SAMPLE FOR REFERENCE

Instruction for Use

CE 2862

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1. Introduction

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1.1 Device Name:

Disposable Laryngeal Mask Airway

1.2 Description

The Disposable Laryngeal Mask Airway is a tubular oropharyngeal airway, to the distal end of which is attached a mask with an inflatable peripheral cuff. It is designed to provide an airtight seal around the laryngeal inlet and so support a secure airway suitable for spont aneous or controlled ventilation during general anaesthesia. It can be inserted without laryngoscope in most cases and a muscle relaxant is seldom required. Once in place, it provides a more secure airway control than a facemask.A sterile range of single-use airway masks manufactured from medical grade silicone to reduces risk of cross infection and cleaning/sterilization costs.And the clear black line on tube to ensure correct orientation of the mask.

1.3 Models

This Instruction for Use apply to the following models:

Model	Reference No.
Disposable Laryngeal Mask Airway-Classic	98.01.001； 98.01.005； 98.01.009； 98.01.013； 98.01.017；98.01.021；98.01.025；98.01.029
Disposable Laryngeal Mask Airway-Classic with Aperture Bars	98.01.031； 98.01.035； 98.01.039； 98.01.043； 98.01.047；98.01.051；98.01.055；98.01.059
Disposable Laryngeal Mask Airway-Reinforced	98.01.201； 98.01.205； 98.01.209； 98.01.213； 98.01.217；98.01.221；98.01.225；98.01.229
Disposable Laryngeal Mask Airway-Reinforced with Aperture Bars	98.01.231； 98.01.235； 98.01.239； 98.01.243； 98.01.247；98.01.251；98.01.255；98.01.259

1.4 Basic UDI-DI

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2. Intended Use

The disposable laryngeal mask airway is a supraglottic airway device,inserted into the patient’s epiglottis, to establish short-term artificial airway during routine and emergency anesthetic procedures or cardiopulmonary resuscitation.

3. Indications

3.1 The disposable laryngeal mask airway may be used as an alternative to the face mask for achieving and maintaining control of the airway during routine and emergency anesthetic procedure.

3.2 Indicated for securing the immediate airway in known or apparent difficult airway

management.It may also be used to secure an immediate airway when tracheal intubation is precluded by lack of available expertise or equipment, or when attempts at tracheal intubation have failed.

3.3 Used to establish an immediate, clear airway during cardiopulmonary resuscitation (CPR) in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes requiring artificial ventilation. It may also be used to secure an immediate airway when tracheal intubation is precluded by lack of available expertise or equipment, or when attempts at tracheal intubation have failed.

4. Intended patient population

The intended patient population ranges from neonates to adults who temporary need to maintain an open airway during the administration of anesthesia or an immediate life-saving measure with a difficult or failed airway.

5. Intended user

The disposable laryngeal mask airway shall only be used by medical professionals trained in airway management.

6. Expected clinical benefits

To maintain an open airway during the administration of anesthesia or an immediate life-saving measure with a difficult or failed airway.
Insertion success rate 90%~100%
Optimum ventilation rate 79%~100%

7. Performance characteristics

The connector at machine end of airway tube shall be a male 15 mm conical connector complying with ISO 5356-1.
The opening at the patient end shall have a plane at 90° ±5° to the long axis of the patient end of the connector.
The free end of the check valve shall be capable of accepting a male conical fitting with a 6 % (Luer) taper, complying with ISO 80369-7.
The cuff,and inflation system should be well sealed, and should be able to withstand 30Kpa air pressure for 15s without air leakage.
The connecting between the connector and airway tube, the inflation tube and the cuff,airway tube and the cuff should be able to withstand 15N axial static tension for 15 seconds without falling off, separating or breaking.

8. Residual risks

Failure to strictly enforce the instructions may result：

The patient had nausea and vomiting，

Sore throat

Airway injury

Airway spasm

Hoarse

9. Particular user qualifications

The disposable laryngeal mask airway shall only be used by medical professionals trained in airway management.

10. Risks of reusing single use devices

This product is a disposable product,reprocessing, resterilization and/or reuse of this product is prohibited, reuse may cause infection or fail to reach the intended use.

