



SURGICAL TECHNIQUE GUIDE

MONSTER[™]
S C R E W S Y S T E M



Subtalar Joint Arthrodesis



Surgical Technique Guide

Subtalar Joint Arthrodesis Using a Monster® 7.0 mm Screw

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DISCLAIMER

The purpose of the Subtalar Joint Arthrodesis Surgical Technique Guide is to demonstrate the best practice for inserting the 7.0 Monster® Screws while outlining and displaying the functionality of the instrumentation unique to the 7.0 mm Monster® Screws. Although various screw patterns and methods can be employed for fixation of a subtalar joint arthrodesis, the fixation options demonstrated were chosen for simplicity of explanation.

This document is contained under the umbrella document “Monster® and Mini-Monster® Surgical Technique Guide”. A more detailed description of the 7.0 mm Monster® Screw instrumentation is contained in the umbrella document. Indications, contraindications and warnings for the Monster® Screw System can be found on pages 3-4 of the Monster® and Mini-Monster® Surgical Technique Guide.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Surgical Technique Guide

Subtalar Joint Arthrodesis: Using a Headed or Headless Screw

INCISION/JOINT PREPARATION

The incision and joint preparation for the subtalar arthrodesis can be performed according to surgeon preference. The surgical technique will begin following adequate joint preparation, appropriate reduction of the joint into a corrected position, and placement of any graft material, if desired.

GUIDE WIRE INSERTION

A 2.3 mm K-wire (guide wire) is selected from the screw caddy. Smooth, threaded and patented Fluoroband™ guide wires are provided.

The 2.3 mm guide wire can be inserted percutaneously into the posterior aspect of the heel above the weight bearing surface. The guide wire is inserted across the subtalar joint, and into the neck of the talus with the position confirmed using fluoroscopy. (A)

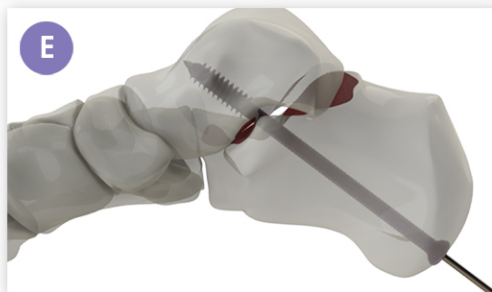
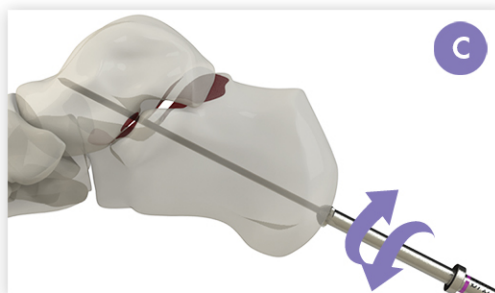


SCREW INSERTION

Monster screws are self-drilling and self-tapping, yet drilling is recommended to optimize thread purchase. (B) An overdrill is available if using a fully threaded screw. Tapping is not necessary with Monster screws but can be performed in instances of considerably hard bone or if surgeon's preference.

TIP: When using a headless screw, measurement is performed prior to countersinking.

Countersinking is recommended. The countersink for the 7.0 mm headed screw is inserted over the guide wire and countersinking is performed. (C) The screw length is measured using the depth gauge. (D) The screw is inserted with the position and size confirmed using fluoroscopy before removing the guide wire. (E) (F)



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Subtalar Joint Arthrodesis: Using the Parallel K-Wire Guide to Insert a 2nd Screw

This surgical technique describes the first of three purposes for using the Paragon 28 Parallel K-Wire Guide: guiding minimum spacing between two 7.0 mm screws such that screw head contact does not occur.



