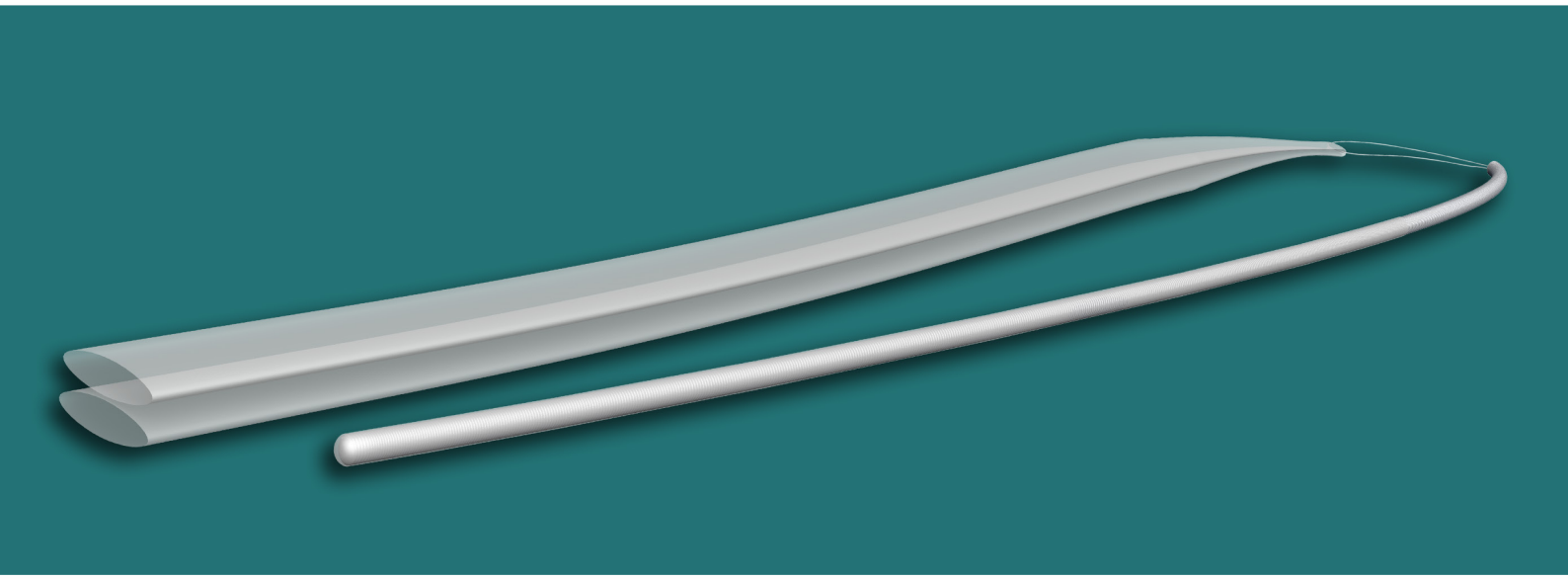
# FlexPasser™

## Tendon Retrieval Kit

For atraumatic retrieval of severed flexor tendons with minimal incisions

# Surgical Technique Manual



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# FlexPasser™
## Tendon Retrieval Kit

**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 Specifications**
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.

**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.

**Packaging**

- The instruments are supplied sterilised by gamma irradiation in a double pouch.

- 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.

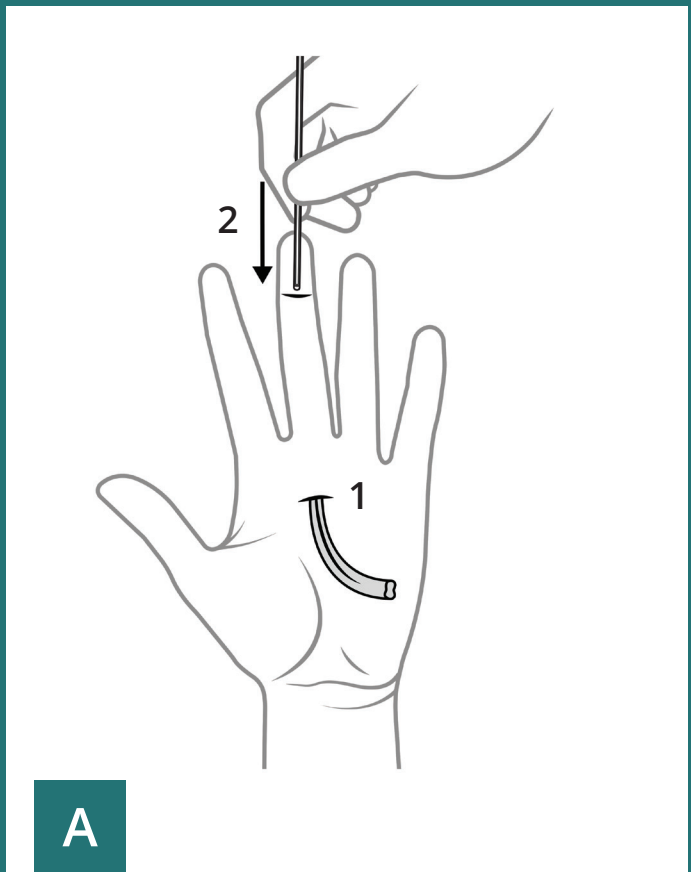
- Packages should be intact upon receipt and once the seal on the sterile package has been broken, the product should not be re-sterilised.
- Store in standard conditions.
- Damaged packages or products should not be used and should be returned to Xiros.

