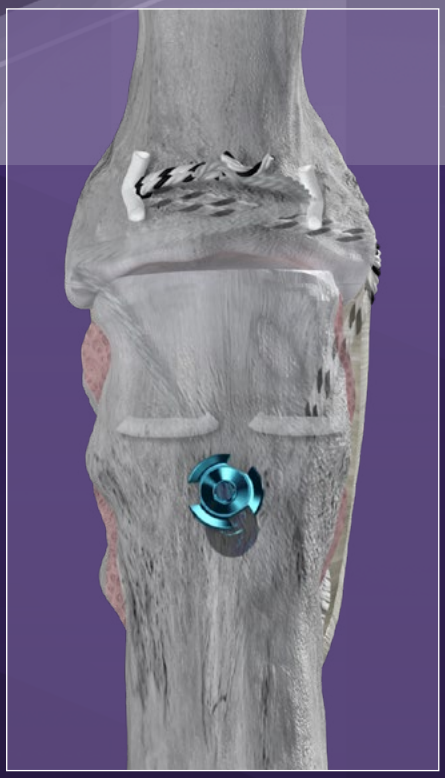
PARATROOPER®

PLANTAR PLATE REPAIR SYSTEM

SURGICAL TECHNIQUE GUIDE

Plantar Plate Repair Using the Paratrooper™ Plantar Plate Repair System



Exclusively foot & ankle

Paragon 28®

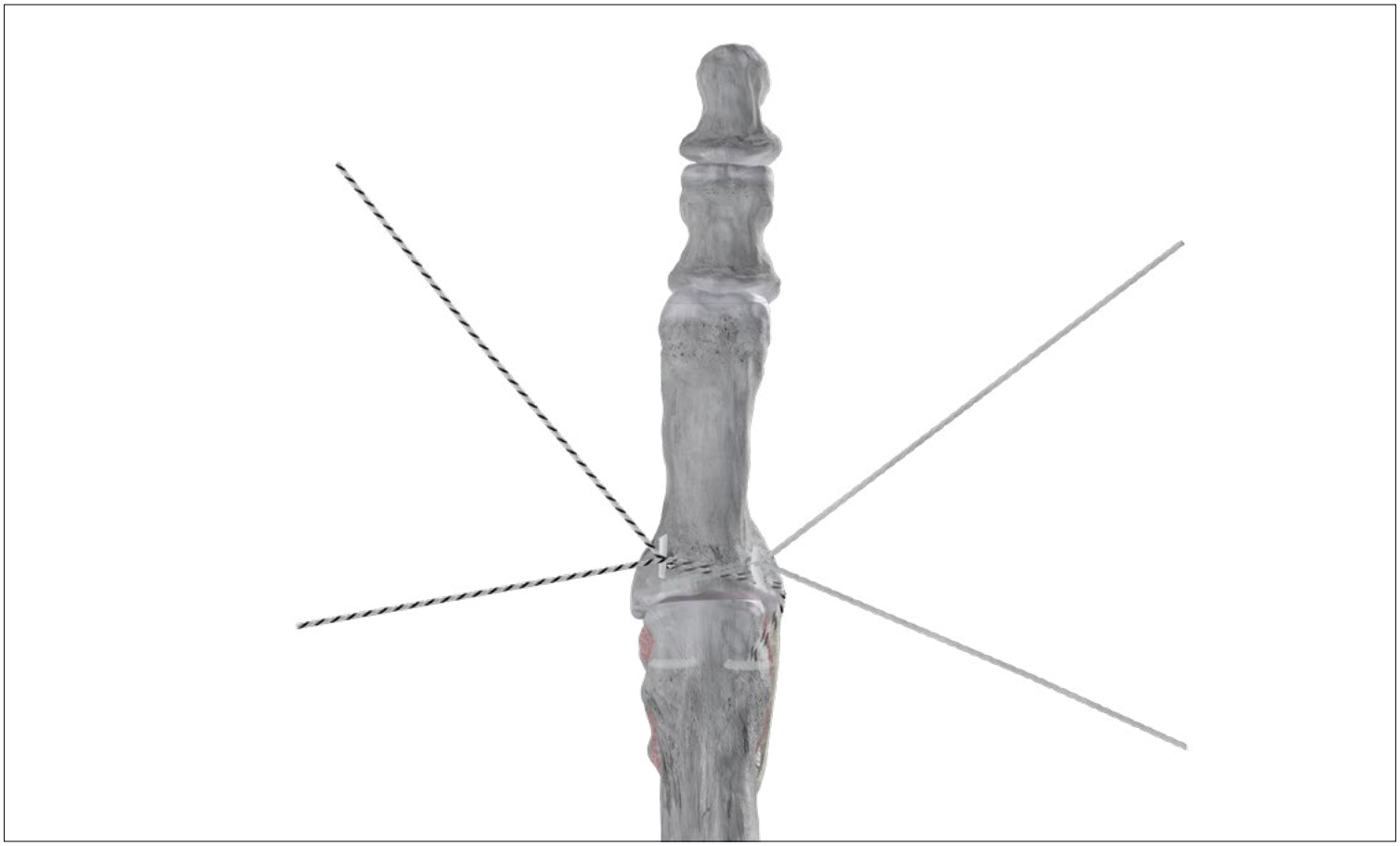
Acknowledgment:
Paragon 28® would like to thank Thomas P. San Giovanni, MD, and Robert L. Thompson, MD, for their contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The Paratrooper™ Plantar Plate Repair System was designed to repair an attenuated or torn plantar plate using a dorsal incision. The Paratrooper™ Plantar Plate Repair System uses an all-suture anchor implant that can be inserted into bone or soft tissue and is delivered in one sterile packaged kit.

Following the Paratrooper™ Suture Implant insertion and tensioning, the implanted all-suture anchor will contract and form into a low profile, flat configuration that is designed to prevent the implant from pulling out of the site.

The system provides for independent tensioning to assist in valgus and varus correction. Additionally, the system provides for self-retention of suture prior to knotting, allowing for partial tensioning of one implant and then the other to allow for precise correction.



Independent tensioning with a single or dual implant construct can assist in valgus and varus correction dependent on patient needs or surgeon preference.

Paragon 28® designed the Paratrooper™ Plantar Plate implant and instruments to allow for simple insertion into tissue through use of an innovative custom needle and delivery method to help ensure guided and reproducible placement of the implant. The implants were designed to directly address plantar plate insufficiency with instrumentation available to facilitate exposure, drilling, and implant placement within a small, limited vascularization environment. The surgical treatment described in this technique helps to reconstruct the anatomic structures that lead to the instability of the lesser MTP joints.

