



LarySeal™
LARYNGEAL MASK AIRWAYS

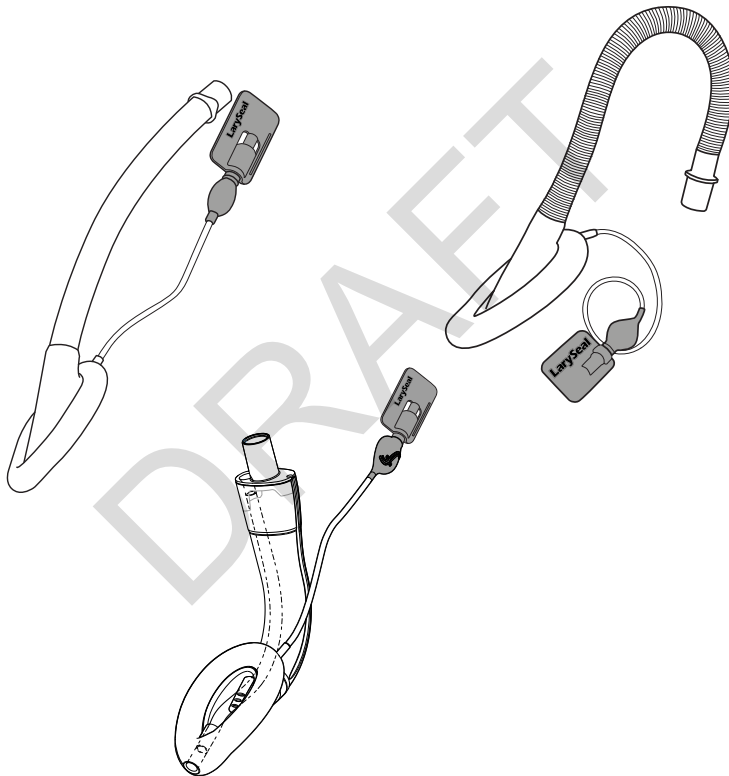


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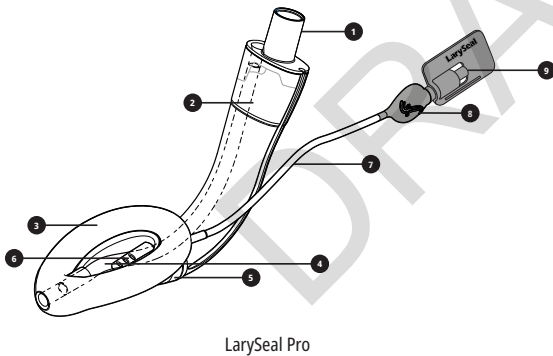
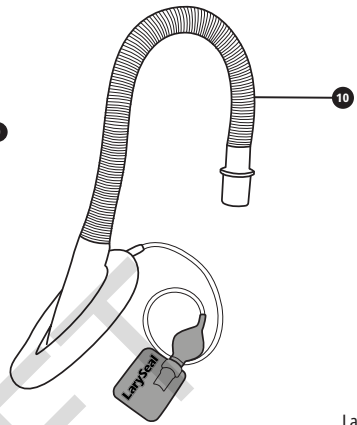
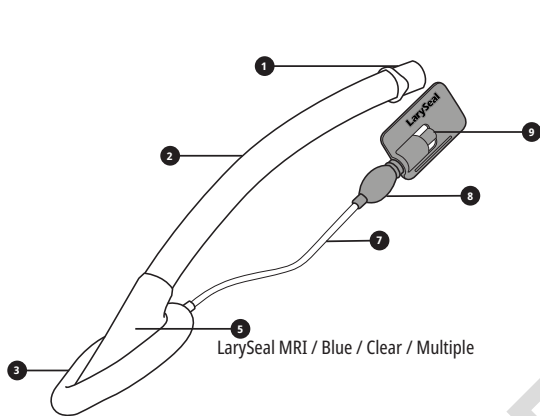
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LARYSEAL PRO / MRI / BLUE / CLEAR / FLEXI / MULTIPLE



 flexicare

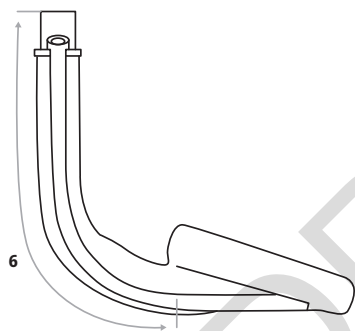
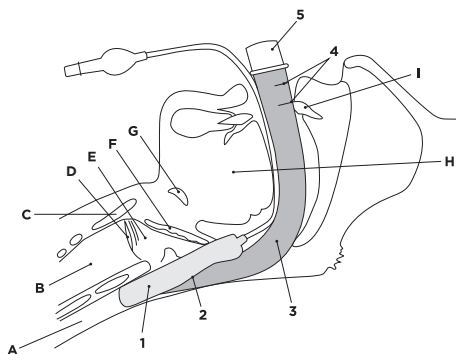
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PRODUCT KEY

