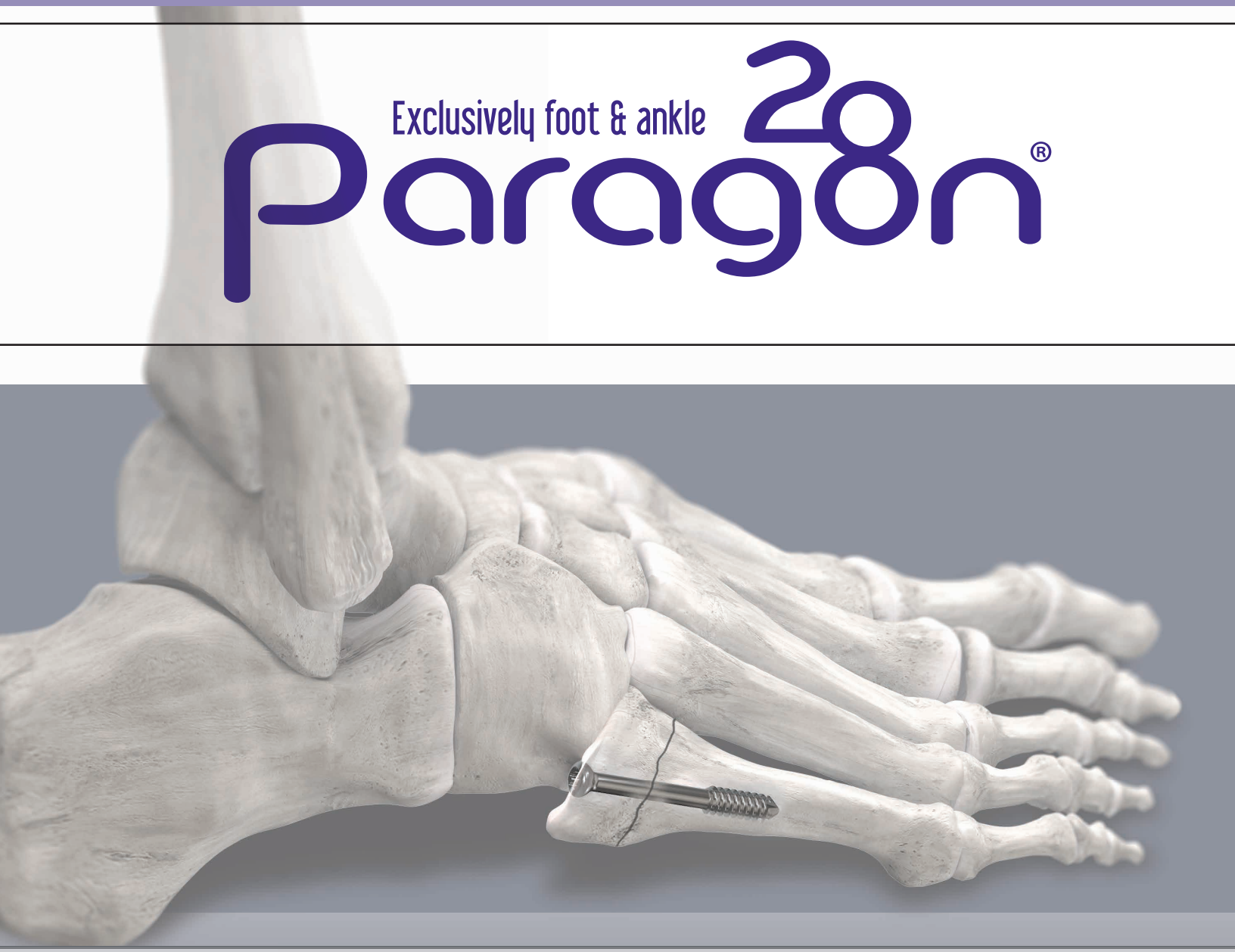
SURGICAL TECHNIQUE GUIDE:

JONES FRACTURE USING THE PRECISION™ JONES FRACTURE SCREW SYSTEM

Exclusively foot & ankle

Paragon 28®



PRECISION™

JONES

FRACTURE SCREW SYSTEM

Acknowledgment:

Paragon 28® would like to thank Patrick Yoon, MD for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The PRECISION™ Jones Fracture Screw System offers extensive options of Type II Anodized Titanium screws. System-specific instrumentation is designed to address procedural challenges while helping to provide maximum stability across fracture sites.

SCREW OFFERING

PRECISION™ Jones Fracture Screw System (120 unique implants)

Solid Screws

4.0 mm Screw	4.5 mm Screw	5.5 mm Screw	6.2 mm Screw

Screw Lengths: 34 mm – 60 mm (2mm increments), 65 mm

Screws Available: 15 per screw diameter

Cannulated Screws

4.0 mm Screw	4.5 mm Screw	5.5 mm Screw	6.2 mm Screw

Screw Lengths: 34 mm – 60 mm (2mm increments), 65 mm

Screws Available: 15 per screw diameter

Screw Features:

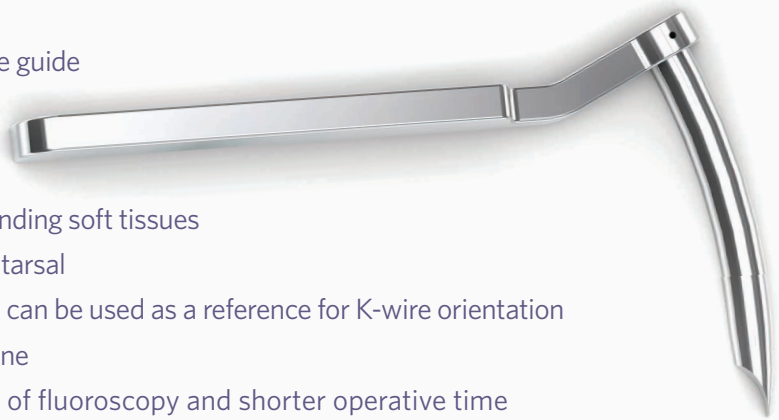
- Constructed from Titanium Alloy that is Type II Anodized for improved fatigue strength
- Shorter, cortical-type threads
- Blunt tip