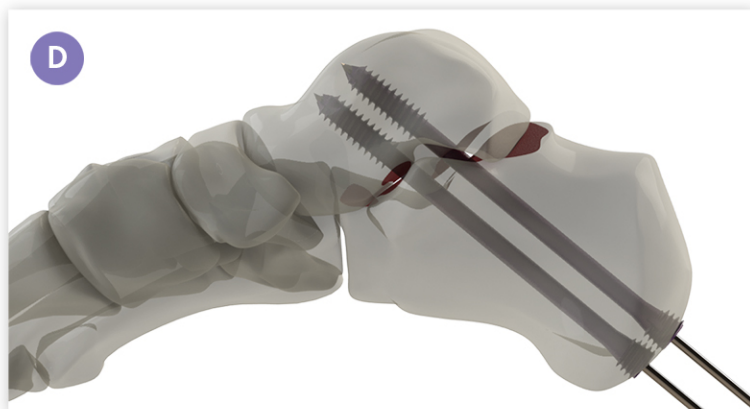
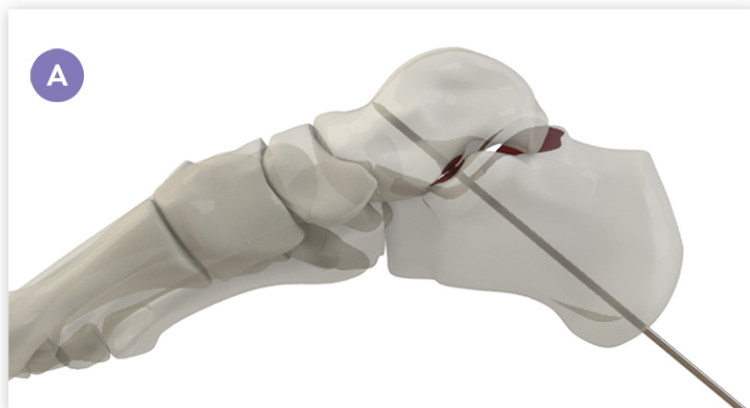
Option 1

This surgical technique begins following the incision, joint preparation, reduction of joint into a corrected position, placement of any graft material, and insertion of an initial guide wire. (A)

The central, isolated hole in the Parallel K-Wire Guide is slid over the initial guidewire. (B)

Depending on whether a headed or headless screw is used, the minimum distance needed for either screw is labeled as "HEADED MIN" and "HEADLESS MIN" on the Parallel K-Wire Guide. This dictates the shortest distance a 2nd guide wire can be located without interference of screw heads. In this case, a headless screw will be used. The second guide wire is placed in the hole guiding the minimum distance between headless screws. (C)