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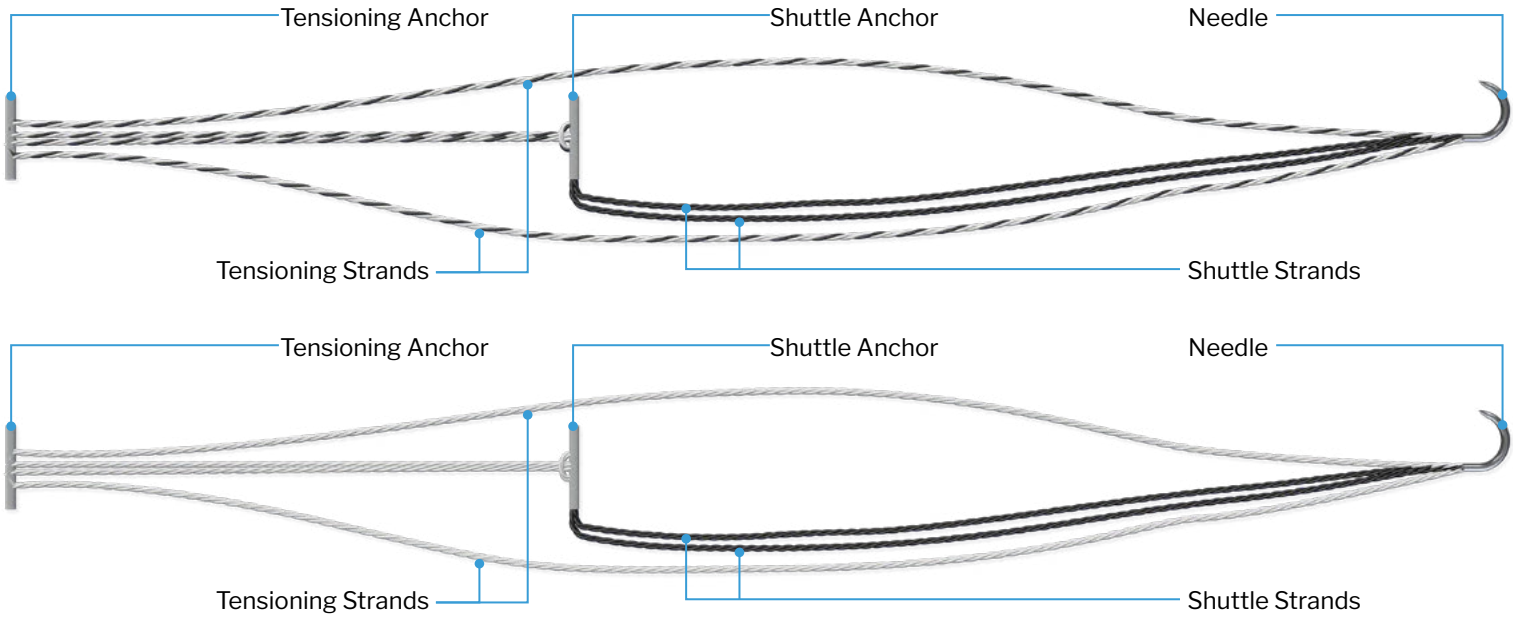
PARATROOPER™ IMPLANT

The Paratrooper™ Plantar Plate Repair System includes two Suture Anchor implants with unique suture colorations. This distinction is to optimize clarity when tensioning. The Tensioning Strands are either all-white or white-black braided, while the all-black Shuttle Strands and white Anchors are consistent for both implants.



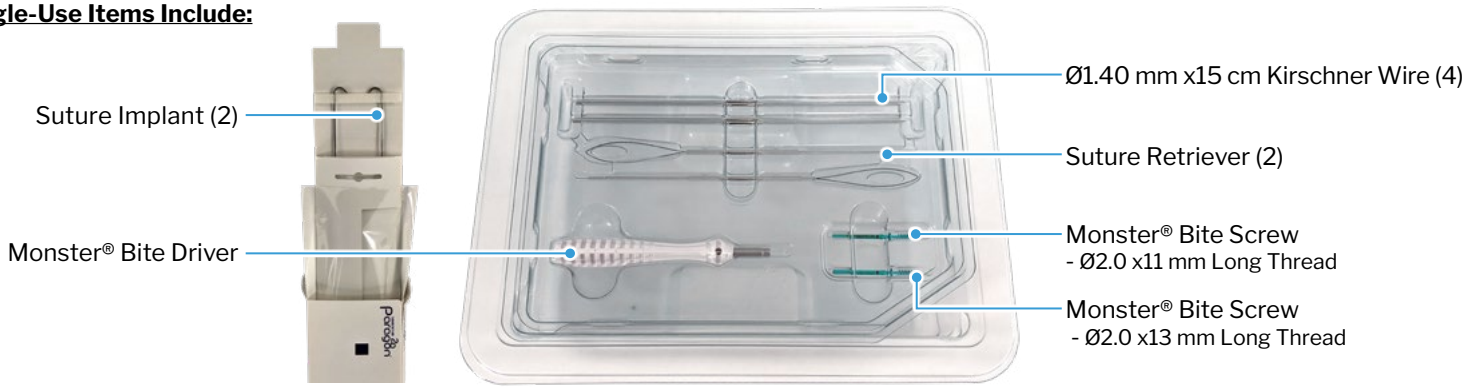
PARATROOPER™ CADDY CONFIGURATIONS

NON-STERILE INSTRUMENTATION CADDY (WEIL KIT)

Reusable Items Include:

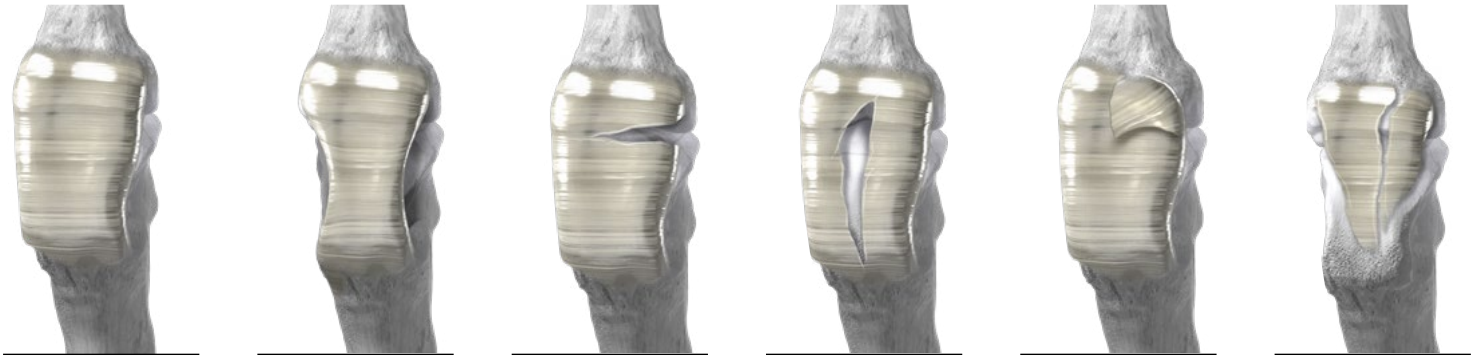
STERILE INSTRUMENTATION CADDY

Single-Use Items Include:



