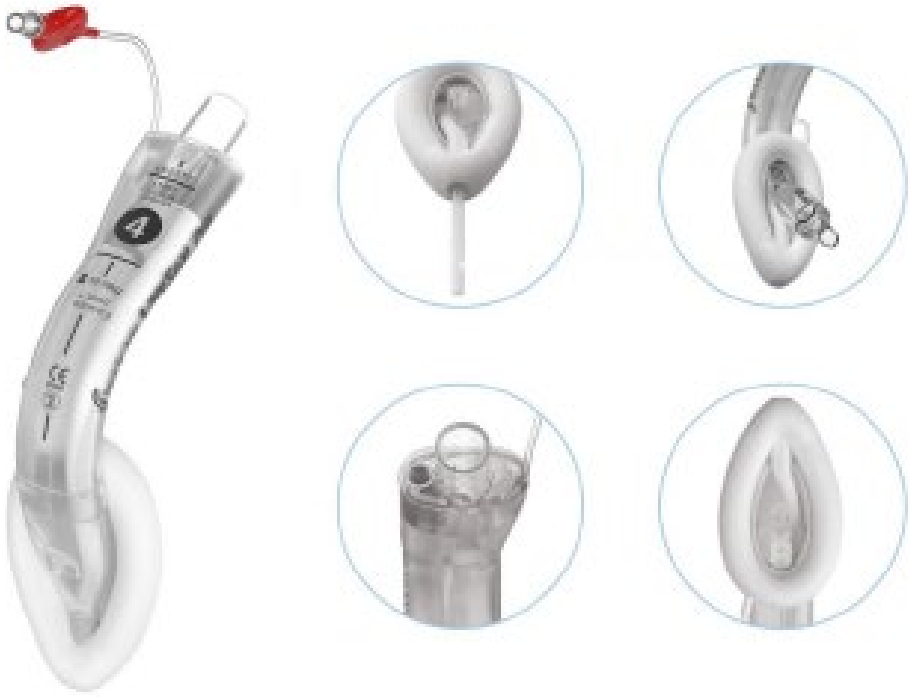
LarySeal™ Pro
Laryngeal Mask Airway

Product Data Sheet

flexicare
TOTAL QUALITY - TOTAL CARE

PRODUCT: LarySeal™ Pro

DESCRIPTION / FUNCTION



LarySeal™ Pro is a supraglottic airway device (SAD) that quickly facilitates a safe airway and provides gastric access and intubating ability. With a curve that better suits the oropharyngeal anatomy and symmetrical cuff with a pointed distal end, the semi rigid LarySeal™ Pro allows for easy insertion into the patient's airway. Attached to the mask is a cuff inflation line with a color-coded pilot balloon and non-return valve for mask inflation and deflation. The ISO standard 15M connector provides a secure connection to all standard breathing systems.
LarySeal™ Pro can be used as a conduit for intubation using an Endotracheal Tube (ETT). This is further aided by the epiglottic flap (Sizes 3 - 5 only) which helps to lift the epiglottis when pushing through the ETT. The design of the LarySeal™ Pro shell contains a semi rigid diverter inside the space of the ventilatory opening that allows the ETT to be diverted over the suction channel and through the vocal cords.

Additionally, LarySeal™ Pro contains an integrated lumen that runs distally along the tubing, in which a suction catheter can be inserted to provide access to the stomach for evacuation of the gastric contents.
LarySeal™ Pro is intended to be used to provide oxygen or anaesthetic gases to a patient during surgery and in the pre-hospital setting. The design also allows access to the gastric contents and acts as a conduit for intubation.
LarySeal™ Pro is used to maintain a patent airway in both spontaneously breathing and ventilated patients during anaesthesia and emergency situations. They are a less invasive alternative to an endotracheal tube, particularly in those patients who are at low risk of aspiration, undergoing a short procedure and not given a muscle relaxant.
This device is intended on being used by trained professionals in hospital and emergency environments.