1. 15M Connector
2. Main Tube
3. Cuff
4. Suction Channel
5. Shell
6. Epiglottic Flap (size 3,4 and 5 Only)
7. Inflation Line
8. Pilot Balloon
9. Non-return Valve
10. Reinforced Main Tube

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Correct position of Laryngeal Mask Airway in relation to Laryngeal Mask Airway parts and anatomical landmarks.

Laryngeal Mask Airway parts:

1. Cuff;
 2. Ventilatory opening;
 3. Ventilatory pathway;
 4. Normal depth of insertion;
 5. Machine end;
 6. Nominal length of internal ventilatory pathway*
- * See Table 1 for the nominal length provided in centimeters.

Anatomical landmarks:

- A. Esophagus;
- B. Trachea;
- C. Thyroid cartilage;
- D. Vocal cords;
- E. Laryngeal inlet;
- F. Epiglottis;
- G. Hyoid bone;
- H. Tongue;
- I. Incisors.

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FIGURE 1: INSTRUCTIONS FOR USE FOR LARYSEAL BLUE/ CLEAR/ MRI/ MULTIPLE / FLEXI

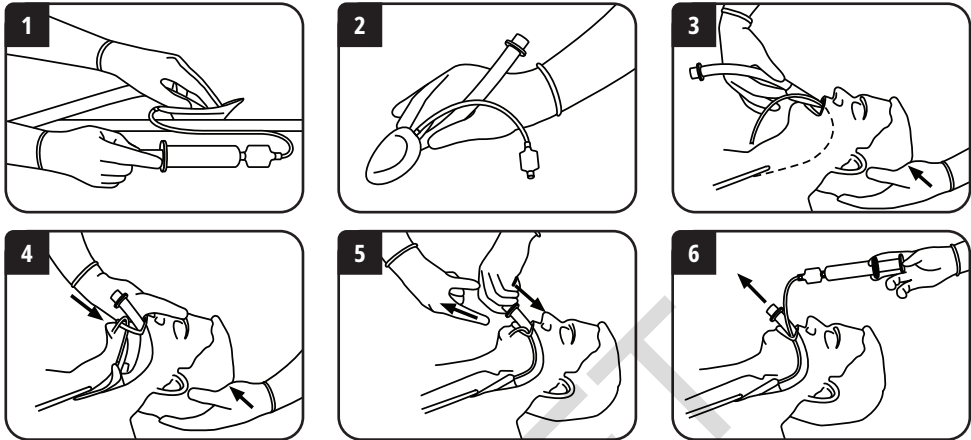
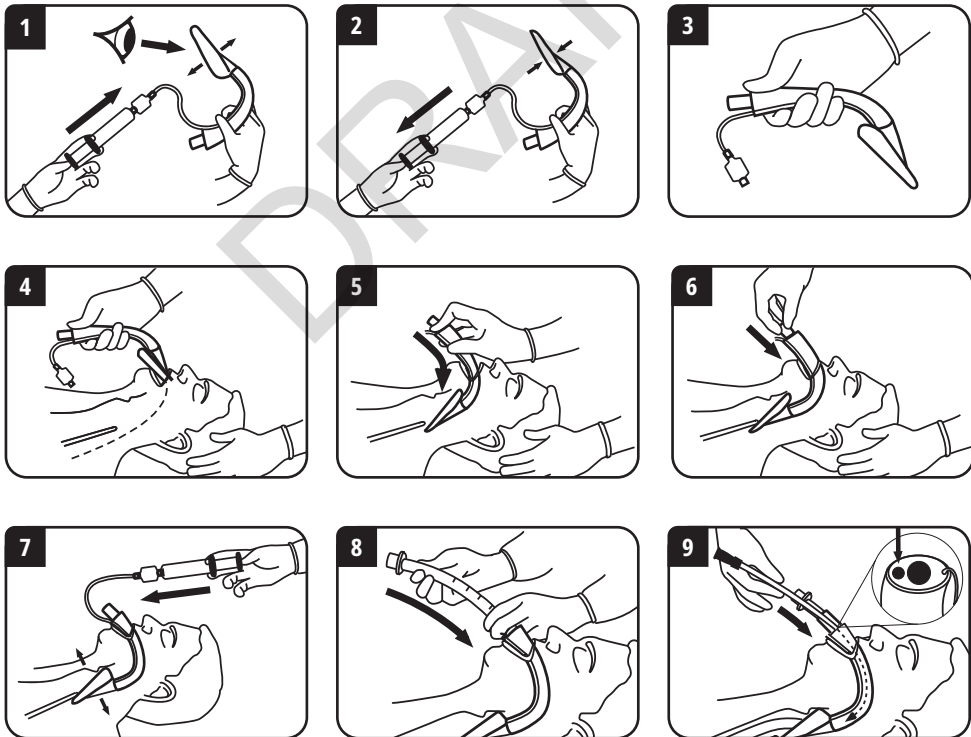