PLANTAR PLATE PATHOLOGY

Plantar View



Healthy plantar plate | *Attenuation* | *Partial tear* | *Longitudinal tear* | *Avulsion* | *Insufficient plate*

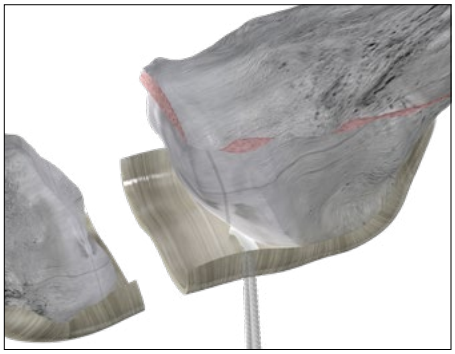
CHEAT SHEET- NEEDLE & ALL-SUTURE ANCHOR PASSING DIRECTION

Refer to pages 6-12 for the complete surgical technique guide. This page is to be used as a quick reference only.

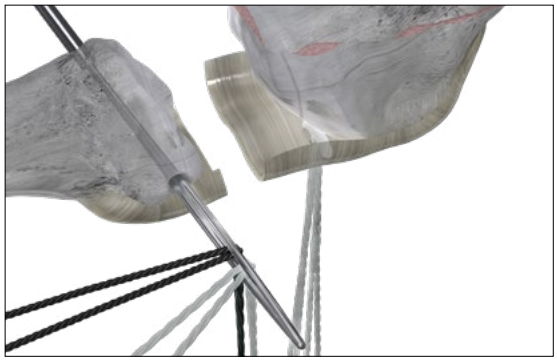
DORSAL APPROACH – PLATE-TO-BONE

Pass the needle through the plantar plate in a dorsal to plantar direction.

Carefully pull the black Shuttle Strands in the plantar direction to pass the Shuttle Anchor through the plate.



Continue to pull the strands until the Tensioning Anchor is seated dorsally on the plantar plate.

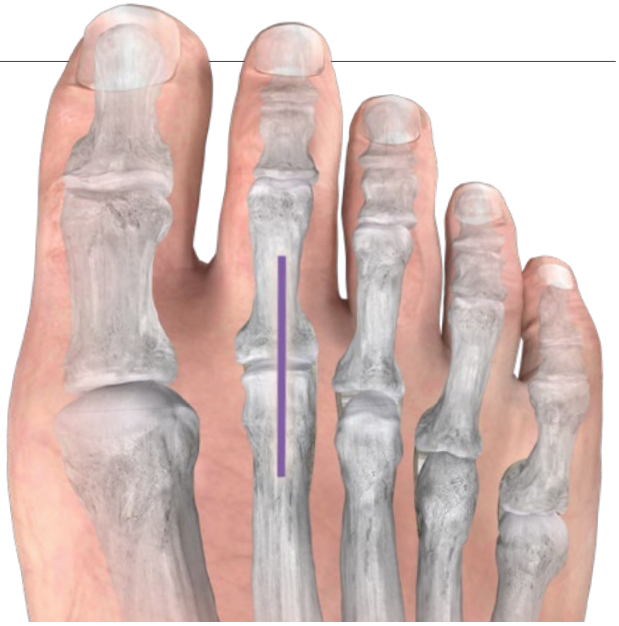


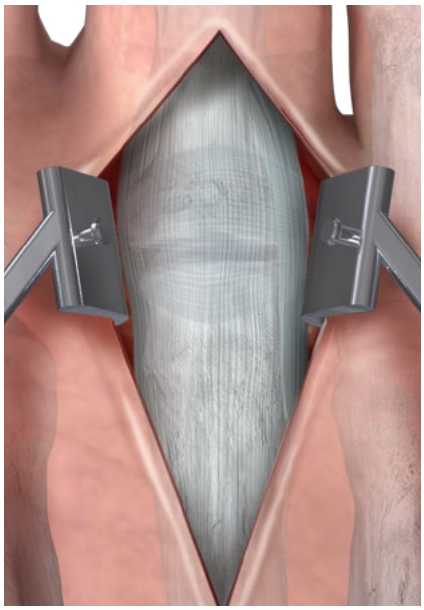
The implant's suture strands will be pulled through the bone tunnel and will terminate dorsally on the opposite side of the phalanx. Pass the four suture strands of each implant through the appropriate bone tunnel in this fashion.

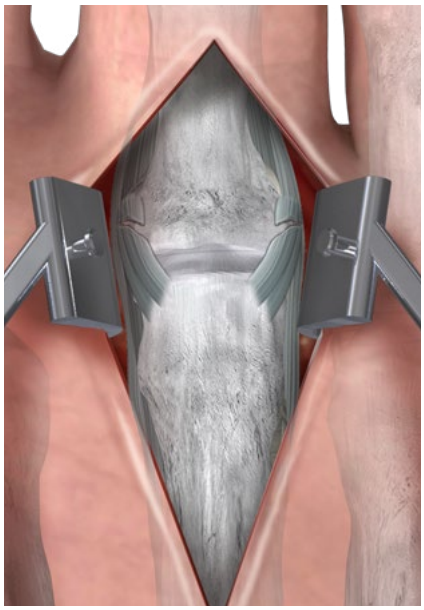
Tie the two Suture Implants together on the dorsal aspect of the bone using at least three knots. Cut the remaining suture ends, leaving a 1-2 mm tail.

INCISION/EXPOSURE

Patient positioning in a supine position is recommended for this procedure. A dorsal linear or curvilinear incision is made over the MTP joint, dissecting down to the joint and over the head of the metatarsal.





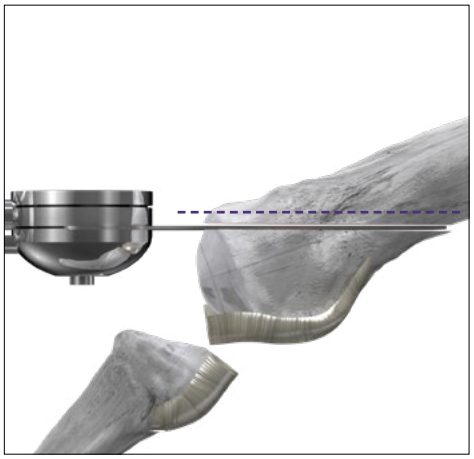


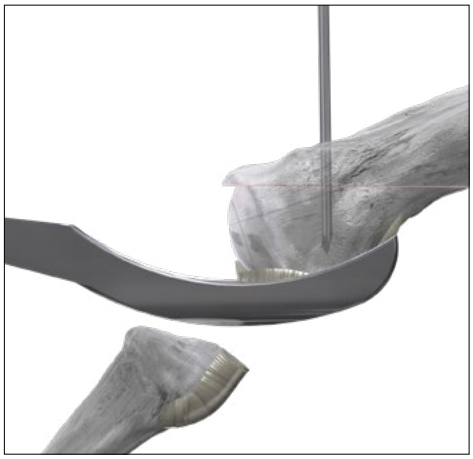
Release the collateral ligaments from the base of the proximal phalanx and then release the dorsal aspect of the flexor tendon sheath. This will enhance visualization of the plantar plate and allow for access when creating bone tunnels in the proximal phalanx.

