GIMA
PROFESSIONAL MEDICAL PRODUCTS

MASCHERA LARINGEA
LARYNGEAL AIRWAY MASK

Manuale d'uso - User manual

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

REF

LA-77215 (GIMA 34424)
LA-77220 (GIMA 34425)
LA-77225 (GIMA 34426)
LA-77230 (GIMA 34427)
LA-77240 (GIMA 34428)
LA-77250 (GIMA 34429)

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M34424-M-Rev.7-09.25

1. Intended Use

• The Laryngeal airway is an oropharyngeal airway, it is a device inserted into a patient's pharynx through the mouth to provide a patient airway.

• Besmed Laryngeal Airway is indicated for use as an alternative to the facemask for achieving and marinating control of the airway during routine and emergency anesthetic procedures. It is not indicated for use as a replacement for the end tracheal tube and is best suited for use in elective surgical procedures where tracheal intubations are not necessary.

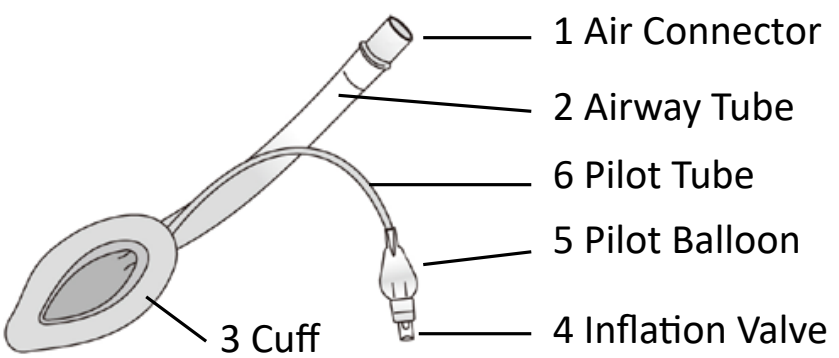
• The airway is also indicated in known or unexpected difficult airway situation. It is also indicated as a method of establishing a clear airway during resuscitation in the profoundly unconscious patient with absent gloss pharyngeal and laryngeal reflexes who may need artificial ventilation. In these cases, the airway should be used only when tracheal intubation is not possible.

2. Specification

Description	Neonate	Infant		Child		Adult	
Size	#1	#1,5	#2,0	#2,5	#3,0	#4,0	#5,0
Patient group weight	< 5Kg	5-10Kg	10-20Kg	20-30Kg	30-50Kg	50-70Kg	> 70Kg
Cuff Inflation	< 10 ml	10 ml		14 ml	20 ml	30 ml	
Maximum Cuff pressure	60 cmH_2O						

Table 1: Selection guildlines for Besmed Laryngeal Airway.

2.1 Name of product parts



3. PREPARATION FOR USE

3.1 Cleaning and sterilization

Cleaning and sterilization as described below must be carried out for each subsequent use.

The Besmed Laryngeal Airway can be used a maximum of 40 times by attending the recommended cleaning, sterilization and handling procedures. Proper cleaning and sterilization of the device is essential to ensure continued safe usage up to 40 times.

Besmed has validated the instructions provided below as being capable of preparing a Besmed Laryngeal Airway for re-use. It remains the responsibility of the processor to ensure that processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

CAUTION
Handle the Besmed Laryngeal Airway carefully as it is made of silicone, which can be torn or punctured. Avoid contact with sharp or pointed objects

WARNING
Do not replace or disassembly any Components of the Besmed Laryngeal Airway as it may cause product failures

3.1.1 Cleaning instruction

It is recommended to follow the described validated manual cleaning procedure to ensure proper cleaning.

CAUTION
Do not expose the inflation valve to any liquid as it may cause premature inflation valve failure

The Besmed Laryngeal Airway should be kept moist between the time of use and subsequent cleaning. Remove excess soil with disposable cloth/paper wipe. Thoroughly rinse the Besmed Laryngeal Airway in cold running water to avoid protein coagulation.

Wash the device thoroughly in water using a mild detergent until all adherent visible soil is removed. It is recommended to wash the Besmed Laryngeal Airway with Endozime manufactured by Ruhof. The working solution should be prepared by using 35 ml Endozime per 4 liter warm water (one ounce of Endozime to 1 gallon of warm water).

