SURGICAL TECHNIQUE GUIDE

Subtalar Joint Arthrodesis Using a Monster® 7.0 mm Screw

Exclusively foot & ankle 2nd Paragon®

MONSTER™ SCREW SYSTEM

Acknowledgment:
Paragon 28® would like to thank Thomas San Giovanni, MD for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

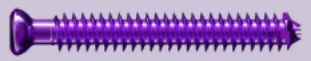
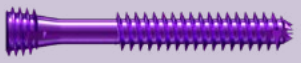
The Paragon 28 Monster® Screw System objectives were set to produce a cannulated screw system that is comprehensive, high quality and specifically designed for the unique anatomy of the foot and ankle. With multiple thread length options, headed and headless varieties in all diameters, the Monster Screw System provides a degree of versatility that allows for fixation of osteotomies, fractures, and joint arthrodesis in the forefoot, midfoot, hindfoot, and ankle.

This surgical technique guide will discuss the patent–pending method of using the Paragon 28 Monster Screw System for Subtalar Arthrodesis. Fixation of the arthrodesis in this surgical technique guide is demonstrated using a Monster Ø7.0 mm Screw. Alternative methods of fixation can be used for this procedure, at the discretion of the surgeon. Other methods and applications for this system can be employed, per surgeon preference.

CONTENTS

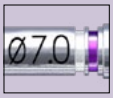
MONSTER® HINDFOOT 7.0 SLIMLINE CASE CONTENTS

The Monster Hindfoot 7.0 SlimLine Case is configured set of Monster instruments and implants curated specifically for hindfoot procedures such as Subtalar Joint Arthrodesis. The follow sections describe the contents of this SlimLine Case; for the full Monster System optionality, please refer to the full Monster System technique guide (P20-STG-0001)

Ø7.0 mm Screws	Headed:		Headless:	
				
Threads Offerings:	Fully Threaded	Partially Threaded: Long	Partially Threaded: Long	Partially Threaded: Medium
Screw Lengths:	40-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments	44-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments	72-90 mm 2 mm increments 60-70 mm 5 mm increments	44-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments
				
Threads Offerings:	Partially Threaded: Medium	Partially Threaded: Short	Partially Threaded: Short	
Screw Lengths:	40-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments	40-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments	40-50 mm and 72-90 mm 2 mm increments 55-70 mm 5 mm increments	

MONSTER® SCREW INSTRUMENTATION

The chart below demonstrates instrumentation sizes that correspond to the Ø7.0 mm Monster Screw.

Screws:	K-wire Size:	Drill Size:	Drill Guide Size:	Overdrill Size:	Overdrill Guide Size:	Tap Size:	Countersink Size:
Ø7.0 mm	 Ø2.3 mm	 Ø4.6 mm	 Ø7.0 mm	 Ø7.0 mm	Not Available	 Ø7.0 mm	 Ø7.0 mm

Monster Screw Washer Options:

- *Bowl Washer allows for the washer to be seated in the countersunk portion of the bone.*
- *Bowl-Slot Washers allow for placement of a washer after screw insertion without the need to back the screw out.*

Washer Options:	Flat	Domed	Bowl	Bowl-Slot
Shape:				
Sizes Offered:	Ø7.0 mm	Ø7.0 mm	Ø7.0 mm	Ø7.0 mm

MONSTER® SCREW INSTRUMENTATION

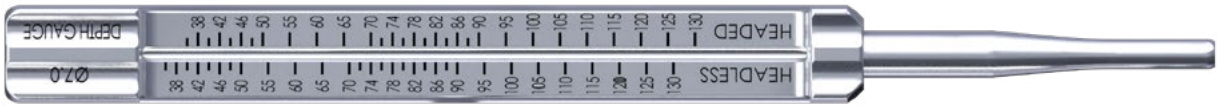
The instruments depicted below are specific for each screw diameter within the Monster systems The instruments shown are for the Ø7.0 mm Monster Screw size as an example. All Monster instrumentation have colored band/ markings that correspond to the screw size.

K-wires

Headed Screw Countersink

Headless Screw Countersink

Depth Gauge



Drill

Drill Guide

Overdrill

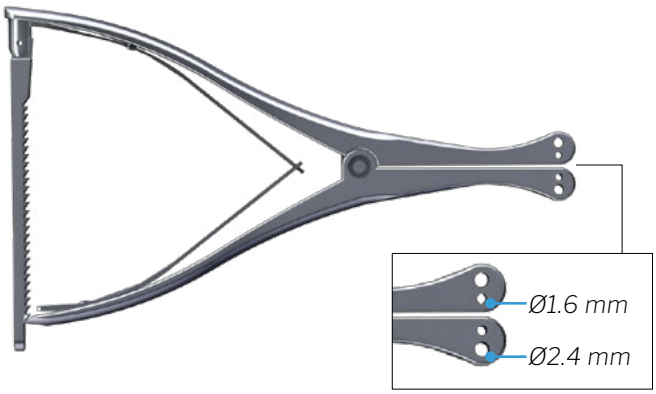
Tap

Driver

MONSTER® SCREW INSTRUMENTATION

Parallel K-wire Guide

Assists in spacing and positioning of K-wires for Ø7.0 mm Monster Screws, to allow for a second K-wire to be placed parallel to the initial K-wire. An indicator is also present to allow for appropriate spacing between two K-wires, such that two Ø7.0 mm Monster Screws can be placed without screw head collision.



Hindfoot Distractor

The larger, outside holes accommodates Ø2.3 mm K-wires but can alternatively be used with a Steinmann Pin up to Ø2.4 mm. The smaller, inner hole accommodates up to Ø1.6 mm K-wires.

3/16" Jacob's Adaptor

Available for the Ø4.5 mm, Ø5.5 mm, and Ø7.0 mm Monster Screw sizes.

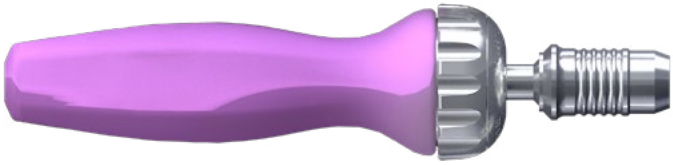
Cleaning Stylet:

FluoroBand™ Guide Wires:

Smooth

Threaded

3-In-1 Tissue Protector



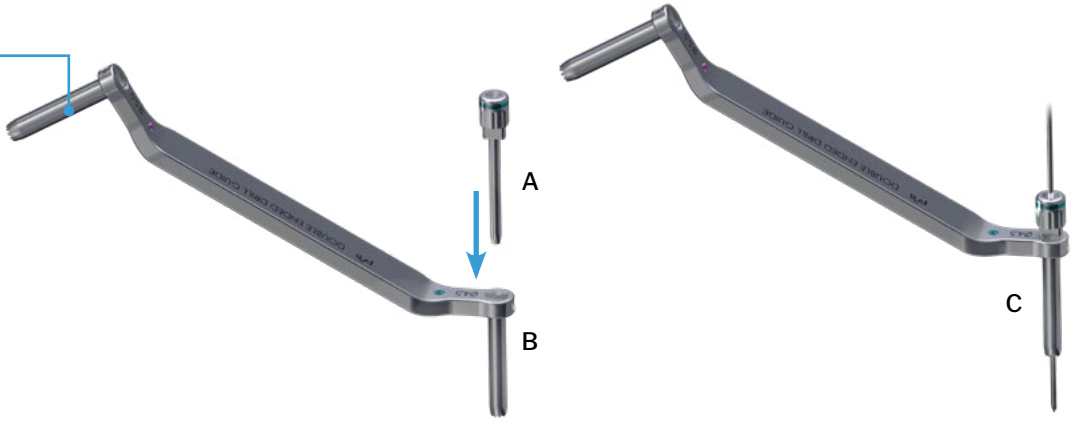
3/16" AO Handle:

The 3/16" AO Handle is for use with the Monster® Screws from Ø4.5 mm - Ø7.0 mm. Available in Solid or Cannulated.

MONSTER® SCREW INSTRUMENTATION

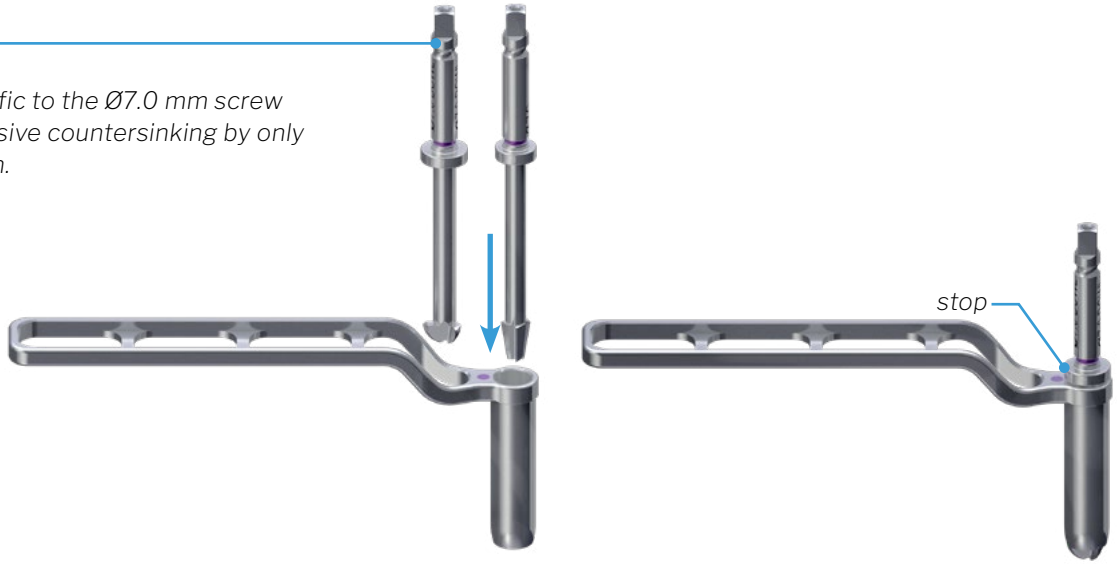
2-in-1 Tissue Protector

*A K-wire guide (**A**) is available for the Monster Screw Systems that inserts into the drill guide (**B**) for the screw size selected. With the K-wire guide inserted into the drill guide, the K-wire can be driven into bone with soft tissue protection. (**C**) Both smooth and threaded K-wires are available in the Monster Screw System Case.*



Countersinks with Stops

The Countersink with a stop is specific to the Ø7.0 mm screw size prevents accidental overaggressive countersinking by only penetrating to the appropriate depth.

