Innovel Medical Ltd

LEAFix

Laryngeal, Endo-tracheal, Airway Fixator

REF	01-5000
Revision:	3
Released:	July 2022
IFU:	19-0601-0002

Device Description

The LEAFix is a Laryngeal, Endo-tracheal, Airway Fixator. It consists of a self-adhesive foam tape and paper backing cover, which has a specialised shape to secure an airway tube to a patient's face. LEAFix is single use and non-sterile.

Principles of Operation and Mode of Action

The self adhesive foam on the LEAFix device has a paper backing cover which is removed before initial use. The Y-shaped edge acts as a dual anchor point that allows fixation to the face. The downwards angled section allows the device to wrap around a variety of airway device tube diameters whilst maximising the surface. Finally, there is a perforated section along the longer end of the device which can divide into two further anchor points to increase the securing options.

The Device adhesive surface makes contact with the skin surface of the face and the airway tube. Following use the device is removed from the surface of the skin and airway tube using a light peeling force. There is no expected intervention between the device and the body other than the fixation properties of the adhesive layer.

Intended Purpose (Intended Use)

The principle intended purpose of the LEAFix device is to secure airway devices in position by affixing them to a patient's face.

Indications for use

The device is intended to be used on patients weighing over 30kg who are under general anaesthesia, to secure airway devices during spontaneous, hand and mechanical ventilation. The device may also be indicated for use during an emergency respiratory arrest, where the patient requires ventilation, cannot breathe unsupported but is not under general anaesthesia.

Contra-indications

- Neonatal or paediatric Patients, or adolescents who weigh less than 30kg.
- Patients with broken, damaged or fragile skin.
- Patients with facial hair that will hinder affixing; if required remove facial hair or use alternative securing method.
- Patients with facial piercings that will hinder affixing. Remove facial piercings where possible or use alternative securing methods.

Warnings and Precautions

- LEAFix is intended to be used by trained medical professionals in a healthcare setting.
- Where a patient has cosmetics or contamination on the skin, clean the skin with alcohol wipes prior to affixing the LEAFix device. Ensure that both the patient's face and the airway tube are dry before affixing the LEAFix device.
- In the event of the LEAFix device not adhering as intended, alternative securing options should be used.
- Inspect both the device and packaging prior to use to ensure device integrity has been maintained. DO NOT use if either the packaging or device has been damaged.
- As with all procedures, the LEAFix device user should follow local procedures to maintain cleanliness including the use of surgical gloves and protective clothing.
- When a LEAFix device is removed from the bag/pouch, ensure that the bag/pouch is resealed to preserve the condition of the remaining devices.
- If the perforated limbs need to be separated, the user must only split the LEAFix device along the length of the perforation and not beyond it.
- The LEAFix device is compatible with endotracheal tubes and supraglottic airway devices ranging from 6.8mm diameter up to the equivalent of 30.9mm diameter.
- The LEAFix device is not intended to be used as a wound dressing.
- Each LEAFix device is designed for single-use only. DO NOT attempt to re-use the LEAFix device as the device may not effectively affix the airways tube. Once used, dispose of the LEAFix device into clinical waste.
- Each LEAFix device is intended to be used for no more than 24 hours and when used consecutively, multiple LEAFix devices are to be used for no more than 30 days in total. Do not use the LEAFix device beyond the stated use by date.
- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the local competent authority.
- If the airway device requires repositioning at any stage during use, it is recommended that a new LEAFix device should be used.
- Do not stretch the LEAFix device when applying to the patient's face/cheek – this may cause pressure sores.

Additional copies of this IFU can be downloaded from the Innovel website www.innovelmedical.com

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Procedural Instructions

Patient Preparation:

1. Wipe down the skin of the patient with alcohol wipes if required.
2. Identify surgical positioning to understand if more than one LEAFix device is required.

Procedure:

3. Peel device from the backing paper.
4. Place Y-shaped end on patient's cheek, close to the mouth. (See Diagram 1)
5. Wrap Leafix around the airway device. (See Diagram 2)
6. If required, separate the perforated limbs. (See Diagram 4)
   For extra purchase on smaller ETT tubes, separate the perforated limbs; one arm can be secured on the opposite side of the face whilst the other is wrapped up and around the length of the airway tube. (Diagram 5)
7. Adhere to patient cheek on the opposite side (See Diagram 6). If the intended position conflicts with the warnings and precautions then choose the most suitable area available.
8. Press and smooth along the whole device to ensure sufficient adhesion.
9. If a second LEAFix device is required, place the Y-shaped end on the opposite cheek to the first LEAFix device. The perforated limbs can then be separated; both arms can be secured on the opposite side of the face. (See Diagram 7)

Disposal

Once used dispose in clinical waste as per local procedures.

Graphic Symbols

The following symbols are used within the instructions for use and on the packaging. Explanation of symbols can also be found in standard BS EN ISO 15223-1:2021

	Do not re-use
	Do not use if packaging is damaged
27°C 10°C	Indicates the temperature limits to which the medical device can be safely exposed.
LATEX	Product is not made with natural rubber latex
LOT	Batch code
REF	Catalogue Number
	Caution: Refer to IFU for warnings and precautions
	Keep away from sunlight
	Consult instructions for use
	Legal manufacturer
	Use-by date
MD	Medical Device
CE	CE Marked device
60% 40%	Humidity Limitation
	Keep Dry

Once this IFU has been reviewed, please replace back into the Use Carton for further reference.

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