FIGURE 2: INSTRUCTIONS FOR USE FOR LARYSEAL PRO



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INTENDED USE

LarySeal Laryngeal Mask Airways are supraglottic airway devices intended to be used for the channeling of oxygen or anaesthetic gases during surgery and to keep the airway open in pre-hospital settings.

The LarySeal range is intended for single use, excluding the LarySeal Multiple, which is reusable up to 40 cycles within 1 year of use.

The LarySeal Pro allows for removal of gastric contents through an additional suction channel.

INDICATIONS FOR USE

Indicated for patient who is presenting with airway apnoea, severe respiratory failure, impending respiratory arrest, failure of endotracheal intubation, general anaesthesia in a spontaneously breathing patient, and cardiac arrest.

CONTRAINDICATIONS

- Patients who are conscious and may resist device insertion.
- Patients with poor pulmonary compliance.
- Patients with high airway resistance.
- Patients who present with pharyngeal/laryngeal pathology that could potentially complicate anatomical fit of the mask.
- Patients with airway obstruction below the larynx.
- Patients who have been injured shortly after ingesting a substantial meal due to the risk of aspiration.
- Patients with the inability to open their mouth to permit insertion.
- Patients who are morbidly obese.

CLINICAL BENEFITS

The device provides fast and effective ventilation for the patient.

PERFORMANCE CHARACTERISTICS

Table 1: Specification of Flexicare Laryngeal Mask Airways

Size	1	1.5	2	2.5	3	4	5
Patient Weight (kg)	<5	5-10	10-20	20-30	30-50	50-70	70-100
Max Cuff Inflation Volume (ml)	4	7	10	14	20	30	40
Max Cuff Inflation Pressure (cm H ₂ O)	60	60	60	60	60	60	60
Max ET Tube (mm) for LarySeal Pro	3.5	4	5	5.5	7.5	8	8
Max Suction Catheter (Fr) for LarySeal Pro	8	10	12	14	16	16	16
Internal Volume (ml)	6.5	7.5	14.5	20	25	30	30
Pressure Drop at 60L/min (cm H ₂ O)	<1.0*	<1.0**	<1.0**	<1.0	<1.0	<1.0	<1.0
Min Interdental Gap (mm)	10	11	13	14	30	30	34
Nominal Length of Internal Pathway (cm)	10	11.5	11.5	13	14	15.5	15.5

*Pressure drop measured at 15L/min

** Pressure drop measured at 30L/min

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LIST OF COMPATIBLE DEVICES/ ACCESSORIES

Flexicare Laryngeal Mask Airways can be used in conjunction with:

- Ventilation equipment, catheter mounts, breathing circuits, bacterial/viral filters, and HMEFs; 15 mm conical connectors in compliance with ISO 5356-1.
- Other accessories; Standard 6 % conical Luer syringe, Water-based lubrication.
- Endotracheal tubes (ETT), Suction Catheter; can be used with LarySeal Pro only for intubation and suction procedure. See Table 1 for information on the maximum suction catheter size and the maximum ETT size that can be used with each LarySeal Pro size.

PRECAUTIONS AND CAUTIONS

- Do not use if this device is damaged, if the unit packaging has been previously opened or damaged, or if it is past the expiry date.
- Before use, visually inspect the device for damage, discoloration, or anything that may reduce the functionality of the device.
- Functional test must be performed prior to use to ensure there is no occlusion or leakage by inflating the cuff and then deflating the cuff ready for use. Do not use the device if it fails any inspection or functional test.
- To avoid tissue trauma, do not use excessive force at any time when inserting and removing this device.
- If airway issues persist or ventilation is inadequate, remove this device and establish an airway using an alternative method.
- The position of this device should be reconfirmed after any change in the patient's head or neck position.
- Seat the connector firmly in the adapter on the ventilation equipment to prevent disconnection during use.
- Wear surgical gloves during preparation and insertion to minimize airway contamination.
- Only use a syringe with a standard luer taper tip for inflation and deflation of the cuff.

