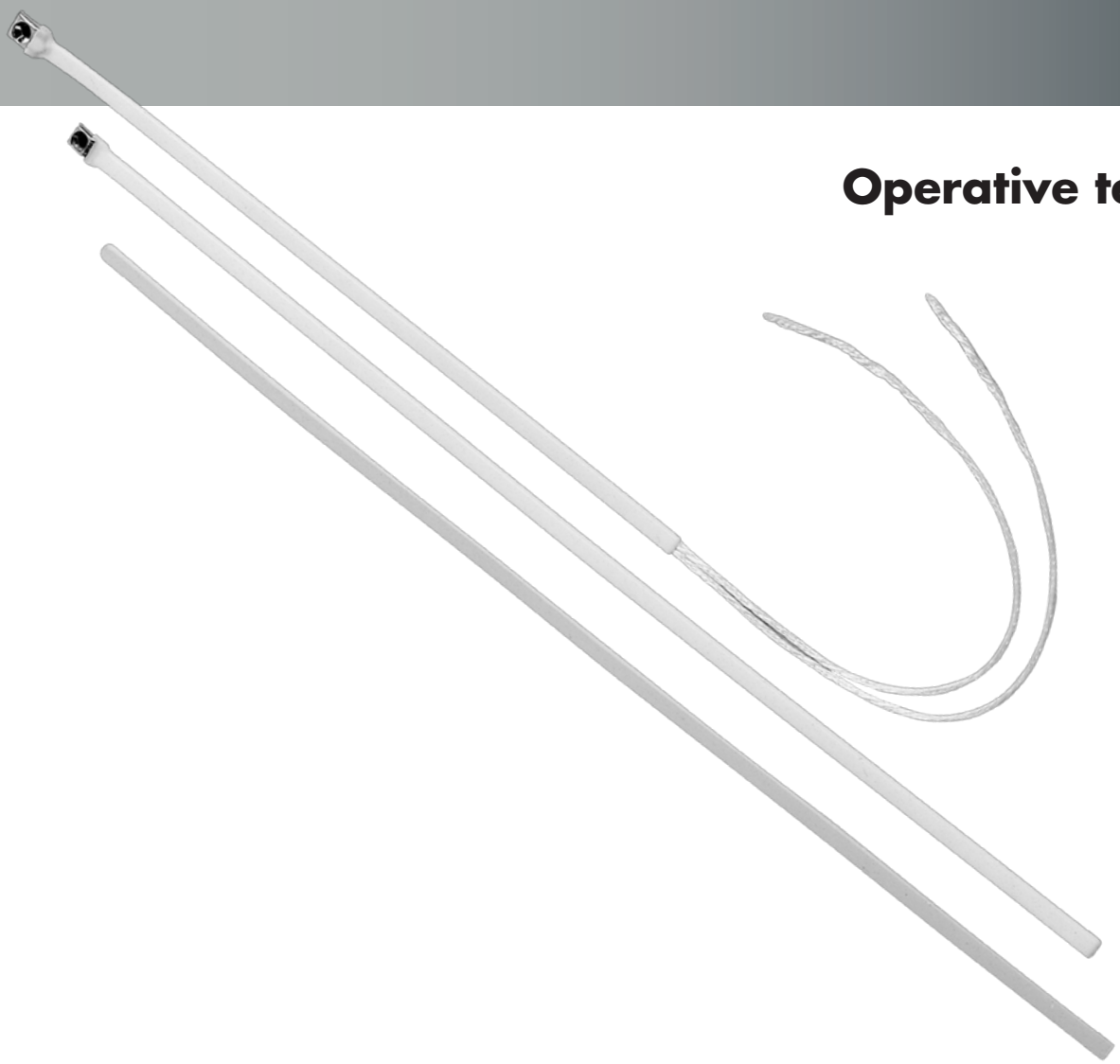
stryker

Hunter

Tendon implants



Operative technique

Hunter Tendon
Implants

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.wright.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Hunter Active Tendon Implant introduction

Device descriptions

The Hunter Active Tendon Implants consist primarily of an implant comprised of a polyester core covered with silicone elastomer (barium-impregnated for radiopacity). The Hunter Active Tendon Implant is double-pouched, and is sterile unless the inner pouch is opened or damaged.

