number	Standard Silicone	Size (ID)
8001004	Solus™ Silicone, laryngeal mask airway, size 1, neonate, <5kg	1.0#
8015004	Solus™ Silicone, laryngeal mask airway, size 1.5, infant, 5-10kg	1.5#
8002004	Solus™ Silicone, laryngeal mask airway, size 2, small pediatric, 10-20kg	2.0#
8025004	Solus™ Silicone, laryngeal mask airway, size 2.5, large pediatric, 20-30kg	2.5#
8003004	Solus™ Silicone, laryngeal mask airway, size 3, small adult, 30-50kg	3.0#
8004004	Solus™ Silicone, laryngeal mask airway, size 4, medium adult, 50-70kg	4.0#
8005004	Solus™ Silicone, laryngeal mask airway, size 5, large adult, 70+kg	5.0#
8006004	Solus™ Silicone, laryngeal mask airway, size 6, overweight adult, >100kg	6.0#
ISG Product Number	**Standard Silicone, AccuCuff**	**Size (ID)**
8001005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 1, neonate, <5kg	1.0#

8015005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 1.5, infant, 5-10kg	1.5#
8002005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 2, small pediatric, 10-20kg	2.0#
8025005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 2.5, large pediatric, 20-30kg	2.5#
8003005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 3, small adult, 30-50kg	3.0#
8004005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 4, medium adult, 50-70kg	4.0#
8005005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 5, large adult, 70-100kg	5.0#
8006005	Solus™ Silicone, laryngeal mask airway with AccuCuff, size 6, overweight adult, >100kg	6.0#
ISG Product Number	**Standard Silicone, AccuCuff**	**Size (ID)**
8001006	Solus Flexible, laryngeal mask airway, size 1, neonate, <5kg	1.0#
8015006	Solus™ Flexible, laryngeal mask airway, size 1.5, infant, 5-10kg	1.5#
8002006	Solus™ Flexible, laryngeal mask airway, size 2, small pediatric, 10-20kg	2.0#
8025006	Solus™ Flexible, laryngeal mask airway, size 2.5, large pediatric, 20-30kg	2.5#
8003006	Solus™ Flexible, laryngeal mask airway, size 3, small adult, 30-50kg	3.0#
8004006	Solus™ Flexible, laryngeal mask airway, size 4, medium adult, 50-70kg	4.0#
8005006	Solus™ Flexible, laryngeal mask airway, size 5, large adult, 70+kg	5.0#
8006006	Solus™ Flexible, laryngeal mask airway, size 6, overweight adult, 100+kg	6.0#
ISG Product Number	**Flexible Silicone, AccuCuff**	**Size (ID)**
8001007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 1, neonate, <5kg	1.0#
8015007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 1.5, infant, 5-10kg	1.5#

8002007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 2, small pediatric, 10-20kg	2.0#
8025007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 2.5, large pediatric, 20-30kg	2.5#
8003007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 3.0, small adult, 30-50kg	3.0#
8004007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 4, medium adult, 50-70kg	4.0#
8005007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 5, large adult, 70-100kg	5.0#
8006007	Solus™ Flexible, laryngeal mask airway with AccuCuff, size 6, overweight adult, 100+kg	6.0#

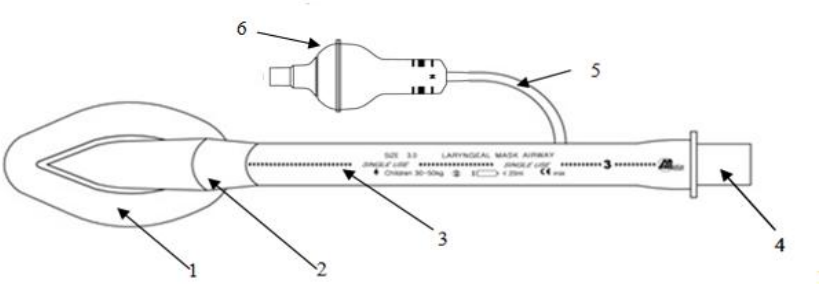
STRUCTURE

The structure composition of the laryngeal mask is as follows:



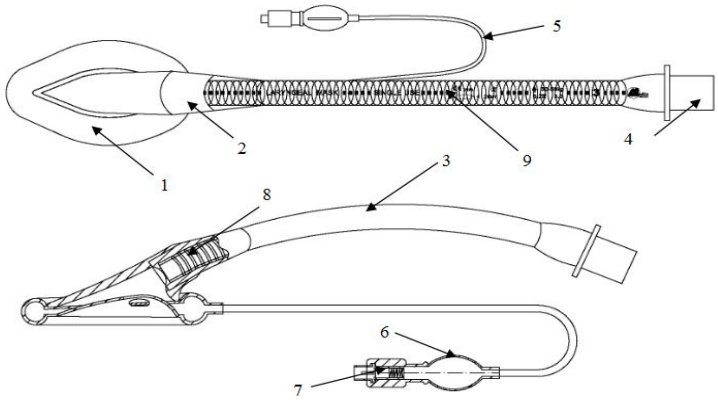
1 cuff, 2 linker piece, 3 airway tube, 4 machine-end connector, 5 inflating tube, 6 pilot balloon, 7 one-way valve

Figure 1 100% Silicone Laryngeal mask, single use



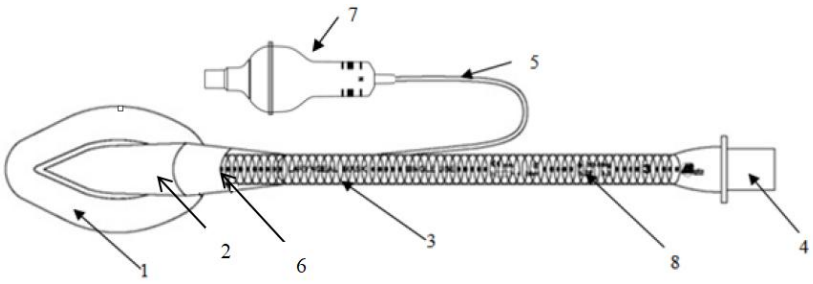
1 cuff, 2 linker piece, 3 airway tube, 4 machine-end connector, 5 inflating tube, 6 pressure indicator

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

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	Neonate	Infant	Child	Child	Teenager	Ordinary	Heavier	Overweight

population						adult	adult	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

INTENDED USE

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.

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 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.

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 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 (HCI).

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 visubility 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；**

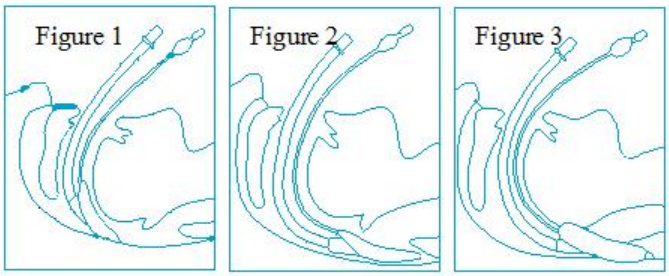


Figure A

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;**

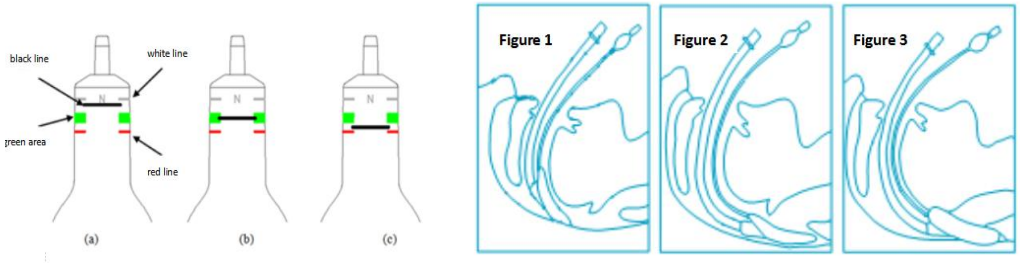


Figure B

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 in 40-60CM H_2O. 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_2O), 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.

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	

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 10–30ºC.

Do not expose to direct sunlight or UV light.

RADIATION AND ELECTROMAGNETIC INTERFERENCE

The device emits neither radiation nor electromagnetic interference.

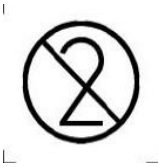
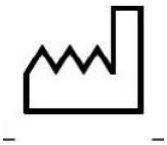
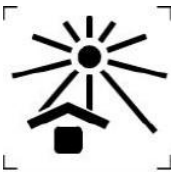
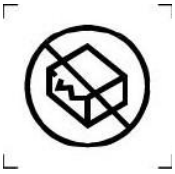
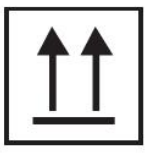
Made in China

Release date:4/2/2021

Revision date:1/9/2025

INTERSURGICAL®

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

Temperature limit

MR Safe

MR unsafe

MR Conditional

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