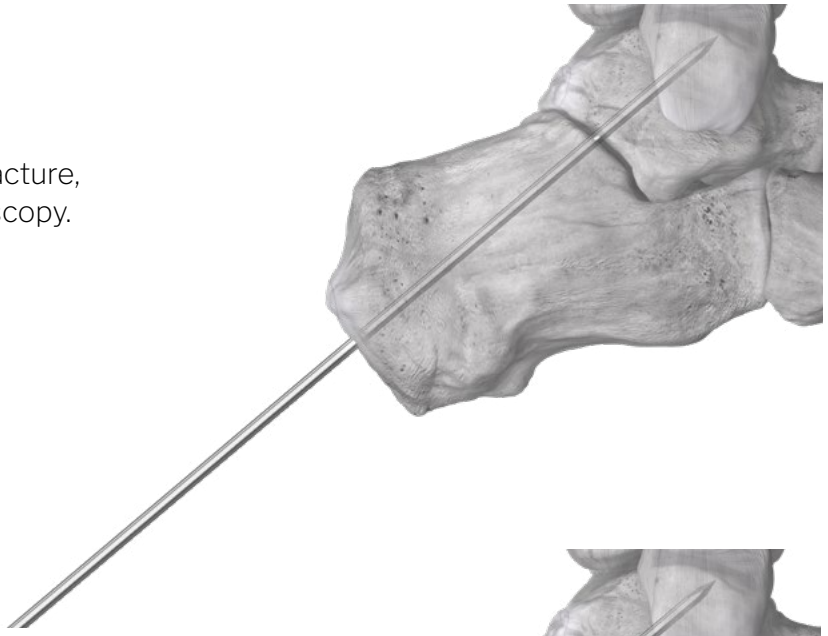


PARTIALLY THREADED HEADED SCREW INSERTION

This surgical technique describes the first of two purposes for using the Paragon 28 Monster Screw System: guiding a partially threaded headed Ø7.0 mm screw. 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.

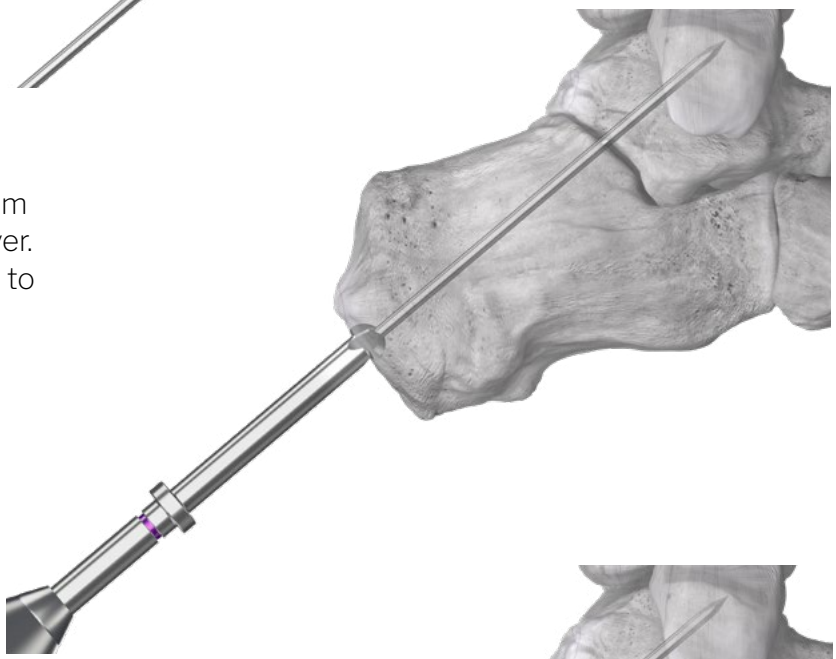
K-wire

Insert a Ø2.3 mm K-wire across the arthrodesis, fracture, or osteotomy site. Confirm trajectory using fluoroscopy.



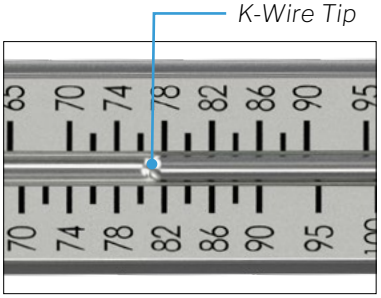
Countersink

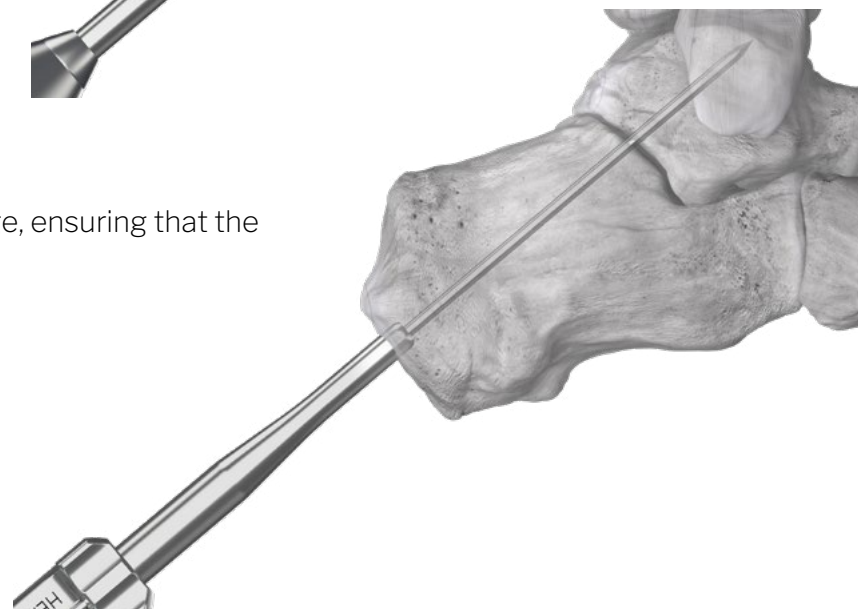
Retrieve the Ø7.0 mm Countersink for the Ø7.0 mm Monster Screw, and attach to the appropriate Driver. Rotate the Countersink clockwise over the K-wire to remove adequate bone to seat the screw.



Measure

Measure for screw length using the Depth Gauge, ensuring that the tip of the gauge is touching the bone.

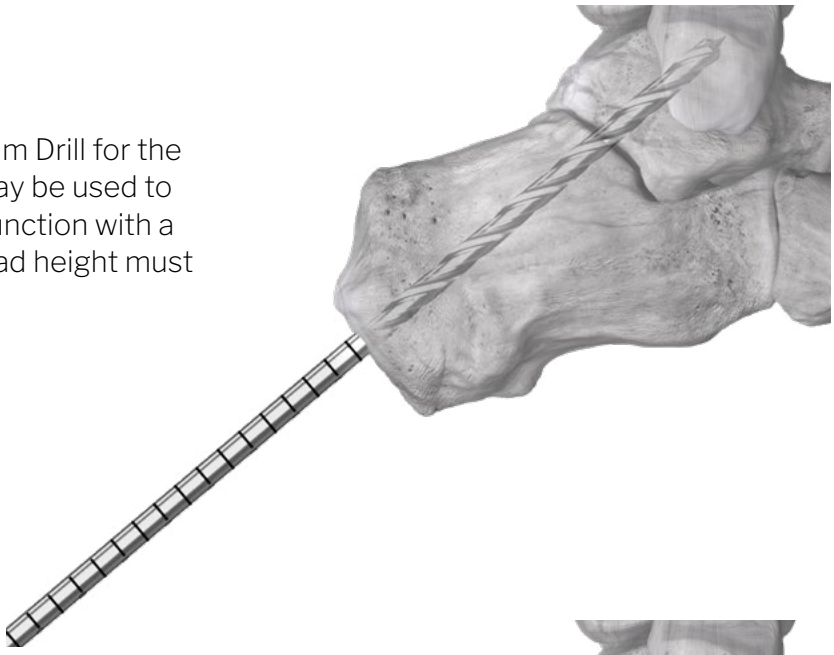




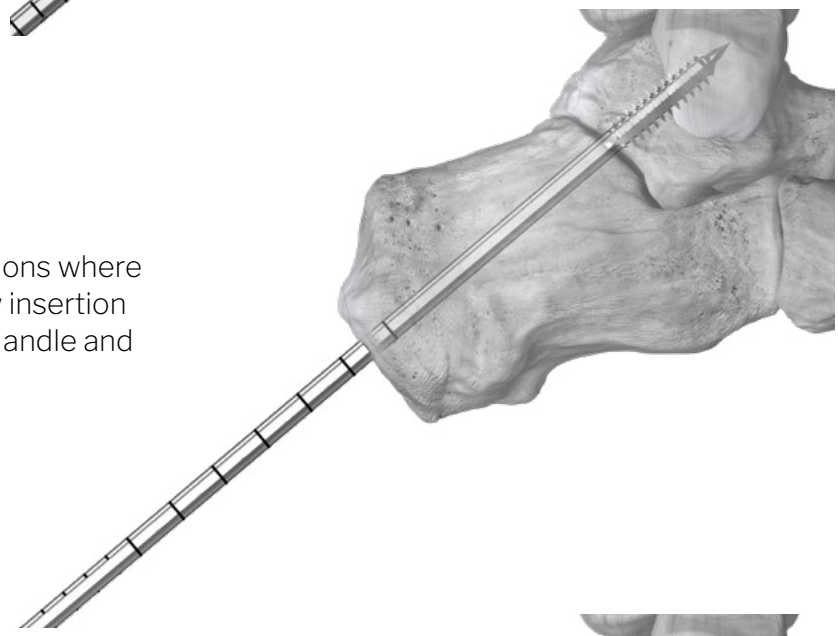
PARTIALLY THREADED HEADED SCREW INSERTION