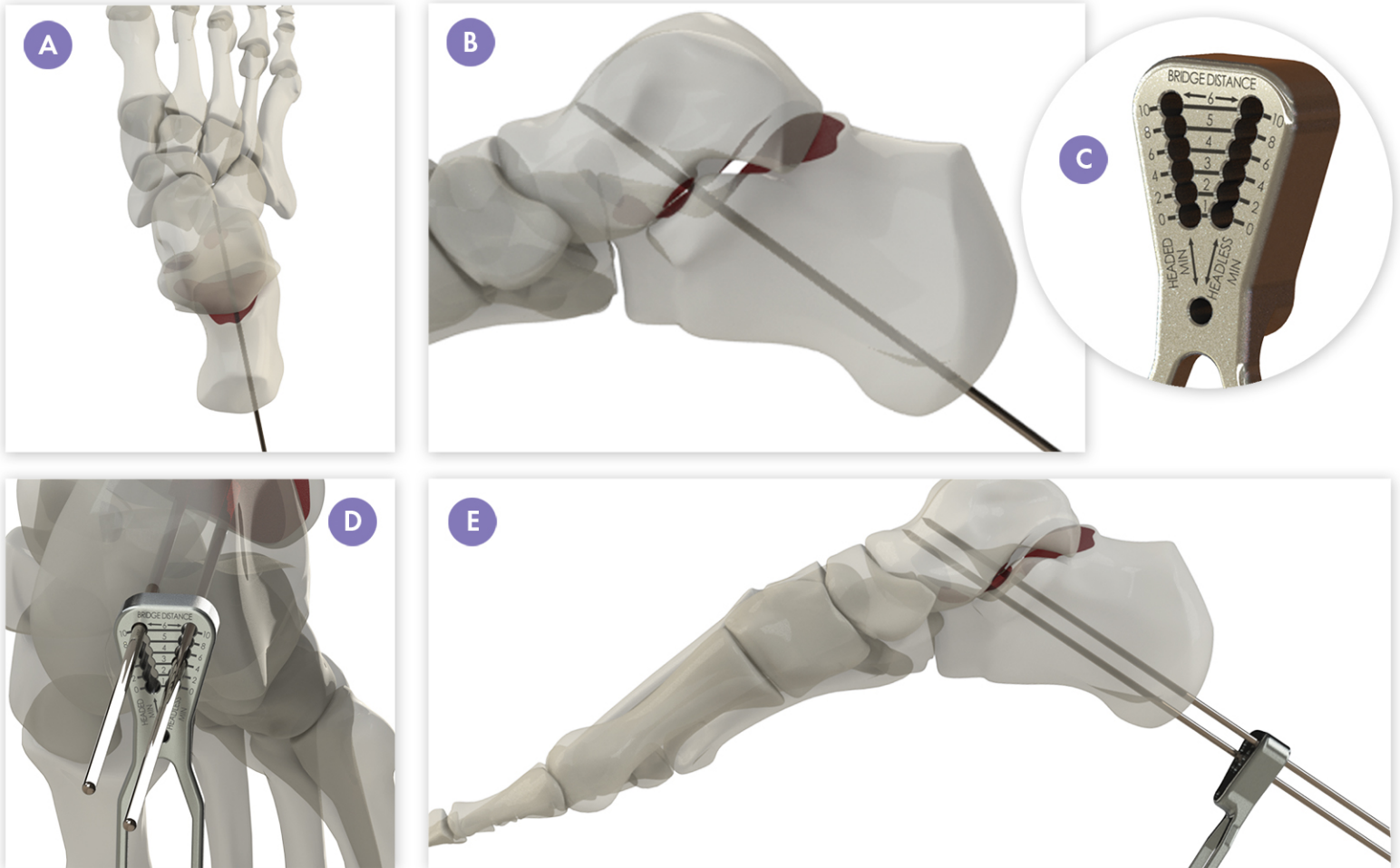
The Parallel K-Wire Guide is removed and headless screws are inserted as depicted in the previous section of this surgical technique guide. (D)



Surgical Technique Guide

Subtalar Joint Arthrodesis: Using the Parallel K-Wire Guide to Reposition a Guide Wire

This surgical technique describes the second of three reasons for using the Paragon 28 Parallel K-Wire Guide: placing a 2nd guide wire across an arthrodesis, osteotomy, or fracture site when the trajectory of the 1st wire is good, but the position is either too medial, lateral, plantar, or dorsal. The Parallel K-Wire Guide is used in this situation to place a 2nd guide wire with the same trajectory as the 1st, but in a different position.



This surgical technique begins following the incision, joint preparation, reduction of the joint into a corrected position, placement of any graft material, and insertion of an initial guide wire. In this situation, a wire was inserted that is too lateral and slightly plantar, yet had a good trajectory. (A, B)

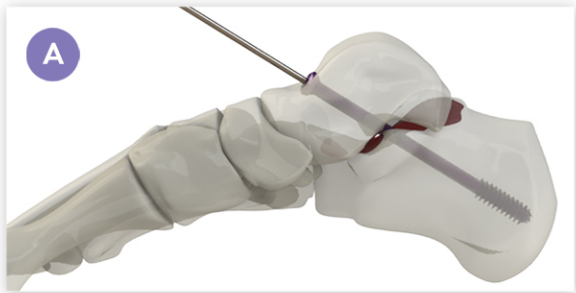
To obtain a better position of the guide wire while maintaining the trajectory, the Parallel K-Wire Guide is slid over the first guide wire, such that the open holes in the Parallel K-Wire Guide are aligned in the desired direction of the new guide wire. The markings on the Parallel K-Wire Guide show tangential lengths between wires, indicating bridge distance, and the markings between adjacent holes – sized in 2 mm increments. (C)

The Parallel K-Wire Guide is slid over the original wire in such a manner that a new wire can be inserted with the same trajectory. In this example, a second K-wire is inserted that is more medial and more dorsal than the original wire, resulting in a better position for screw placement. (D) (E)