Indications for use

The Hunter Active Tendon Implants are indicated for use in stage one of the two-stage procedure developed by Dr. James M. Hunter for the reconstruction of flexor and extensor tendons in individuals having significant hand tendon injury. The device is intended to be implanted temporarily in order to encourage the formation of a pseudosynovial sheath which will later nourish and lubricate an autogenous tendon graft.

The interval between Stage One (implantation of the device and formation of the pseudosynovial sheath) and Stage Two (removal of the device and autogenous tendon grafting) should be two to six months to permit maturation of the tendon bed to the point where it can nourish and lubricate a tendon graft. The surgeon must determine, on the basis of the findings in the hand, the appropriate time within that period at which to commence Stage Two of the procedure. The Hunter Active Tendon Implants are specifically indicated in cases in which proximal anastomosis must be executed deep in the proximal forearm. The Hunter Active Tendon Implant is specifically indicated in cases in which proximal anastomosis must be executed deep in the proximal forearm.

Contraindications for use

This device is not intended for any use other than that indicated. Residual antecedent infection is a contraindication for the use of this device. Appropriate surgical and antimicrobial treatment and subsequent wound healing will allow the procedure to be carried out at a later date. A digit that has a scarred tendon bed, borderline nutrition, nerve deficit and severe joint stiffness could possibly be salvaged; however, this should probably be undertaken only in the patient with very special requirements. Subsequent functional expectations are limited.

Instructions for use

The following procedure is offered as an aid to the surgeon and is not intended to replace individual clinical judgment.

The following instructions for use of the Hunter Active Tendon Implant is based on the surgical procedures employed by Dr. James M. Hunter, who participated in the development of the device. Note that only the methods for implantation and removal of the device are presented here.

ATPC

Operative technique

Implantation of Hunter Active Tendon Implant

Preparation

1. The damaged flexor tendons and their scarred sheaths are exposed by means of the Brunner zigzag incision in the finger and palm. The proximal portions of the flexor tendons and their musculotendinous junctions in the forearm are exposed by means of a curvilinear incision on the volar ulnar aspect of the forearm.

2. The retinacular pulley system should be preserved or reconstructed. An adequate, intact pulley system is essential for good function. When the retinacular pulley system is inadequate and bowstringing is noted, reconstruction of the system is indicated. Four pulleys are preferable (A1, A2, A3, A4).

3. All scar tissue should be meticulously excised. The entire system from the proximal edge of A1 pulley to the distal phalanx should be exposed and explored. All remnants of the flexor tendons should be excised through multiple transverse incisions in the retinacular pulley systems. Contracted or scarred lumbrical muscle should also be excised in order to prevent paradoxical motion of the lumbricals after tendon grafting.

4. Undamaged portions of the flexor fibro-osseous retinacula which are not contracted are retained.

Operative technique

Insertion of the active implant

5. Pass the device in a distal-to-proximal direction. Moistening the device with sterile Ringer's solution will facilitate this process. Advance the proximal cords through the pulleys and use the cords to gently pull the implant portion through.

6. Pass the device from palm to forearm through the carpal canal in a similar manner. Prepare the canal by passing a blunt metal obturator instrument (such as the Ober tendon passer) superficial to the profundus tendon and pull the polyester cords into the forearm. Use the cords to gently pull the implant portion through. Observe the distal fixation component and guide it to a position slightly proximal to its anticipated location over the phalanx.

Distal attachment for ATPC

Note:
To secure the distal component to bone in a way which will achieve a strong, durable juncture, the following technique developed by Dr. Hunter should be used.

The recommended bone screw is a stainless steel 2.0mm bi-cortical screw (with cruciform recess).