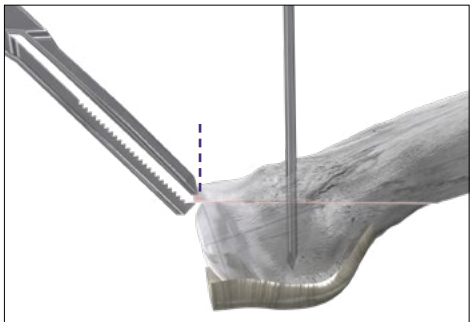
DISTAL METATARSAL OSTEOTOMY

Use a McGlamry Elevator to gently release the proximal section of the plantar plate to increase exposure, if required. Perform a distal metatarsal osteotomy per surgeon preference. Alternative distal metatarsal osteotomies to the Weil osteotomy are shown on page 7.

If performing a Weil osteotomy, the cut is made 1-2 mm inferior to the dorsal articular cartilage of the metatarsal from dorsal distal to plantar proximal at an angle parallel to the weight bearing surface. Proximally displace the capital fragment and temporarily fix with a Ø1.4 mm K-wire. Ensure that the K-wire does not extend beyond the plantar cortex of the metatarsal. With a Freer Elevator, sweep plantarly under the metatarsal head to ensure the K-wire has not violated the far cortex and entered the plantar plate, as this can inhibit plantar plate advancement and tensioning in later steps. If the Freer Elevator connects with the K-wire, back the K-wire out and recheck its positioning with the Freer Elevator. Leave the entirety or majority of the dorsal shelf intact until permanent fixation of the osteotomy to ensure proper positioning and repair.



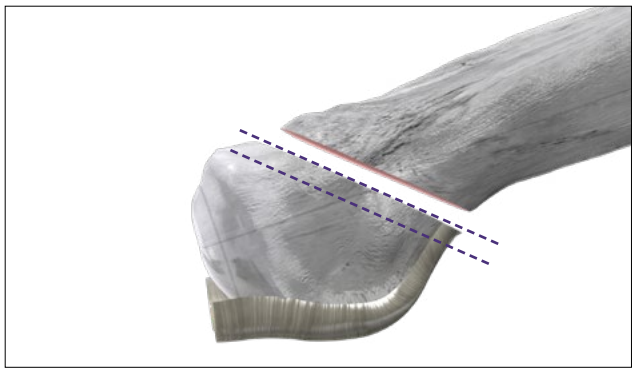


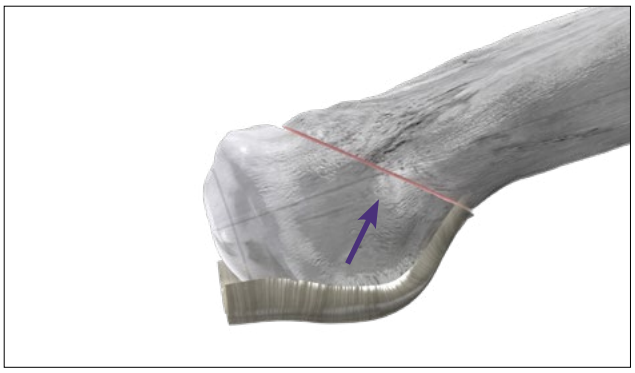


Alternatively, wait until permanent fixation before removing the dorsal shelf to ensure the proper amount of bone resection.

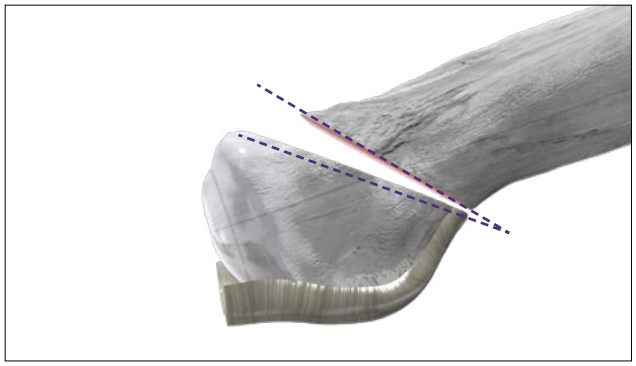
NOTE: Surgeon preference, visualization requirements, and correction will dictate osteotomy. Two different techniques are illustrated below.