**Potential Adverse Effects**

Below is a list of the potential adverse effects (e.g. complications) associated with the use of the device:

- Pertinent risks associated with any surgical procedure include: Infection and wound dehiscence or scar contractures due to incisions.
- 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.

## Surgical Technique

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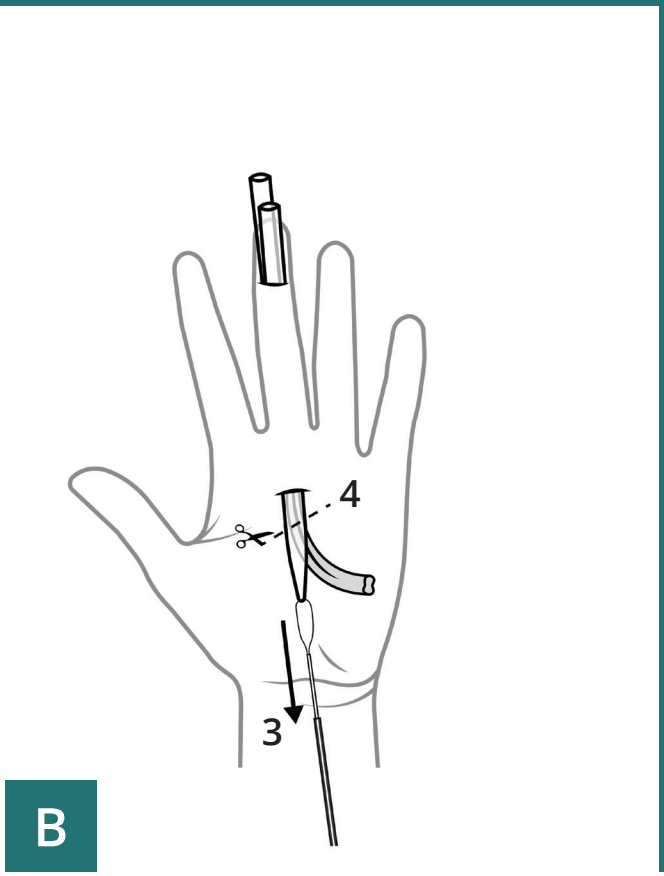


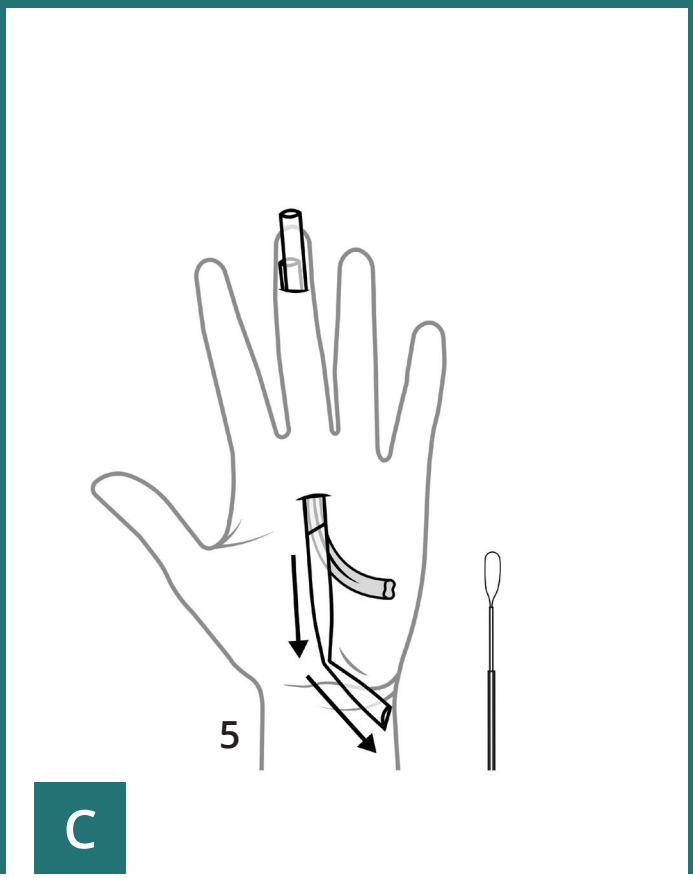

B

**Step 1.**
The proximal retracted tendon stump should be delivered to the palm via a small incision close to or within the crease of the palm (*Figure A*); this is to minimise the visible scarring and allow for contraction post-operatively. Alternatively, a more distal point can be used if the vinculum is to be preserved. The palm is preferred to minimise incisions on the digit.