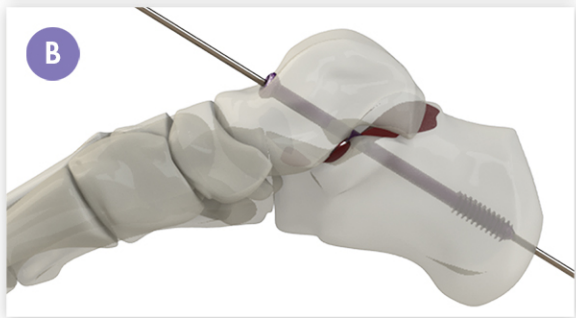
Surgical Technique Guide

Subtalar Joint Arthrodesis: Using the Parallel K-Wire Guide to Place a Posterior to Anterior Screw When an Anterior to Posterior Screw is Present

This surgical technique describes the last of three purposes for using the Paragon 28 Parallel K-Wire Guide, which is more specific to a subtalar joint arthrodesis: placing a posterior to anterior screw across the subtalar joint after a 1st screw has already been placed from anterior to posterior. When the Parallel K-Wire Guide is used in this situation, the issue with intersecting screw trajectories is avoided.



The surgical technique begins following the incision, joint preparation, reduction of joint into a corrected position, placement of any graft material, and insertion of an initial screw from the neck of the talus into the calcaneus. An appropriately sized screw has been placed, but the guide wire is not removed. (A)

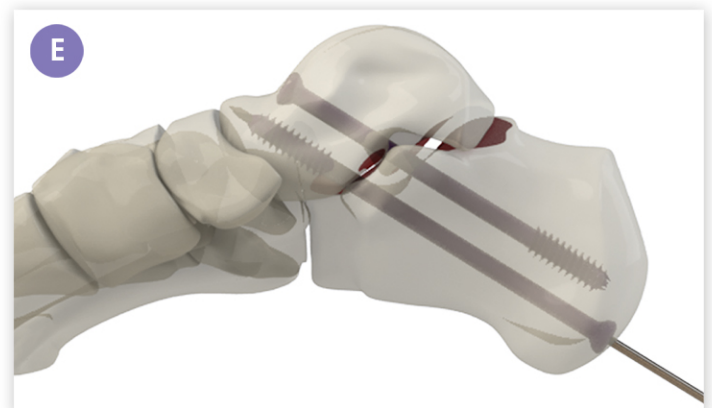


Instead of removal, the guide wire for the 1st screw is driven plantarly through the posterior aspect of the heel. (B)

The Parallel K-Wire Guide central hole is slid over the guide wire. (C)

A second guide wire is inserted into another hole in the Parallel K-Wire Guide in a desired location, thereby preventing intersection with the 1st screw. (D)

The Parallel K-Wire Guide is removed along with the guide wire for the 1st screw. A 2nd screw is inserted using the technique originally described. (E)