Drill

Drill over the K-wire using the Cannulated Ø4.6 mm Drill for the Ø7.0 mm Monster Screw. The Cannulated Drill may be used to measure for screw length when it is used in conjunction with a Drill Guide. For Headed screws, the estimated head height must be subtracted from the length drilled.

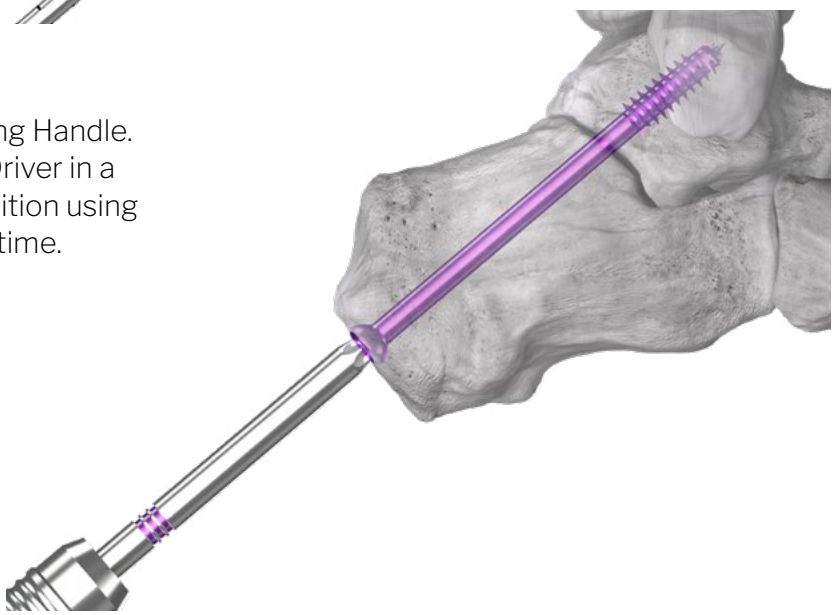


Optional: Taps are provided to be used in situations where hard bone is encountered, or resistance to screw insertion occurs. Attach the Tap to the appropriate sized Handle and hand tap.



Screw Insertion

Attach the appropriate Driver to the corresponding Handle. Insert a Ø7.0 mm Monster screw by turning the Driver in a clockwise manner. Confirm screw length and position using fluoroscopy. Remove the Ø2.3 mm K-wire at this time.

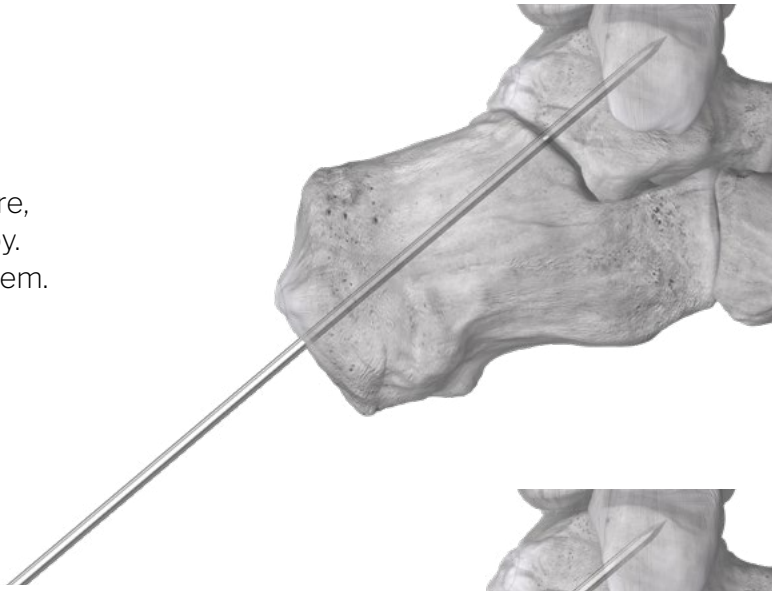


PARTIALLY THREADED HEADLESS SCREW INSERTION

This surgical technique describes the second of two purposes for using the Paragon 28 Monster Screw System: guiding a partially threaded headless Ø7.0 mm screw. 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.

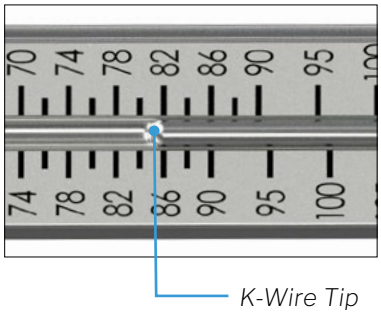
K-wire

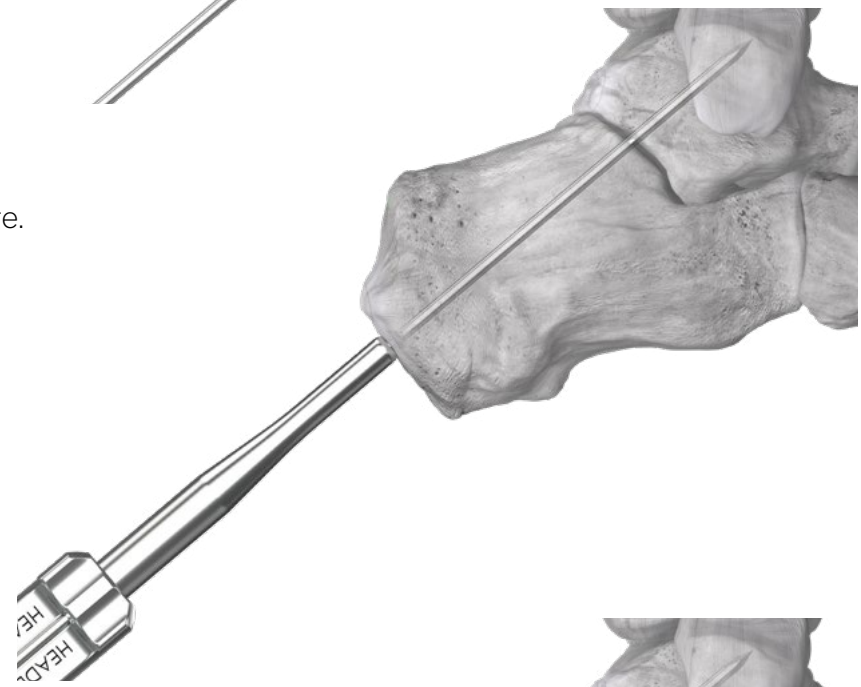
Insert a Ø2.3 mm K-wire across the arthrodesis, fracture, or osteotomy site. Confirm trajectory using fluoroscopy. A K-wire Guide is available for the Monster Screw System.



Measure

Measure for screw length using the Depth Gauge.





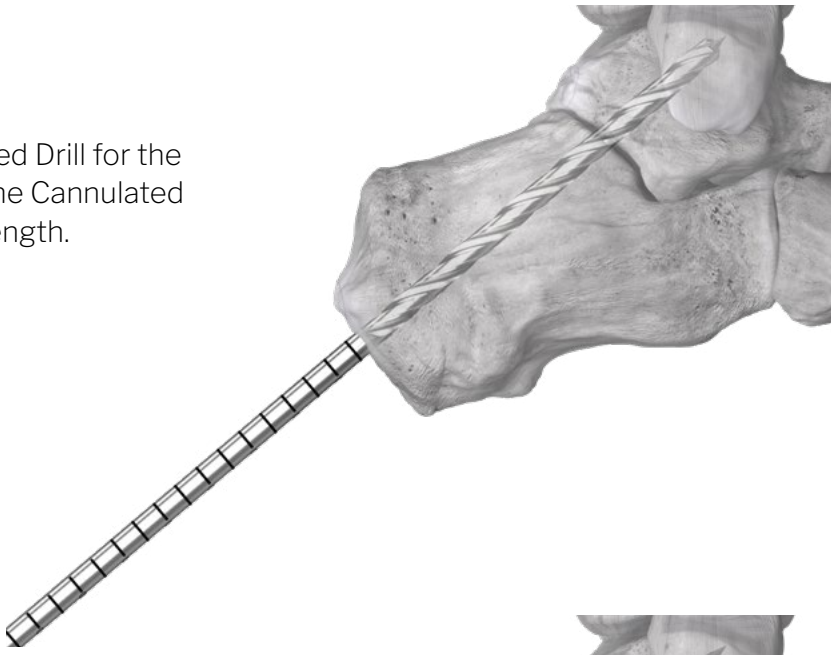
Countersink

Retrieve the Ø7.0 mm Countersink for the Ø7.0 mm Monster Screw, and attach to the appropriate Driver. Rotate the Countersink clockwise over the K-wire to remove adequate bone to seat the screw.