FEATURED INSTRUMENTS

Nitinol K-wire

- 1.5 mm thickness
- Pliability allows for K-wire to follow pathway through medullary canal, rather than exiting the cortex if initial angle is not centered
- Made of flexible Nitinol for use with provided curved K-wire guide

Curved K-wire Guide (patent pending)



- Helps to create ideal "high and inside" K-wire entry point
- Designed to avoid surgeon and handle contact with surrounding soft tissues
- Tip of guide is shaped to match angle of proximal 5th metatarsal
- Handle is perpendicular to the K-wire exit trajectory, which can be used as a reference for K-wire orientation
- Allows surgeon to adjust K-wire guide in the transverse plane
- Intended to ease insertion of K-wire resulting in less use of fluoroscopy and shorter operative time

OTHER INSTRUMENTATION

NOTE: All instrumentation is cannulated to be used over the Nitinol K-wire. A cannulated or solid screw can be inserted for final fixation depending on surgeon preference.

Ø2.8mm Drill for Ø4.0mm Screw

Ø3.2mm Drill for Ø4.5mm Screw

Ø3.8mm Drill for Ø5.5mm Screw

Ø4.2mm Drill for Ø6.2mm Screw

Ø4.0mm Tap

Ø4.5mm Tap

Ø5.5mm Tap

Ø6.2mm Tap

Ø4.0/Ø4.5mm Countersink

Ø5.5mm Countersink

Ø6.2mm Countersink

Ø4.0mm/Ø4.5mm Driver

Ø5.5mm/Ø6.2mm Driver

Depth Gauge

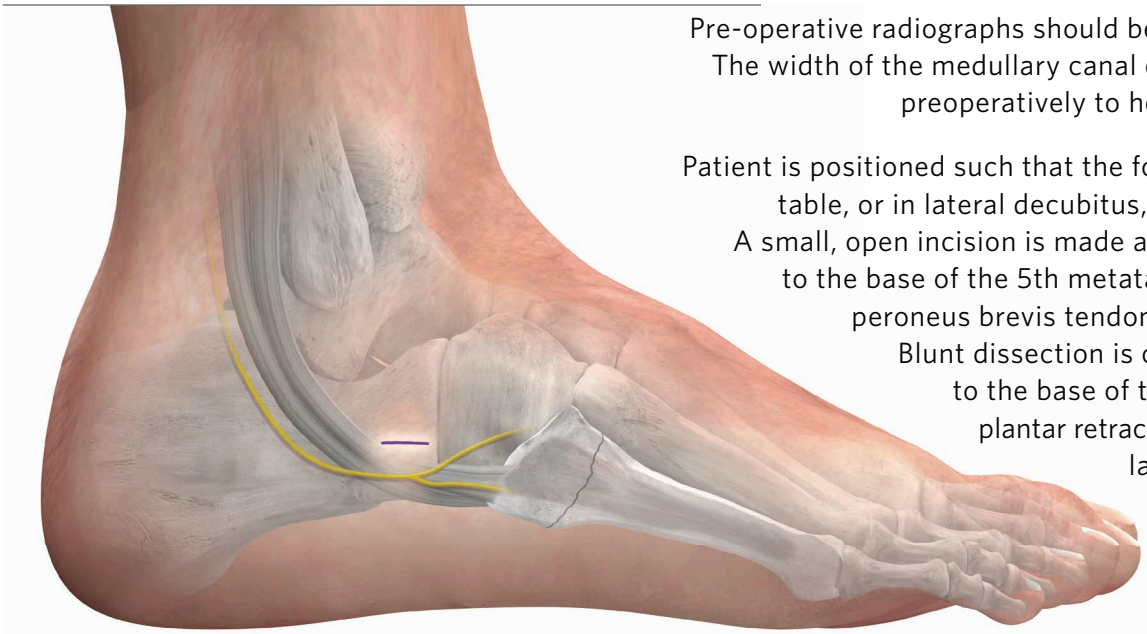
Drill Guides

Tissue Protectors

Medium 3/16" Handle

Large 3/16" Handle

INCISION/EXPOSURE

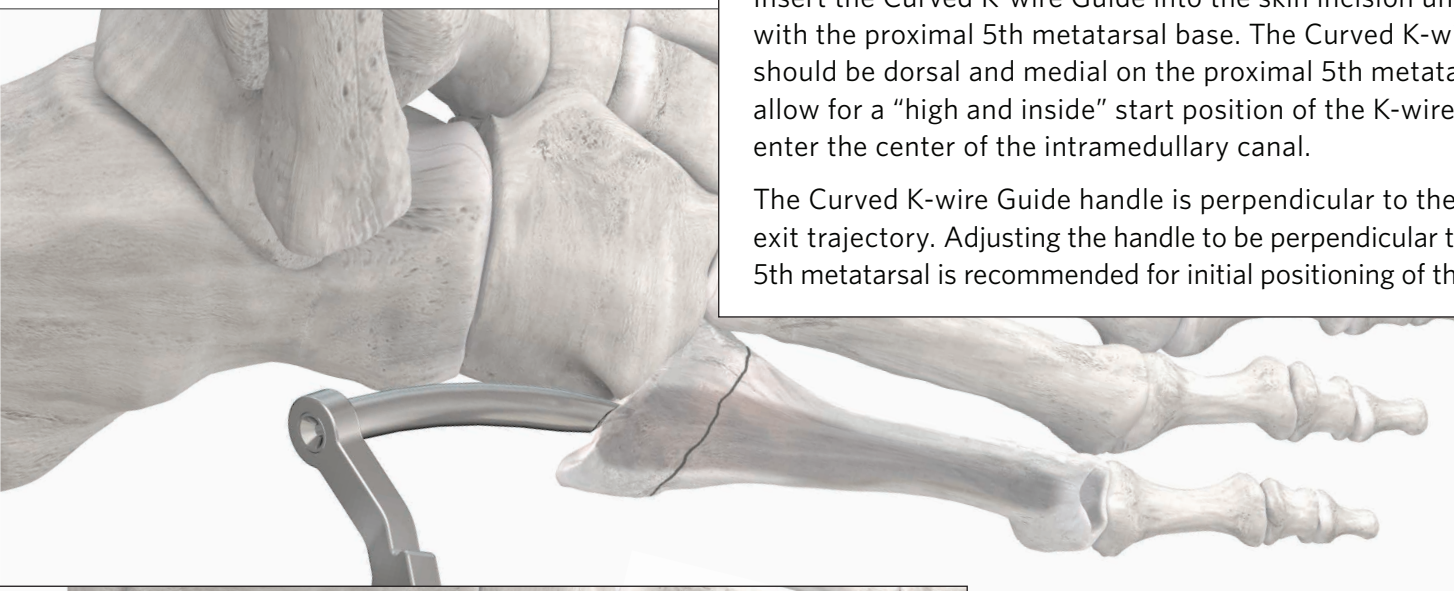


