

TENO^TTACTM

SOFT TISSUE FIXATION SYSTEM

SURGICAL TECHNIQUE GUIDE

Tendon Transfer using the TenoTac[®] Soft Tissue Fixation System

Exclusively foot & ankle **20**
Paragon[®]



Acknowledgment:

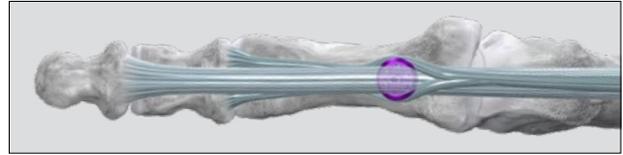
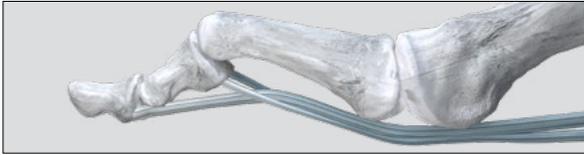
Paragon 28® would like to thank Douglas Blacklidge, DPM for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

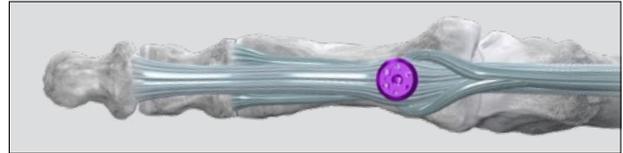
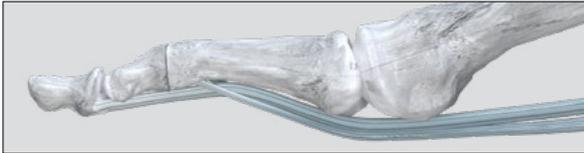
The Paragon 28® TenoTac® Soft Tissue Fixation System was developed to provide surgeons an alternative fixation option for flexible hammertoes, mallet toes or claw toes. Additionally, the TenoTac® System was designed to supplement fixation of rigid hammertoes and plantar plate repair by providing stabilization of the metatarsophalangeal (MTP) joint in the sagittal and transverse planes. The standard system allows the surgeon to select whether only the flexor digitorum brevis (FDB) tendon, flexor digitorum longus (FDL) tendon or both are “tacked” down against the proximal phalanx, depending on deformity. The large (hallux) system is also available to tack down the flexor hallucis longus (FHL) for a hallux malleus deformity. Medial and lateral tendon tensioning can be performed to correct transverse plane deformity prior to securing the implant.

Examples of use include:

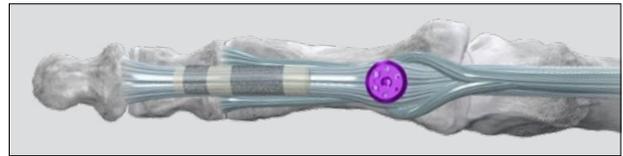
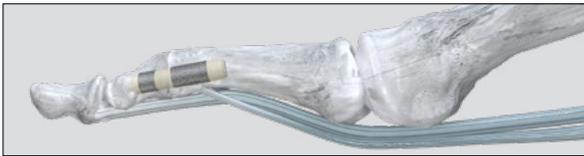
- *Replacement for Girdlestone-Taylor procedure for flexible hammertoes*



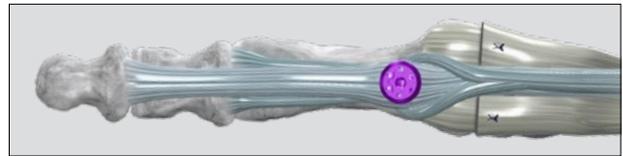
- *Used in conjunction with proximal interphalangeal joint (PIPJ) arthroplasty to stabilize the metatarsophalangeal joint*



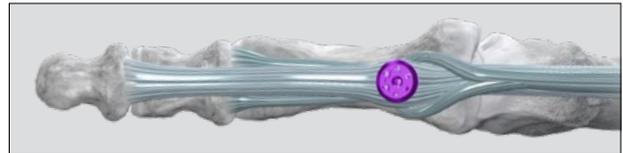
- *Used in conjunction with PIPJ arthrodesis to stabilize the metatarsophalangeal joint*