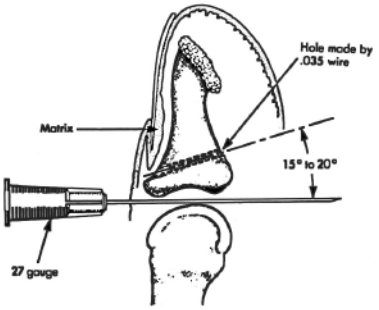


Figure 1A

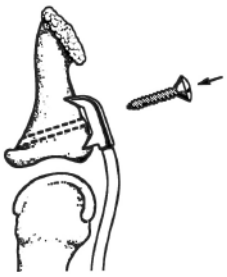


Figure 1B

Note:

Alternate distal attachments
The distal component is designed to permit fixation with twisted wire through bone, as well as with screw. If, during preparation for screw insertion, the screw fixation is inadequate, fixation with twisted wire can be utilized. | FigureS 2A, 2B, 2C. If the bone has been fractured or shows osteoporosis, fixation with twisted wire through a single lateral drill hole is preferred | FigureS 3A, 3B, 3C. In either case, the distal fixation component must be attached tightly and securely to the bone to prevent slippage during cyclic motion. When completing fixation, always base the twist on the edge of the fixation component and tuck excess bulk into the countersink of the component.

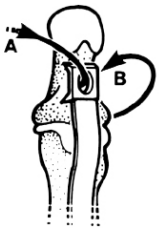


Figure 2A

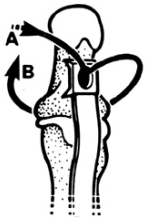


Figure 2B

Figure 2C

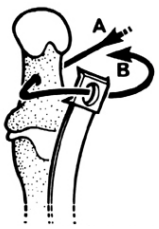


Figure 3A

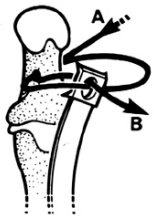


Figure 3B

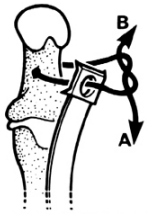


Figure 3C

1. A strip of profundus should be retained, drawn over the distal component and sutured laterally to act as a soft tissue buffer.

2. Remove the tourniquet, review all wounds, wash out and close the distal incision.

Operative technique

Proximal attachments for type ATPC

1. Select motor tendon: The profundus motor is of first preference, the superficials, second. Desired excursion of the motor tendon is 4cm for the FDP and 3cm for the FDS.

2. The rod portion of the tendon can be shortened if necessary. With care, the silicone rubber can be peeled away from the polyester cord at the proximal end and trimmed with a scalpel. Care must be taken not to damage the polyester weave during this step. The two cords are attached by sewing crossing stitches of dacron from side to side. These stitches must be carefully cut to free the two dacron cords for the attachment to bone or tendon during the reconstructive surgery.

3. The proximal cords are woven into the lateral borders of the motor tendon and fixed with Mersilene sutures at points of exit. Approximately 10mm from the end of the motor tendon, make a small (2 to 3 mm) longitudinal slit in the lateral aspect of the motor tendon to allow passage of a fine line curved hemostat. Insert the hemostat, with its tip moving distally, into the slit such that the tip exits from the end of the motor tendon | Figure 4A. Grasp the corresponding tendon cord with the hemostat and draw it back through | Figure 4B. Repeat the procedure on the opposite side. After each cord has been passed through the tendon one time, draw the tendon up so the proximal edge of the rod is adjacent to the end of the tendon and secure each cord with a suture | Figure 4C. Test the tension by moistening the implant, followed by flexion and extension of the wrist. The finger should lie in extension during wrist flexion and show a position of balance with the adjacent fingers on wrist extension. If balance is acceptable, make two or three additional passes | Figure 4D, securing each with Mersilene suture. Retest tendon balance to be sure there has been no loss of tension. If balance is acceptable, the proximal cords can be tied securely and reinforced with 3-0 polyester sutures; excess proximal cord is cut with electric cautery | Figure 4E.