Surgical Technique Guide

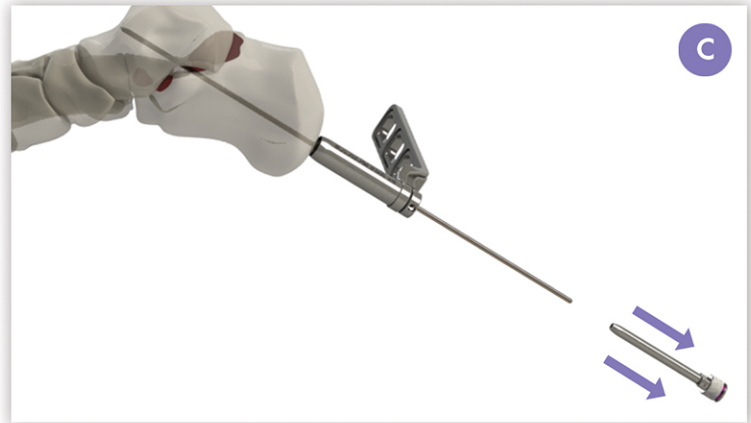
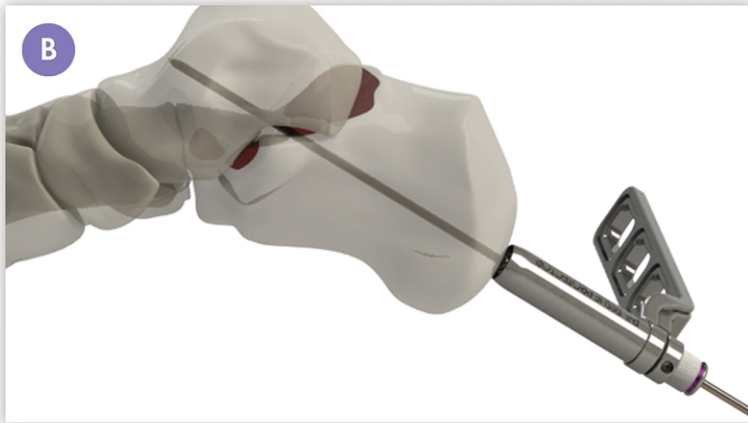
Subtalar Joint Arthrodesis: Using the 3-in-1 Tissue Protector

This surgical technique describes using the Paragon 28 3-in-1 Tissue Protector for a subtalar joint arthrodesis. The 3-in-1 Tissue Protector is available for minimally invasive insertion of a 7.0 mm screw, offering soft tissue protection during guide wire insertion, drilling, and screw insertion. Slight extension of the percutaneous incision may be required with use of the 3-in-1 Tissue Protector to accommodate the diameter of the protective sleeve.

This surgical technique begins following incision, joint resection, reduction of the subtalar joint into a corrected position and placement of any graft material. The 3-in-1 Tissue Protector is assembled on the back table, and is passed through a small incision at the projected screw entry point.

The 3-in-1 Tissue Protector is inserted into the soft tissue until it reaches the bone. (A)

The guide wire is inserted into the 3-in-1 Tissue Protector using a powered driver across the subtalar joint and into the talar neck. (B) The k-wire guide is removed from the 3-in-1 Tissue Protector. (C)



The 4.6 mm drill (for a 7.0 mm screw) is used in the drill guide to drill to the desired depth. The length of the screw can be determined by reading the length of the screw off of the drill markings against the drill guide. Subtract a necessary amount of screw length to account for a headed screw as well as for compression of the screw according to surgeon preference. (D) (E)

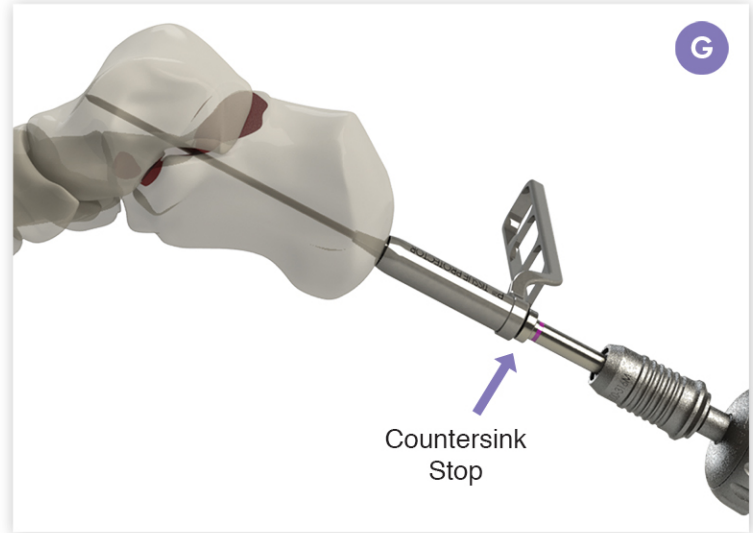
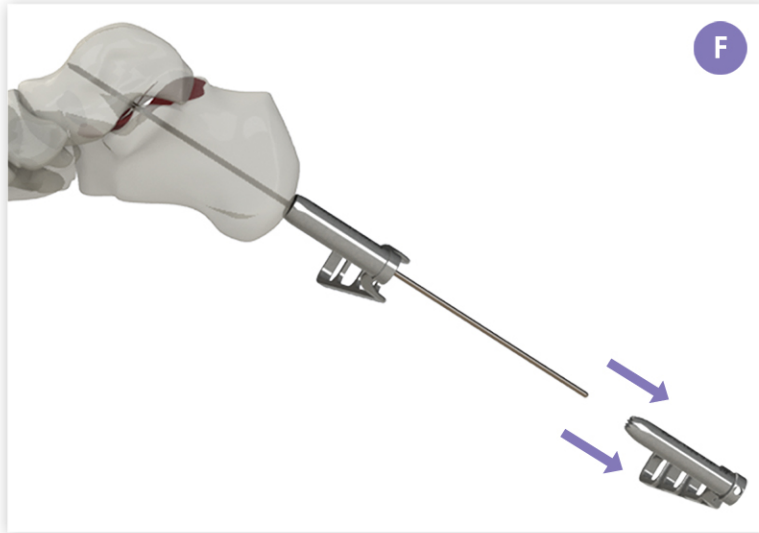


