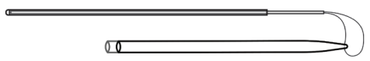
FlexPasser™
Tendon Retrieval Kit



EN Instructions for use

CE 2797

LAB 281 3.00

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GMDN 57874

English

EN Do not use if package is damaged

EN Do not reuse

EN Consult instructions for use

EN Batch code

EN Do not resterilize

EN Catalogue number

EN Sterilized using irradiation

EN Use by date

EN Manufacturer

EN Caution

EN Caution: US federal law restricts this device to sale by or on the order of a physician

English

Ordering Information (supplied sterile)
Part No. 202-1500

Description
The FlexPasser™ Tendon Retrieval Kit consists of two components:
- An integrated probe and needle carrier
- A plastic sleeve for lining the sheath of the severed tendon.

The integrated probe and needle carrier consists of a flexible elongated device with a smooth, semi rigid, rounded end. At the other end there is a more flexible section to allow for a curved needle and suture to be transferred through the sheath. There is also a wire loop at this end to which is attached the plastic sleeve. This sleeve allows the probe and needle carrier, and then the tendon to be passed through the tendon sheath from proximal to distal without snagging.

Material Specification
The device is manufactured from Stainless Steel, Low-Density Polyethylene (LDPE) and Fluorinated Ethylene Propylene (FEP).

Intended Use
The FlexPasser Tendon Retrieval Kit is intended for use in the retrieval of the proximal tendon stump(s) during the repair of a lacerated digital flexor tendon(s) in the hand.

Indications for use
The FlexPasser Tendon Retrieval Kit is indicated for use in patients undergoing repair of lacerated flexor tendons in the hand.

Contraindications
The instrument must not be used for any procedure other than the intended use.

English

Warnings
- The device is for SINGLE USE only as it is not suitable for reprocessing which amongst other risks may lead to cross-infection, loss of function and patient injury. Do not use after the expiration date. Discard any open, unused product.
- The devices included in this kit are NOT intended for implantation.
- The surgeon must be thoroughly familiar with these instructions and the recommended surgical procedure before using the device.
- The general principles of patient selection and sound surgical judgement apply.
- The surgeon should give consideration to the patient's hand size, as FlexPasser may not be appropriate for smaller digits.
- The instruments must be checked for damage prior to use and are not to be used if there are any signs of visible damage.
- The device should not be used in patients with a known sensitivity to Stainless Steel, LDPE or FEP. If the patient is suspected of having any foreign body sensitivity, appropriate tests should be made prior to use.
- Caution should be used when introducing the needle into the carrier. Use of needle holders is recommended to avoid needle prick injuries.

Precautions
- Inspect the device, packaging and labelling prior to use and do not use if damaged.
- Avoid damage when handling the FlexPasser Tendon Retrieval Kit. Avoid crushing or crimping when using surgical instruments such as forceps or needle holders.
- Use only needles between 11 and 26 mm in length, needles outside this range have not been approved for use with this product. Some needle sizes may be too large for the patient.
- We recommend a needle with a 3/8 circumference, although a small needle with 4/8 circumference may still pass.
- Use sterile technique throughout the procedure.

Packaging
- The instruments are supplied sterilized by gamma irradiation in a double pouch.
- Packages should be intact upon receipt and once the seal on the sterile package has been broken, the product SHOULD NOT BE RE-STERILIZED.
- Store in standard conditions.
- Damaged packages or products should not be used and should be returned to Xiros.

Potential Adverse Effects
Below is a list of the potential adverse effects (e.g. complications) associated with the use of the device including, 1) risks associated with any surgical procedure; 2) risks associated with flexor tendon retrieval and repair. Additional surgery may be required to correct some of these events.

1. Pertinent risks associated with any surgical procedure include: Infection and wound dehiscence or scar contractures due to incisions.
2. Risks associated with tendon retrieval and repair, include: damage to the tendon and/or surrounding tissue when retrieving the tendon; adhesions; rupture of the repair; reduced active motion and disruption of Camper's chiasm.