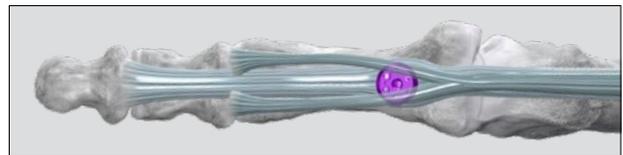
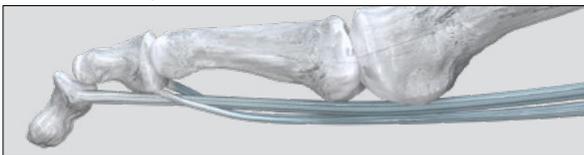
- *Combined with plantar plate repair to bolster the repair and correct the digital deformity*



- *Used as a sole implant to correct flexible claw toe*



- *Used as a sole implant to correct flexible mallet toe*

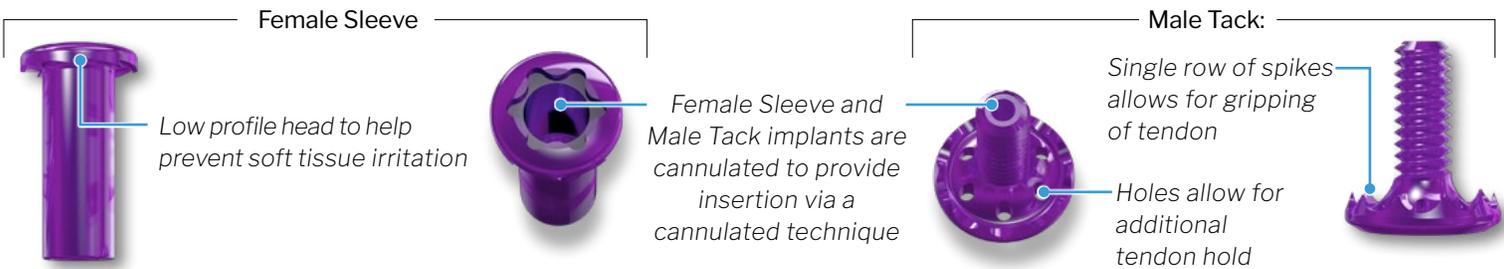


IMPLANT FEATURES

NOTE: Standard non-sterile and sterile kits use S,M and L where as the sterile large (hallux) kit uses M, L and XL

	Short (S)	Medium (M)	Long (L)	Extra Long (XL)
Female Sleeve:				

	Standard	Large (Hallux)
Male Tack:		

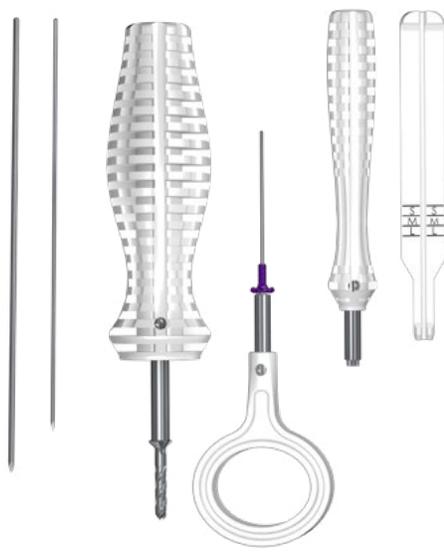


INSTRUMENTATION



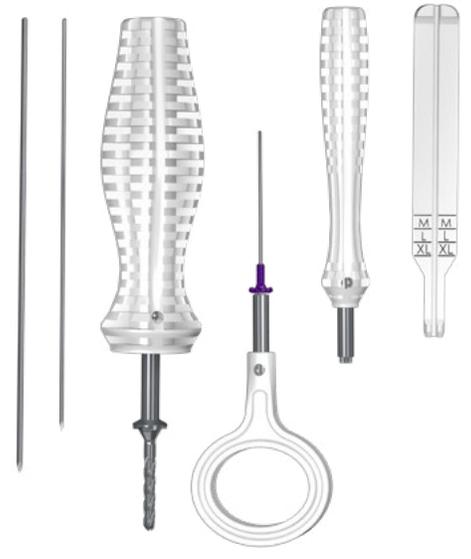
**Teno Tac®
Non-Sterile Caddy
(Standard only)**