4. Wash out and close the proximal incision.

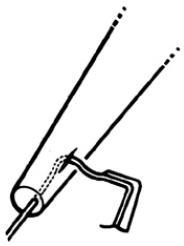


Figure 4A

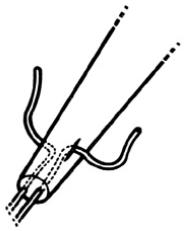


Figure 4B

Figure 4C

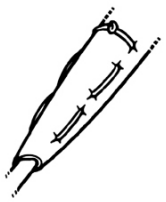


Figure 4D

Note:
The Hunter Tendon silicone contains barium that gives an x-ray view of the implant loosening or migrating.

Hunter Passive Tendon Implant introduction

Device descriptions

The Hunter Standard Tendon Implant consists primarily of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). This design is intended to provide the necessary combination of inert qualities, firmness and flexibility as well as the smooth surface required to induce pseudosynovial sheath formation and assist with ease of insertion and gliding through the finger, palm and forearm.

The Hunter Passive Tendon Implant consists primarily of a woven polyester core covered with barium-impregnated silicone elastomer. At the distal end of the device is a fixation component made of type 316 stainless steel. A hole in the fixation component accommodates a stainless steel bone screw (not provided) which is used to secure the device of the phalanx. (See Step 8 of Implantation procedures for screw specifications.) The Hunter Standard Tendon Implant and Passive Tendon Implant are double-pouched, and are sterile unless the inner package is opened and damaged.

Indications for use

This device is indicated for use in stage one of the two-stage procedure developed by Dr. James M. Hunter for the reconstruction of flexor and extensor tendons in individuals having significant hand tendon injury. The device is intended to be implanted temporarily in order to encourage the formation of a pseudosynovial sheath which will later nourish and lubricate an autogenous tendon graft.

Contraindications for use

This device is not intended for any use other than that indicated. Residual antecedent infection is a contraindication for the use of this device. Appropriate surgical and antimicrobial treatment and subsequent wound healing will allow the procedure to be carried out at a later date. Severe joint stiffness and poor soft tissue nutrition are contraindications for the use of this device.

Instructions for use

The following procedure is offered as an aid to the surgeon and is not intended to replace individual clinical judgment.

The following instructions for use of the Hunter Standard Tendon Implant and Passive Tendon Implant are based on the surgical procedures employed by Dr. James M. Hunter, who participated in the development of the device. Note that only the methods for implantation and removal of the device are presented here.

Operative technique

Implantation of the Hunter Standard Tendon Implant/Passive Tendon Implant

1. The damaged flexor tendons and their scarred sheaths are exposed by means of the zigzag incision in the finger and palm. The proximal portions of the flexor tendons and their musculotendinous junctions in the forearm are exposed by means of an ulnarly curved volar incision. A stump of profundus tendon, one centimeter in length, is left attached to the distal phalanx.

2. Scarred tendons, sheath and retinacula are then excised. Contracted or scarred lumbrical muscle should also be excised in order to prevent paradoxical motion of the lumbricals after tendon grafting.

3. Undamaged portions of the flexor fibro-osseous retinacula which are not contracted are retained, as well as any portion of the retinacula that can be dilated instrumentally with a hemostat. The remainder is excised.

4. The retinacular pulley system should be preserved or reconstructed adjacent to the axis of motion of each joint to assure that normal gliding of the tendon will be restored. Four pulleys are preferable, one proximal to each of the three finger joints and one at the base of the proximal phalanx.

5. The device is placed on sponges moistened with sterile Ringer's solution on the volar aspect of the forearm. A tendon passer, having a diameter slightly larger than that of the device, is passed proximally from the palm along the floor of the carpal tunnel into the forearm.

Operative technique

Note:
Step 6 pertains to the standard passive tendon implant.

6. One end of the standard tendon implant is secured to the tendon passer and pulled into the forearm. It is then pushed into the distal end of the finger. Wetting the rod with NSS or ringer's solution will ease its passage. When the rod is in position, the appropriate length is determined and, if necessary, the rod is cut at the distal end. The distal end of the rod is then sutured beneath the stump of profundus tendon using No. 32 or 34 monofilament stainless steel wire or 4-0 Dacron suture | Figure 1A. In addition, medial and lateral sutures of No. 35 multifilament wire are placed through the tendon, the implant and fibroperiosteum for further fixation | Figure 1B. For secure attachment, sutures must pass through the inner polyester core of the device.