Surgical Technique Guide

Subtalar Joint Arthrodesis: Using the 3-in-1 Tissue Protector

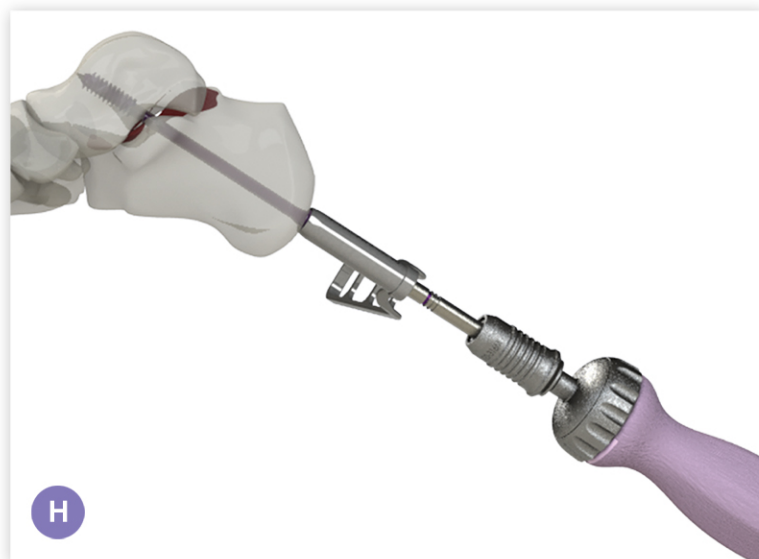
The drill guide is removed from the 3-in-1 Tissue Protector. (F)

The countersink for the 7.0 mm screw is inserted through the 3-in-1 Tissue Protector and is rotated until flush against the countersink stop. (G)



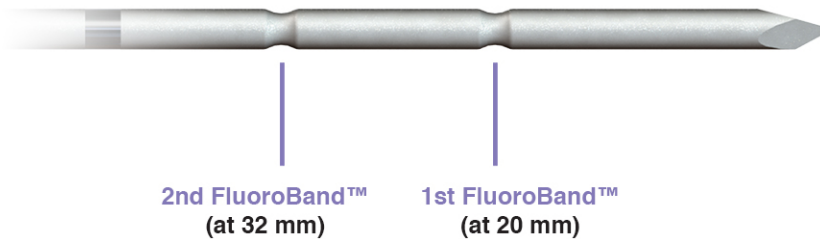
The 7.0 mm screw is inserted into the calcaneus and across the arthrodesis site through the tissue protector. (H)

The tissue protector is then removed and additional advancement of the screw can be performed if necessary once checked using fluoroscopy. (I)



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Subtalar Joint Arthrodesis: Using the FluoroBand Guide Wire



