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LEAFix
Airway Fixation Device

en

LFX-MDF-LBL-001-EN
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Device description

LEAFix is a Laryngeal, Endo-tracheal, Airway Fixation Device. It is composed of an adhesive tape and a protective paper cover that is specially shaped to securely affix an airway tube to a patient's face.
LEAfix is a single-use device and is non-sterile.

Device Name	Product Code	UDI
Leafix™ Airway Fixation Device	01-5000	15060247810079

Principles of Operation and Mode of Action

The LEAFix's self-adhesive tape has a protective paper 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 airway tubes of various diameters while maximising the surface area. Finally, there is a perforated section along the longer end of the device which can be divided into two further anchor points to increase fixation options.
The device's adhesive surface makes contact with the surface of the facial skin and the airway tube. Following use, the device should be removed from the skin's surface and the airway tube with gentle 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 principal 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 more than 20kg and who are under general anaesthetic, in order to secure airway devices during spontaneous, manual or mechanical ventilation. The device may also be indicated for use during an emergency respiratory arrest, where the patient requires ventilation, cannot breathe unaided, but is not under general anaesthetic.

Intended Users

LEAFix is intended to be used by trained medical professionals in a healthcare setting.

Patient Population

All population ages weighing more than 20kg.

Contact with Patient

The device is intended to contact with uninjured skin only.

Duration of Use

Each LEAFix device is intended to be used for a maximum of 48 hours, but on clinician discretion this can be extended up to 72 hours.

Shelf Life

3Years.

Contraindications

- Not to be used on patients weighing less than 20kg.
- Patients with damaged, broken or fragile skin.
- Patients with facial hair that hinders adhesion; remove the facial hair if necessary.
- Patient with facial piercings that hinder adhesion. Remove the facial piercings whenever possible or use an alternative fixation option.

Warnings & Precautions

Consult Clinical when using on patients with any know skin allergies.

- Where a patient has cosmetics or contamination on the skin, clean the skin with sterile 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 that the LEAFix device does not affix as intended, seek alternative fixation device.
- Inspect both the device and the packaging before use to ensure that device integrity has been maintained. DO NOT use if either the packaging or the device has been damaged.
- As with all procedures, the LEAFix device user must follow all 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, 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** in diameter to the equivalent of **30.9mm** in 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 reuse the device, as the airway tube is unlikely to affix correctly. Once used, dispose of the LEAFix device in clinical waste.
- Multiple LEAFix devices should be used for a maximum of 30 days in total.
- Do not use the LEAFix device after the indicated expiration date.
- If the airway device requires repositioning at any time during use, the use of a new LEAFix device is recommended.
- Do not stretch the LEAFix device when applying to the patient's face/cheek - this may cause pressure sores.

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Procedural Instructions



Patient Preparation:

1. Clean the patient's skin with sterile wipes if necessary.
2. Identify the surgical position to determine whether more than one LEAFix device is required.

Procedure:

3. Remove the protective paper from the device.
4. Place the Y-shaped end on the patient's cheek, near the mouth. (See Diagram 1)
Wrap the LEAFix around the airway device. (See Diagram 2)
5. If required, separate the perforated limbs. (See Diagram 4) For extra grip on smaller ETT tubes, separate the perforated limbs; one arm can be secured to the opposite side of the face while the other is wrapped around the length of the airway tube. (Diagram 5)
6. Affix to the patient's cheek on the opposite side (see Diagram 6). If the intended position conflicts with the warnings and precautions, choose the most suitable area available.
7. Press and flatten along the entire length of the device to ensure sufficient adhesion.
8. 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 and both arms can be secured to the opposite side of the face. (See Diagram 7)

Disposal

Once used, dispose in clinical waste following local procedures.

Applicable Standards

Standards which have been applied in full to document compliance with the General Safety Performance Requirements for Conformance of the EU MDR (EU) 2017/745.

Regulatory Compliance

LEAFix is a Class I non-sterile Medical Device under Rule 1 of Annex VIII of the EU MDR (EU) 2017/745 Medical Devices Regulations for the Medical Devices, conforming to the General Safety & Performance Requirements. The application of the classification rules is governed by the intended purpose of the device.

Symbols

The following symbols are used on the LEAFix device.

UNIQUE DEVICE IDENTIFICATION

A labels required by some countries regulations regarding identification of medical device also known as Unique Device Identification. The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix).
(01) 00000000000000 (Global Trade Item Number / UDI-DI)
(17) 000000 (Expiry Date)
(10) 000000 (Batch/LOT)

Symbols	Description	Source
	Keep Away from sunlight	EN ISO 15223-1
	Keep Dry	EN ISO 15223-1
	Do not use if damage packaging	Do not use if damage packaging
	Consult Instructions For Use or consult electronic Instructions For Use (eIFU)	Consult Instructions For Use or consult electronic Instructions For Use (eIFU)
MD	Medical Device	EN ISO 15223-1
	Do not reuse	EN ISO 15223-1
	No Latex	EN ISO 15223-1

Symbols	Description	Source
REF	Catalogue Number	EN ISO 15223-1
LOT	Batch No	EN ISO 15223-1
UDI	Unique Device Identifier	EN ISO 15223-1
EU REP	Indicates the authorized representative in the identified country or jurisdiction	EN ISO 15223-1
	EU Importer	EN ISO 15223-1
	Distributor	EN ISO 15223-1
	Manufacturer	EN ISO 15223-1
	Country of Manufacture	EN ISO 15223-1
	Use by date	EN ISO 15223-1
	Packaging unit (number of pieces in package)	ISO 7000 - 2794
CE	Certification Mark	EU MDR regulatory requirement (Class I)
	Storage Temperature Limit	EN ISO 15223-1
	Humidity	EN ISO 15223-1

Getting More Help and Support

For more information about Frequently Asked Questions (FAQs), please visit our website: www.innovelmedical.com
Please ensure that any serious incident that has occurred in relation to this device should be reported immediately to the manufacturer. Users should also report the incident to the competent authority of the Member State in which the user and/or patient is esta blished, in accordance with local requirements. Where applicable, reports may also be submitted through the manufacturer's authorised representative or distributor.

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Approval Signoff and Revision table

Internal Purposes Only

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REVISION HISTORY

ISSUE LEVEL	ACTION LOG NO.	SUMMARY OF CHANGES:	ISSUE DATE:
1.0	N/A	First release	Feb 2021
2.0	N/A	IFU Updated.	July 2022
3.0	N/A	IFU Updated.	July 2022
4.0	N/A	IFU Updated.	Nov 2024
5.0	N/A	IFU Updated.	May 2025
6.0	CR 081	Symbols, applicable standards, alignment statement, warnings, economic operators updated to align with EU MDR requirements	July 2026

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