CAUTION
All detergents should be used in the recommended dilution/concentration, temperature, water quality (e.g., ph, hardness), and exposure (soak or contact) time, in accordance with the detergent manufacturer's directions

WARNING
Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde, ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize the Besmed Laryngeal Airway. The material absorbs such substances, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use a Besmed Laryngeal Airway that has been exposed to any of these substances.

To ensure proper cleaning of the airway tube it is recommended to use a soft bristle brush. Brushes should have a tight fit, but be able to move back and forth in the area being cleaned. Never use hard brushes or other materials, which might damage the silicone cuff or surface.

Remove all cleaning residues by thoroughly rinsing the cuff and airway tube in running tap water for 1 minute. Make sure that the water passes through the tube. Closely examine the Besmed Laryngeal Airway to ensure that all visible foreign matter has been removed. Repeat the above procedure as necessary.

CAUTION
Effective cleaning must be carried out to achieve proper sterilization.

3.1.2. Sterilization instruction

The only recommended sterilization method is steam autoclaving. Strictly adhere to the following validated instructions to ensure sterilization and to prevent damage.

Immediately prior to steam autoclaving, deflate the cuff completely.

Ensure that the valve and syringe used to deflate the cuff are dry.

Caution: Any air moisture left in the cuff will expand during autoclaving process and will cause irreparable damage to the cuff and /or pilot balloon.

If a deflated mask immediately and spontaneously reinflates (even slightly),do not autoclave or reuse this mask. This may indicate the leak or valve malfunctioning.

The Besmed Laryngeal Airway should be placed in an appropriate steam autoclave-proof bag before steam autoclaving. Ensure that the pack is large enough to contain the device

without stressing the seals. It is recommended to use the following sterilization cycle according to AAMI TIR 12:2004

Item	Exposure time At 135°C (275°F)	Drying time
Wrapped utensils	10 min	30 min

Table 2. Parameters for gravity-displacement steam sterilization cycles

The record card should be completed each time the Besmed Laryngeal Airway is sterilized.

After sterilization the Besmed Laryngeal Airway should be stored in accordance with accepted hospital practice. The Besmed Laryngeal Airway should not be exposed to direct sunlight or elevated temperatures during storage. Store in unopened bags at temperature between -20°C/-4°F and 60°C/140°F

3.2. Functional testing

Functional testing as described below must be carried out before using the device. The tests should be conducted in a manner consistent with accepted medical practice that minimizes contamination of the Besmed Laryngeal Airway prior to insertion.

WARNING
Do not use and destroy the device if any one test fails.
Dispose of the Besmed Laryngeal Airway in a safe manner according to local guidelines of medical waste.

CAUTION
Always wear gloves during the preparation and insertion of the Besmed Laryngeal Airway to minimize contamination.

3.2.1 Test-1-Visual inspection

Closely examine the surface of the Besmed Laryngeal Airway for any damage, perforation scratches, etc. Do not use the Besmed Laryngeal Airway if it is damaged in any way.

Check that the interior of the tube and cuff are free from blockage and any loose parts. Parts and blockages should be removed as these may prevent the device from functioning properly. Do not use the Besmed Laryngeal Airway if any of loose parts or blockages cannot be removed.

Check that the airway connector on the Besmed Laryngeal Airway is fitted tightly to the airway tube. Ensure that it cannot easily be pulled off. Do not twist the connectors as this

may break the seal. Closely examine the pilot balloon for any damages.

WARNING
Do not use the Besmed Laryngeal Airway if the mask connector does not fit tightly into the outer end of the airway tube.

3.2.2. Test 2-Inflation/deflation test

Deflate the cuff of the Besmed Laryngeal Airway completely. Once deflated, check the cuff thoroughly for any wrinkles or folds.

Over-inflate the cuff to the appropriate volume as specified in Table 3. Check that the inflated cuff is symmetrical and smooth. There should not be any bulge nor any sign of leakage in the cuff, pilot tubing or balloon.

WARNING
Do not use the Besmed Laryngeal Airway if there are any bulges on the cuff or if there are any signs of leakage.