Pre-operative radiographs should be used for procedure planning. The width of the medullary canal can be estimated or measured preoperatively to help determine screw diameter.

Patient is positioned such that the foot is placed off the end of the table, or in lateral decubitus, based on surgeon preference. A small, open incision is made approximately 2-3 cm proximal to the base of the 5th metatarsal parallel and dorsal to the peroneus brevis tendon to help avoid the sural nerve. Blunt dissection is carried down from the incision to the base of the 5th metatarsal, with gentle plantar retraction of the peroneal tendon and lateral dorsal cutaneous branch of the sural nerve.

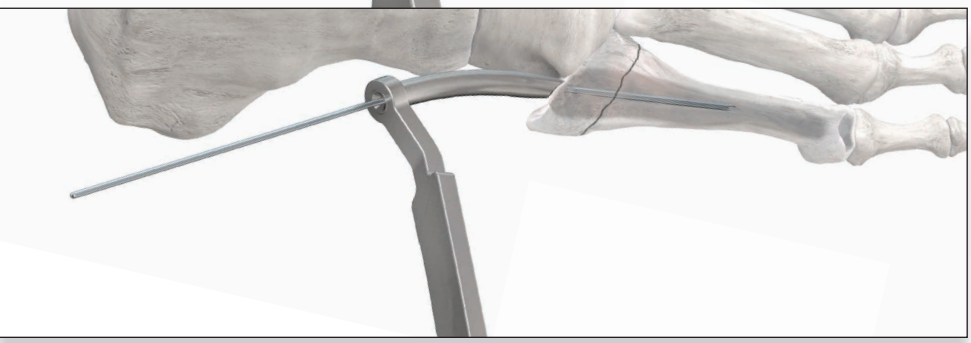
TIP: In the case of a non-union or for a patient where bone graft is required, a second incision is made over the fracture site or a single continuous incision can be made for screw entry and fracture site preparation. Blunt dissection is carried down to the fracture site and necrotic bone is debrided from the area. Bone graft is packed into the site.

GUIDE WIRE PLACEMENT



Insert the Curved K-wire Guide into the skin incision until flush with the proximal 5th metatarsal base. The Curved K-wire Guide should be dorsal and medial on the proximal 5th metatarsal to allow for a "high and inside" start position of the K-wire and enter the center of the intramedullary canal.

The Curved K-wire Guide handle is perpendicular to the K-wire exit trajectory. Adjusting the handle to be perpendicular to the 5th metatarsal is recommended for initial positioning of the guide.

