SURGICAL TECHNIQUE GUIDE:

PROXIMAL INTERPHALANGEAL JOINT ARTHRODESIS

HAMMERTUBE™ SYSTEM

Exclusively foot & ankle

Paragon 28®

Acknowledgment:

Paragon 28® would like to thank Mark Myerson, M.D. and Thomas San Giovanni M.D. for their contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The patent-pending HammerTube™ System is a single piece titanium plasma sprayed PEEK implant intended for hammertoe correction. The instrumentation provided supports versatility in surgical technique, allowing for surgeon preference to dictate technique. A standard technique can be performed that allows direct drilling and placement of the implant, starting on page 4. A retrograde technique can be performed with initial K-wire placement determining toe position, starting on page 7. The retrograde technique allows for a K-wire to be left in to temporarily stabilize the MTP joint when used with a straight implant, if desired. The HammerTube™ system is offered in two configurations: a non-sterile caddy and a sterile packed kit.

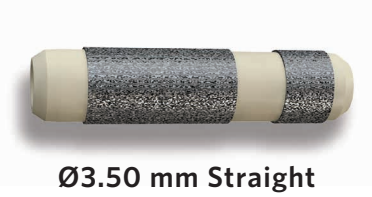
CONCEPT FOR FIXATION

The implant was designed to provide the following advantages over a K-wire:

- A press fit is accomplished between the implant and bone due to a controlled, precise interference between the drill hole and titanium plasma spray
- Implant is made of PEEK which closely matches the mechanical properties of bones [1]
- Instrumentation in this system provides ease of insertion
- In cases where implant removal is necessary, features have been designed into the implant to interface with available instrumentation to ease implant removal

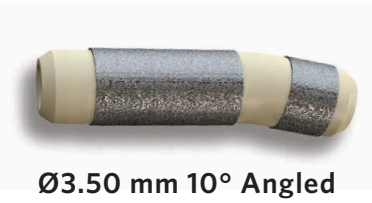
IMPLANT OFFERING

Ø2.75 mm Straight HammerTube™



Ø3.50 mm Straight HammerTube™

Ø2.75 mm 10° Angled HammerTube™



Ø3.50 mm 10° Angled HammerTube™

Implant Size:	Instrument Size:
Ø2.75 mm	Ø1.40 mm K-wire Ø1.40 mm Trocar Insert Ø2.75 mm Cannulated Drill * Ø1.40 mm Blunt K-wire Ø2.75 mm Inserter

Implant Size:	Instrument Size:
Ø3.50 mm	Ø1.60 mm K-wire Ø1.60 mm Trocar Insert Ø3.50 mm Cannulated Drill * Ø1.60 mm Blunt K-wire Ø3.50 mm Inserter

* Actual drill size is adjusted a proprietary amount to provide interference with the titanium plasma spray on the respective implant.

INSTRUMENTS (NON-STERILE CADDY AND STERILE PACKED KIT)

Trocar Insert, Ø1.40 mm

Trocar Insert, Ø1.60 mm

Cannulated Drill, Ø2.75 mm*

Cannulated Drill, Ø3.50 mm*

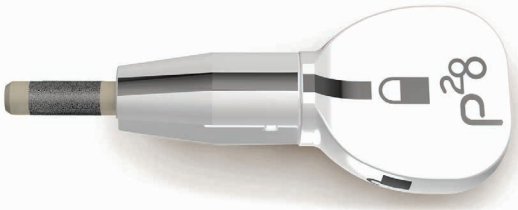
Blunt K-wire for Retrograde Technique, Ø1.40 mm

Blunt K-wire for Retrograde Technique, Ø1.60 mm

Non-Sterile Inserter, Ø2.75 mm

Sterile Inserter, Preloaded Ø2.75 mm

Non-Sterile Inserter, Ø3.50 mm



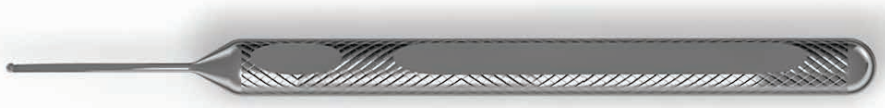
Sterile Inserter, Preloaded Ø3.50 mm

Double Trocar K-wire for Retrograde Technique, Ø1.40 mm

Double Trocar K-wire for Retrograde Technique, Ø1.60 mm

INSTRUMENTS (NON-STERILE CADDY ONLY)

Planer, Ø8.0 mm

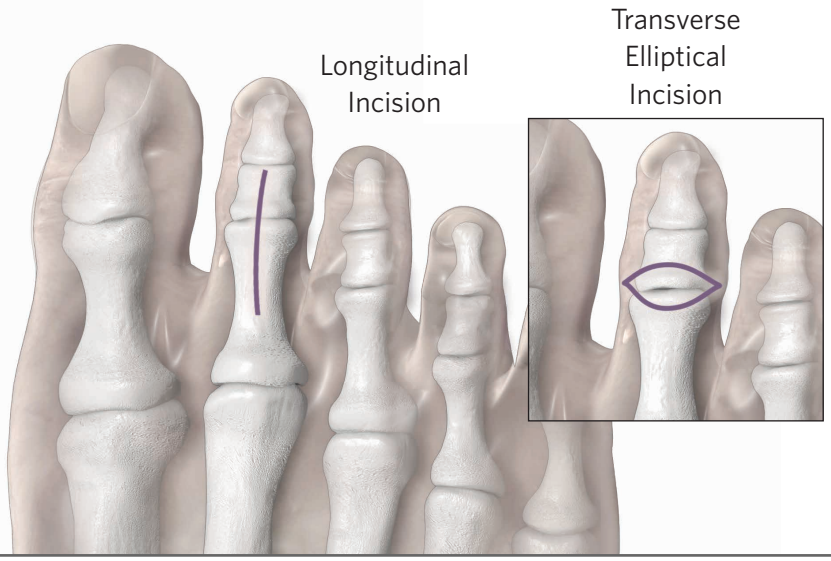


Implant Puller

INCISION/EXPOSURE

Proximal interphalangeal joint (PIPJ) arthrodesis may be performed as a sole procedure or combined with other procedures to address multiple deformities.

