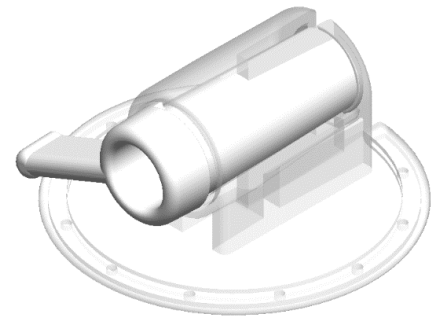


LockeT User Manual [EN]

Instructions for Use
Catheter Precision, Inc.



Indications for Use

LockeT is intended for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure.

Intended Use

The suture retention device is intended to temporarily secure sutures and then aid clinicians in locating and removing sutures efficiently.

Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- The device is intended for single use only. Do not resterilize and/or reuse this device. Reuse of the device could result in bacterial or viral infection. It could also result in deterioration or damage to the device
- Device is provided sterile using an ethylene oxide (EO) sterilization process. Do not use the product if there is doubt as to whether the product is sterile.
- Store in a dark, dry, cool place. Avoid extended exposure to light.
- Upon removal from package, inspect the product to ensure no damage has occurred.
- Repositioning of the device is possible after deployment; use caution to ensure device is in appropriate position to obtain best possible clinical results.
- The amount of force and duration of application that are tolerable will vary with patients.

Potential Adverse Events

- Undesired bleeding at the site could occur if caution is not used when securing the device at deployment.
- Hematoma/Bleeding
- Patient Fever

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority in the region which the user and/or patient is established.

Contraindications

There are no known contraindications for this device

Suggested Method of LockeT

The LockeT is indicated for post operative wound healing when a figure of eight suture closure is used.

Step 1: Suture





















Complete figure of eight suture per standard of care using suture sizes 7-0 – 1.

Step 2: Thread and close

Place the round, flat end of the LockeT directly over the suture and thread the excess suture into the open stopcock. Close the stopcock to hold the suture in place

Step 3: Remove

Once hemostasis is achieved, return the stopcock to the original position (handle pointing up) to unlock the suture. Lift the device from the wound. Cut sutures and remove as per standard of care.

Symbol Glossary		
Symbol	Title Reference	Description
	Manufacturer 5.1.1 ^[1]	Indicates the medical device manufacturer
	Authorized representative 5.1.2 ^[1]	Indicates the authorized representative in the identified country or jurisdiction.
	Date of Manufacture 5.1.3 ^[1]	Indicates the date when the medical device was manufactured
	Use-by date 5.1.4 ^[1]	Indicates the date after which the medical device is not to be used
	Batch code 5.1.5 ^[1]	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue number 5.1.6 ^[1]	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Sterilized using ethylene oxide 5.2.3 ^[1]	Indicates a medical device that has been sterilized using ethylene oxide
	Do not resterilize 5.2.6 ^[1]	Indicates a medical device that is not to be resterilized
	Do not use if package is damaged and consult instructions for use 5.2.8 ^[1]	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Single sterile barrier system 5.2.11 ^[1]	Indicates a single sterile barrier system
	Single sterile barrier system with protective packaging outside 5.2.14 ^[1]	Indicates a single sterile barrier system with protective packaging outside
	Temperature Limit 5.3.7 ^[1]	Indicates the temperature limits to which the medical device can be safely exposed
	Do not re-use 5.4.2 ^[1]	Indicates a medical device that is intended for one single use only.
	Consult Instructions for Use 5.4.3 ^[1]	Indicates the need for the user to consult the instructions for use
	Medical device 5.7.7 ^[1]	Indicates the item is a medical device
	Unique device identifier 5.7.10 ^[1]	Indicates a carrier that contains unique device identifier information
	Prescription only 21 CFR 801.109	Caution: Federal law restricts this device to sale by or on the order of a physician
	CE Marking MDR 2017/745 Article 20	Signifies European technical conformity.
	Swiss authorized representative Section 3[2]	Indicates the authorized representative in Switzerland
	Quantity (No applicable reference)	Indicates the quantity of devices contained in the packaging.

[1] ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

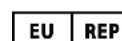
[2] Swissmedic, Obligations Economic Operators CH, VM-ID: MU600_00_016e / V4.0 / mea / pmi / 06.04.2023



Catheter Precision, Inc.
1670 Highway 160 West, Suite 205,
Fort Mill, SC 29708, USA
+1 (973) 691-2000



MedNet SWISS GmbH,
Bäderstrasse 18,
5400 Baden,
Switzerland



MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany



2460