PARTIALLY THREADED HEADLESS SCREW INSERTION

Drill

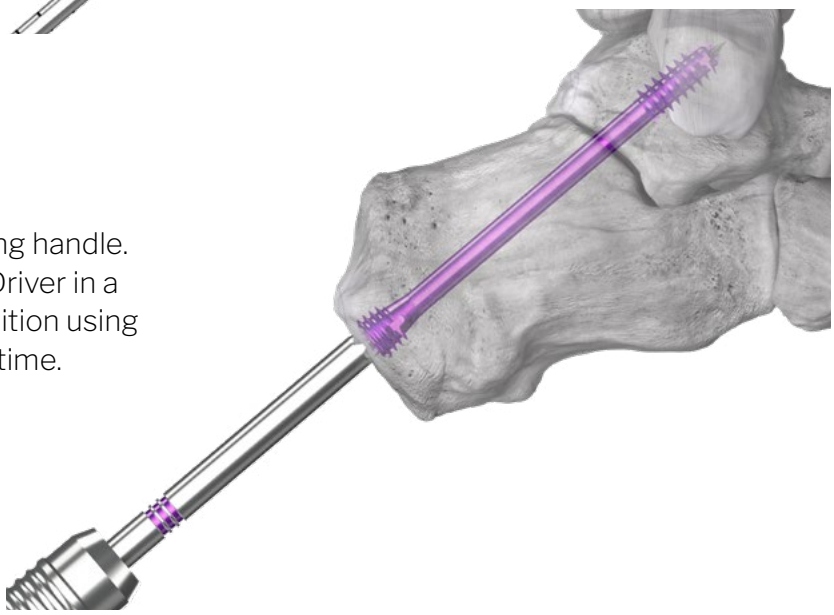
Drill over the K-wire using the Ø4.6 mm Cannulated Drill for the Ø7.0 mm Monster Screw. For Headless screws, the Cannulated Drill may be used to directly measure for screw length.



Optional: Taps are provided to be used in situations where hard bone is encountered, or resistance to screw insertion occurs. Attach the Tap to the appropriate sized handle and hand tap.

Screw Insertion

Attach the appropriate Driver to the corresponding handle. Insert a Ø7.0 mm Monster Screw by turning the Driver in a clockwise manner. Confirm screw length and position using fluoroscopy. Remove the Ø2.3 mm K-wire at this time.



3-IN-1 TISSUE PROTECTOR TO INSERT A HEADLESS SCREW

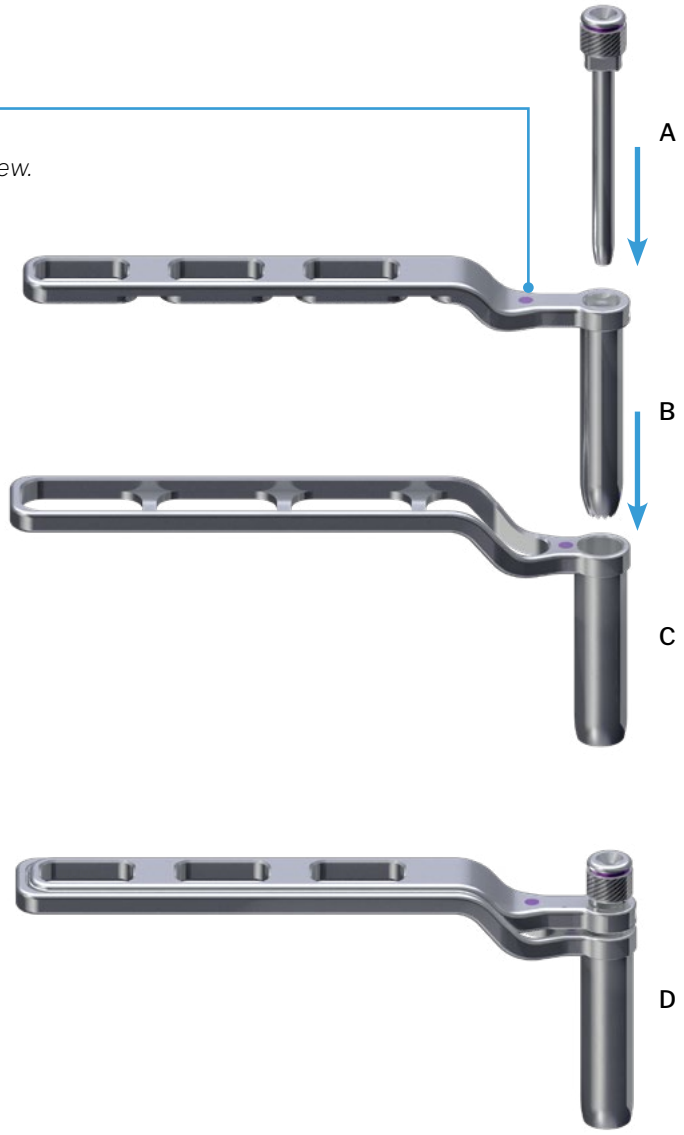
This surgical technique describes using the Paragon 28 3-in-1 Tissue Protector for a subtalar joint arthrodesis. The 3-in-1 Tissue Protector is available for minimally invasive insertion of a Ø7.0 mm screw, offering soft tissue protection during guide wire insertion, drilling, and screw insertion. Slight 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.

The surgical technique begins following the incision, joint preparation, reduction of joint into a corrected position, and placement of any graft material.

3-In-1 Tissue Protector

Available for minimally invasive insertion of a Ø7.0 mm screw.

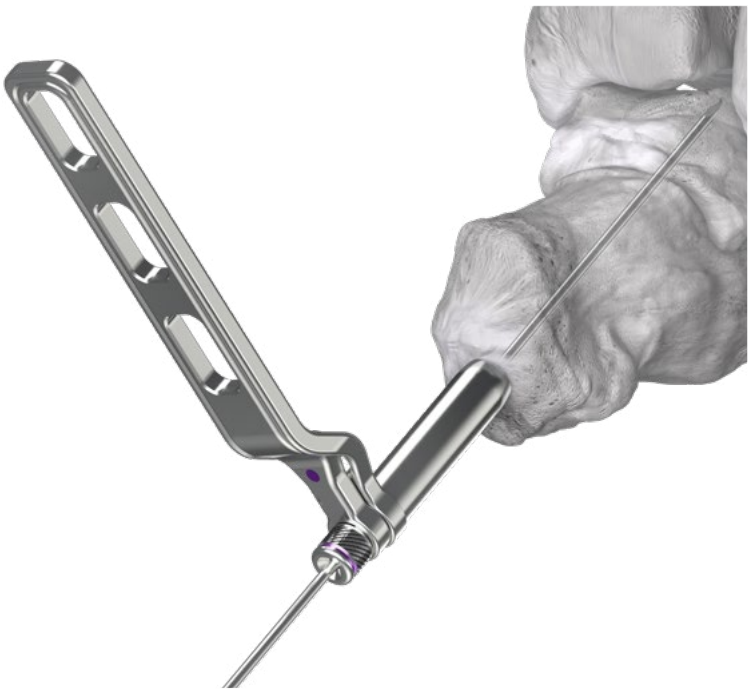
The assembly contains:
*K-wire Guide (**A**), Drill Guide (**B**),*
*and Tissue Protector (**C**),*
*which can be pre-assembled (**D**)*



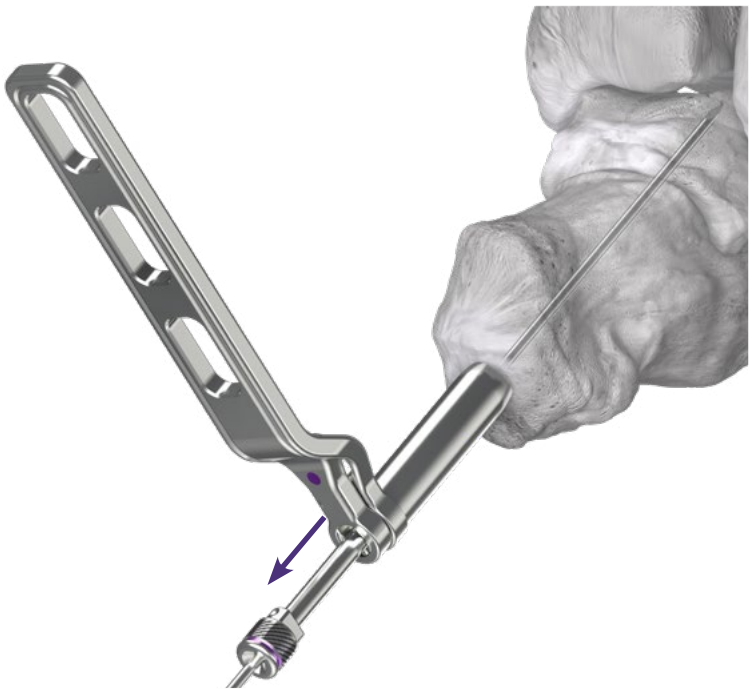
The 3-in-1 Tissue Protector is assembled on the back table, and is passed through a small incision at the projected screw entry point.