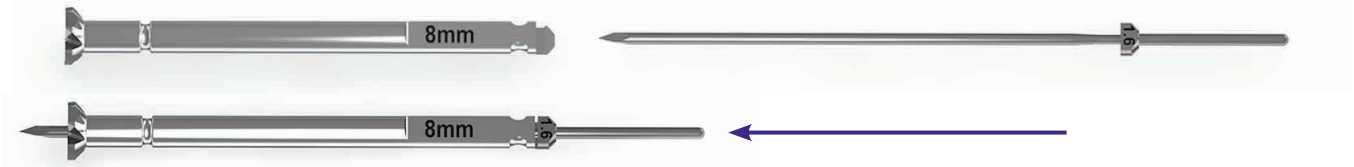
A longitudinal or transverse elliptical incision can be performed based on surgeon preference. Dissection is carried down to expose the proximal interphalangeal joint.



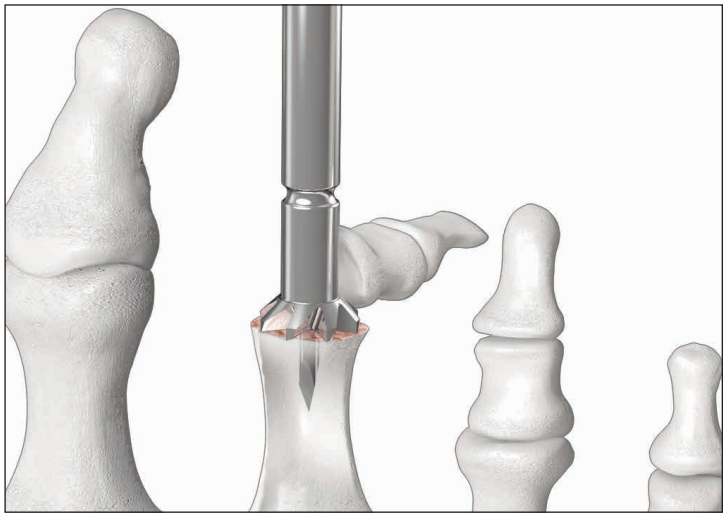
JOINT PREPARATION

A sagittal saw or hand-held bone cutter is used to resect the cartilage at the head of the proximal phalanx. It is necessary to make the cut at the level of the condyles to allow passage of the implant into the middle phalanx during insertion.

TIP: Alternatively, if using the non-sterile caddy configuration, the planer can be used to remove cartilage from the proximal phalanx or to provide further resection after the sagittal saw cut. The trocar insert should be placed inside the planer.

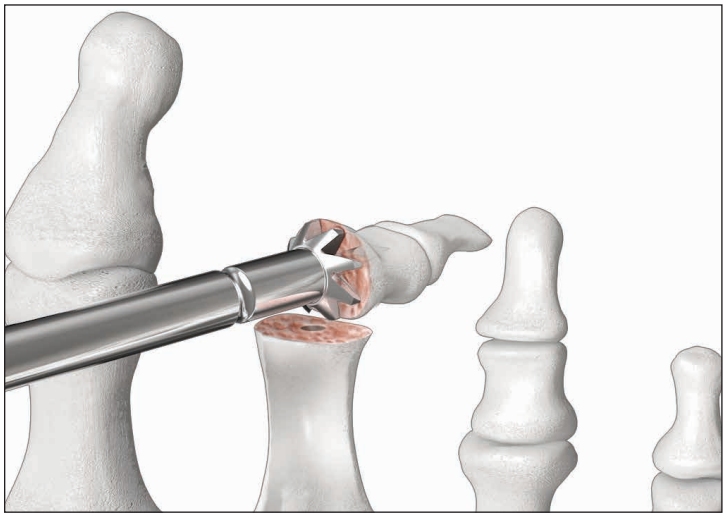


Place the trocar in the planer. Insert until a "click" is heard or felt.



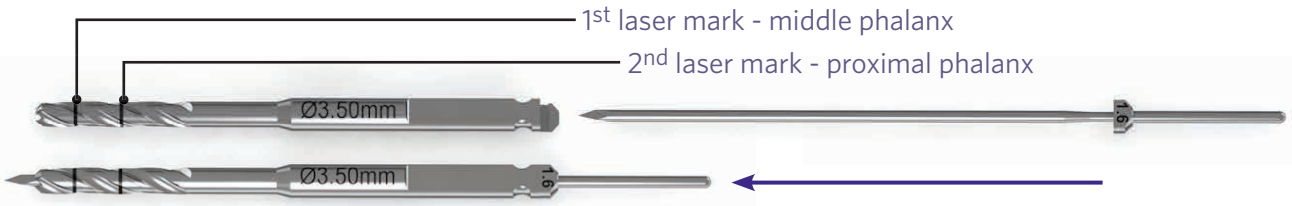
Center the trocar on the proximal phalanx.
Begin movement of the planer prior to contacting bone.
Continue to engage the planer until all cartilage is removed from the head of the proximal phalanx.

TIP: Do not attempt planer use without the trocar or K-wire.

