LARYNXLOCK

Instruction for Use

Version 3.0

LMA Optimizer B.V.

Table of Contents

1 General Information

1.1 Read the instructions for use

This document contains the instructions for use and is a guide for the users of LarynxLock. In this document, it is assumed that the operator is a professional and trained user, see the section about intended users for more information.
Proper functioning of the system can be guaranteed only if the instructions, warnings and cautions in this document are adhered to. Please study this document thoroughly before using the system.
The downloadable PDF version of the electronic Instruction for Use (eIFU), along with a video instruction are available at https://larynxlock.com/pdd. Scan the QR code below to access the page:

Read all the instructions before use. Obey all warnings and cautions throughout these instructions.

1.2 Manufacturer

LMA Optimizer B.V.
Oxfordlaan 55
6229 EV Maastricht
The Netherlands

1.3 Medical Device

LarynxLock
GTIN: 8720892631909 (small box of 5 products)
8720892631923 (medium container for 6 small boxes containing 30 products)

1.4 Acronyms and Abbreviations

LMA: Laryngeal Mask Airway
SAD: Supraglottic Airway Device

1.5 Guide to Symbols and Markings

Symbol	Meaning
	Manufacturer
	Batch code
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Temperature limit

	Humidity Limitation
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
	Medical device
	Unique Device Identifier
	Use by date

2 Intended use

2.1 Intended purpose and performance

LarynxLock is designed to effectively reduce oropharyngeal air leakage during patient ventilation using a Supraglottic Airway Device (SAD). In patients with decreased consciousness, for example during procedural sedation, LarynxLock is designed to maintain airway patency. The headband is made from flexible material that can be applied without needing to take the patient off the ventilation.

2.2 Intended patient population

Non-obese adult (18 years or older) patients with no teeth or elderly patients may best benefit from the device.

2.3 Intended User, education and training

Healthcare professionals who can assess the security of the patient’s airway and ventilation needs.

2.4 Clinical benefits

When used on patients ventilated using SAD, LarynxLock reduces air leakage to an acceptable level below 10% of tidal volume and keeps this stable during the medical procedure. When used on sedated patients, LarynxLock maintains airway patency. Skilled operators can put on the device and apply the correct pressure within 15 seconds. These functions contribute to safer and more effective patient management in the operating room, pre-hospital, or sedation scenarios.

3 Information for safety

3.1 Residual risks

The pressure applied by LarynxLock may decrease perfusion to the area around the pusher, causing red marks on the skin. Refer to Cautions (see 3.4) and Warnings (see 3.5).

3.2 Limitations

There is no limitation identified for the use of LarynxLock.

3.3 Contraindications

There is no contraindication identified for the use of LarynxLock.

3.4 Cautions

Temporary red marks can appear on the skin where LarynxLock is applied, usually resolving within 30 minutes after removal. To prevent serious adverse events, ensure correct placement, and monitor regularly.

3.5 Warnings

The device may obstruct perfusion in the area where the pusher is applied. The recommended maximum duration is 2.5 hours; if longer use is needed, remove the device for at least 10 minutes after every 2 hours.

4 Storage and/or handling condition

- Keep dry (20% to 60% humidity).
- Single-use only.
- Do not use if the product is damaged.
- Product is non-sterile.
- Temperature recommendation for storage: +10°C to +35°C.

5 Product

Each box contains five pieces of LarynxLock.

5.1 Product description

The LarynxLock device is designed to support airway management in patients with reduced consciousness by minimizing oropharyngeal leakage when a Supraglottic Airway Device (SAD), such as a Laryngeal Mask Airway (LMA), is used by medically qualified personnel. The LarynxLock comprises two main components:

- Pusher

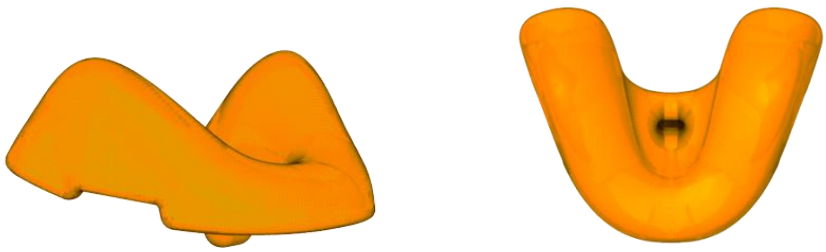


Figure 1. Pusher part of LarynxLock

- Headband

Figure 2. Illustration of the headband part of LarynxLock in use, attached to the pusher