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

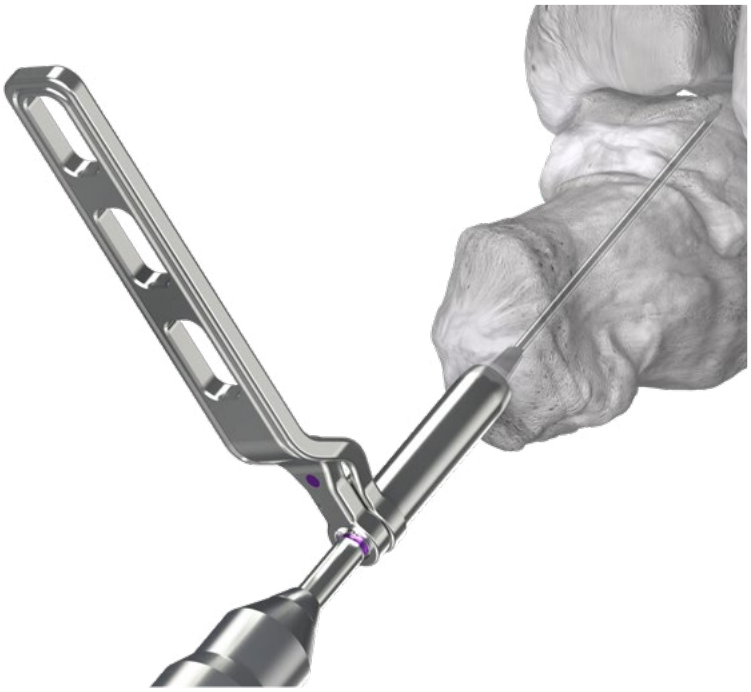
3-IN-1 TISSUE PROTECTOR TO INSERT A HEADLESS SCREW



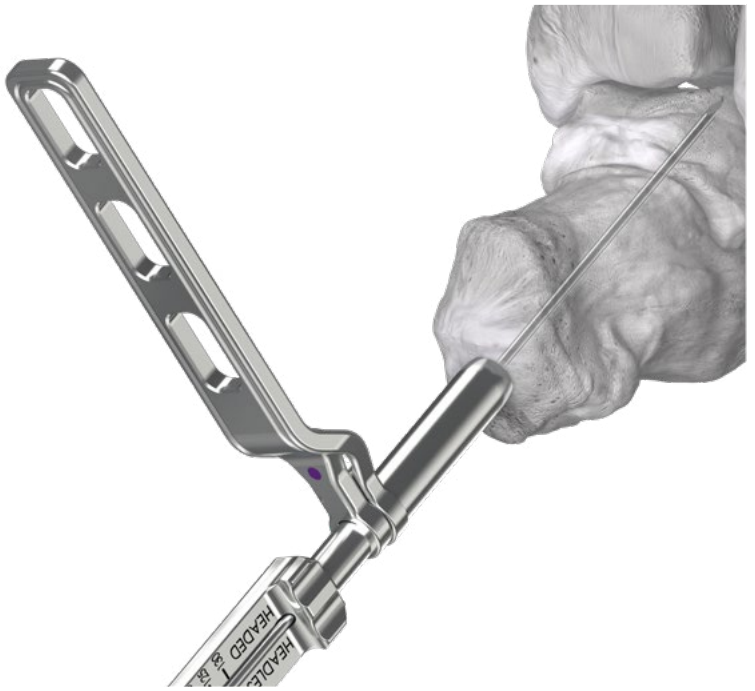
Insert the 2.3 mm K-wire through the 3-in-1 Tissue Protector using a powered driver across the subtalar joint and into the talar neck.



Remove the K-wire Guide from the 3-in-1 Tissue Protector.



Insert the countersink for the 7.0 mm Headless Screw is through the 3-in-1 Tissue Protector and rotate until flush against the countersink stop.



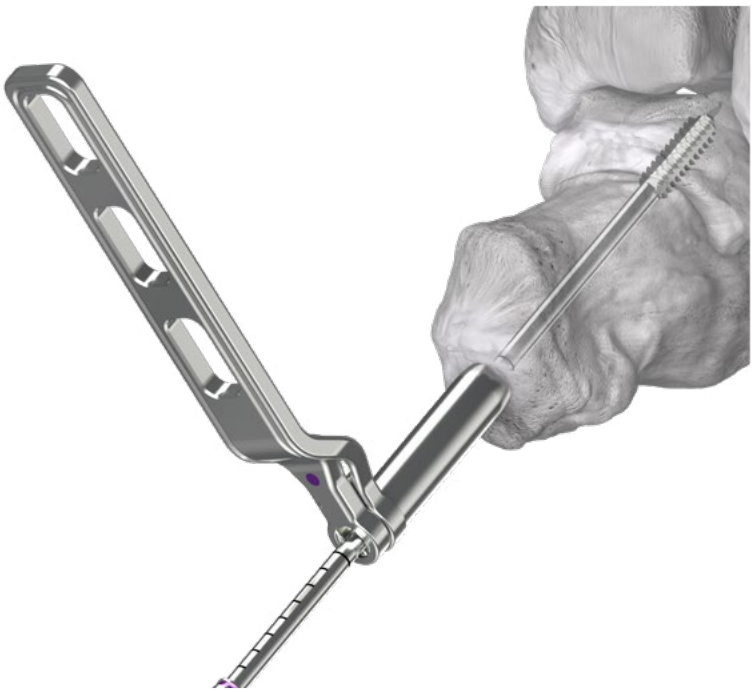
Measure for screw length using the Depth Gauge.

Note: *When using a Headed screw, the Countersink should be done before the depth gauge to ensure an accurate measurement.*

3-IN-1 TISSUE PROTECTOR TO INSERT A HEADLESS SCREW

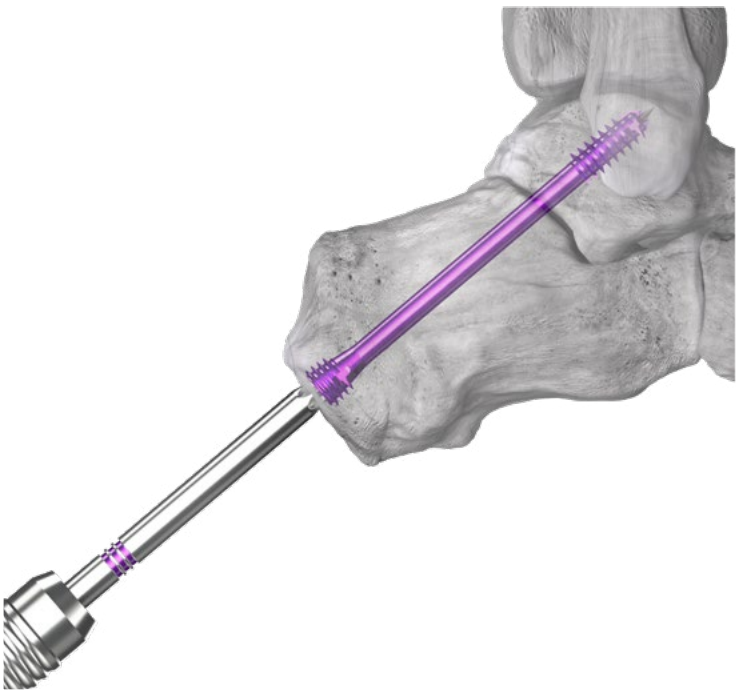
Use the Ø4.6 mm Cannulated Drill through the Drill Guide to drill over the K-wire to the desire depth. For Headed screws, the estimated head height must be subtracted from the length drilled.

Remove the Drill Guide from the 3-in-1 Tissue Protector.



Optional: Taps are provided to be used in situations where hard bone is encountered, or resistance to screw insertion occurs. Attach the tap to the appropriate sized handle and hand tap.

Insert the 7.0 mm screw into the calcaneus and across the arthrodesis site through the tissue protector.



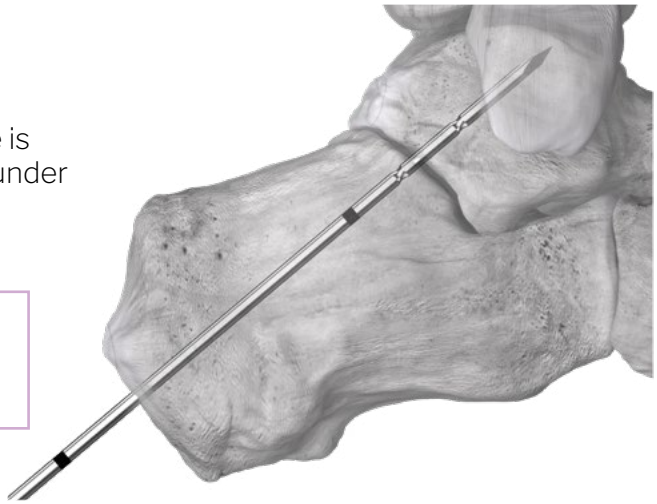
Remove the Tissue Protector. Additional advancement of the screw can be performed if necessary once checked using fluoroscopy. Remove the K-wire at this time.

FLUOROBAND™ GUIDE WIRE

This surgical technique describes using the Paragon 28 FluoroBand™ guide wire. 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.

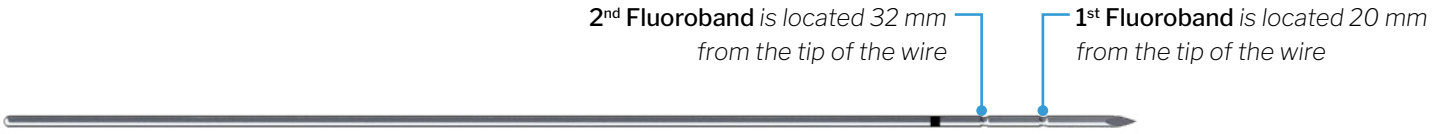
This surgical technique begins following incision, joint preparation, reduction of the joint into a corrected position and placement of any graft material.