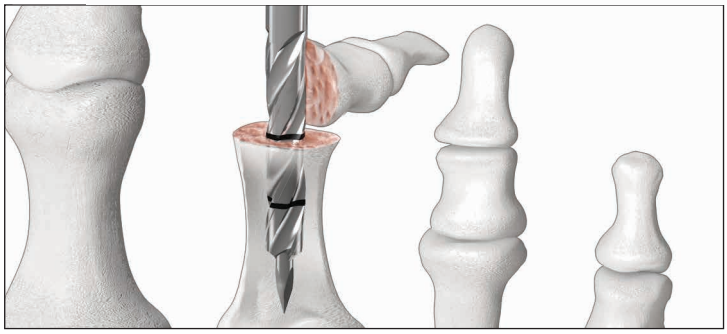


The planer can be used for cartilage resection on the middle phalanx bone. Center the trocar on the middle phalanx.
Begin movement of the planer prior to contacting bone.
Continue to engage the planer until no cartilage remains.

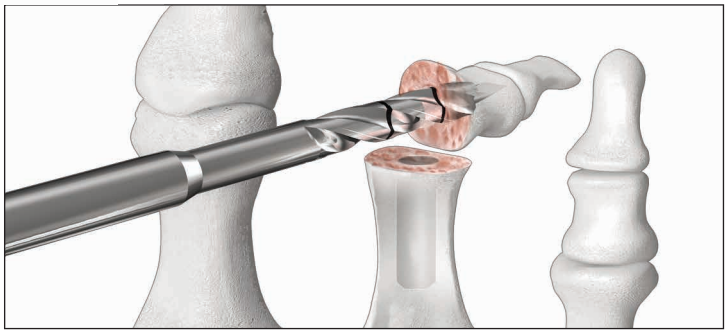
BONE PREPARATION



Place the trocar in the drill. Insert until a "click" is heard or felt.



Center the trocar on the proximal phalanx and drill to the second laser marking on the drill.



The same trocar/drill unit is then used to drill the middle phalanx. Center the trocar on the middle phalanx and drill to the first laser marking on the drill.

IMPLANT SELECTION AND ASSEMBLY

Use direct visualization intraoperatively to determine implant size. It is recommended to start with a smaller drill size and go up a drill size if there is not sufficient resistance to the drill. A 0° or 10° implant can be selected at this time.

Non-Sterile Caddy Configuration

1. Resting state of inserter prior to implant insertion.

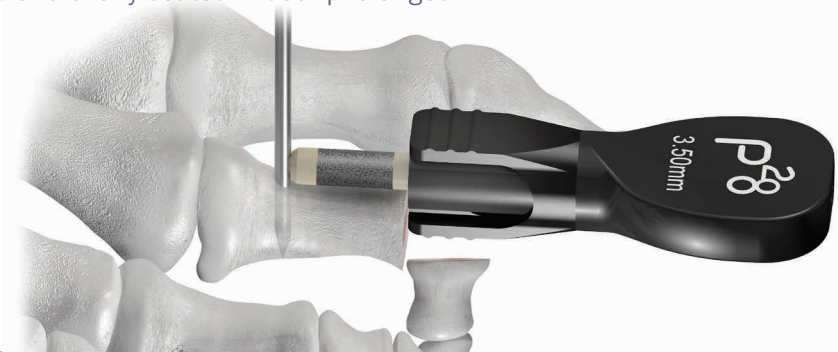
2. Insert implant into inserter by depressing movable tabs to open up the canal for the implant.

3. The distal end is loaded into the inserter such that no further advancement of the implant into the inserter can be achieved. Release pressure on movable tabs.

Sterile Packed Kit Configuration

The implant is packaged pre-loaded in the inserter.

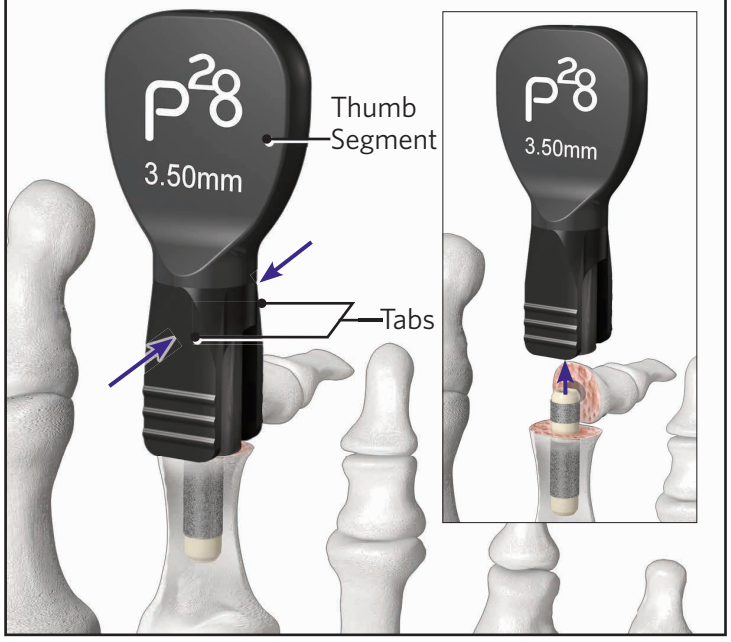
TIP: To prevent proximal migration of the implant during surgery, a K-wire can be placed proximal to the anticipated proximal end of the implant. This position can be determined by placing the loaded inserter over the proximal phalanx and inserting the K-wire. Remove K-wire after implant is fully seated in both phalanges.