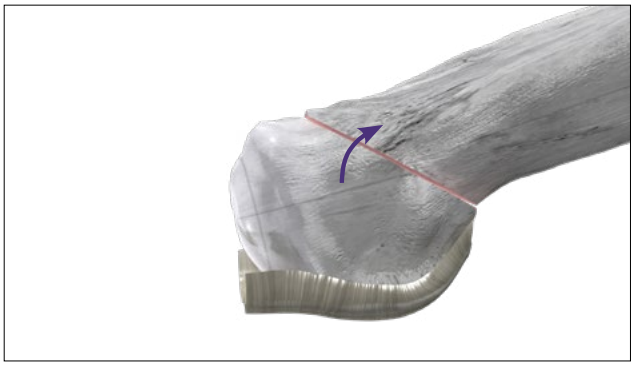
SEGMENTAL RESECTION OSTEOTOMY



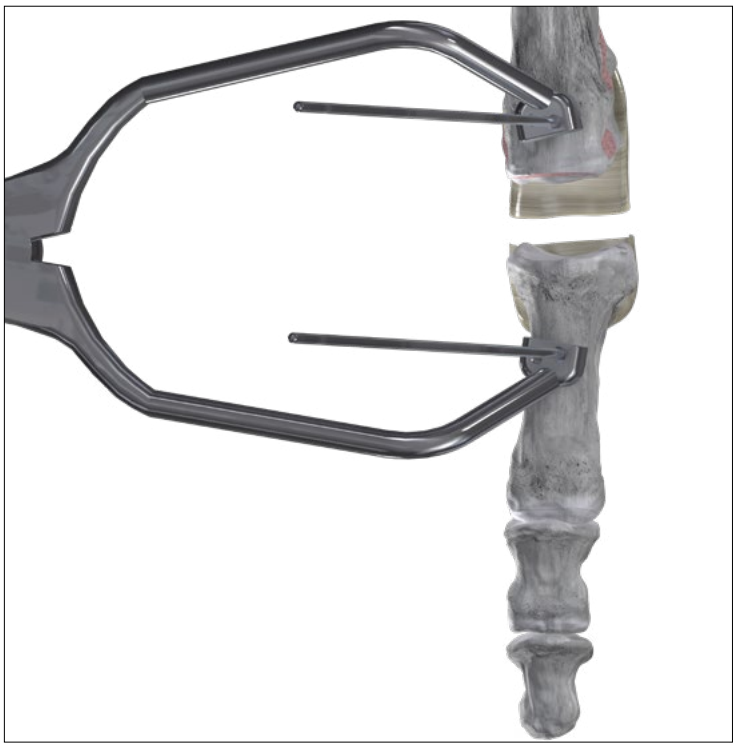


DORSAL CLOSING WEDGE OSTEOTOMY





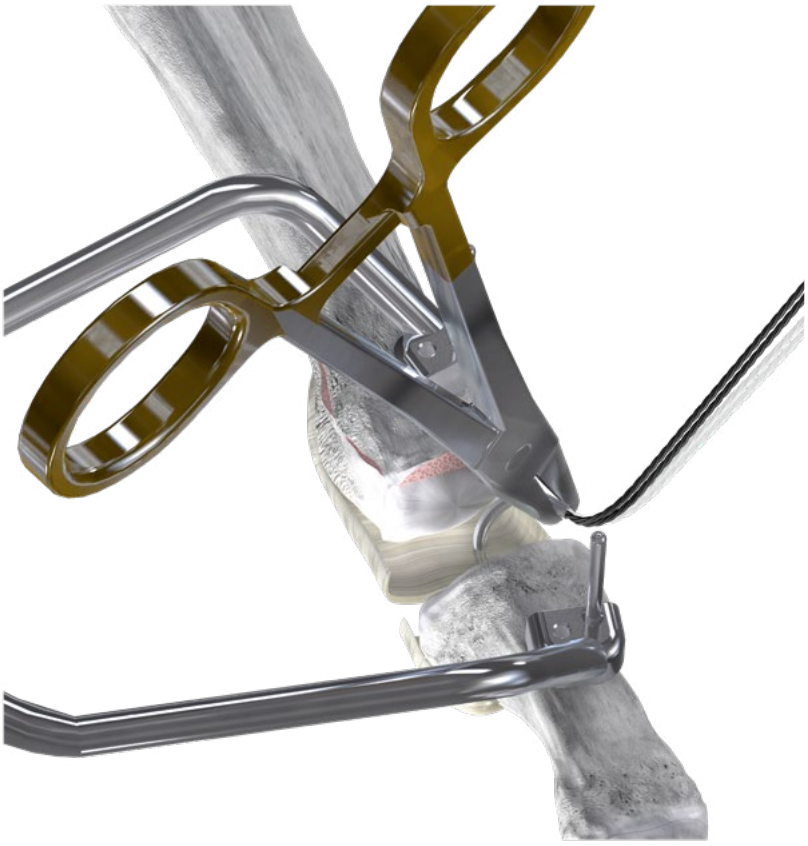
JOINT DISTRACTION AND ACCESS



Place a second Ø1.4 mm K-wire into the proximal phalanx. Ensure this position is distal to the intended bone tunnel sites within the proximal phalanx. Only place the distal K-wire once, as multiple K-wire insertions in the proximal phalanx may compromise the repair. Insert both K-wires through the small joint Pin Distractor. Open the Distractor to visualize the plantar plate. If necessary, complete the plantar plate tear and resect the diseased plantar plate. If the plantar plate tear is completed, ensure that the flexor tendons are avoided and remain intact.

TIP: Using pin cutters, cut both wires in the Pin Distractor to help avoid future interference with instrumentation and implants. Leave K-wires 2-3 cm proud for maneuvering during the procedure and for subsequent removal.

IMPLANT INSERTION – PLANTAR PLATE



Using the provided Needle Driver, attach the Needle Driver to the needle of the implant, such that the Needle Driver grips the needle in a perpendicular orientation. Do not grab the needle at the swage.

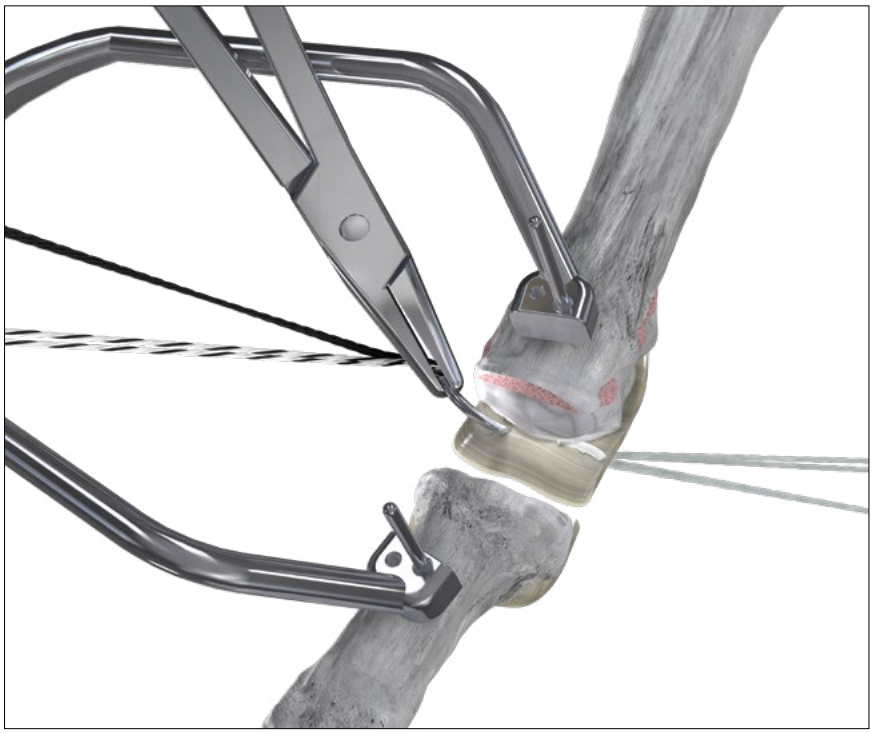
Evaluate the available tissue of the plantar plate, and consider anchor placement to allow enough room for placement of separate medial and lateral anchors. Carefully pass the needle through the plantar plate from dorsal to plantar.