11. Contraindication

11.1 Patients with high lung inflation pressures.
11.2 Patients who have not fasted, including patients whose fasting cannot be confirmed.
11.3 Patients with severe facial trauma.
11.4 Patients with inadequate mouth opening to permit insertion.
11.5 Patients with oropharyngeal pathology or abnormal anatomy.
11.6 Patients who have had radiotherapy to the neck involving the hypopharynx.
11.7 Patients representing for emergency surgery who are at risk of massive reflex, such as acute intestinal obstruction or patients having been injured shortly after ingesting a substantial meal.
11.8 Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the airway forms a low - pressure seal around the pharynx.
11.9 Patients who is prolonged bag-valve-mask ventilation, morbid obesity, second or third trimester pregnancy, upper gastrointestinal bleeding maybe increased risk of aspiration.

12. Adverse Events

There is currently no data documenting significant adverse effects.Some instances of minor adverse effects (eg. sore throat) following use of the disposable laryngeal mask airway have been reported in the published literature.

13. Caution

The user should be familiar with the following cautions when considering or attempting laryngeal mask airway use:

13.1 The Disposable laryngeal mask airway should only be used in patients, who have been clinically evaluated by medical professionals trained in airway management, as eligible for a laryngeal mask or in a situation where other attempts to establish and airway have failed.
13.2 Surgical gloves should be worn during preparation and insertion to minimize contamination of the airway.
13.3 To avoid trauma, excessive force should not be used at any time during insertion of this device.
13.4 The security of all anaesthetic breathing system connectors should be checked when the breathing circuit is established and frequently thereafter. Devices used in or during inflation of the cuff must be clean and free from all foreign matter. The inflation device must be removed from the inflation valve immediately after use.
13.5 If airway problems persist or ventilation is inadequate, this device should be removed and an airway established by some other means.

13.6 Always check for proper placement of device once the patient's head or neck position changed.

13.7 An incorrectly placed mask may result in an unreliable or obstructed airway. Always check for proper placement after insertion.

13.8 Laryngeal spasm may occur if the patient becomes too lightly anesthetized during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anesthesia. If laryngeal spasm occurs, treat the cause. Only remove the device when airway protective reflexes are fully competent.

13.9The device used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.

13.10The bite block should be used to protect the airway of device during operation.

14. **Warning**

14.1 The laryngeal mask airway is for SINGLE USE ONLY and has to be disposed after use.Used device shall follow a handling and elimination process for bio‐hazard products, in accordance with all local and national regulations.

14.2 Reprocessing, resterilization and/or reuse of this product is prohibited.

14.3 Do not use this device if the device is damaged or the unit packaging is damaged or opened.

14.4 When applying lubricant, avoid blockage of the airway aperture.A water-soluble lubricant should be used. Do not use silicone-based lubricants as they degrade device components. Lubricants containing Lidocaine are not recommended for use. Lidocaine can delay the return of the patient’ s protective reflexes after removal of the device; may possibly provoke an allergic reaction, or may affect the surrounding organs, including the vocal cords.

14.5 Do not insert the device unless the cuff is fully deflated.Ensure all removable denture work is removed before inserting the device.

14.6 Do not exceed the maximum recommended inflation air volumes.

14.7 Nitrous oxide diffuses into the cuff causing a rise in pressure. Diffusion rate and resulting peak pressure may vary with the initial volume of air injected into the cuff, the type of gases used to inflate the cuff, and the percentage of nitrous oxide in the inhaled mixture.

14.8 Laryngeal mask airway are potentially flammable in the presence of lasers and electrical cautery.

14.9 Furthermore, failure to read and thoroughly understand the contents of this instruction manual may result in serious injury to the patient and/or user. It is essential to follow the instructions, as well as instructions found in other instruction manuals, infection control requirements and current hospital protocols for usage, cleaning and sterilization.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.

15. Principles Of Operation

The Disposable laryngeal mask provided eight different sizes for patients of different weight. See table below for selection guidelines and max inflation volumes. Please note that the cuff inflation volumes shown in below table are maximum volumes. Applying the stated maximum inflation volume may respond to a cuff pressure above the maximum of 60 cm H_2O. It is recommended to continuously monitor the cuff pressure.

	Mask size							
Size	#1	#1.5	#2	#2.5	#3	#4	#5	#6
Patient weight	3.5-5 kg	5-10 kg	10-20 kg	20-30 kg	30-50 kg	50-70 kg	70-100 kg	>100 kg
Min,inter dental gape	20mm	22mm	25mm	30mm	32mm	35mm	38mm	40mm
Max cuff inflation volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml	50 ml
Maximum cuff pressure	60 cm H2O							

15.1 Open the package, take the laryngeal mask airway out of the packaging and be careful not to contaminate.

15.2 Examine the surface of this device for damage, including cuts, tears, scratches or kinks.

15.3 Examine the interior of the airway tube to ensure it is free from blockages or loose particles. Any particles present in the channels should be removed. Do not use the airway if a blockage or particle cannot be removed.