IMPLANT INSERTION

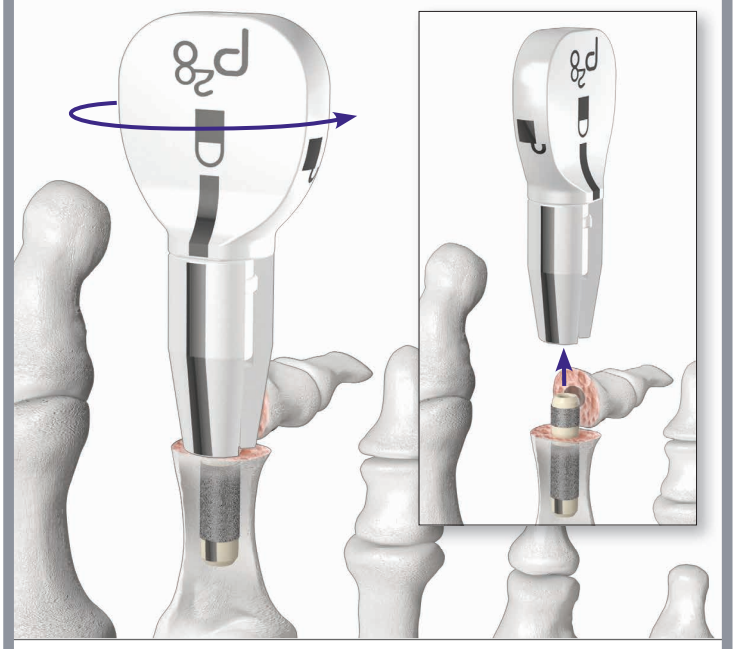
While holding the thumb segment of the inserter, insert the implant into the proximal phalanx drill hole until the inserter contacts the distal surface of the proximal phalanx, and no further advancement can be achieved. It is recommended to push the implant in fully with one motion rather than incrementally. Tap the end of inserter lightly with a mallet rather than twisting the implant to complete insertion, if necessary.

Non-Sterile Configuration



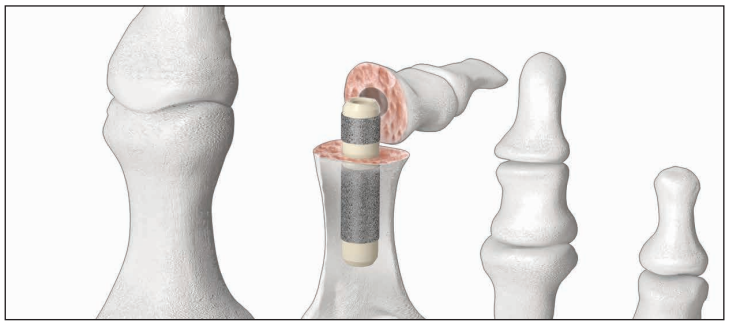
Depress the two movable tabs of the inserter to release the implant into its seated position. Remove the inserter from the implant.

Sterile Packed Kit Configuration



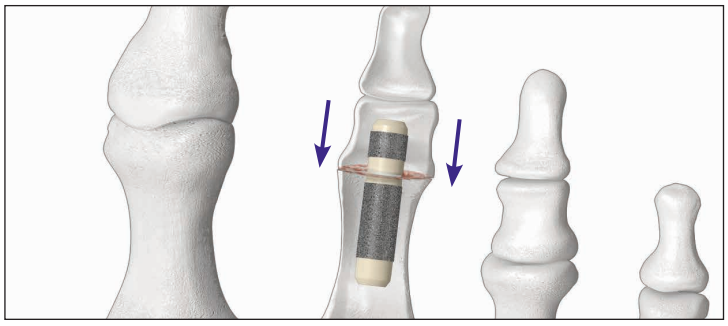
To release the implant from the sterile kit inserter, rotate the thumb segment from the locked to the unlocked position.

TIP: When inserting an angled implant, proximal and dorsal pressure should be applied to the sterile packed inserter.



The distal portion of the toe is then carefully distracted distally and translated dorsally to allow the protruding distal portion of the implant to seat within the drilled hole in the middle phalanx.

TIP: If the middle phalanx is unable to be pulled over the implant, increased soft tissue release can be performed at the PIPJ. If the implant still cannot be placed in the middle phalanx, remove the implant and use the planer to remove more bone at the PIPJ.



Once seated in the middle phalanx, pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved.

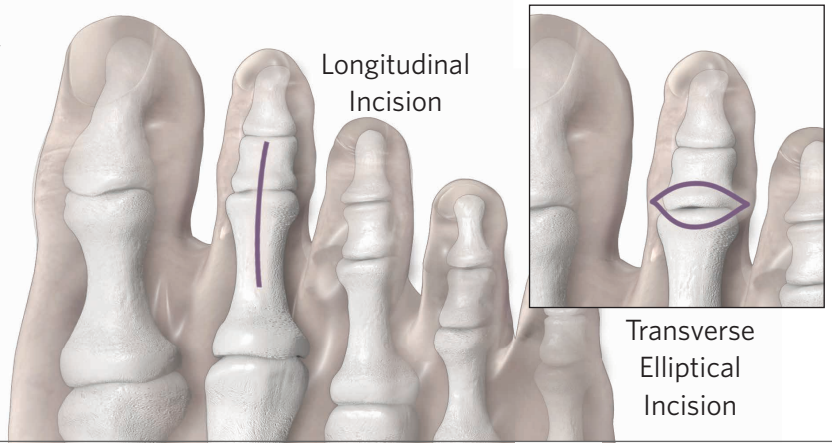
CLOSURE

Proceed to soft tissue and incision closure at this time.

INCISION/EXPOSURE

Proximal interphalangeal joint (PIPJ) arthrodesis may be performed as a sole procedure or combined with other procedures to address multiple deformities.

A longitudinal or transverse elliptical incision can be performed based on surgeon preference. Dissection is carried down to expose the proximal interphalangeal joint.