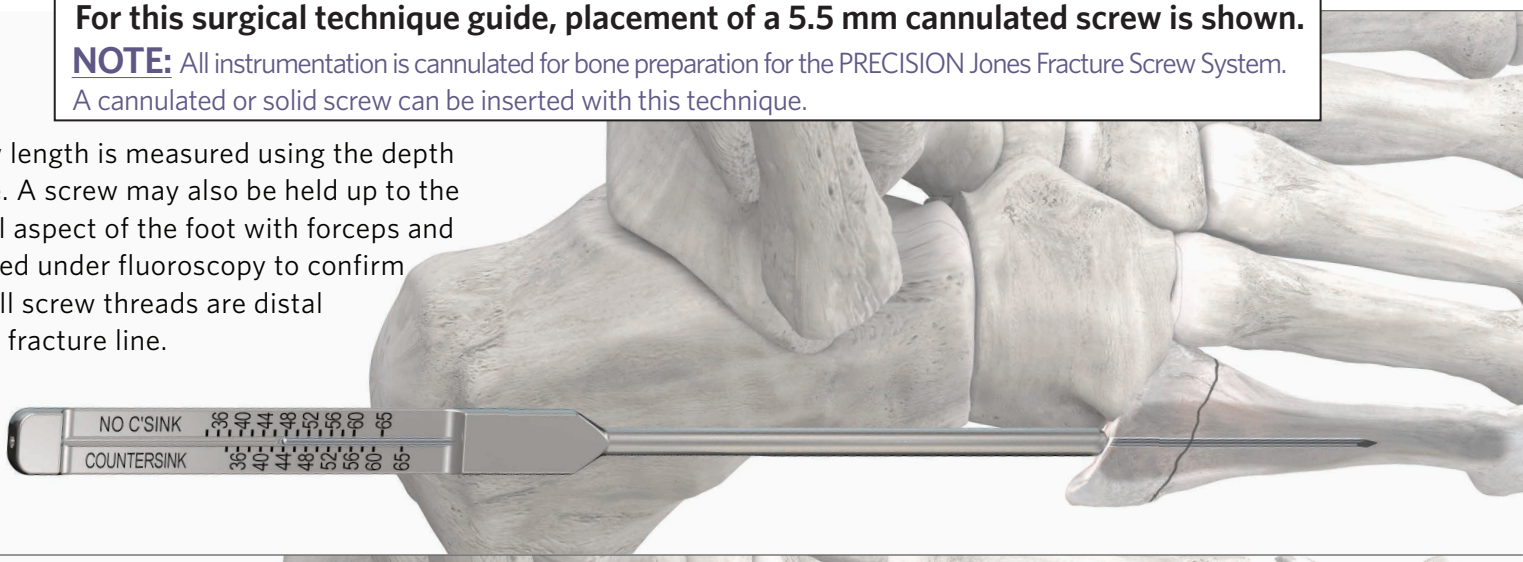


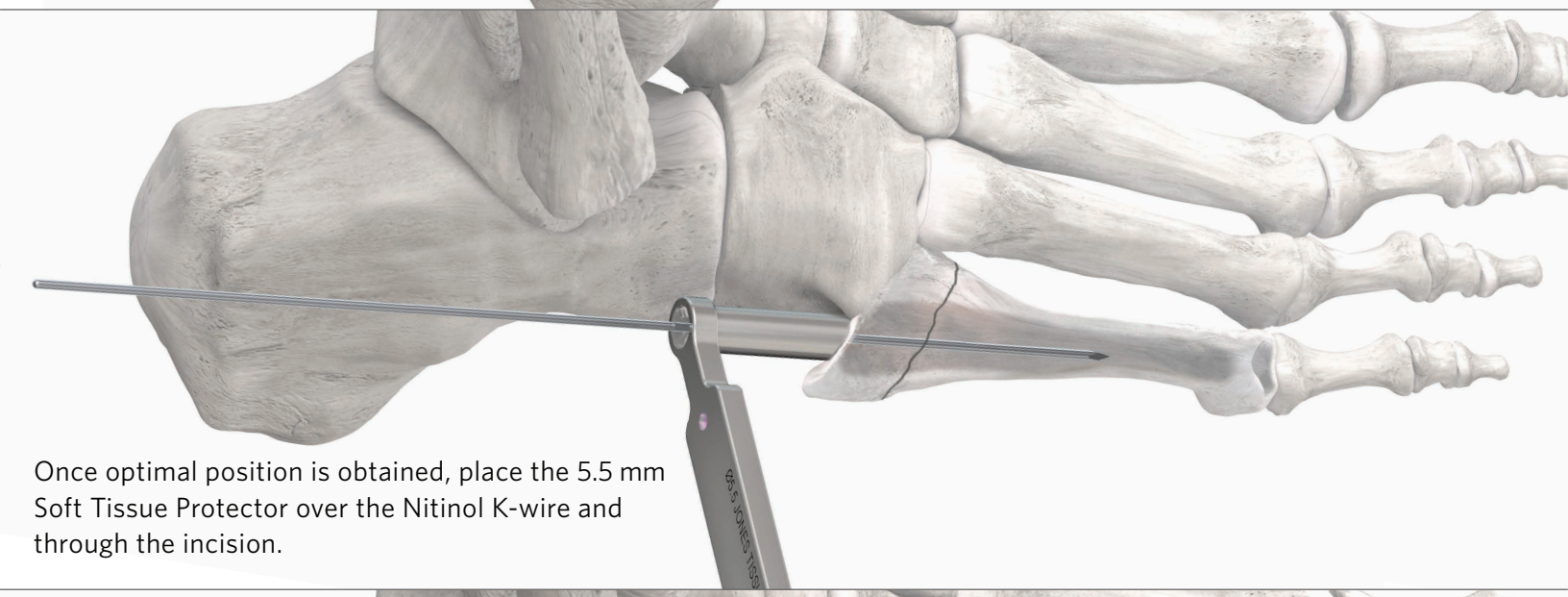
Begin insertion of the Nitinol K-wire. Check position of the Nitinol K-wire using fluoroscopy to determine correct start position. Once a good start position is established, advance the Nitinol K-wire past the fracture line, but ending before the curve in the distal diaphysis of the 5th metatarsal shaft. Confirm wire placement using fluoroscopy.