- Ø0.9 mm K-wire
- AO Handle
- Ø2.8 mm Cannulated Drill/ Countersink
- Male Tack Inserter
- Female Sleeve Driver
- Female Sleeve Length Gauge



**Teno Tac®
Standard Sterile Packed Kit
(Standard Kit Specific Instruments)**

- Ø0.9 mm K-wire
- Ø1.1 mm K-wire
- Ø2.8 mm Cannulated Drill/ Standard Countersink with Handle
- Male Tack Inserter with respective Standard or Large
- Female Sleeve Driver
- Female Sleeve Standard Length Gauge

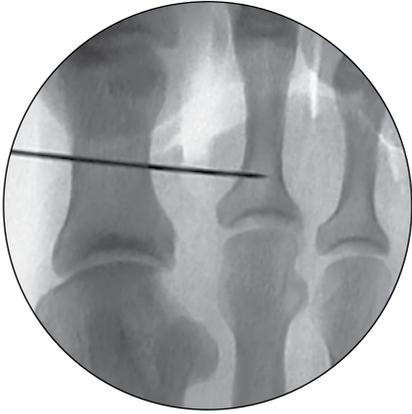


**Teno Tac®
Large/Hallux Sterile Packed Kit
(Large/Hallux Kit Specific Instruments)**

- Ø0.9 mm K-wire
- Ø1.1 mm K-wire
- Ø2.8 mm Cannulated Drill/ Large Countersink with Handle
- Male Tack Inserter with respective Standard or Large
- Female Sleeve Driver
- Female Sleeve Large Length Gauge

K-WIRE PLACEMENT

The procedure shown demonstrates repair of a flexible hammertoe deformity, with “tacking” down of the medial and lateral slips of the FDB tendon and a portion of the central FDL tendon, using the non-sterile standard caddy configuration. Other than visual appearance of the instrumentation, there are no additional surgical technique steps required with the standard and large (hallux) sterile packed kits.

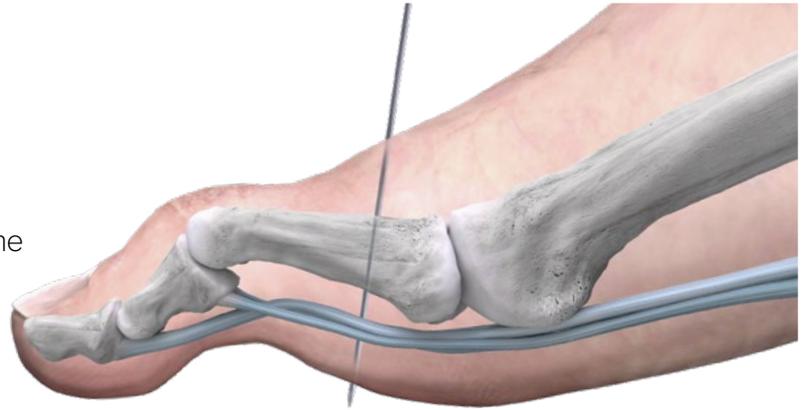


Supine patient positioning with fluoroscopy available is recommended. Place the tip of the Ø0.9 mm K-wire on the dorsal, central aspect of the base of the proximal phalanx.

Confirm start position of the Ø0.9 mm K-wire under fluoroscopy.

Drive the Ø0.9 mm K-wire from dorsal to plantar, exiting the plantar skin.

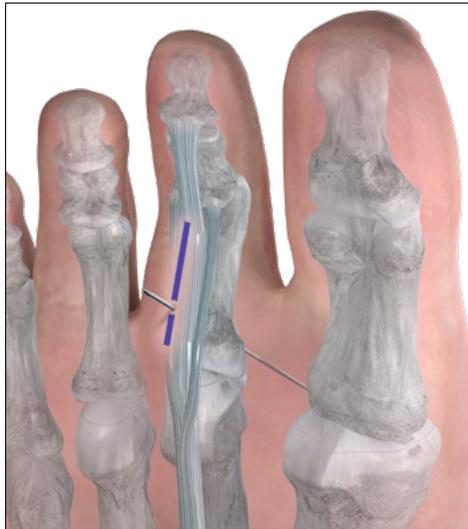
Confirm final K-wire position using fluoroscopy.