English

Surgical Technique
Step 1.
The proximal tendon stump is delivered to the palm via a small incision in the crease of the palm (*Figure A*), or proximal point of choice if the vinculum is to be preserved. The palm is preferred, to minimise incisions on the digit.
Step 2.
The finger should be gently extended. The probe is advanced with its round end leading through the flexor sheath, from the site of the distal flexor stump/opening in the sheath to the site of the proximal flexor stump. Hold the device close to the tip and advance in stages, maintaining the orientation of the probe to avoid buckling and rotation (*Figure A*).
Step 3.
Maintain the probe's orientation as it is pulled through the proximal incision (*Figure B*), leaving the plastic sleeve in place protruding from both incisions, **ensure the sleeve has not twisted before proceeding.**
Step 4.
The full thickness of one leg of the sleeve is cut across obliquely (*Figure B*) at the base of the tapered segment. The oblique cut creates a larger entry point for the tendon than a transverse cut.
Step 5.
The leg that has not been cut can be removed from the digit, leaving a single sleeve in place (*Figure C*).
Step 6.
The proximally retracted flexor tendon stump is sutured using the surgeon's preferred technique for the repair, leaving the suture ends long enough for retrieval. The needle is to be kept on the suture (*Figure D*).
Step 7.
The free end of the suture is introduced into the open end of the needle carrier to about 4-5 cm. Then, using a needle holder, the entire body of the curved needle is introduced in the carrier antegrade (*Figure D*), gently curving the carrier to preserve the needle tip.
Step 8.
The Integrated probe and needle carrier is threaded through the plastic sleeve from the proximal to distal incisions and removed at the distal incision (*Figure E*), once the needle and suture have been passed through the sleeve they can be released from the carrier (*Figure F*).
Step 9.
We recommend that a small volume of saline should be used to lubricate the sleeve and tendon prior to passing the tendon through the plastic sleeve lining the sheath. Gentle traction is applied to both ends of the suture (*Figure F*), whilst the plastic sleeve is held in place with forceps at the proximal incision, to guide the proximal tendon stump(s) through the cavity of the sleeve and to the distal wound (*Figure F*).
The following steps are not illustrated
Step 10.
Keeping tension on the suture, the sleeve is then pulled from the distal wound out of the tendon sheath thus freeing both ends of the suture in readiness for the tendon repair.
The two stumps can now be connected by continuing the chosen repair technique with the same needle and suture material.

If the FDP and FDS both require repair, then they should be placed in the anatomic orientation prior to proceeding as per steps 6 – 10. One suture pair at a time should be passed through the plastic sleeve. Then the four suture strands are used to draw the two tendons simultaneously to the distal incision where each can be sutured to its own stump.

Disposal
No specific disposal requirements other than handling contaminated items as clinical waste.

Complaints
Any health care professional who has any complaints or experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, usability, effectiveness, and/or performance, should notify the manufacturer and distributor immediately.
If the product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the manufacturer and relevant local regulatory authority should be notified immediately by telephone, email or written correspondence.
When filing a complaint, provide the component(s) name and number, lot number(s), your name and contact details and the nature of the complaint.

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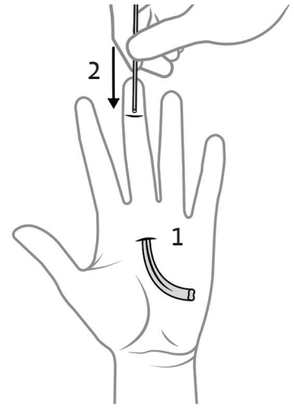

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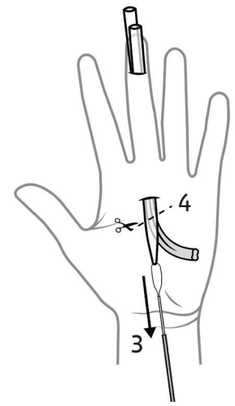

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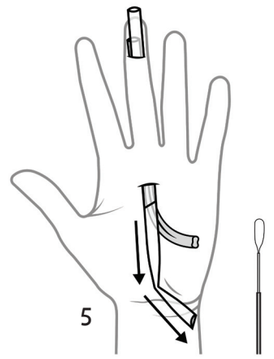

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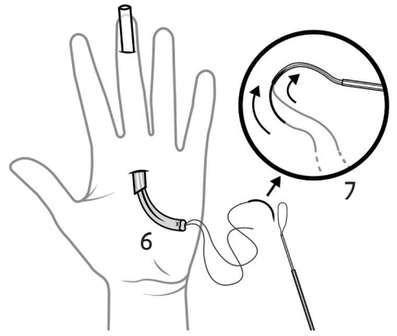

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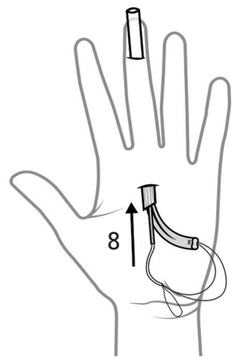

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