SCREW SELECTION AND INSERTION

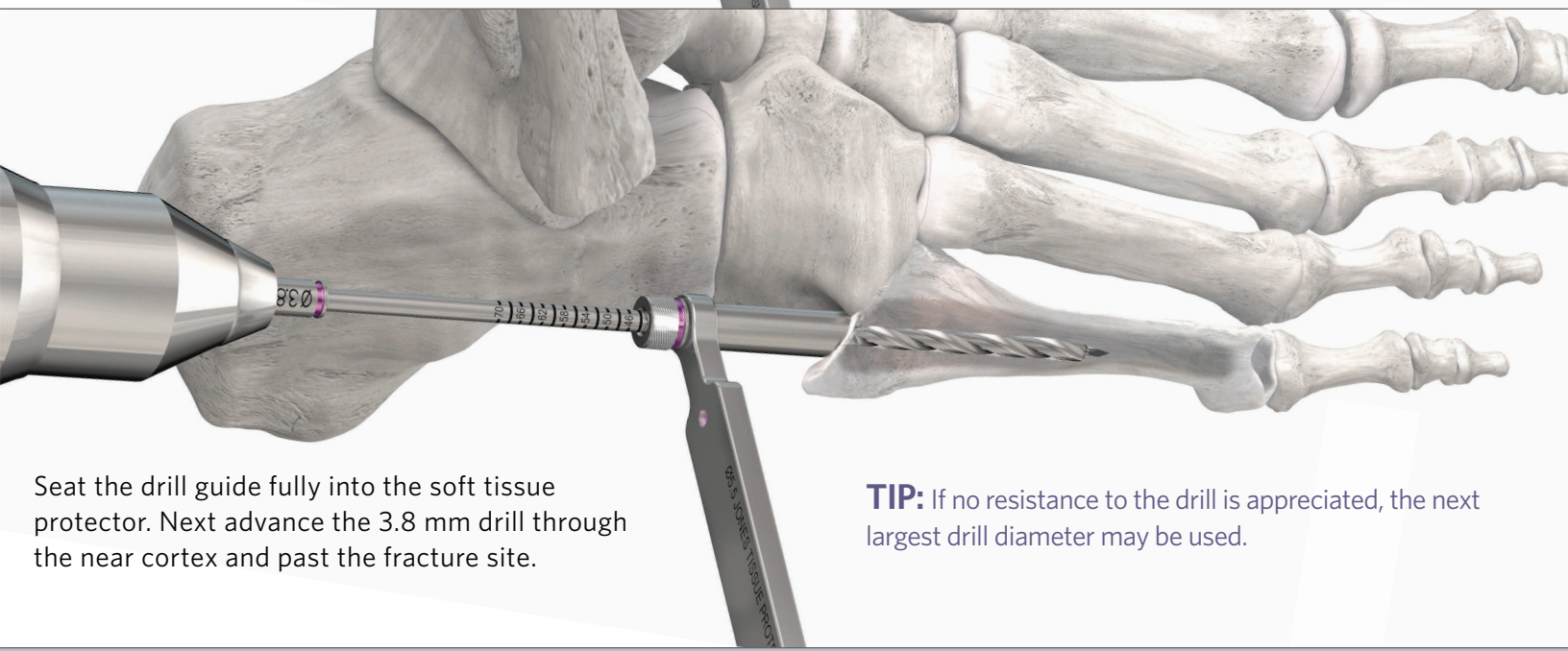
For this surgical technique guide, placement of a 5.5 mm cannulated screw is shown.
NOTE: All instrumentation is cannulated for bone preparation for the PRECISION Jones Fracture Screw System. A cannulated or solid screw can be inserted with this technique.

Screw length is measured using the depth gauge. A screw may also be held up to the lateral aspect of the foot with forceps and checked under fluoroscopy to confirm that all screw threads are distal to the fracture line.





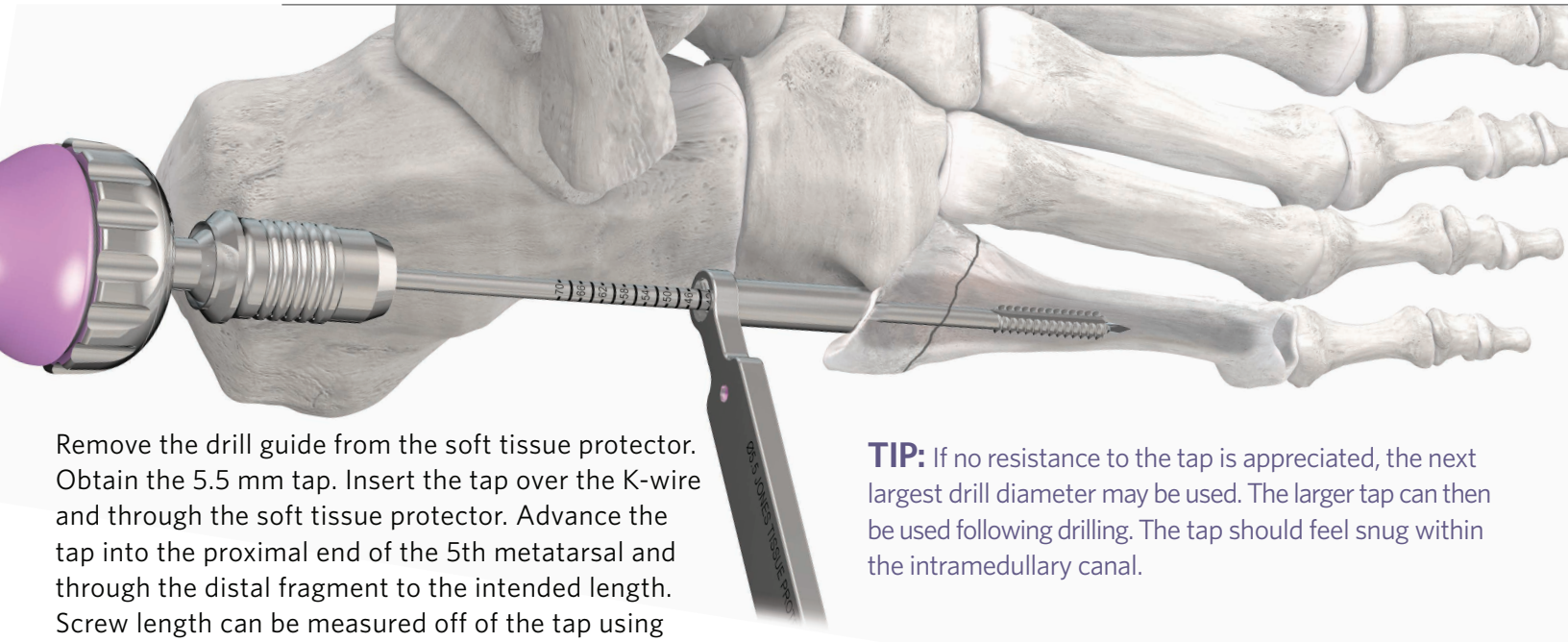
Once optimal position is obtained, place the 5.5 mm Soft Tissue Protector over the Nitinol K-wire and through the incision.



Seat the drill guide fully into the soft tissue protector. Next advance the 3.8 mm drill through the near cortex and past the fracture site.