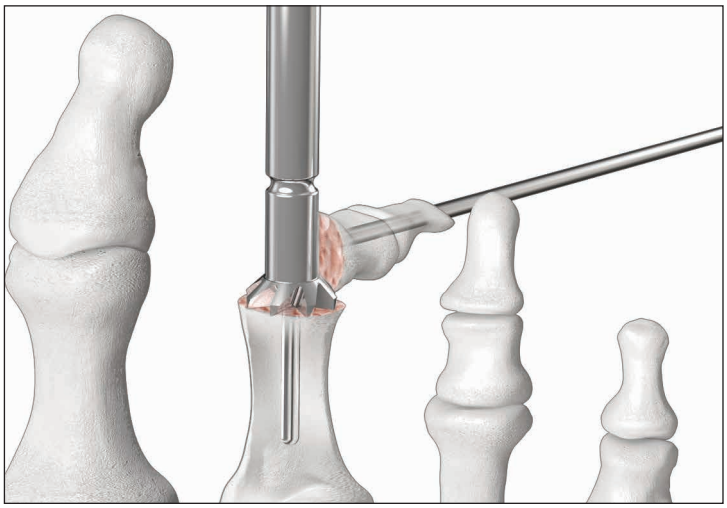


JOINT PREPARATION AND ALIGNMENT

A sagittal saw or hand-held bone cutter is used to resect the cartilage at the head of the proximal phalanx. It is necessary to make the cut at the level of the condyles to allow passage of the implant into the middle phalanx during insertion.

The retrograde technique is used to help determine final position of the toe:

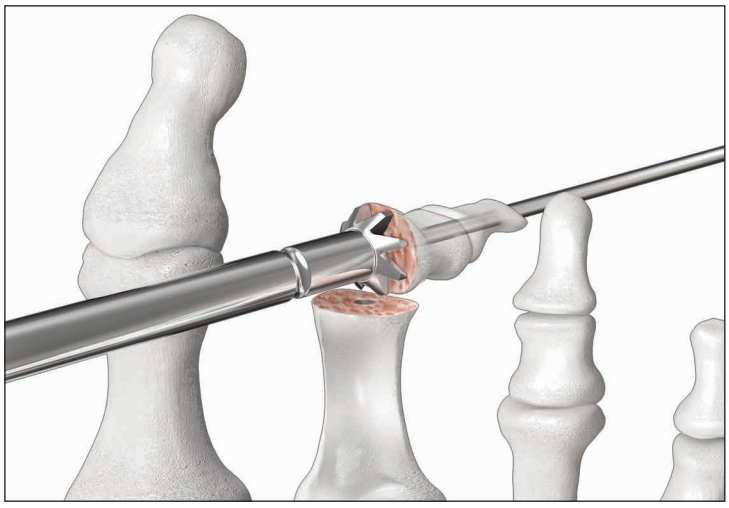
- Insert the K-wire from the PIPJ into the middle phalanx, exiting the distal phalanx centrally plantar to the nail.
- The K-wire is inserted into the central medullary canal of the proximal phalanx in a retrograde fashion.
- Fluoroscopy is used to determine K-wire and toe position.
- Once optimal positioning of the K-wire is determined, pull the K-wire distally such that only 2-3 mm of wire protrudes from the base of the middle phalanx.



TIP: Alternatively, the planer can be used to remove cartilage from the proximal phalanx or to provide further resection after the sagittal saw cut.

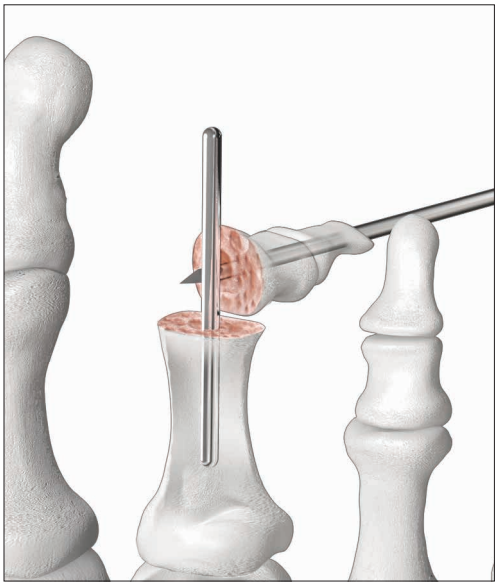
The blunt K-wire is positioned in the canal of the proximal phalanx created by the K-wire. Slide the planer over the blunt K-wire. **Begin movement of the planer prior to contacting bone.** Continue to engage the planer until all cartilage is removed from the head of the proximal phalanx. Remove the K-wire when planing is complete.

TIP: Do not attempt planer use without the trocar or K-wire.

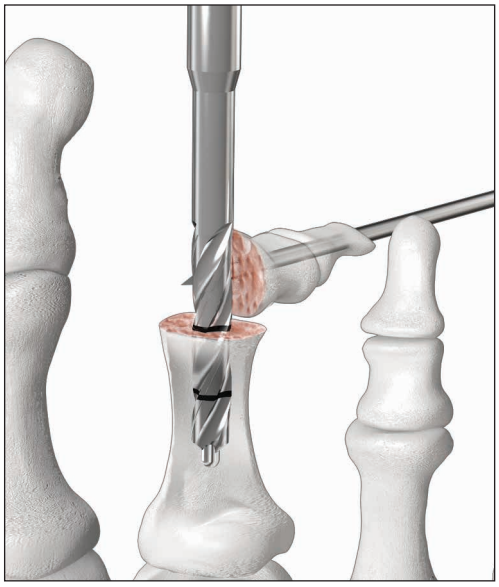


Using the planer on its own, place the planer over the K-wire extending from the middle phalanx. **Begin motion of the planer prior to contacting the bone.** Continue to engage the planer until no cartilage remains.

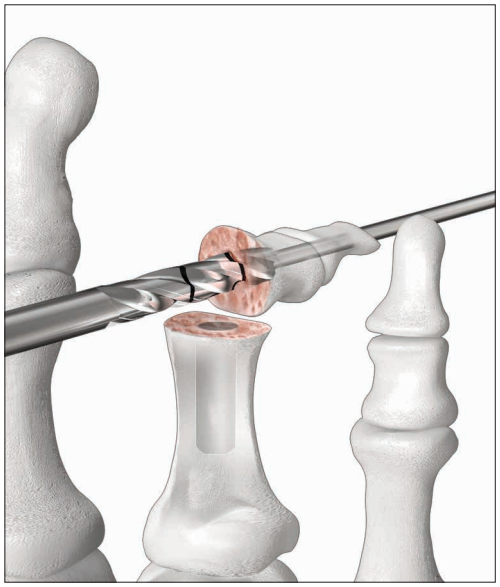
BONE PREPARATION



The blunt K-wire is placed in the canal of the proximal phalanx.