**Step 2.**
Gently extend the finger, and then advance the probe by its rounded end through the opening in the tendon sheath from the site of the laceration to the site of the proximal tendon (*Figure A*). During this action hold the probe near the opening of the tendon sheath to avoid buckling of the probe.

**Step 3.**
Maintain the probe's orientation as it is pulled through the proximal incision (*Figure B*), thus ensuring the sleeve does not become twisted as it is pulled into place. The plastic sleeve should protrude from both incisions once in place.

**Step 4.**
Cut across the full thickness of one leg of the sleeve obliquely (*Figure B*) at the base of the tapered segment. An oblique cut creates a larger entry point for the tendon than a transverse cut.

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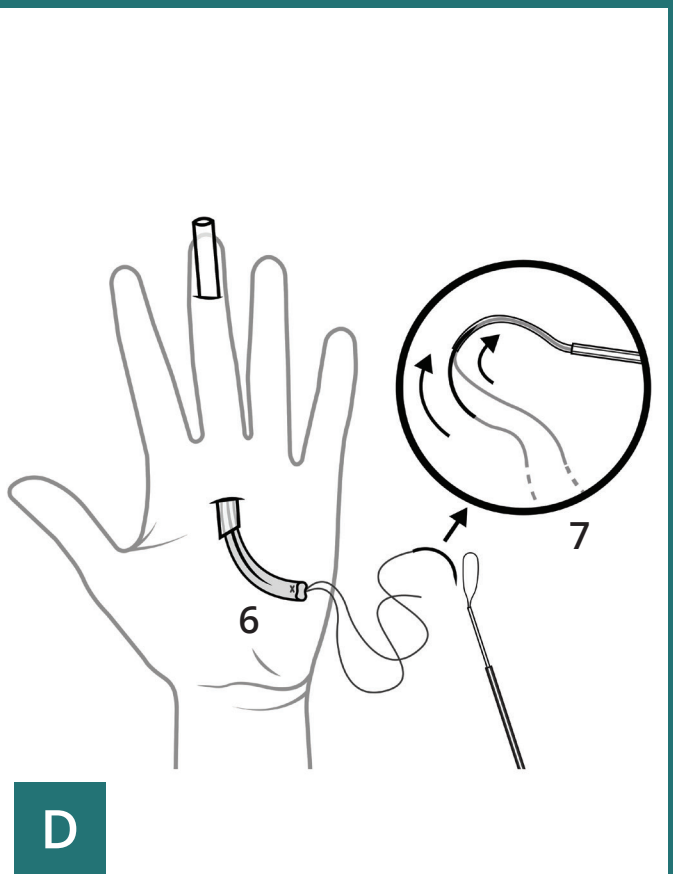
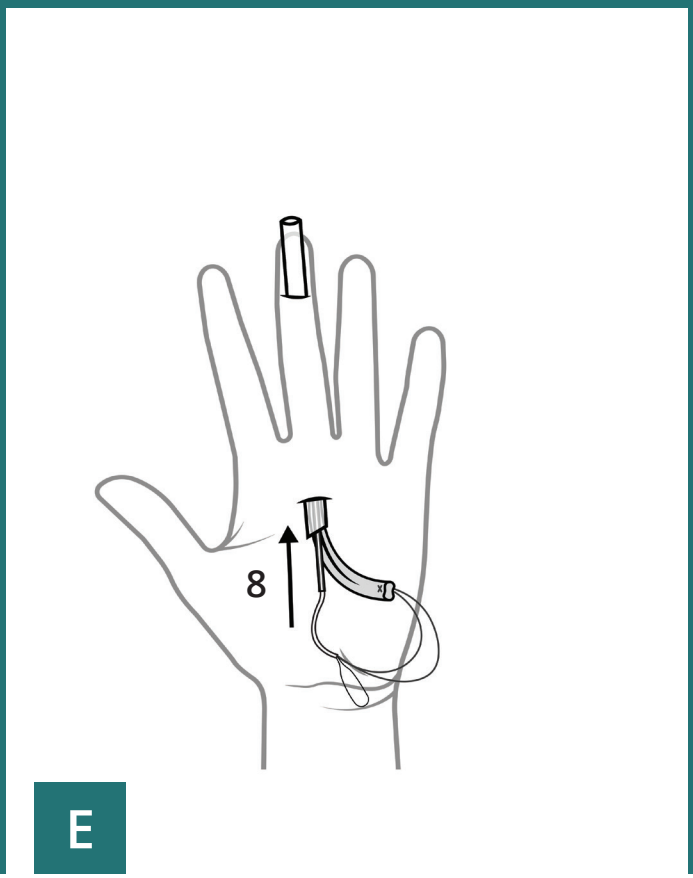