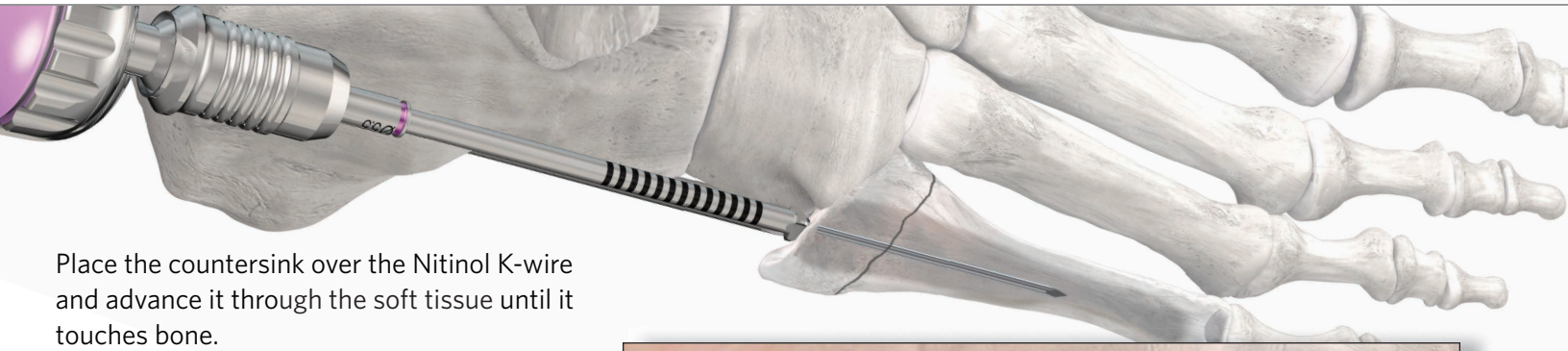
TIP: If no resistance to the drill is appreciated, the next largest drill diameter may be used.

SCREW SELECTION AND INSERTION

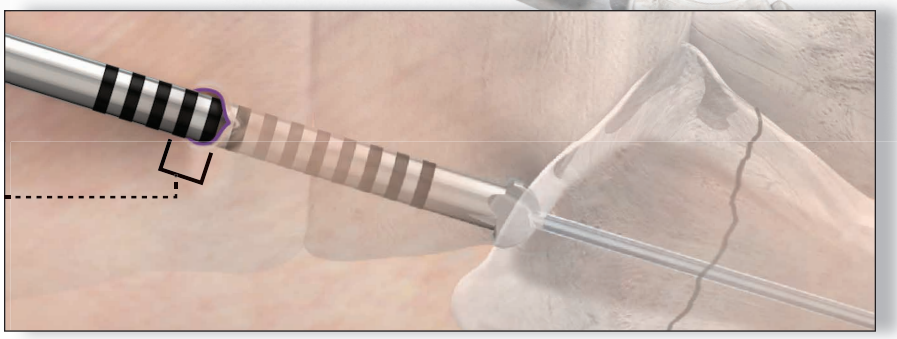


Remove the drill guide from the soft tissue protector. Obtain the 5.5 mm tap. Insert the tap over the K-wire and through the soft tissue protector. Advance the tap into the proximal end of the 5th metatarsal and through the distal fragment to the intended length. Screw length can be measured off of the tap using the soft tissue guide, if desired, while viewing tap depth using fluoroscopy.

TIP: If no resistance to the tap is appreciated, the next largest drill diameter may be used. The larger tap can then be used following drilling. The tap should feel snug within the intramedullary canal.



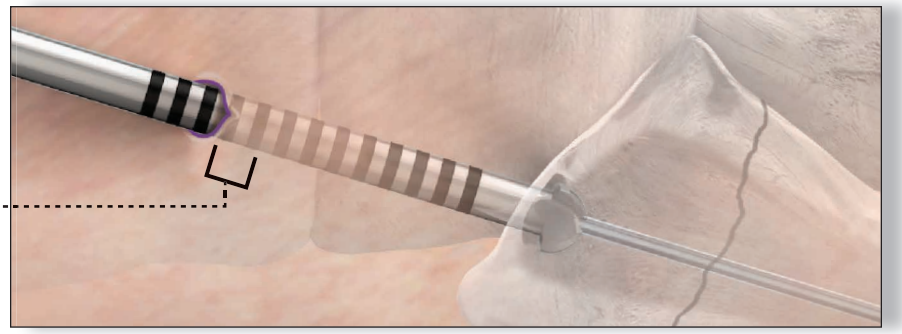
Place the countersink over the Nitinol K-wire and advance it through the soft tissue until it touches bone.



NOTE: The laser markings (silver or black) are seen at the skin where the countersink touches bone.