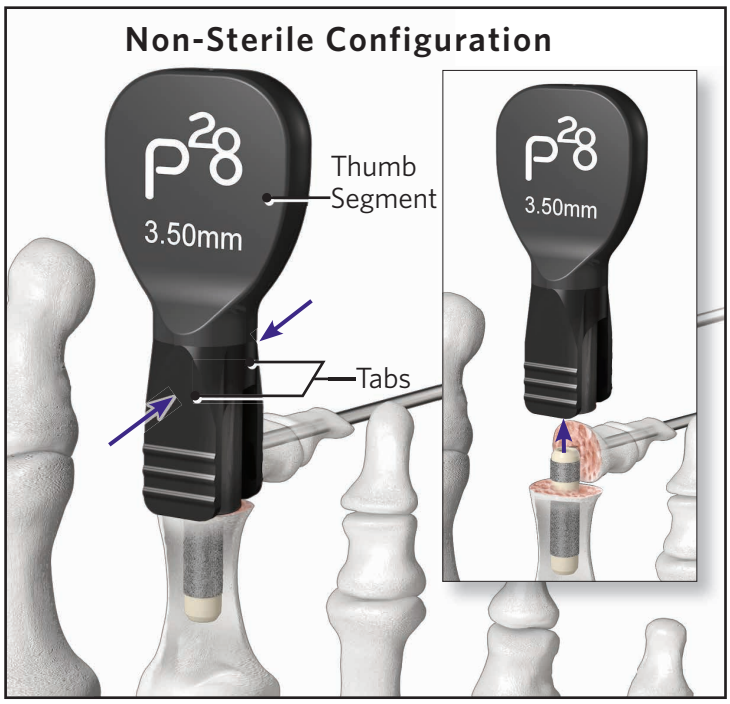
Drill over the blunt K-wire to the second laser marking on the drill.



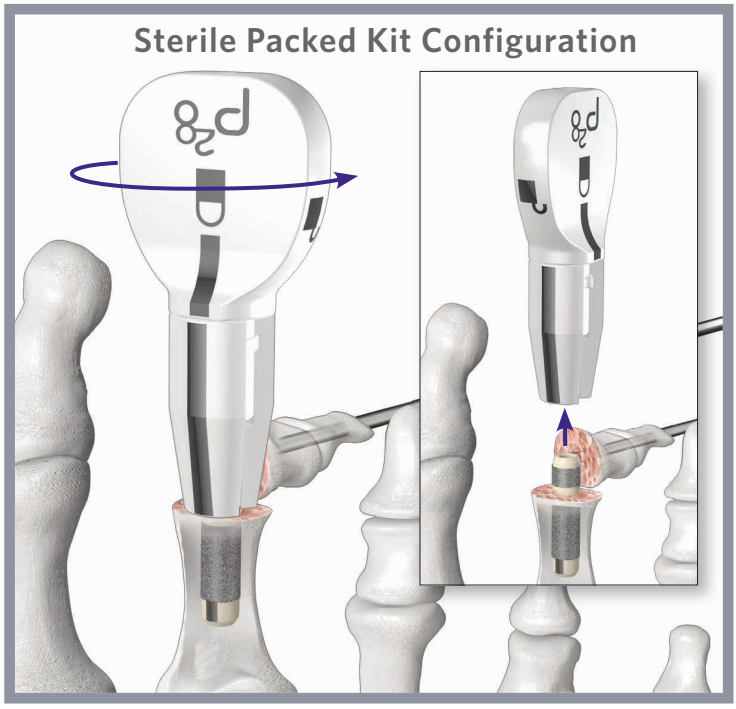
The blunt K-wire is removed. The same drill is then used to drill the middle phalanx. Insert the K-wire into the cannula of the drill. Drill to the first laser marking on the drill.

IMPLANT INSERTION

While holding the thumb segment of the inserter, insert the implant into the proximal phalanx drill hole until the inserter contacts the distal surface of the proximal phalanx, and no further advancement can be achieved. It is recommended to push the implant in fully with one motion rather than incrementally. Tap the end of inserter lightly with a mallet rather than twisting the implant to complete insertion, if necessary.



Depress the two movable tabs of the inserter to release the implant into its seated position. Remove the inserter from the implant.

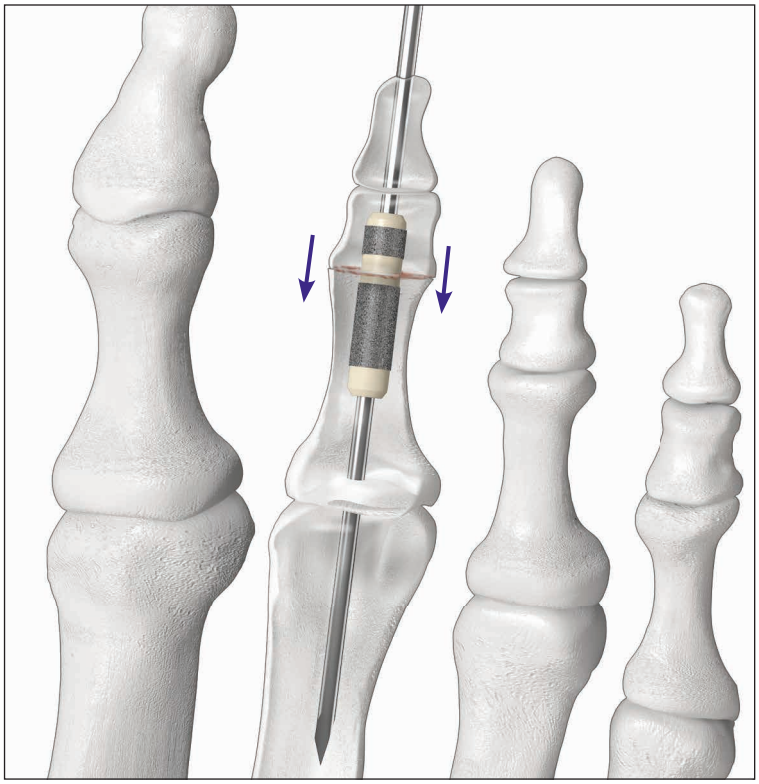


To release the implant from the sterile kit inserter, rotate the thumb segment from the locked to the unlocked position.