	Mask Size						
Size	#1	#1,5	#2,0	#2,5	#3,0	#4,0	#5,0
Over-inflation cuff volumes	6ml	10ml	15ml	21ml	30ml	45ml	60ml

CAUTION: The inflation volumes specified in Table 3 are for testing purposes only. These volumes are not to be used during normal use of the device- the recommended standard inflation volumes can be found in Table 1.

Table 3. Over-inflation volumes for the Besmed Laryngeal Airway.

4. INSERTION

4.1. Pre-insertion preparation:

Before insertion of the Besmed Laryngeal Airway, the cuff should be completely deflated so that the cuff is flat and free of wrinkles. Simply press the cuff down onto a flat sterile surface (e.g. a piece of sterile gauze) while at the same time deflating the device with a syringe. Complete deflation results in a shape like the rim of a saucer, and facilitates insertion and correct positioning of the device.

To further facilitate insertion into the patient, a sterile, water-based lubricant (e.g. K-Y Jelly®) should be applied to the distal posterior surface of the cuff (local anesthesia is not recommended.)

WARNING
Lubricate only the posterior tip of the cuff to prevent blockage of the airway aperture or aspiration of the lubricant.

4.2. Insertion

Before insertion, it is essential that all clinicians using the Besmed Laryngeal Airway are familiar with the warnings, precautions and indications, found in these directions for use.

The following points are extremely important

- Check for correct deflation andlubrication as described above.
- The size of the Besmed Laryngeal Airway must fit the patient. Use the guidelines in Table 1 combined with clinical judgement to select the correct size.
- Always have a spare Besmed Laryngeal Airway ready for use.
- Pre-oxygenate and use standard ready for use.
- Check that the level of anesthesia (or unconsciousness) is adequate before attempting insertion.
- The head of the patient should be extended with flexion of the neck in a position normally used for tracheal intubation (i.e. “the sniffing position”)
- Never use excessive force.

4.3. Inflation

After insertion, the line on the airway tube should be oriented anteriorly toward the patient's nose. Without holding the tube, inflate the cuff with just enough air to obtain a seal, equivalent to intracuff pressures of approximately 60cmH20. In many cases, only half of the maximum volume is sufficient to achieve a seal-please refer table 1 for maximum volume.

Check the cuff pressure at start and periodically, either with a cuff pressure gauge or by feeling the tension in the pilot ballon. This is especially important when N2O gases are used.

Never over-inflate the cuff. Avoid prolonged intracuff pressures greater than 60cmH2O. The initial cuff pressure varies according to patient, mask size, head position, and depth of anesthesia. Do not hold the tubing during inflation as this prevents the mask from seating itself correctly. A small outward movement of the tube is often seen as the mask settles into the hypopharynx.

To avoid overinflation, it is very important to strictly adhere to the cuff inflation volumes stated in table 1. Over-inflation can be entirely avoided by completely deflating the cuff