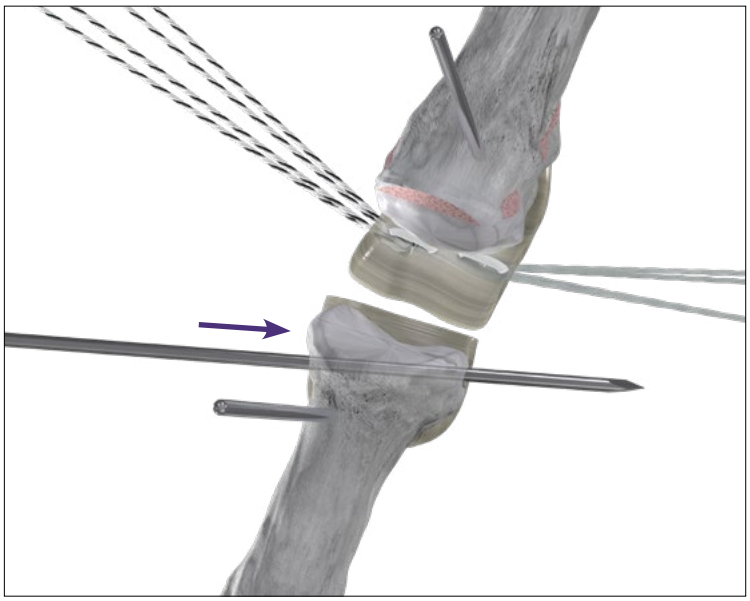
Retrieve the needle from the plantar aspect of the plantar plate and pull the Shuttle Anchor through the plantar plate, seating the Tensioning Anchor against the dorsal surface of the plantar plate.

Per surgeon preference, the Tensioning Anchor can be seated on the plantar side of the plate as well. If this orientation is preferred, pass the needle in a plantar to dorsal direction.

IMPLANT INSERTION – PLANTAR PLATE

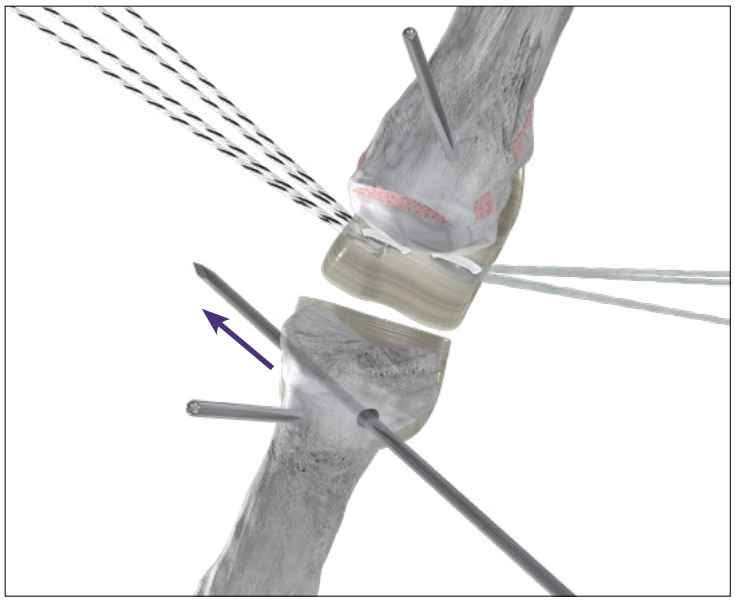
Per surgeon preference, place the second implant on the side opposite to the first implant (shown) with the technique described previously.





Remove the Pin Distractor from the Ø1.4 mm K-wires, but leave the K-wires in place. When creating the bone tunnels, the distal K-wire for the Pin Distractor in the proximal phalanx may be used to lever the phalanx plantarly to gain access to the plantar base of the phalanx.

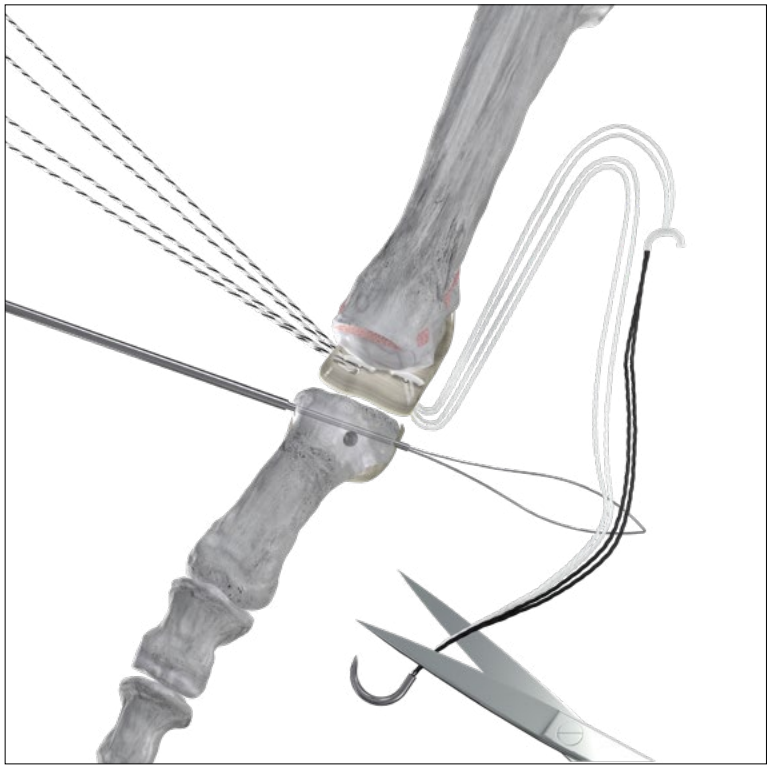
Insert a Ø1.4 mm K-wire in the proximal phalanx to create an oblique bone tunnel from the distal lateral to proximal medial direction.



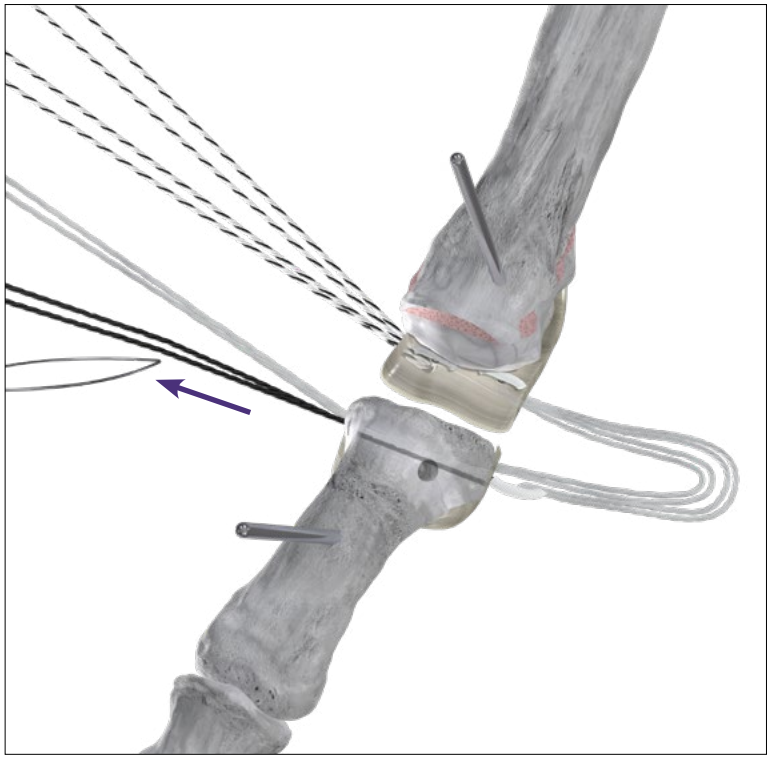
Create a second oblique bone tunnel through the proximal phalanx from the distal medial to proximal lateral direction. Move the K-wires in and out to clear soft tissue. Clearing out as much soft tissue as possible from the bone tunnel entrance will greatly assist in the upcoming steps.