IMPLANT SELECTION AND INSERTION

The distal portion of the toe is then carefully distracted distally and translated dorsally to allow the protruding distal portion of the implant to seat within the drilled hole in the middle phalanx and the K-wire to sit within the cannulation of the implant.

TIP: If the middle phalanx is unable to be pulled over the implant, increased soft tissue release can be performed at the PIPJ. If the implant still cannot be placed in the middle phalanx, remove the implant and use the planer to remove more bone at the PIPJ.



Once seated in the middle phalanx, pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved. The K-wire is then driven proximally into the proximal phalanx and into the metatarsal, if desired.

CLOSURE

Proceed to soft tissue and incision closure at this time.

REVISION/REMOVAL OF HAMMERTUBE IMPLANT

If removal and/or revision of a HammerTube Implant is necessary, several instruments are available for removal. Removal of the K-wire implant should be performed prior to performing these steps.

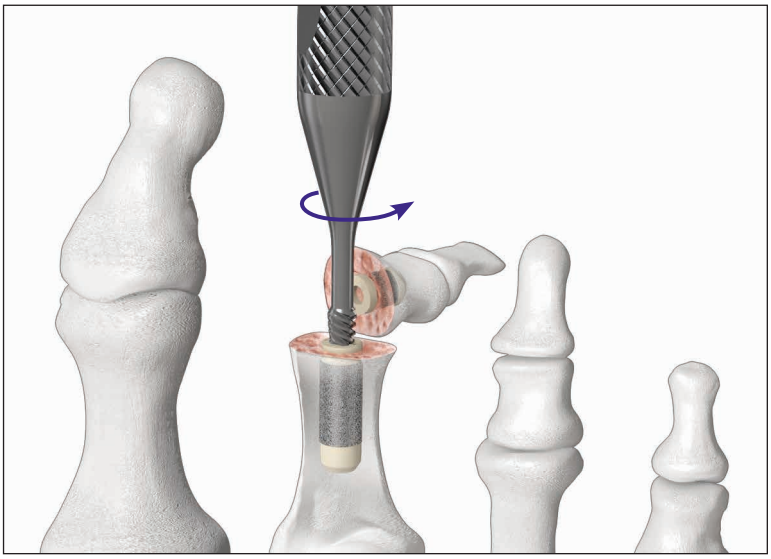
HammerTube Extractor

Implant Puller

If the implant is not integrated into the bones of the phalanges, use the implant puller to hook the proximal or distal aspect of the implant, respectively, and pull out of the phalanx. For implants that are integrated into the bones of the phalanges and/or where bony fusion has occurred across the PIPJ, it is recommended to use the HammerTube Extractor.

Use a sagittal saw to cut through the joint and the implant. Once the canal of the implant is visible, the extractor can be threaded into the canal of one side of the implant by turning in a counter-clockwise direction.

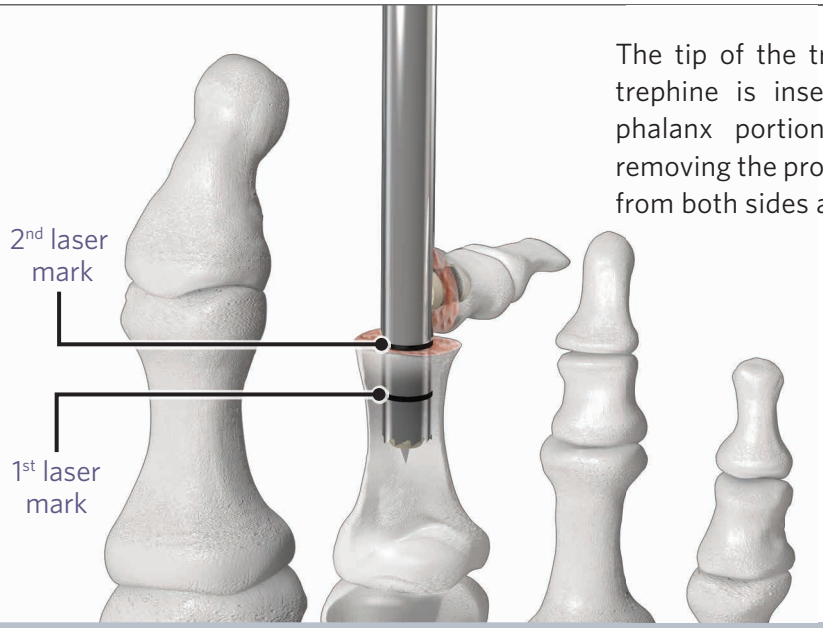
Once the extractor is solidly inserted into one side of the implant, either continue counter-clockwise motion of the extractor to force counter-clockwise rotation of the implant, thus loosening the implant from bone, or use a mallet to tap the base of the extractor handle to loosen the implant from bone. Repeat these steps on the second side of the implant to complete removal.