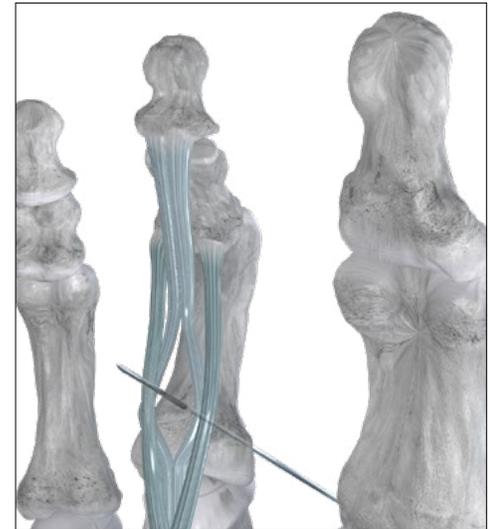
INCISION/EXPOSURE



Make a small, dorsal incision at the entry point of the K-wire, approximately 5-7 mm in length, to allow exposure of the extensor tendons. Perform blunt dissection to bone, to allow for Drill penetration and Female Sleeve placement.



A longitudinal plantar incision is made on either side of the K-wire, allowing for adequate access to the flexor tendons and the plantar surface of the base of the proximal phalanx.



Continue plantar dissection around the K-wire to expose the FDL and FDB tendons. The FDL tendon can be retracted medially or laterally, or split longitudinally at its median raphe (shown) to allow for retraction of the FDL and FDB tendons medially and laterally, exposing the base of the proximal phalanx.

OPTIONAL SUTURE REPAIR TECHNIQUE



Pass the suture needle through the flexor tendons from the *plantar* to *dorsal* aspect.



Wrap the suture around the flexor tendons.

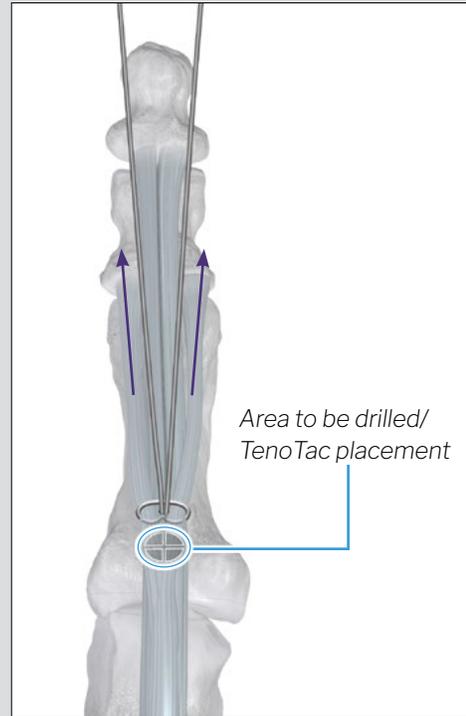


Pass the suture needle through the flexor tendons from the *dorsal* to *plantar* aspect.

 **NOTE:** Ensure both suture ends are similar in length. For the suture, refer to the manufacturer's labeling for proper use and handling.



To secure the flexor tendons, pull both suture ends tightly.