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.

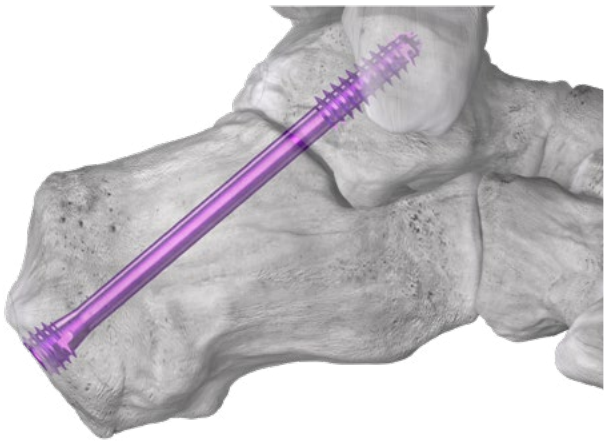


TIP: *If redirection of the FluoroBand guide wire is necessary at this time, the FluoroBand guide wire must be removed completely prior to re-direction. Do not create bend in the FluoroBand guide wire.*

The first FluoroBand is positioned in the talus and the second 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 Ø7.0 mm screw. The long partially threaded Ø7.0 mm screw would have threads that cross the subtalar joint, thereby preventing compression.



- *The Monster Screw thread length is determined by which Fluoroband is at or crossing the arthrodesis, osteotomy or fracture site.*
  - *If the 1st FluoroBand is not across the site, then use a short thread length screw.*
  - *If the 1st FluoroBand is across the site but not 2nd FluoroBand, use either a short or medium thread length screw.*
  - *If the 2nd FluoroBand is across the site then use the long thread length screw.*



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

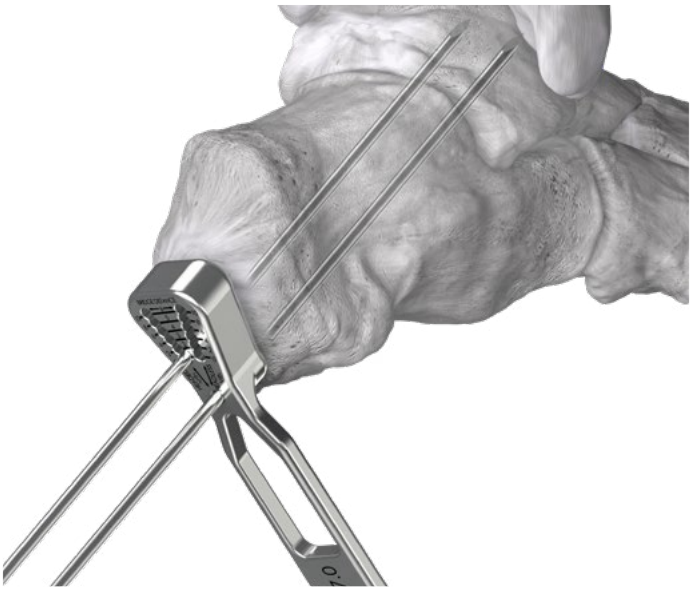
PARALLEL K-WIRE GUIDE TO INSERT A SECOND SCREW

This surgical technique describes the first of three purposes for using the Paragon 28 Parallel K-Wire Guide: guiding minimum spacing between two Ø7.0 mm screws such that screw head contact does not occur.

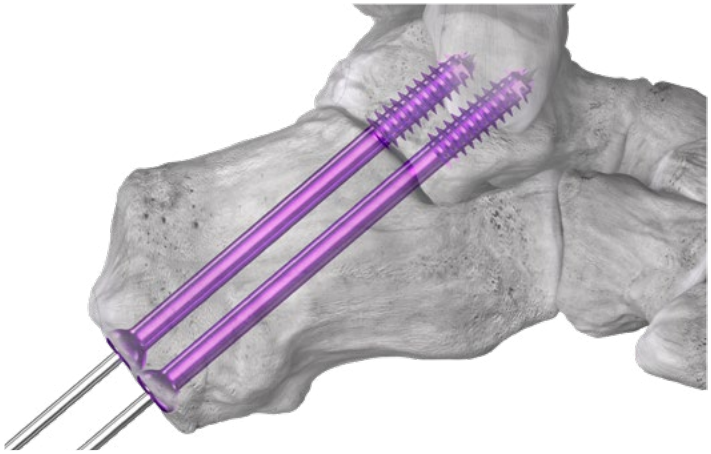
The surgical technique begins following the incision, joint preparation, reduction of joint into a corrected position, and placement of any graft material.

Following the incision, preparation, and reduction of the joint into a corrected position, place any required graft material and insert the initial K-wire across the joint.

Slide the Parallel K-wire Guide over the K-wire through the central hole.



Place a parallel K-wire through the appropriate hole in the guide and across the joint; Depending on if a Headed or Headless screw is used, the Parallel K-wire Guide is labeled with “Headed Min” and “Headless Min” to denote the shortest distance a second K-wire can be located without interference of the screw heads. In this situation a Headed screw is used.

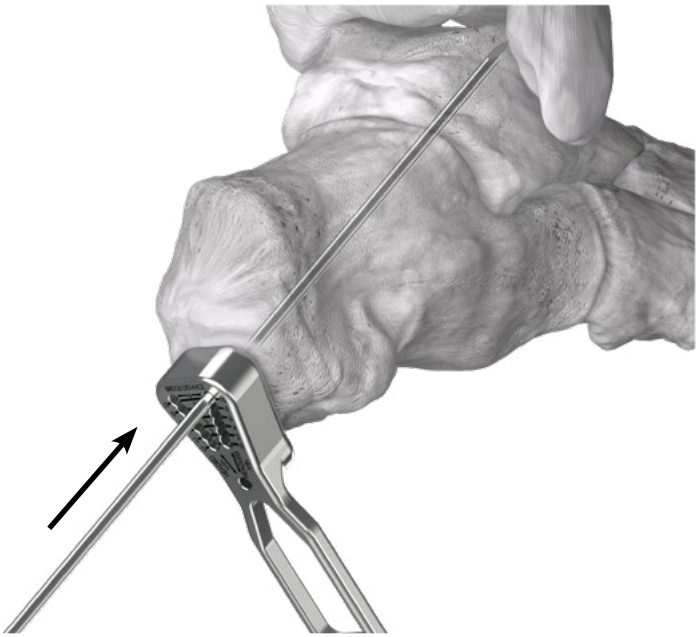


Remove the Parallel K-wire Guide and insert the Headed screws using the same technique as previously depicted on page 7 for Headed screws or page 9 for Headless screws..

PARALLEL K-WIRE GUIDE TO REPOSITION A GUIDE WIRE

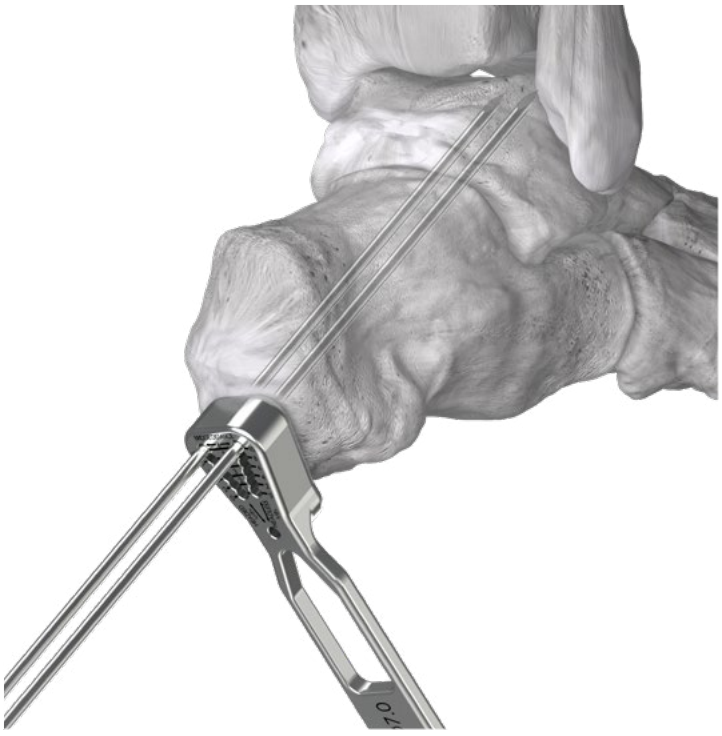
This surgical technique describes the second of three reasons for using the Paragon 28 Parallel K-Wire Guide: placing a second guide wire across an arthrodesis, osteotomy, or fracture site when the trajectory of the first wire is correct, but the position is either too medial, lateral, plantar, or dorsal.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

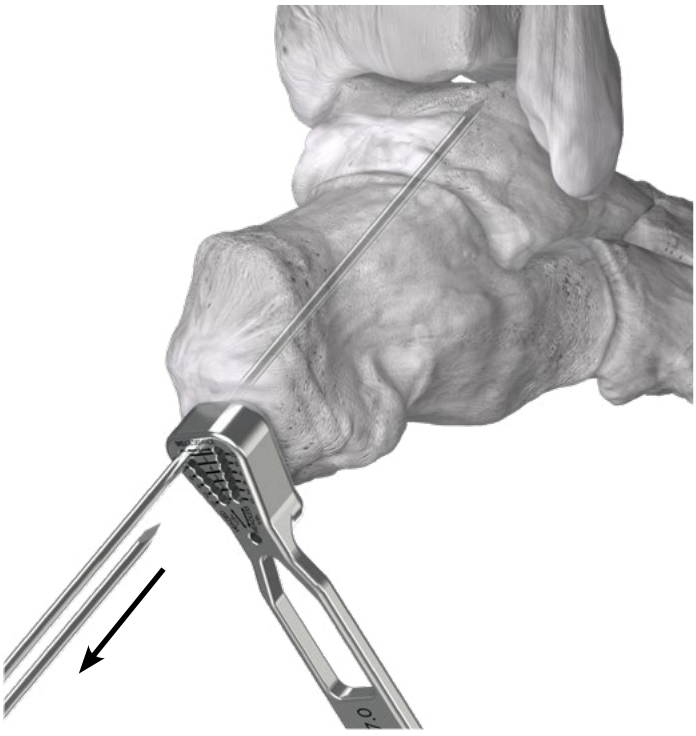
The surgical technique begins following the incision, joint preparation, reduction of joint into a corrected position, and placement of any graft material.