HammerTube Trephine, Ø2.75 mm

HammerTube Trephine Ø3.50 mm

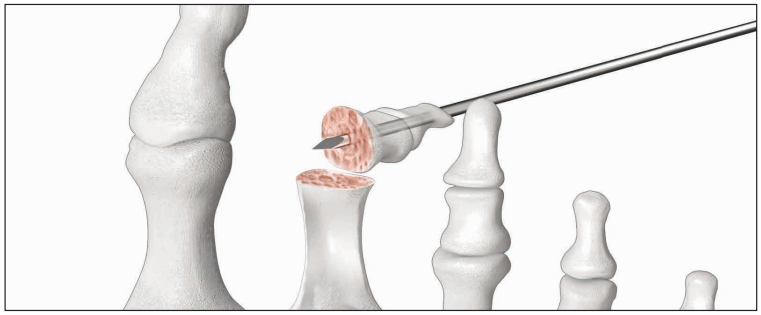
If removal cannot be accomplished using the HammerTube Extractor, a HammerTube Trephine is provided for each diameter of the implant. The trephine is cannulated to allow for insertion of the trocar insert into the trephine.



The tip of the trocar is inserted into the canal of the implant and the trephine is inserted to the first laser mark if removing the middle phalanx portion of the implant, or to the second laser mark if removing the proximal phalanx portion of the implant. Remove the implant from both sides after use of the trephine.

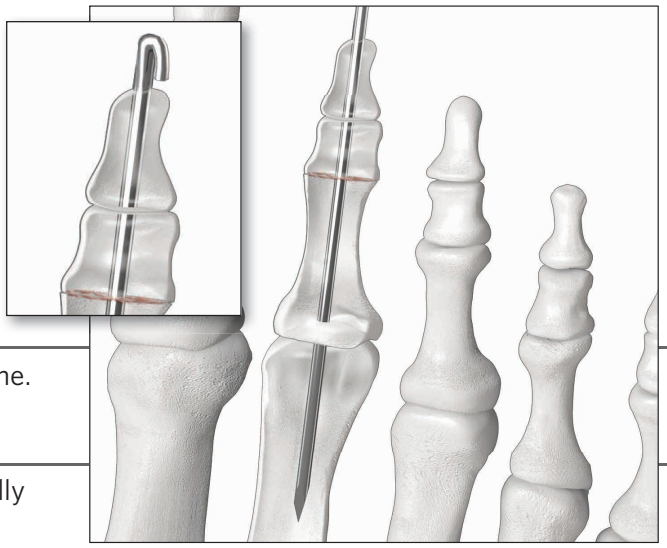
TIP: If backfill of bone is required upon removal of the HammerTube Implant, the trephine matching the implant size can be used in an alternative location (such as the calcaneus) to harvest bone to use across the PIPJ. The trephine size will remove a bone plug that is approximately the same diameter as the implant that was removed.

IMPLANT SELECTION AND INSERTION



An appropriately sized K-wire for the patient's anatomy may be used as a standalone implant for hammertoe correction. Following resection of the proximal interphalangeal joint, insert the K-wire from the PIPJ into the middle phalanx. Exit the distal phalanx centrally plantar to the nail, allowing a few millimeters of the K-wire to remain visible in the PIPJ.

Pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved. In a retrograde fashion, drive the K-wire proximally into the proximal phalanx. If necessary, the K-wire can be driven across the MTP joint into the metatarsal.



Confirm K-wire and toe position with fluoroscopy, if desired. Cut or bend K-wire distally to preferred length.

CLOSURE

Proceed to soft tissue and incision closure at this time.

REMOVAL

Pull K-wire distally from tip of distal phalanx until fully removed from the digit.

HAMMERTUBE CADDY

HammerTube Non-Sterile Caddy

Single-Use Items Include:

- Trocar Inserts
- K-wires
- ≤ Ø2.79 mm Cannulated Drills

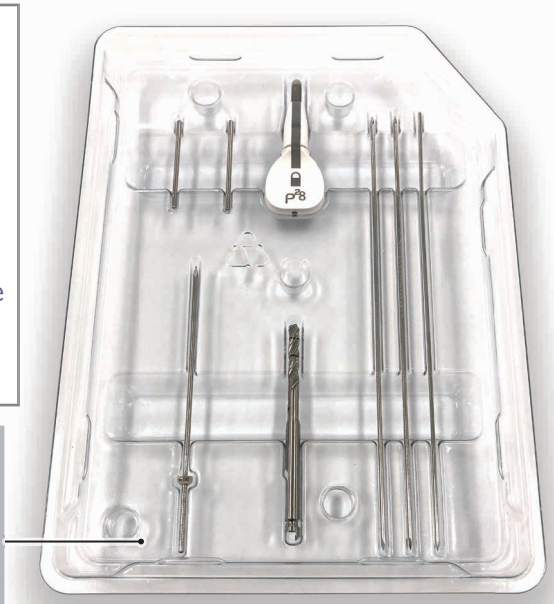
Reusable Items Include:

- Inserters
- Planer
- Implant Puller
- K-wire Gauge
- Ø3.50 mm Cannulated Drills

* Implants are provided sterile packed.

HammerTube Sterile Packed Kit

The sterile packed kit contains the specific implant size pre-loaded in the inserter with the appropriately sized drill, trocar insert and K-wires.



INDICATIONS FOR USE

The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery ofimplants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS

The HammerTube™ System is contraindicated for use in patients with an active or suspected infection; in patients who are physiologically or psychologically inadequate; in patients previously sensitized to titanium; in patients with insufficient quantity or quality of bone to permit stabilization of the bony segments; in patients with high level of activity; or where there is a possibility for conservative treatment.

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
- 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 techniqueor 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.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the HammerTube™ System.**
- **Do not re-sterilize the HammerTube™ System sterile implants or sterile instrumentation.**

MR SAFETY INFORMATION

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

HAMMERTUBE™ SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

www.PARAGON28.com

Endnotes:

[1] Kurtz S & Devine J. PEEK Biomaterials in Trauma, Orthopedic and Spinal Implants. Biomaterials (2007); 28 (32): 4845-69.

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Patents: www.paragon28.com/patents

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