D

**Step 5.**
The leg that has not been cut is then removed from the digit, leaving a single sleeve in place (*Figure C*). The removed leg can be used to repair tendons in a second digit of the same patient by inserting the cut leg back through the wire loop of the probe and repeating steps 1-5 with the remaining whole leg.

**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 section of the device to about 4-5 cm. Then, using a needle holder, the entire body of the curved needle is introduced antegrade in the carrier section (*Figure D*), gently curving the carrier section to preserve the needle tip.

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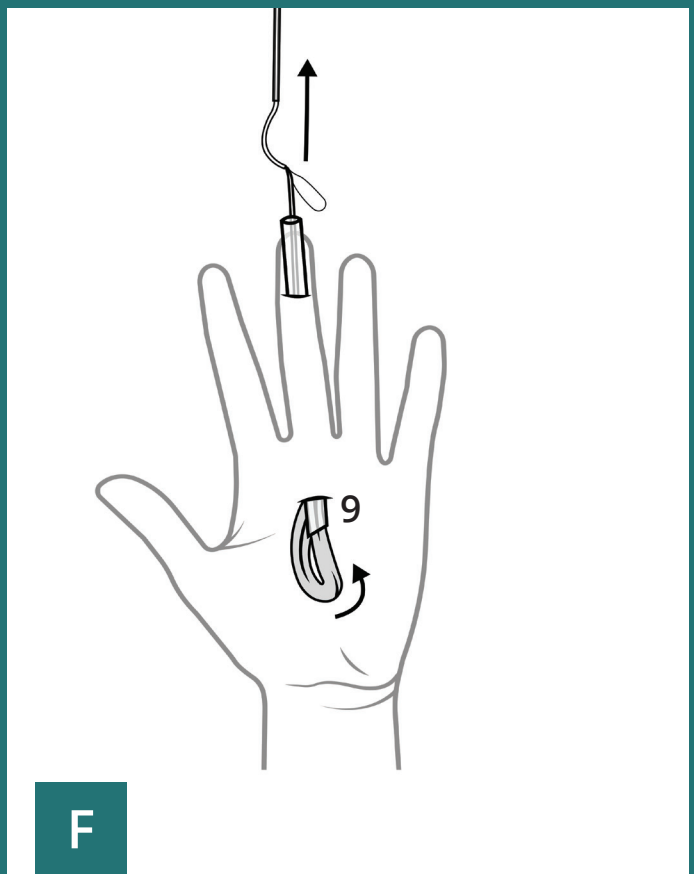


F

**Step 8.**
With the suture end and needle secure within the needle carrier, the probe is threaded through the plastic sleeve from the proximal to distal incisions and removed at the distal incision (*Figure E*). Once passed through the sleeve, the needle and suture can be released from the needle carrier (*Figure F*).

**Step 9.**
It is recommended 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. With gentle traction applied to both ends of the suture (*Figure F*), whilst the plastic sleeve is held in place with forceps at the proximal incision, introduce the proximal tendon stump into the sleeve, guiding it through the cavity and to the distal wound (*Figure F*).

**Step 10.**
Keeping tension on the suture, pull the sleeve 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 with the chosen repair technique with the same needle and suture material.

*The following steps are not illustrated*

If the FDP and FDS both require retrieval and repair, then they should be placed in the anatomic orientation prior to proceeding as per steps 6 – 8. Each tendon stump should be sutured independently and one suture pair at a time should be passed through the plastic sleeve. Then all four suture strands are used to draw the two tendons simultaneously to the distal incision where each can be sutured to its own stump as per steps 9 and 10.

# Further information

## 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 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.

# Ordering information

**202-1500 FlexPasser™ Tendon Retrieval Kit (supplied sterile) includes:**

Please refer to the Instructions for Use leaflet packaged with the **FlexPasser** Tendon Retrieval Kit for essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from the Xiros Sales Department.

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Developed and manufactured by:
**Xiros™ Ltd**
Springfield House
Whitehouse Lane
Yeadon
Leeds LS19 7UE
UK

Tel: +44 (0) 113 238 7200
Fax: +44 (0) 113 238 7201
salesorders@xiros.co.uk
enquiries@xiros.co.uk
**www.xiros.co.uk**

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