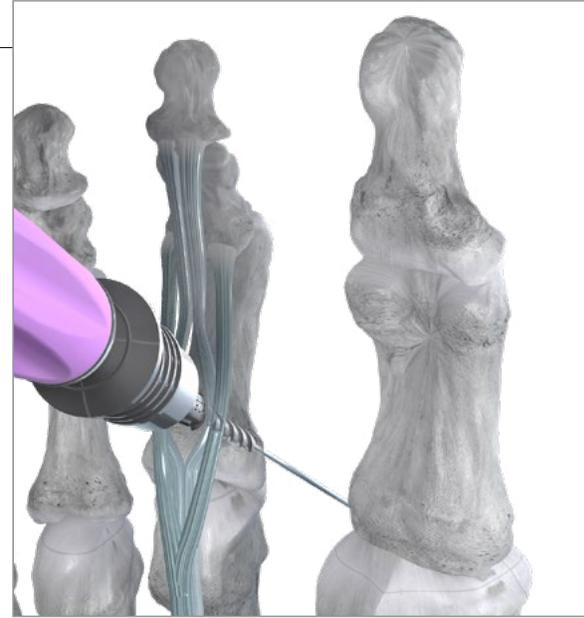
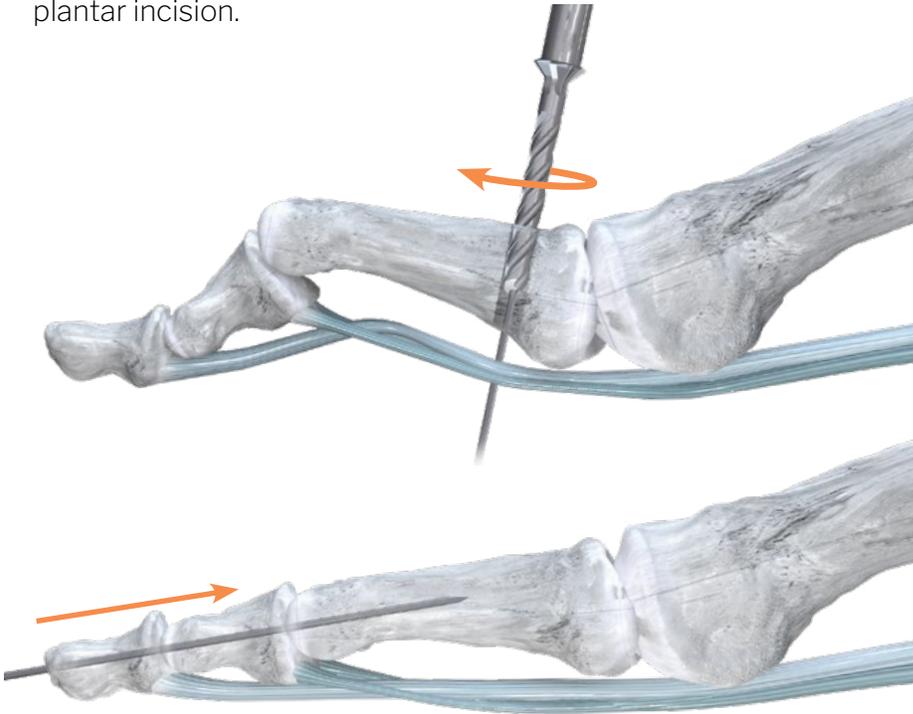


During drilling and placement of the Teno Tac, pull the suture strands distally and place the Drill proximally to the suture loop.

DRILLING/COUNTERSINKING

Connect the provided Drill/Countersink to the AO Handle. Rotate the Drill clockwise, by hand, bi-cortically through the proximal phalanx. The Drill portion will exit the dorsal incision.

Rotate the Drill/Countersink approximately 3 times once the Countersink contacts the bone to allow for adequate countersinking of the proximal phalanx. Remove the Drill/Countersink from the plantar incision.



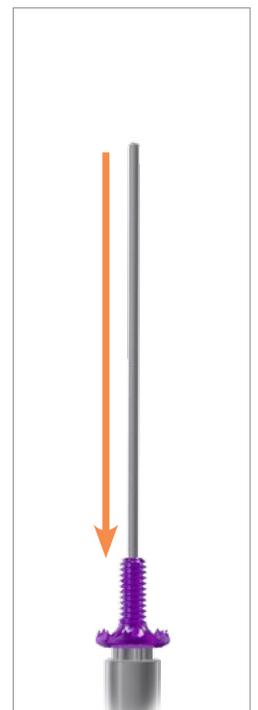
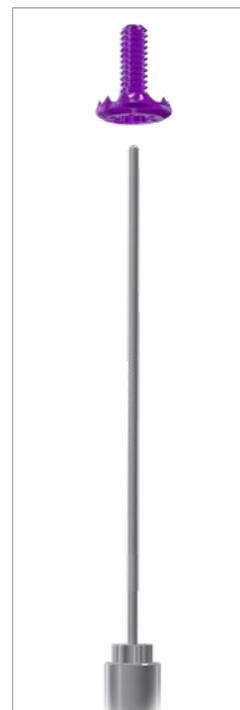
Insert the Drill/Countersink over the K-wire at the dorsal aspect of the proximal phalanx and rotate it a few times to clear any remaining bone debris.