PRECAUTIONS/WARNINGS

- Do not use if package has been previously opened or damaged, or after the expiry date.
- Keep at ambient storage conditions and avoid exposure to ultraviolet light during storage.
- Before use, visually inspect the device for damage, discolouration or anything that may reduce the functionality of the device.
- Carry out a functional test to ensure there is no occlusion or leaking by inflating the cuff and then deflating the cuff ready for use.
- Lubricate the back of the cuff prior to insertion.
- The position of the LarySeal™ Pro 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.
- Apply good medical judgement when using this product.
- If the device is incorrectly placed, there is a potential risk of aspiration to the patient.
- In the presence of certain medical gases, the cuff volume or pressure may change. Care should be taken to check the cuff pressure level during the administration of anaesthesia.
- DO NOT apply suction directly to the end of the suction channel.
- DO NOT use in procedures which will involve the use of a laser beam or electro-surgical active electrode in the immediate area or the laryngeal mask airway.
- DO NOT resterilise or reuse.
- Ensure the suction catheter and Endotracheal Tube (ETT) are adequately lubrication prior to insertion.
- 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.
- DO NOT over inflate the cuff.
- Obstruction may occur if the LarySeal™ Pro becomes dislodged or in incorrectly inserted. Incorrect insertion may cause the epiglottis to block the airway.
- Incorrect placement of the cuff tip into the glottis may mimic bronchospasm.
- The maximum duration of use of the LarySeal™ Pro is 24 hours.

SPECIFICATION / KEY FEATURES

- Conduit for intubation using an ETT.
- Integrated suction channel for access to gastric contents.
- Mask cuff conforms to the contours of the oropharyngeal area, providing a secure seal for airway management.
- Valve tag prevents pressure build-up in the cuff during transport and storage.
- ISO 5356 compliant 15M connector provides a universal connection.
- ISO 80369-7 compliant valve.
- ISO 17712 compliant supralaryngeal airway device.
- Thin-walled pilot balloon indicates the inflation pressure of the cuff.
- Colour coded pilot balloon indicates mask size.

TABLE 1: LarySeal™ Pro Guidelines on inflation

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 (ml)	60	60	60	60	60	60	60
MAX ET TUBE	3.5	4	5	5.5	7.5	8.0	8.0
MAX SUCTION CATHETER (Fr)	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_2O)	<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

PRODUCT RANGE & PART NUMBERS

Product Code	Product Description	Pilot Balloon Colour
038-94-810	LarySeal™ Pro Laryngeal Mask Airway Size 1	White
038-94-815	LarySeal™ Pro Laryngeal Mask Airway Size 1.5	Blue
038-94-820	LarySeal™ Pro Laryngeal Mask Airway Size 2	Light Green
038-94-825	LarySeal™ Pro Laryngeal Mask Airway Size 2.5	Dark Green
038-94-830	LarySeal™ Pro Laryngeal Mask Airway Size 3	Orange
038-94-840	LarySeal™ Pro Laryngeal Mask Airway Size 4	Red
038-94-850	LarySeal™ Pro Laryngeal Mask Airway Size 5	Yellow

MATERIALS

Component	**Material**
Connector	Acrylonitrile Butadiene Styrene (ABS)
Suction Channel	Polyvinyl Chloride (PVC)
Epiglottic Flap **	Polyvinyl Chloride (PVC)
Cuff	Polyvinyl Chloride (PVC)
Shell	Polyvinyl Chloride (PVC)
Main Tube	Polyvinyl Chloride (PVC)
Inflation Line	Polyvinyl Chloride (PVC)
Pilot Balloon	Polyvinyl Chloride (PVC)
Non return Valve • Valve Body • Spring • Valve Rod • Seal Ring	Polyvinyl Chloride (PVC) Stainless Steel Acrylonitrile Butadiene Styrene (ABS) Silicone

**Sizes 3-5 only

LATEX CONTENT

Flexicare's LarySeal™ Pro does not contain natural rubber latex..

DEHP CONTENT

Flexicare's LarySeal™ Pro does not contain phthalate DEHP.

SINGLE-USE

Flexicare's LarySeal™ Pro is single use only.

STERILITY

Flexicare's LarySeal™ Pro is supplied sterile by Ethylene Oxide (EO) gas.

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life of 5 years from the date of manufacture. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product pouch.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Primary – Polyvinyl Chloride (PVC) and Tyvek
Secondary – Cardboard