In this situation a K-wire is being depicted as inserted too lateral and plantar but with a correct trajectory.

To correct the K-wire while maintaining the trajectory, slide the Parallel K-wire Guide over the existing K-wire. Ensure the open holes of the Parallel K-wire Guide are aligned in the desired location of the new K-wire. The markings on the Parallel K-wire Guide shows tangential lengths between K-wires, indicating bridge distance, and the markings between adjacent holes in 2 mm increments.

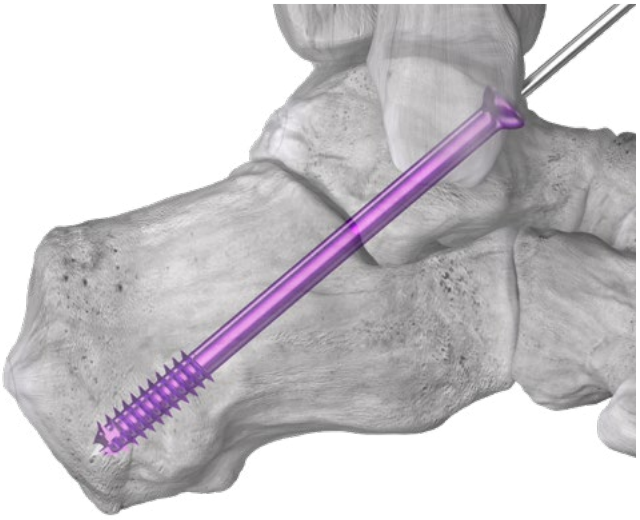




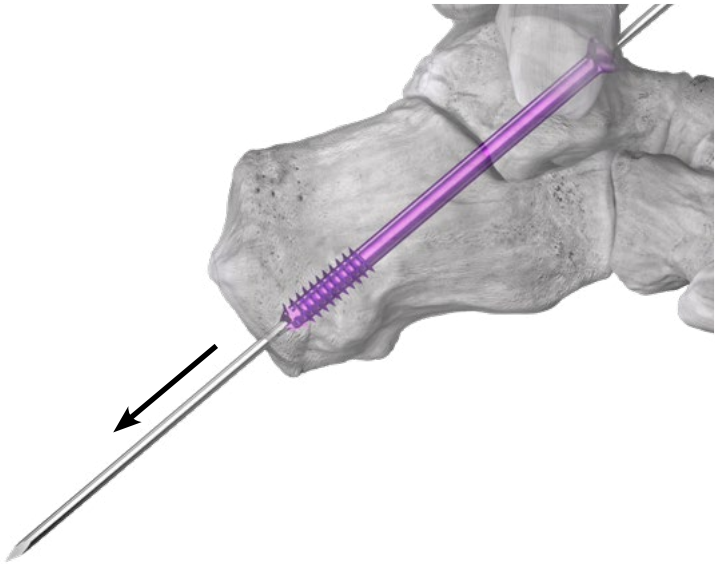
The Parallel K-wire Guide allows for the new K-wire to be placed with the same trajectory. In this case, the position is being corrected to be more medial and dorsal in relation to the original K-wire position.

PARALLEL K-WIRE GUIDE TO PLACE A POSTERIOR TO ANTERIOR SCREW WHEN A SCREW IS PRESENT

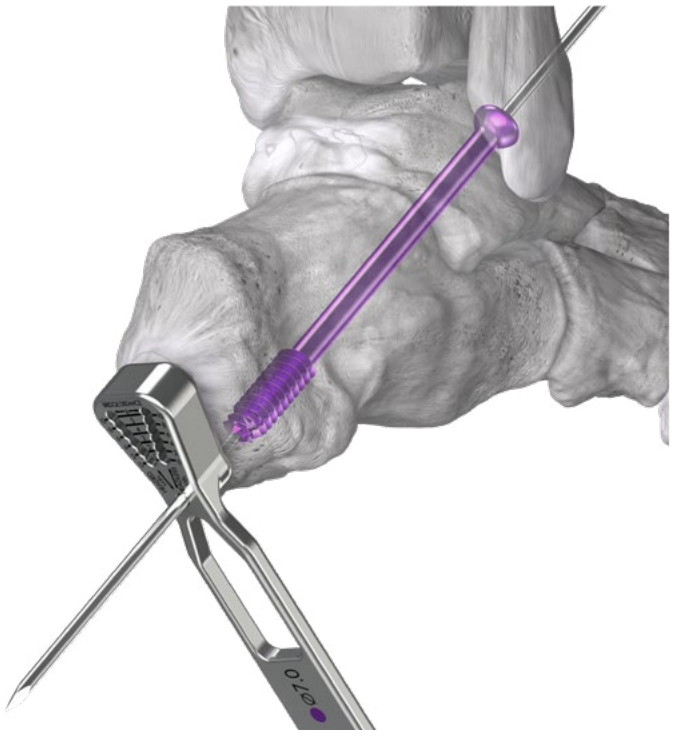
This surgical technique describes the final purpose for using the Paragon 28 Parallel K-wire Guide: placing a posterior to anterior screw across the subtalar joint after the first screw has already been placed from anterior to posterior. The use of a Parallel K-wire Guide avoids the risk of intersecting screw trajectories.



Insert a K-wire through the neck of the talus into the calcaneus to allow for the insertion of the first screw.

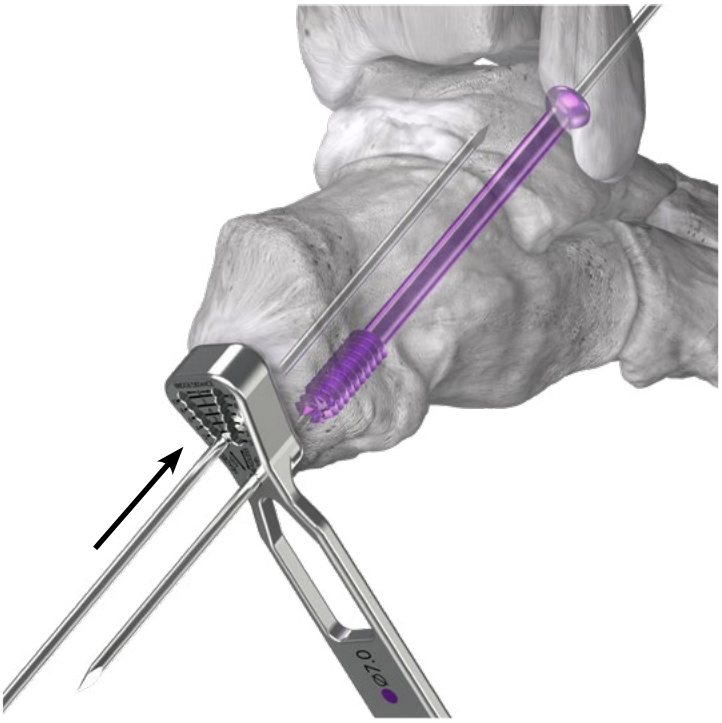


Ensure the K-wire is driven plantarly through the posterior aspect of the calcaneus.

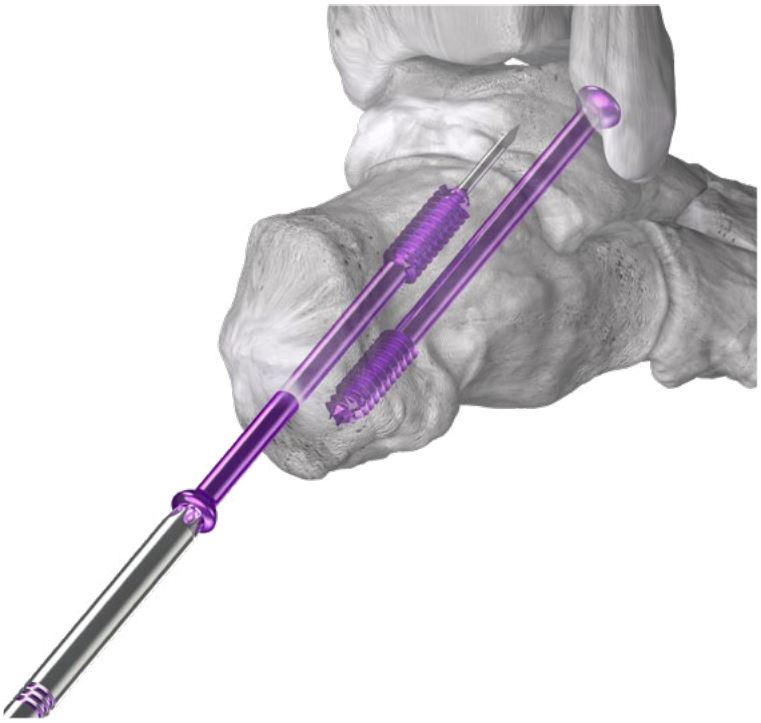


Do not remove the K-wire at this time. Place the Parallel K-wire Guide over the K-wire using the central hole of the guide.