IMPLANT INSERTION – PLANTAR PLATE

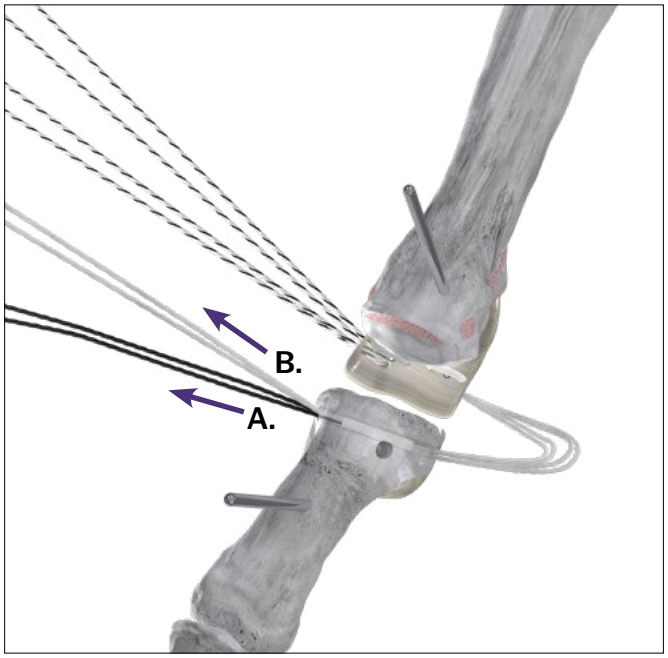
Insert the Suture Retriever from distal to proximal through the desired bone tunnel. Retrieve the needle for the suture anchor that is on the same side (medial or lateral) as where the Suture Retriever exits. Pass the needle with the Shuttle Strands and white-black or white Tensioning Strands through the Suture Retriever loop. Cut the needle from the four suture strands once passed through the loop.



Carefully pull the four suture strands through the bone tunnel using the Suture Retriever. **Once the Suture Retriever has completely passed through the bone tunnel, remove the four suture strands from the Retriever loop and pull the four suture strands by hand** until the Shuttle Anchor has reached the entrance of the bone tunnel.



IMPLANT INSERTION – PLANTAR PLATE



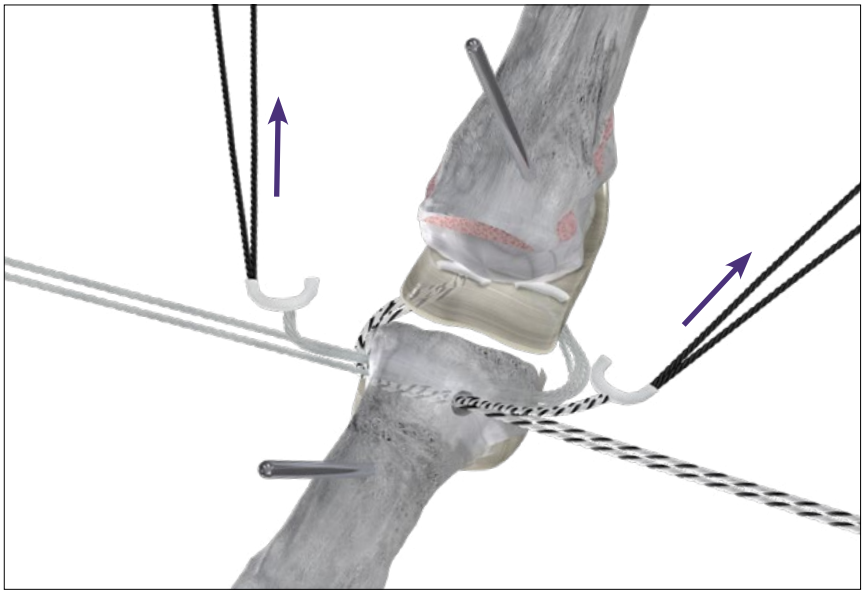
Orient the Shuttle Anchor so that it lines up with the entrance to the bone tunnel. Some back pressure on the repair sutures may help to align the Shuttle Anchor with the bone tunnel.

Pull the two black Shuttle Strands, either by hand or by using a rolling hemostat technique shown on the right (**A**). Once the anchor is through, pull by hand the remaining slack from the white or white-black Tensioning Strands through the bone tunnel (**B**).