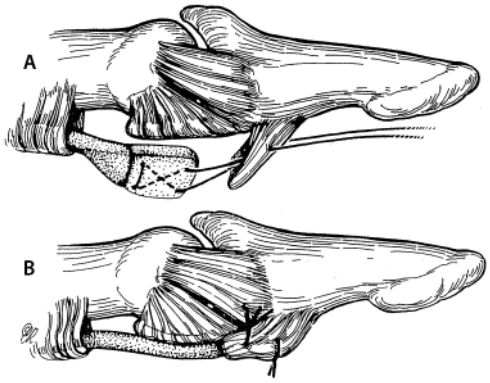


Figure 1A **Figure 1B**

Note:
Steps 7-9 pertain to the passive tendon implant only.

7. The Passive Tendon Implant usually has to be threaded distal to proximal. However, with the plastic cover over the fixation component it may be slipped proximal to distal if pulleys are large. Moistening the device with Ringer's Solution will facilitate this process. Discard the plastic cover after tendon placement.

8. The distal end of the implant is affixed to the base of the distal phalanx by means of a bone screw. The screw is inserted through the fixation component and into the underlying bone, through the cortex. Recommended Bone Screw: 2.0mm bi-cortical screw with cruciform recess. Drill Size: 1.5mm. Tap Size: 2.0mm (unless self-tapping screw is preferred). Length: 10mm (Range: 6.0mm to 20mm in 2.0mm increments).

   The phalanx is prepared for screw fixation by elevating the periosteum over the proximal one-third of the distal phalanx.

   The device is centered, care being taken to assure that the juncture of the fixation component and the flexible segment of the implant is adjacent to and distal to the interphalangeal joint.

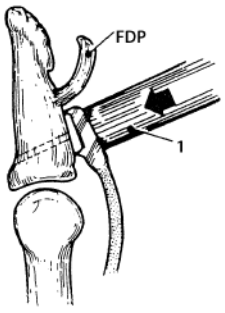


Figure 2A

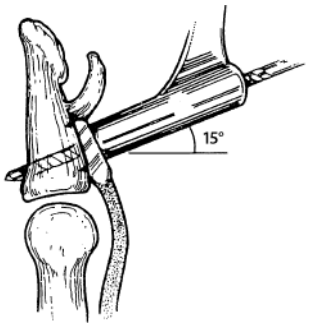


Figure 2B

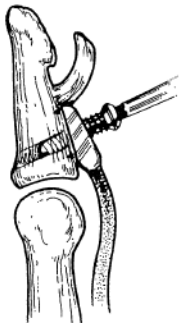


Figure 2C

Figure 2D

Operative technique

The bone screw plate component is pressed into the bone and tapped with a mallet until it is flat | Figure 2A. The drill is passed through the bone at a 15 to 20° angle from perpendicular so as not to drill through the nail bed | Figure 2B. The device is then securely affixed to the phalanx by means of the bone screw | Figure 2C. The distal stump is placed over the bone screw plate and secured with lateral sutures | Figure 2D.

The dorsum of the finger is checked to assure that the tip of the screw is not palpable in the nail bed.

Note:
The same technique can be used for fixation of the device to the middle phalanx, except that the length of the bone screw used for fixation should be greater. This alternate procedure establishes sublimus tendon function, eliminating extensive surgery in certain scarred fingers, as well as assisting the surgeon and hand therapist with an easier postoperative training program. If the implant is attached to the middle phalanx, arthrodesis or tenodesis of the distal interphalangeal joint is required. | Figure 3. In cases where the bone is compromised by osteoporosis or fracture, the bone screw plate may be wired to the phalanx with stainless wire | Figure 4

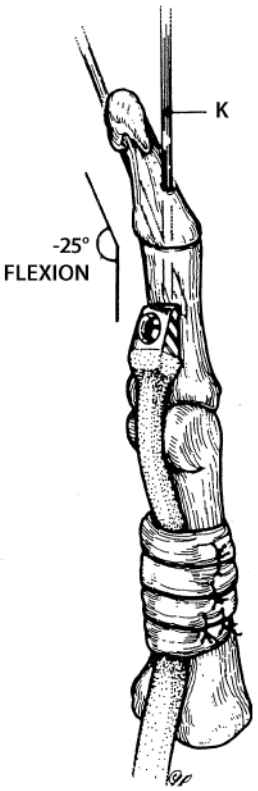


Figure 3

9. When the implant is in position, the appropriate length is determined and, if necessary, the device is cut at the proximal end.