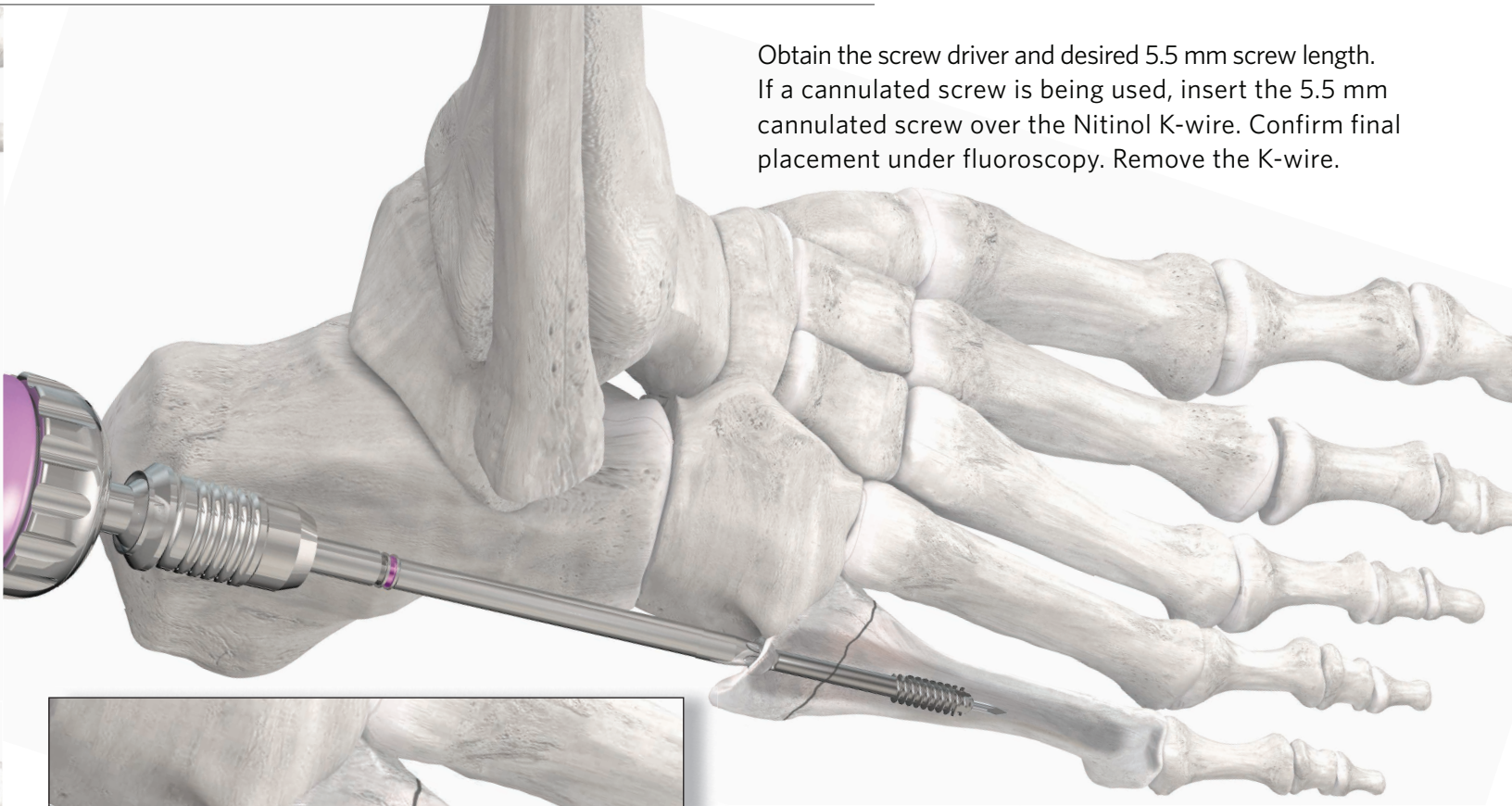
Continue to advance the countersink until three total sections (silver or black) are buried in the soft tissue.

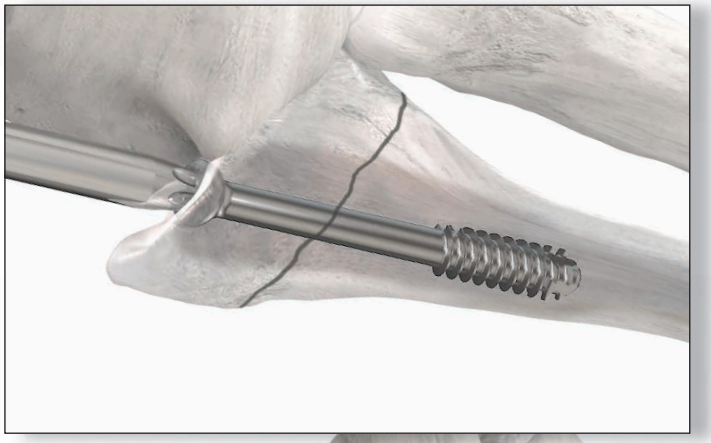
Each line segment, black or silver, denotes 1/3 of the screw head depth.



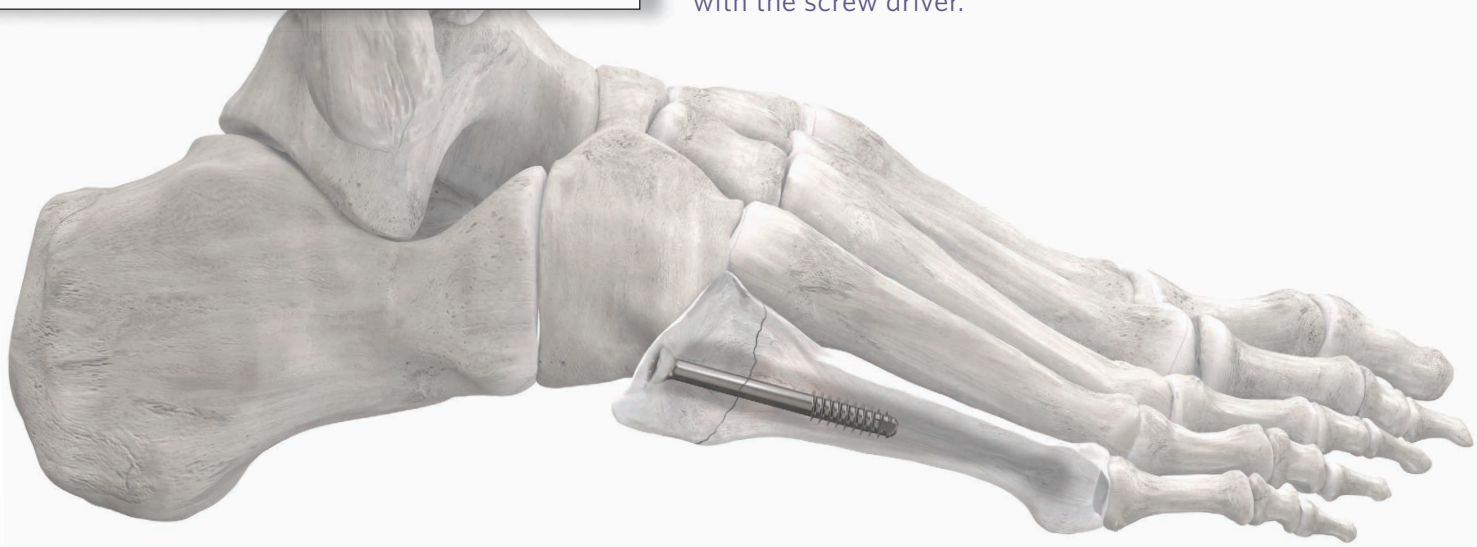
SCREW SELECTION AND INSERTION

Obtain the screw driver and desired 5.5 mm screw length. If a cannulated screw is being used, insert the 5.5 mm cannulated screw over the Nitinol K-wire. Confirm final placement under fluoroscopy. Remove the K-wire.