Remove the Drill/Countersink and K-wire.

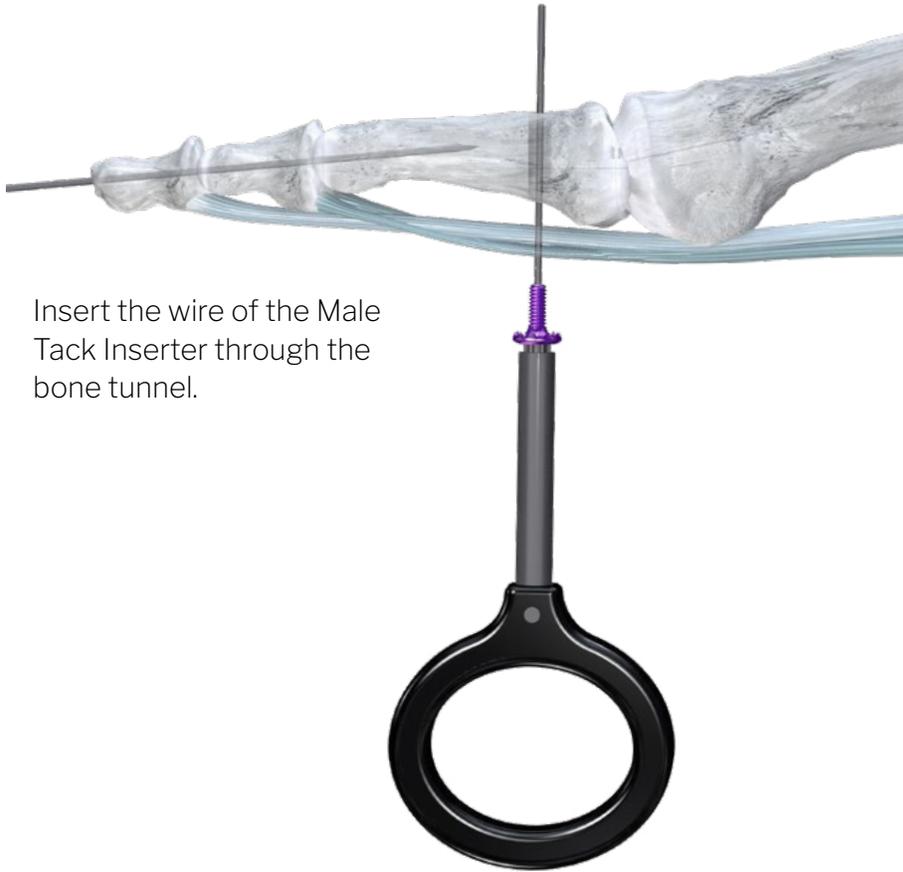
Insert a $\text{\O}1.1$ mm or larger K-wire from the distal portion of the distal phalanx through the middle phalanx and halfway into the proximal phalanx to hold the PIPJ in the corrected position while performing the subsequent steps of implant insertion.

MALE TACK IMPLANT INSERTION

Remove retraction of the tendons. Place the Male Tack implant on the Male Tack Inserter. The surgeon's thumb should go into the hole of the Male Tack Inserter.