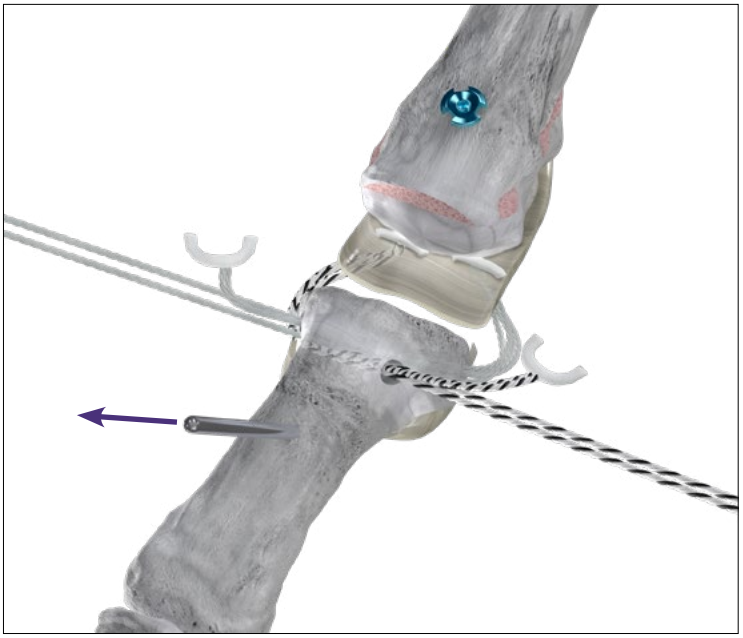
IMPLANT INSERTION – BONE ATTACHMENT

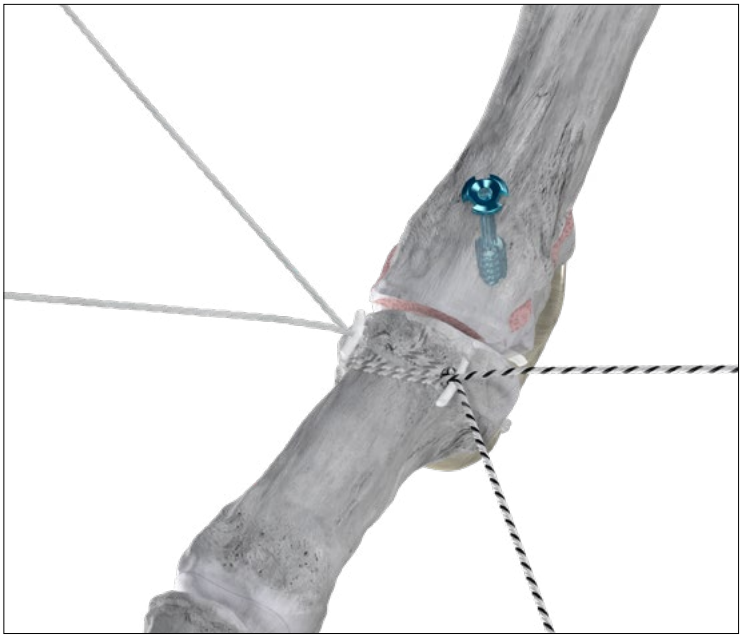
Unthread the black Shuttle Strands from the suture anchor and discard.

Repeat the steps on pages 10 and 11 for the second Suture Implant.



IMPLANT TENSIONING





Ensure that the capital fragment of the osteotomy is in the correct position.

Once the osteotomy position is confirmed, place a Monster® BITE Screw before tensioning both implants against the dorsal aspect of the proximal phalanx using the Monster® BITE Screw Surgical Technique Guide (P24-STG-0001).

Remove the K-wires from the proximal phalanx and metatarsal at this time.

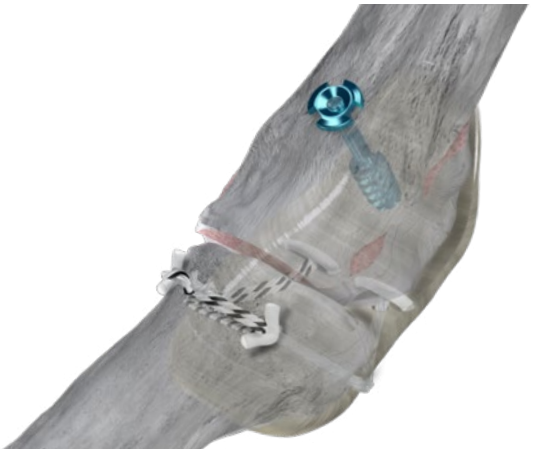
NOTE: Do not fully tension prior to passing the second implant through the bone tunnel to allow for appropriate access to the suture strands and proximal phalanx base. Final tensioning will be performed after the second implant is placed. Recommended final tensioning toe position is 30˚ plantarflexed while gently pressing proximally.

To tension the implants, separate the striped white-black or white Tensioning Strands. Pull to tension the implant enough to clear excess suture from the metatarsophalangeal joint. Repeat the steps for the second Suture Implant.

Confirm tension on the implants after the Monster® BITE Screw placement. Tie the two Suture Implants together on the dorsal aspect of the proximal phalanx using at least three knots. Cut remaining suture ends, leaving a 1-2 mm tail.

CLOSURE

Proceed to incision closure/concomitant procedures at this time.



REMOVAL

PARATROOPER™ PLANTAR PLATE REMOVAL

Removal of the Paratrooper™ Plantar Plate Repair implant requires no product specific instrumentation. Cut the suture if necessary and unthread the anchor from the plantar plate or bone surface.

MONSTER® BITE SCREW REMOVAL

Locate Screw

Utilizing radiographs, determine the location of the implant. Palpate screw head and remove surrounding soft tissue to gain maximum exposure. In cases of bone ongrowth, a dental pick or small rongeur may be used to remove bony matter from the head of the screw to allow the Driver to engage.

Remove Screw

Use the Monster® BITE Screw Driver to engage the head of the screw and rotate counterclockwise by hand until the screw is removed.

If the screw head is stripped, engage the proximal shaft of the screw under the screw head with a medium sized Kern forceps and continue turning Driver shaft counterclockwise while exerting light pressure upwards with Kern forceps. If the screw is integrated into bone, core out the appropriate sized trephine drill.

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

INDICATIONS FOR USE

The Paratrooper™ Plantar Plate Repair System is intended for fixation of tissue to bone and tissue to tissue. Specific indications:

Foot/ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Metatarsal Ligament and Tendon Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfers
- Mid-foot Reconstruction
- Plantar Plate Repair

CONTRAINDICATIONS

The Paragon 28® Paratrooper™ Plantar Plate Repair System implants are not designed or sold for any use except as indicated. Use of the Paratrooper™ Plantar Plate Repair System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients with a known allergy to the implant material(s)
- 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
- Use in cardiac indications
- Indications not included in the INDICATIONS FOR USE

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:
- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count

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 failure of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting altered range of motion
- 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
- Implant degradation with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone resorption or over-production

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 implant in areas of high functional stresses may lead to implant failure.
- The implants are intended for single use only.
- Instruments and implants are to be treated as sharps.
- Avoid K-wires and sutures through the implant.
- Avoid flawing implant surfaces to minimize the potential for early fatigue failure.
- Do not use other manufacturer's instruments or implants in conjunction with the Paratrooper™ Plantar Plate Repair System.
- Do not resterilize the Paratrooper™ Plantar Plate Repair System Implants and Instruments.

MR SAFETY INFORMATION

The Paratrooper™ Plantar Plate Repair 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 Paratrooper™ Plantar Plate Repair System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PARATROOPER®

PLANTAR PLATE REPAIR SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P13-STG-0001 RevB [2022-12-02]

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Englewood, CO 80112 USA
(855) 786-2828

DISCLAIMER

Caution: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician. The purpose of the Paratrooper™ Plantar Plate Repair System Surgical Technique Guide is to demonstrate the optionality and functionality of the Paratrooper™ Plantar Plate Repair System implants and instrumentation. Although variations in placement and use of the Paratrooper™ Plantar Plate Repair System 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 Paratrooper™ Plantar Plate Repair System can be employed, appropriate for the size of the device.