10. When the distal end of the device has been fixed in place, traction is applied to the proximal end, to assure that the attachment of the device is distal to the distal interphalangeal joint and its volar plate and that there is no binding of the tendon during flexion and extension.

11. The device is also observed during passive flexion and extension of the finger, it should glide freely with no binding or buckling distal to any part of the pulley system. If free gliding does not occur, one of the pulleys may be too tight and modification of the pulley system may be necessary.

12. The proximal end of the device should lie in the forearm if possible so that the subsequently formed pseudosynovial sheath will extend to the region of the musculotendinous junction of the motor muscle. The device may be placed deep to the antebrachial fascia or deep in one of the intermuscular planes. The track for the device can be formed by separating connective tissue and tendon mesenteries with the moistened, gloved finger.

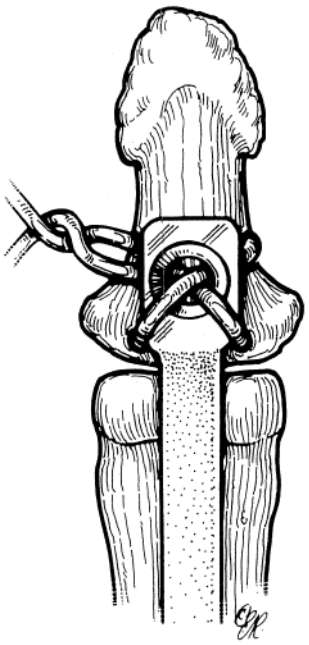


Figure 4

Operative technique

The track formed for the device must permit free passive gliding during flexion and extension of the finger. If this is not possible, the device must be shortened so that when the finger is fully extended, the proximal end of the device lies just proximal to the flexion crease at the wrist.

13. Importantly, the surgeon under vision should look at the proximal end gliding and distal end fixation. Then the surgeon should put the patient in a passive range of motion to visually see continuous gliding and to visually check two places for problems. If there is difficulty in the range of motion, it is most likely a tight pulley which needs to be loosened or the implant is too long which can cause buckling.

14. Following skin closure, a standard postoperative hand dressing is applied, with the wrist and metacarphophalangeal joints in moderate flexion (40° to 50°) and the interphalangeal joints in slight flexion (20° to 30°).

Note:
The Hunter Tendon silicone contains barium that gives an x-ray view of the implant loosening or migrating.

Operative technique

Removal of the Standard Tendon Implant/Passive Tendon Implant

Note:
Details of management during the interval between implantation of the device and formation of the pseudosynovial sheath (Stage I) and removal of the device and autogenous tendon grafting (Stage II) are found in Hunter and Salisbury (1971), Hunter and Jaeger (1977), and the AAOS Symposium of Tendon Surgery in the Hand (1975).[1,2] The interval between Stage I and Stage II should be two to six months, or long enough to permit maturation of the tendon bed to the point where it can nourish and lubricate a tendon graft. The surgeon must determine, on the basis of the findings in the hand, the appropriate time at which to commence Stage II of the procedure.