WARNINGS

- For use by trained medical professionals in airway management only.
- The device is supplied sterile for single use (except LarySeal Multiple). It must not be resterilised or re-used. Reuse may result in hazards such as, but not limited to, cross-contamination and reduced product reliability and functionality.
- LarySeal Multiple can be reprocessed up to 40 cycles, please refer to instructions for reprocessing, IP0000-346.
- This device does not protect the airway from aspiration.
- In the presence of nitrous oxide, oxygen, or other medical gases, the cuff volume or pressure may change. Care should be taken to regularly measure the cuff pressure level during the surgical procedure.
- The device may be flammable in the presence of lasers and electrocautery equipment.
- Do not overinflate the cuff after insertion. An appropriate intra-cuff pressure is 60 cm H₂O. This pressure should not be exceeded.
- Obstruction may occur if this device becomes dislodged or is incorrectly inserted. Incorrect insertion may cause epiglottitis to block the airway.
- Incorrect placement of the cuff tip into the glottis may mimic bronchospasm.

Laryseal Pro Only:

- Do not apply suction directly to the end of the suction channel.
- Ensure the suction catheter and ETT are adequately lubricated prior to insertion.
- Incorrect positioning of the LarySeal Pro into the patient's airway, may result in ETT not being able to be placed into the trachea.
- Do not use non-standard suction catheters or ETT.
- Do not use suction catheter or ETT larger than the recommended size applicable to the device (refer to Table 1).
- The maximum duration of use of the LarySeal Pro is 24 hours.

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INSTRUCTIONS FOR USE FOR LARYNGEAL MASK AIRWAYS

Before Use

- Choose the correct size of device. Refer to Table 1 for patient weight and size information.
- The following inspections and functional test must be conducted prior to use:
 - Visually inspect the surface of this device for damage, such as perforation, scratches, cuts, tears, loose parts, sharp edges etc.
 - Check that the interior of the main tube, the suction channel and the cuff are free from blockage and any loose parts. Do not use the device if it is blocked or damaged.
 - Deflate the cuff completely. Once deflated, check the cuff thoroughly for any wrinkles or folds. Inflate the cuff to the volume specified in Table 1. Check that the inflated cuff is symmetrical and smooth. There should not be any bulge nor sign of leakage in the cuff, pilot tubing or pilot balloon. Deflate the cuff again before insertion.
- Lubricate the back of the cuff with a sterile water-based lubricant.

During Use

- Use the images in **Figure 1** as a guide for the instructions for use of **LarySeal Blue/ Clear/ MRI/ Multiple/ Flexi**, insert the device using currently accepted medical techniques.
- Use the images in **Figure 2** as a guide for the instructions for use of **LarySeal Pro**, insert the device using currently accepted medical techniques.
- Once seated, inflate the cuff, taking care not to exceed the maximum cuff pressures, as indicated in Table 1.

Tracheal Intubation (LarySeal Pro only)

- Intubation through the device should always be performed according to local guidelines.
- Select an ETT of the appropriate size to pass through the device. Refer to Table 1 for ETT size.
- Adequately lubricate with a water-soluble lubricant the external surface of the fully deflated ETT sufficiently to permit ease of passage through the device.

Gastric drainage (LarySeal Pro only)

- The suction channel facilitates the channelling of fluids and gases emerging from the stomach.
- Gastric suction via LarySeal Pro should be carried out using currently accepted medical techniques.
- Select a suction catheter of the appropriate size to pass through the suction channel of LarySeal Pro. Refer to Table 1 for suction catheter size.
- Adequately lubricate the suction catheter prior to insertion through the suction channel.
- Insert the suction catheter slowly and carefully and suction should not be performed until the suction catheter has reached the stomach.
- Do not apply suction directly to the end of the suction channel.

After Use

- Fully deflate the cuff and simultaneously remove the device **ONLY** when the patient can open their mouth on command.
- If the cuff is fully deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm.
- Patient monitoring should continue throughout the recovery phase.

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

DISPOSAL

After use, dispose in accordance with local policies and/ or as advised by your local healthcare provider.

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STORAGE AND TRANSPORT

Store the device in ambient storage conditions and avoid exposure to ultraviolet light during storage.



www.flexicare.com/symbols



Flexicare Medical Limited
Cynon Valley Business Park,
Mountain Ash, CF45 4ER, UK
+44 (0)1443 474647
enquiries@flexicare.com
www.flexicare.com



Flexicare Deutschland GmbH
Ohlenhohnstrasse 34
53819 Neunkirchen-Seelscheid,
Germany



Flexicare Medical Switzerland GmbH
c/o BK-Services AG Suurstoffi 22, 6343
Rotkreuz Switzerland