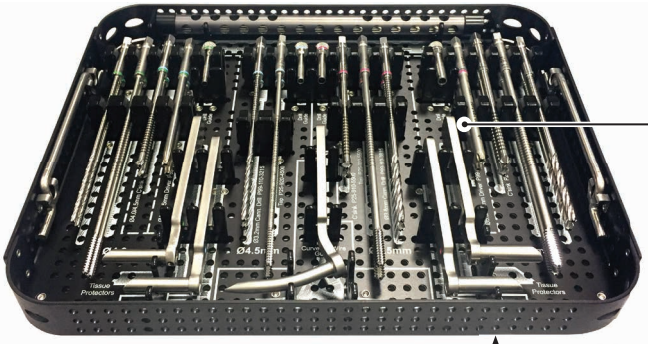


NOTE: All instrumentation is cannulated for insertion of the PRECISION Jones Fracture Screw System. A cannulated or solid screw can be inserted with this technique. If a solid 5.5 mm screw is being used, remove the K-wire prior to placing the screw with the screw driver.



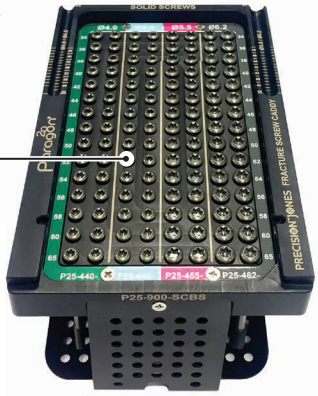
CLOSURE

Proceed to incision closure or concomitant procedures at this time.



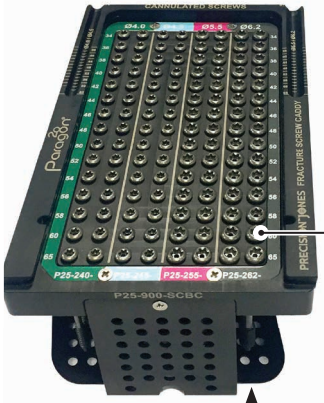
Instrument Tray

The Curved K-wire Guide, 1.5 mm Nitinol K-wires, countersinks, tissue protectors, taps, drills and drill guides for each size of PRECISION™ Jones Fracture Cannulated or Solid Screws are located in the top Instrument Tray.



Solid Screw Caddy

Two solid PRECISION™ Jones Fracture Screws are available for each length. The Solid Screw Caddy options range from 34-65 mm in length.



Cannulated Screw Caddy

Two cannulated PRECISION™ Jones Fracture Screws are available for each length. The Cannulated Screw Caddy options range from 34-65 mm in length.

PRECISION™ Jones Fracture Screw System Case

A depth gauge, forceps, handles and a Jacobs adapter are located at the bottom of the PRECISION™ Jones Fracture Screw System Case.

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

INDICATIONS FOR USE/INTENDED PURPOSE (Monster®)

System(s)	Indications
Monster Screws Cannulated Screws and Washers in Diameters: 4.5 mm, 5.5 mm, and 7.0 mm	The Monster Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Mini-Monster Screws Cannulated Screws and Washers in Diameters: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, and 4.0 mm	The Mini-Monster Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Mini-Monster Solids Screws Solid Screws and Washers in Diameters: 2.7 mm, 3.5 mm, and 4.2 mm	The Mini-Monster Solids Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Precision Jones Screws Solid and Cannulated Type II Anodized Screws and Washers in Diameters: 4.0 mm, 4.5 mm, 5.5 mm and 6.2 mm	The Precision Jones Screws of the Monster Screw System are indicated for use in the foot for: • Fracture repair/fracture fixation
Joust Beaming Screws Solid and Cannulated Type II Anodized Screws in Diameters: 5.0mm, 5.5 mm, and 7.2 mm	The Joust Beaming Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Fracture repair/fracture fixation
Monster BITES Screws Snap-off Screws in Diameters: 2.0 mm and 2.7 mm	The Monster BITES Screws of the Monster Screw System are indicated for use in the foot for: • Bone reconstruction/osteotomy • Fracture repair/fracture fixation

CONTRAINDICATIONS

Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status
- 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
- Pronounced left shift in the differential leukocyte count

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

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 wound 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 the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue 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® 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 screw 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, guide wires, and sterile packaged instruments are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System. These implants are provided sterile and are not to be re-sterilized.

MR SAFETY INFORMATION

The Monster® Screw System has been evaluated for safety and compatibility in the MR environment. It has been tested for heating, migration or image artifact in the MR environment. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 3.0 T or less Maximum spatial field gradient of 1900 gauss/cm (19 T/m)

Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the Paragon 28 Orthopedic Screw is expected to produce a maximum temperature rise of less than 7.8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Paragon 28 Orthopedic Screw when imaged with a gradient echo pulse sequence in a 3.0 T MR system.

PRECISION™ JONES

FRACTURE SCREW SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

www.PARAGON28.com

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DISCLAIMER

The purpose of the PRECISION™ Jones Surgical Technique Guide is to demonstrate the optionality and functionality of the PRECISION™ Jones implants and instrumentation. Although variations in placement and use of the PRECISION™ Jones Screw System 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 PRECISION™ Jones Screw System can be employed, appropriate for the size of the device.