5.2 Single-use

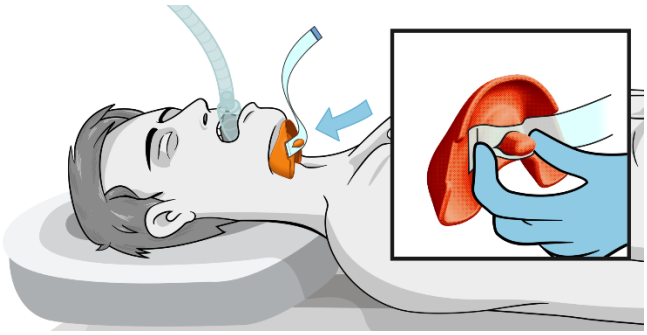
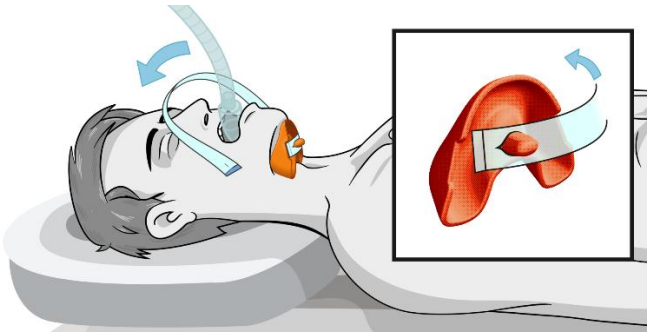
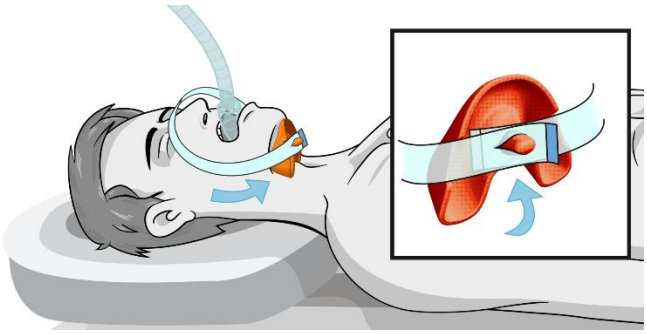
LarynxLock is intended for single use only. The pusher is made from a porous material that readily absorbs fluids, which can reduce its effectiveness and increase the risk of contamination.

The headband is engineered to provide a specific balance of force and flexibility, both of which will degrade after prolonged and/or repeated use. For these reasons, reuse of the device is not acceptable, as its performance and safety cannot be guaranteed once its functional properties have changed.

5.3 Compatibility with other devices

LarynxLock is compatible with all types of SADs.

5.4 Using the product

1.  Use the pusher to apply pressure and check for leaks.	**2.**  Place the headband around the head.
3.  Fix the headband on the pusher's pin.	**4.**  Place the headband over the ears.

For a video guide on how to use the product, visit https://larynxlock.com/pdd.

5.4.1 Modes of Operations

There is no mode of operation restriction for LarynxLock.

5.4.2 Cleaning

LarynxLock is a single-use, non-sterile device.

5.5 Lifetime

Under suitable storage conditions, the expected lifetime of the device is two years. Refer to the packaging for the year by which it is safe to use and check for product damage before use.

6 Disposal information

The pusher and strap are intended to be disposable. The pusher part of LarynxLock can be disposed of as wastepaper or compost.

7 Contact Information / Getting help

If a serious incident occurs in relation to the use of LarynxLock, inform LMA Optimizer B.V. via email to info@larynxlock.com and the corresponding authorities of the country in which the healthcare facility staff and patient are established. Serious incident means any incident that directly or indirectly led or might lead to any of the following:

- The death of a patient, user, or other person.
- The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health.
- A serious public health threat.

8 Regulations

8.1 Classification

LarynxLock is a non-invasive device. Rule 1 non-invasive device, condition for Class I applies for LarynxLock according to EU-MDR 2017/745. As a result, LarynxLock is considered a Class I medical device.

8.2 Reporting of incidents and errors

If any incidents or errors occur in relation to the use of LarynxLock, inform LMA Optimizer B.V. via email to info@larynxlock.com.

8.3 Copyright

8.4 CE mark

CE

9 Version identifier of the instruction for use

Version 3.0.