MALE TACK IMPLANT INSERTION

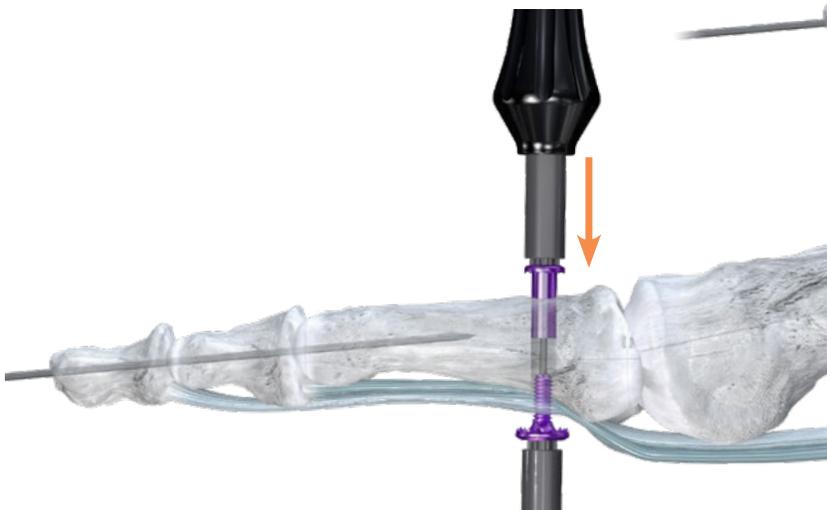


As the Male Tack portion of the implant nears the bone, the surgeon should ensure that the desired tendons to be “tacked” down to the proximal phalanx are between the Male Tack implant and the proximal phalanx.

FEMALE SLEEVE IMPLANT INSERTION

Place the Female Sleeve Length Gauge over the wire of the Male Tack Inserter until contact is made with the dorsal proximal phalanx. Read the wire length on the Female Sleeve Length Gauge to determine Female Sleeve size. If Length Gauge lands on the line between two sizes, select the smaller of the two sizes.

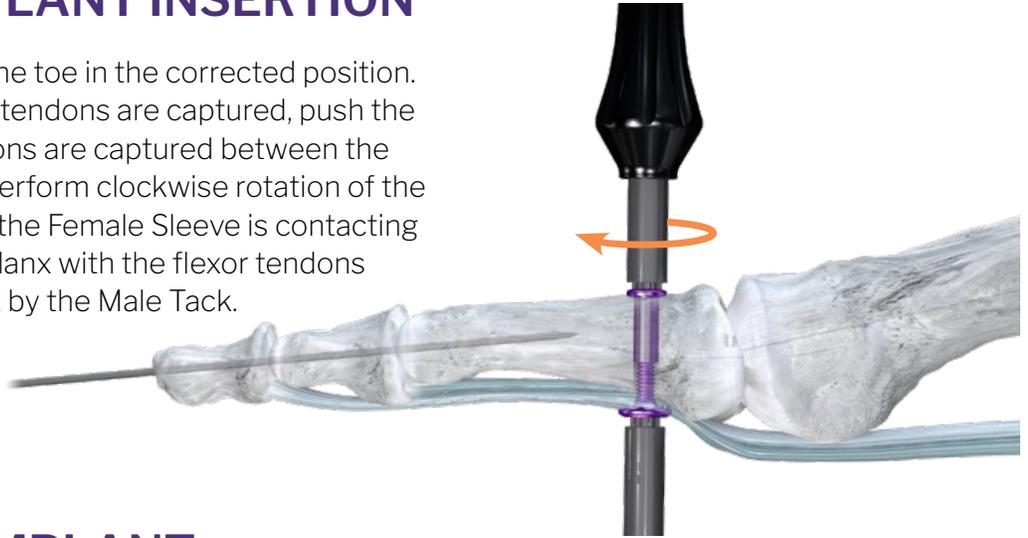
Relax plantar pressure on the Male Tack against the proximal phalanx to allow for entry of the Female Sleeve, if necessary.



Select the measured Female Sleeve size. Place the Female Sleeve over the wire of the Male Tack Inserter and push the Female Sleeve Driver from dorsal to plantar until the Female Sleeve enters the bone.

FEMALE SLEEVE IMPLANT INSERTION

The non-dominant hand should hold the toe in the corrected position. While ensuring that the desired flexor tendons are captured, push the Male Tack dorsally such that the tendons are captured between the Male Tack and the proximal phalanx. Perform clockwise rotation of the Female Sleeve until the flat portion of the Female Sleeve is contacting the dorsal surface of the proximal phalanx with the flexor tendons captured against the proximal phalanx by the Male Tack.



CONFIRMATION OF IMPLANT

Confirm implant position visually and using fluoroscopy, if desired. If correct toe position is achieved, the K-wire across the PIPJ can be removed, if desired.

If appropriate tensioning and the toe position is not achieved, insert the Male Tack Inserter plantarly into the Male Tack. Insert the Female Sleeve Driver into the Female Driver and rotate counterclockwise to loosen the grip on the flexor tendons. Reposition the tendons under the Male Tack at the appropriate tension, and re-tighten the female by rotating the Female Sleeve Driver in a clockwise manner.