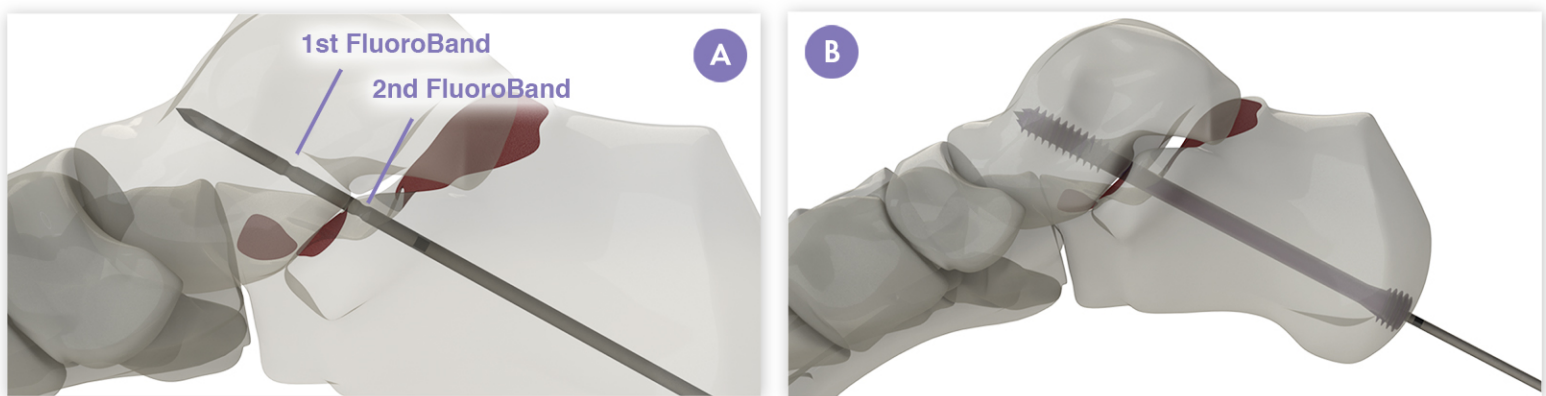
This surgical technique begins following incision, joint preparation, reduction of the joint into a corrected position and placement of any graft material. A FluoroBand guide wire is selected from the back table and is connected to the K-wire driver. The FluoroBand guide wire is inserted percutaneously into the posterior aspect of the heel above the weightbearing surface. The FluoroBand guide wire is inserted across the subtalar joint and into the neck of the talus with the position accessed using fluoroscopy.

TIP: If redirection of the FluoroBand guide wire is necessary at this time, the FluoroBand guide wire must be removed completely prior to re-direction. Do not create bend in the FluoroBand guide wire.

Once correct positioning and length of the FluoroBand guide wire is achieved and confirmed using fluoroscopy, the wire is examined under fluoroscopy for the position of the FluoroBands. (A)

In Figure A, the 1st FluoroBand is positioned in the talus and the 2nd FluoroBand is positioned in the calcaneus, just proximal to the subtalar joint. This particular situation would require either a short partially threaded or medium partially threaded 7.0 mm screw. The long partially threaded 7.0 mm screw would have threads that cross the subtalar joint, thereby preventing compression.

The medium length partially threaded screw is inserted across the subtalar arthrodesis site, as outlined in the previous techniques. (B)



| | |
|--|--|
| 1st Fluoroband not beyond arthrodesis site | Use short threaded screw |
| 1st Fluoroband at or beyond arthrodesis site | Able to use medium or short threaded screw |
| 2nd Fluoroband at or beyond arthrodesis site | Able to use long, medium or short threaded screw |

SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

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

INDICATIONS FOR USE (MONSTER®)

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Fractures and Osteotomies

- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
- Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
- Talar fractures
- Ankle fractures
- Navicular fractures
- Fractures of the fibula, malleolus, and calcaneus
- Metatarsal and phalangeal osteotomies
- Weil osteotomy
- Calcaneal osteotomy

Hallux Valgus Correction

- Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Arthrodesis/Deformity Correction

- 1st MTP arthrodesis
- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint arthrodesis
- Talonavicular arthrodesis
- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Fusion resulting from neuropathic osteoarthopathy (Charcot) such as:

- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

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

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

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 and guide wires 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.**

MR SAFETY INFORMATION

The Monster® Screw 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 Monster® Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.