EN Instructions for use

EN 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 low density polyethylene (LDPE) and fluorinated ethylene propylene (FEP) plastic sleeve

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 device must not be used for any procedure other than the intended use.

Material Specification
The device is manufactured from stainless steel, low density polyethylene (LDPE) and fluorinated ethylene propylene (FEP).

EN 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 infections and risk of infection.

Step 2. The finger should gently extended. The probe is advanced with its rounded leading through the flexor sheath from the site of the digital flexor stump or opening in the sheath to the site of the proximal flexor stump. The device close to the tip and advance in stages, maintaining the orientation of the probe to avoid buckling and rotator (Figure A).

Step 3. Advance the probe further as it is pulled through the proximal incision (Figure A), 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 incision 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 an incision cut.

Step 5. The suture that has not been cut can be removed from the incision, leaving a single sleeve in place (Figure C).

Step 6. The previously retrieved flexor tendon stump is sutured using the surgeon's preferred technique for the repair, leaving the sutures 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 cm. Then, using a needle holder, the entire body of the curved needle is introduced into the carrier antegrade (Figure E), 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 F), 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 G), whilst the plastic sleeve is held in place with forceps at the proximal incision, to guide the proximal tendon stump through the cavity of the sleeve and to avoid buckling and rotation (Figure H).

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, freeing both ends of the suture in the 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 anatomical orientation prior to proceeding as steps 6 – 10. One suture pair at a time should be passed through the plastic sleeve. Then the four sutures are used to draw the two tendons simultaneously to the distal incision where each can be sutured to its own stump.

Drapes
No specific disposal requirements other than handing contaminated items as clinical waste.

Complaints
Any health care professional who has any complaints or experienced any dissatisfaction in the product quality, usability, durability, reliability, safety, usability, health or performance of the device should contact the manufacturer and distributor immediately.

If the producer or any of its agents 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, (if necessary), your name and contact details and the nature of the complaint.