Remove the K-wire across the PIPJ.



CLOSURE

Proceed to incision closure or concomitant procedures at this time.

IMPLANT REMOVAL

Retrieve the Male Tack Inserter and insert it through the Male Tack until the Driver portion engages the head of the Male Tack. Retrieve the Female Sleeve Driver. Engage the Female Sleeve Driver into the head of the Female Sleeve, and while stabilizing the Male Tack with the Male Tack Inserter, rotate the Female Sleeve Driver counterclockwise until the Female Sleeve implant is disengaged from the Male Tack.

Remove the Female Sleeve and pass from the operative field. Confirm complete removal of the implant using fluoroscopy.



TENOTAC® SOFT TISSUE FIXATION SYSTEM CADDY

The TenoTac® System is available as a non-sterile caddy or a sterile packed kit. Both options contain the Male Tack implant. In the non-sterile caddy, all female sizes are included in the caddy, whereas in the sterile packed kit, the Female Sleeves are provided separately.



TenoTac® Non-Sterile Caddy

Single-Use Items Include:

- Male Tack
- Female Sleeves
- K-wires

Reusable Items Include:

- Male Tack Inserter
- Female Sleeve Driver
- Cannulated Drill/Countersink
- Female Sleeve Length Gauge
- Screw Forceps
- AO Handle

TenoTac® Standard Sterile Packed Kit

The sterile packed kit contains the standard male implant pre-loaded on the Inserter with the necessary instrumentation for insertion.

*The three Female Sleeve implants are offered in individual sterile packages in S, M and L that are provided with the Sterile Packed Kit.

TenoTac® Large/Hallux Sterile Packed Kit

The sterile packed kit contains the large male implant pre-loaded on the Inserter with the necessary instrumentation for insertion.

*The three Female Sleeve implants are offered in individual sterile packages in M, L and XL that are provided with the Sterile Packed Kit.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

The TenoTac® Soft Tissue Fixation System is intended to be used for soft tissue to bone fixation

Specific indications for the TenoTac® include:

- Foot & Ankle: Medial/lateral repair and reconstruction, mid and forefoot repair, hallux valgus repair, hallux malleus repair and reconstruction, metatarsal ligament/tendon repair and reconstruction including plantar plate attenuation and tear, and the correction of hammer toe, claw toe, mallet toe, crossover toe, floating toe, and any other lesser toe deformities, correction of metatarsophalangeal joint instability due to shortening from interphalangeal fusion, correction of metatarsophalangeal joint instability due to shortening from Weil osteotomy, Achilles tendon repair.
- Hand & Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, tendon transfers in phalanx, Volar plate reconstruction.

CONTRAINDICATIONS

The Paragon 28® TenoTac® Soft Tissue Fixation System implants are not designed or sold for any use except as indicated. Use of the TenoTac® Soft Tissue Fixation System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients previously sensitized to titanium
- Insufficient quantity or quality of bone or soft tissue to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- In patients where there is a possibility for conservative treatment
- **Indications not included in the INDICATIONS FOR USE**

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement

- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and K-wires are intended for single use only.
- Instruments and implants are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the TenoTac® Soft Tissue Fixation System.**
- **Do not resterilize the sterile packaged TenoTac® Soft Tissue Fixation System implants and instruments. The sterile packaged implants and instruments are intended for single use only.**

MR SAFETY INFORMATION

The TenoTac® Soft Tissue Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the TenoTac® Soft Tissue Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

TENOTTACTM

SOFT TISSUE FIXATION SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle ²⁸
Paragon[®]

P42-STG-0001 RevE [2022-02-22]

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Patents: www.paragon28.com/patents

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DISCLAIMER

The purpose of the TenoTac[®] Soft Tissue Fixation System Surgical Technique Guide is to demonstrate the optionality and functionality of the TenoTac[®] implants and instrumentation. Although variations in placement and use of the TenoTac[®] implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the TenoTac[®] screws can be employed, appropriate for the size of the device. Caution: Federal law restricts this device to sale by or on the order of a physician.

www.Paragon28.com