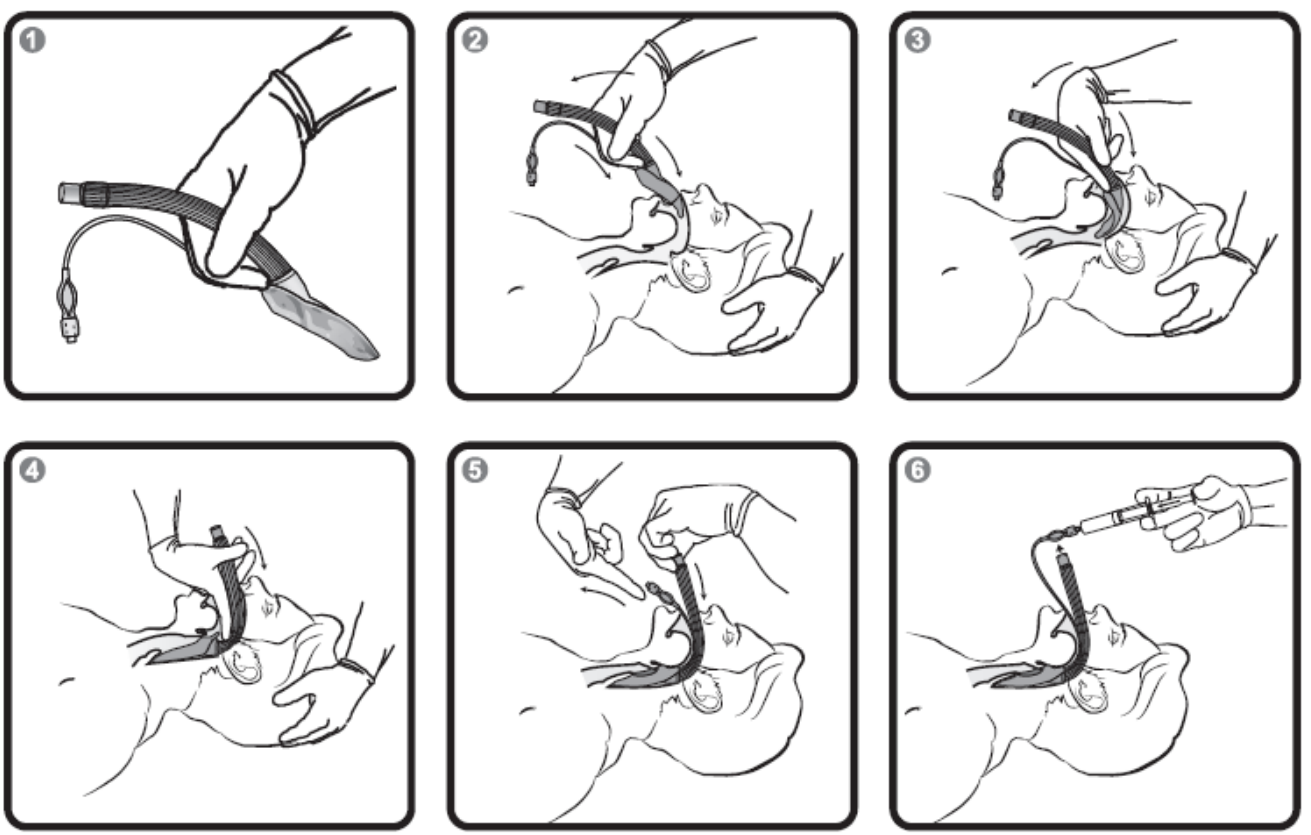
prior to insertion by withdrawing all of the air with a suitable syringe. This is the method recommended by Besmed.

In instances where an alternative technique is adopted, for example if the cuff is inserted in a neutral or semi-inflated state, there is a risk that the cuff may be over-inflated. Extra care therefore has to be taken after insertion to compensate for the air already in the mask when subsequently inflating the cuff. The maximum extra volume depends on mask size and initial volume of air in the mask when inserted.

WARNING
Never overinflate the cuff after insertion.

Looking for the following signs of correct placement: the slight outward movement of the tube upon cuff inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.

4.4 Usage



5. REMOVAL PROCEDURE

Removal should always be carried out in an area where suction equipment and the facility for rapid tracheal intubation are available.

Do not fully deflate the cuff until after its removal to avoid secretions entering the larynx and to prevent laryngospasm. Alternatively, it may be removed moderately inflated to aid complete removal of secretions.

If the mask is to be removed in the Post-Anesthesia Care Unit, recovery room staff should receive thorough training in all aspects of the Besmed Laryngeal Airway.

6. ADVERSE EFFECTS

Use of the Besmed Laryngeal Airway may cause minor adverse effects (e.g., sore throat) and major adverse effects (e.g. aspiration).

LEGEND OF SYMBOLS

CE	Medical Device compliant with Directive 93/42/EEC	REF	Product code
	Imported by		Manufacturer
	Please read instructions carefully		Date of manufacture
LOT	Lot number		Disposable device, do not re-use
	Expiration date (see box / package)		Keep in a cool, dry place
	Keep away from sunlight	EC REP	Authorized representative in the European community
	Not made with natural rubber latex		No-DEHP formulation
	Temperature limit	STERILE EO	Sterilized using ethylene oxide
MD	Medical Device		Single sterile barrier system

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.