1. At operation, the limits of extension and flexion of the finger are measured and recorded.
2. A short zigzag incision is made to locate the distal end of the device where it is attached to the phalanx. This attachment is left intact and a second ulnarly curved volar incision is made through the previous Stage I incision in the forearm, so as to expose the proximal end of the device and the musculotendinous junction of the superficialis or profundus tendon, whichever is to be used as a motor for the tendon graft.
3. The excursion of the proximal end of the device, as the finger is moved from full extension to full flexion, should be measured, so as to determine the amount of excursion that the motor muscle must have to provide full finger motion.
4. Either the plantaris tendon or a long toe extensor tendon is obtained from the leg for use as the tendon graft.
5. One end of the tendon graft is sutured to the proximal end of the device with catgut or polyester suture.
6. Leaving the distal end of the device attached to the distal phalanx, the rest of the device, with the attached tendon graft, is pulled distally through the new sheath | Figure 5A. The device is then removed and discarded.
7. The Stage II procedure is completed by following established techniques for tendon grafting | Figure 5B.

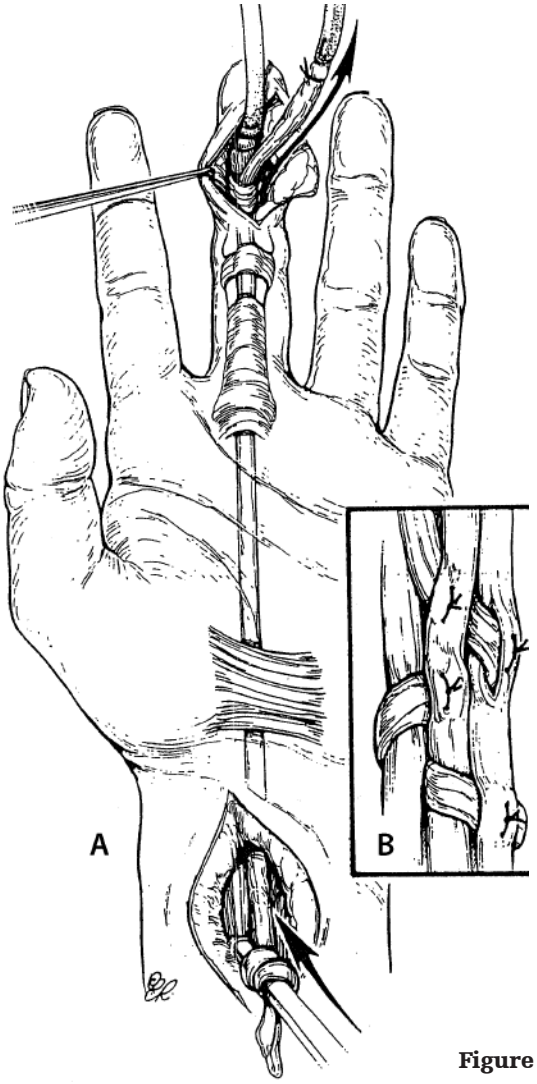


Figure 5A & B

Ordering information

Hunter Standard Tendon Implant 24.5cm length

Reference	Description
TR200000	2mm Wide
TR300000	3mm Wide
TR400000	4mm Wide
TR500000	5mm Wide
TR600000	6mm Wide

Hunter Passive Tendon Implant 25cm length

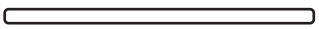
Reference	Description
PT300000	3 mm Wide
PT400000	4 mm Wide
PT500000	5 mm Wide
PT600000	6 mm Wide

Hunter Active Tendon Implant 4mm width

Reference	Description
ATPC1640	16cm Long
ATPC1840	18cm Long
ATPC2040	20cm Long
ATPC2240	22cm Long
ATPC2640	26cm Long

Swanson Tendon spacer

Reference	Description
24270003	24cm × 3mm
24270004	24cm × 4mm
24270005	24cm × 5mm
24270006	24cm × 6mm
24370001	Swanson sizers (provided non-sterile) (Green=3, Blue=4, Yellow=5, Red=6)



Notes:

References

1. Hunter, J M, and R E Salisbury. “Flexor-tendon reconstruction in severely damaged hands. A two-stage procedure using a silicone-dacron reinforced gliding prosthesis prior to tendon grafting.” The Journal of Bone and Joint Surgery. American volume vol. 53,5 (1971): 829-58
2. Hunter, James M., and Scott H. Jaeger. “Tendon Implants: Primary and Secondary Usage.” Orthopedic Clinics of North America, vol. 8, no. 2, 1977, pp. 473–489

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