15.4 Over-inflate the cuff to the appropriate volume. Check that the inflated cuff is symmetrical and smooth. There should not be any bulge nor any sign of leakage in the cuff, inflation tube or pilot balloon.

15.5 Deflate the cuff completely with syringe.Lubricate the posterior surface of the mask with water-soluble lubricant just prior to insertion.

15.6 Stand behind or beside the patient's head. Place the head in the neutral, or slight "sniffing" position (sniffing position = extension of the head and flexion of the neck).

15.7 Hold the device at the junction of the cuff and tube,With the head extended and neck flexed, carefully flatten the Laryngeal Mask Airway tip against the hard palate.

15.8 Use the index finger to push carefully keeping pressure on the tube and advance the mask until definite resistance is felt at the base of the hypo-pharynx.

15.9 Without holding the tube, using a syringe inflate the cuff with enough air to obtain a proper seal. Do not over-inflate the cuff.

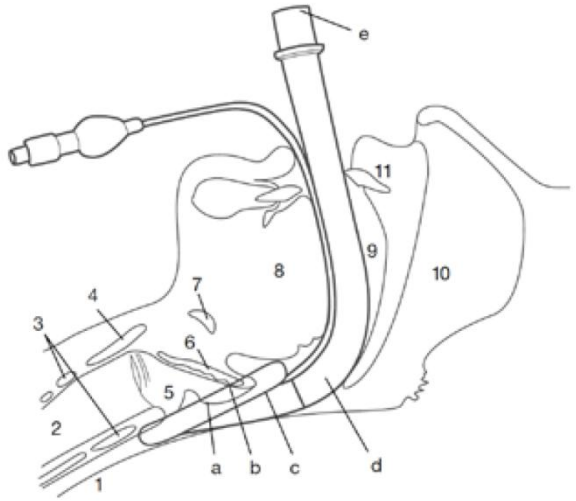
15.10 Carefully connect the device to the anaesthetic circuit or ventilation bag and initiate gentle manual ventilation, looking for any signs of leakage.

15.11 If deemed necessary, secure the patient's face with adhesive tape or with a mechanical tube holder suited for this purpose.

15.12 On completion of surgery the laryngeal mask should be removed only after the patient's protective reflexes have returned and the patient responds to verbal commands.Patient monitoring should continue throughout the recovery stage.Removal should always be carried out in an area where suction equipment and the facility for rapid tracheal intubation are available.

15.13 Use a syringe to deflate the cuff,the mask may be removed with moderately inflated cuff to aid removal of secretions. Do not fully deflate the cuff until after its removal to avoid secretions entering into the larynx and to prevent laryngospasm.

15.14 Correct Position of the device on anatomical landmarks.



Mark	Name
1	Esophagus
2	Trachea
3	Cricoid cartilage
4	Thyroid cartilage
5	Laryngeal inlet
6	Epiglottis
7	Hyoid bone
8	Tongue

Mark	Name
9	Buccal cavity
10	Nasopharynx
11	Incisors
a	Patient end
b	Ventilatory opening
c	Sealing mechanism
d	Ventilatory pathway
e	External end connector

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16. Storage

Please store the device in a dark cool,keep the temperature between 0 ℃ to 40 ℃ and a relative humidity of no more than 80% environment, avoiding direct exposure to sunlight and chemical fume.

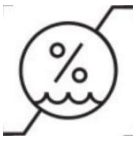
17. Sterilization

EO sterilization

18. Shelf Life

3 Years.

19. Explanation Of Symbols Used On Labels And Instructions For Use

	Consult accompanying documents		Authorized representative in the European Community
	Do not use if package is damaged		Batch code
	Do not resterilize		Date of manufacture
	Do not re-use		Manufacturer
	Sterilized using ethylene oxide		Catalogue number
	Use-by date		Patient weight
	Keep dry		Humidity limit
	Keep away from sunlight		Temperature limit

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CE 2862	CE marking of conformity, and Notified Body Code		Single sterile barrier system

Hangzhou Trifanz Medical Device Co., Ltd.
Add：Room 501-1, Building 36, No. 488-1
Donghu North Road, Linping District,
Hangzhou City, Zhejiang Province,
China.
Tel：+86-571-88553769
Fax: +86-571-85859315
www trifanz com

EC REP **MedPath GmbH**
Add：Mies-van-der-Rohe-Strasse 8,
80807 Munich, Germany.
Tel:+49(0)89 189174474
Fax: +49(0)89 5485 8884

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