PARALLEL K-WIRE GUIDE TO PLACE A POSTERIOR TO ANTERIOR SCREW WHEN A SCREW IS PRESENT



Determine the desired location of the second K-wire using the Parallel K-wire Guide holes. This will prevent any intersection with the existing screw.



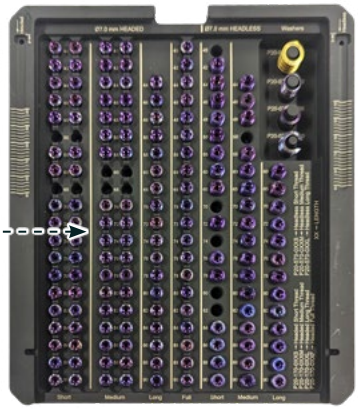
Remove the Parallel K-wire Guide and insert the second screw.

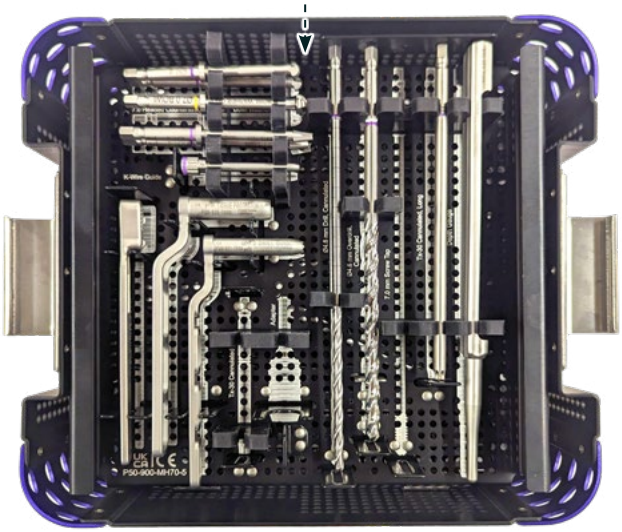
Insert the second screw using the technique previously described on page 7 for Headed screws or page 9 for Headless screws.

THE MONSTER® Ø7.0MM SLIMLINE (SL) CADDY

IMPLANT CADDY

All Monster Screws and Washers are located in the Implant Caddy





INSTRUMENT CADDY

The Countersinks, Tap, Tissue Protector, Drill Guides, K-wire Guide, Depth Gauge, 3/16" to Jacobs Adapter, Drills, and Overdrills are located in the Instrument Caddy in the top of the case

INSTRUMENT CASE

The K-wires, Screw Forceps, Cleaning Stylet, Hindfoot Distractor, and 3/16" Ratcheting Handle are located in the bottom of the instrument case

INSTRUMENTS

Part #	Description	Use
P20-910-7000	Countersink, 7.0mm, Headed	Reusable
P20-910-WB70	Monster®, Countersink, 7.0mm, Bowl Washer	Reusable
P20-915-7000	Monster® Screw Headless Countersink, 7.0 mm	Reusable
P20-920-7000	Monster® Screw Tap, 7.0 mm	Reusable
P20-930-7000	Tissue Protector, 7.0mm	Reusable
P20-931-7000	Drill Guide, 7.0 mm	Reusable
P20-932-7000	K-Wire Guide, 2.3 mm	Reusable
P20-935-7000	Parallel K-Wire Drill Guide, 7.0 mm	Reusable
P20-952-7000	Depth Gauge, 7.0 mm	Reusable
P99-000-316A	Adapter, 3/16" Sq. To Jacobs	Reusable
P99-000-316L	Axial Ratcheting Handle, Large, 3/16" Sq. Adaptor	Reusable
P99-110-4622	Drill, Cannulated, 3/16 Sq Connection, 4.6 X 220 mm	Reusable
P99-110-7020	Overdrill, Cannulated, 7.0 X 200 mm	Reusable
P99-150-0001	Screw Forceps	Reusable
P99-150-0010	Hindfoot Distractor, 2.5 & 3.0 K-Wire	Reusable
P99-190-TX30	Screw Driver Attachment, Cannulated, 3/16" Sq. Connection, Tx-30 X 85 mm	Reusable
P99-190-TX30-17	Tx-30, 170 mm Long Monster Screw Cannulated Driver	Reusable
P99-192-2323	K-Wire, Single Ended Trocar Tip, Smooth, 2.3 X 230mm	Single-use
P99-193-2323	K-Wire, Single Ended Trocar Tip, Threaded, 2.3 X 230 mm	Single-use
P99-194-2323	K-Wire, Single Trocar Tip, Smooth, W/ Flouroband, 2.3 X 230 mm	Single-use
P99-195-2323	K-Wire, Single Trocar Tip, Threaded, W/ Flouroband, 2.3 X 230 mm	Single-use
P99-900-1007	Square Foot Plate	Reusable
P99-998-0023	Cleaning Stylet for Cannulated instruments, 2.3 X 240 mm	Reusable

IMPLANTS

Part #	Description	Use
P20-070-WB00	Bowl Washer, 7.0mm	Single-use
P20-070-WD00	Dome Washer, 7.0mm	Single-use
P20-070-WF00	Monster® Screw Flat Washer, 7.0 mm	Single-use
P20-070-WFS0	Slotted Bowl Washer, 7.0mm	Single-use
P20-170-040F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 40 mm	Single-use
P20-170-042F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 42 mm	Single-use
P20-170-044F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 44 mm	Single-use
P20-170-046F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 46 mm	Single-use
P20-170-048F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 48 mm	Single-use
P20-170-050F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 50 mm	Single-use
P20-170-055F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 55 mm	Single-use

IMPLANTS

Part #	Description	Use
P20-170-060F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 60 mm	Single-use
P20-170-065F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 65 mm	Single-use
P20-170-070F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 70 mm	Single-use
P20-170-072F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 72 mm	Single-use
P20-170-074F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 74 mm	Single-use
P20-170-076F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 76 mm	Single-use
P20-170-078F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 78 mm	Single-use
P20-170-080F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X80 mm	Single-use
P20-170-082F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 82 mm	Single-use
P20-170-084F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 84 mm	Single-use
P20-170-086F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 86 mm	Single-use
P20-170-088F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 88 mm	Single-use
P20-170-090F	Monster® Cannulated, Full Thread Screw, Headed, 7.0 X 90 mm	Single-use
P20-170-040M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 40 mm	Single-use
P20-170-042M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 42 mm	Single-use
P20-170-044M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 44 mm	Single-use
P20-170-046M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 46 mm	Single-use
P20-170-048M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 48 mm	Single-use
P20-170-050M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 50 mm	Single-use
P20-170-055M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 55 mm	Single-use
P20-170-060M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 60 mm	Single-use
P20-170-065M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 65 mm	Single-use
P20-170-070M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 70 mm	Single-use
P20-170-072M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 72 mm	Single-use
P20-170-074M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 74 mm	Single-use
P20-170-076M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 76 mm	Single-use
P20-170-078M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 78 mm	Single-use
P20-170-080M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 80 mm	Single-use
P20-170-082M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 82 mm	Single-use
P20-170-084M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 84 mm	Single-use
P20-170-086M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 86 mm	Single-use
P20-170-088M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 88 mm	Single-use
P20-170-090M	Monster® Cannulated, Medium Thread Screw, Headed, 7.0 X 90 mm	Single-use
P20-170-042S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 42 mm	Single-use
P20-170-044S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 44 mm	Single-use
P20-170-046S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 46 mm	Single-use

IMPLANTS

Part #	Description	Use
P20-170-048S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 48 mm	Single-use
P20-170-050S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 50 mm	Single-use
P20-170-055S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 55 mm	Single-use
P20-170-060S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 60 mm	Single-use
P20-170-065S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 65 mm	Single-use
P20-170-070S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 70 mm	Single-use
P20-170-072S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 72 mm	Single-use
P20-170-074S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 74 mm	Single-use
P20-170-076S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 76 mm	Single-use
P20-170-078S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 78 mm	Single-use
P20-170-080S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 80 mm	Single-use
P20-170-082S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 82 mm	Single-use
P20-170-084S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 84 mm	Single-use
P20-170-086S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 86 mm	Single-use
P20-170-088S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 88 mm	Single-use
P20-170-090S	Monster® Cannulated, Short Thread Screw, Headed, 7.0 X 90 mm	Single-use
P20-170-044L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 44 mm	Single-use
P20-170-046L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 46 mm	Single-use
P20-170-048L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 48 mm	Single-use
P20-170-050L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 50 mm	Single-use
P20-170-055L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 55 mm	Single-use
P20-170-060L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 60 mm	Single-use
P20-170-065L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 65 mm	Single-use
P20-170-070L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 70 mm	Single-use
P20-170-072L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 72 mm	Single-use
P20-170-074L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 74 mm	Single-use
P20-170-076L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 76 mm	Single-use
P20-170-078L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 78 mm	Single-use
P20-170-080L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 80 mm	Single-use
P20-170-082L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 82 mm	Single-use
P20-170-084L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 84 mm	Single-use
P20-170-086L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 86 mm	Single-use
P20-170-088L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 88 mm	Single-use
P20-170-090L	Monster® Cannulated, Long Thread Screw, Headed, 7.0 X 90 mm	Single-use
P20-570-044M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 44 mm	Single-use
P20-570-046M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 46 mm	Single-use

IMPLANTS

Part #	Description	Use
P20-570-048M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 48 mm	Single-use
P20-570-050M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 50 mm	Single-use
P20-570-055M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 55 mm	Single-use
P20-570-060M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 60 mm	Single-use
P20-570-065M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X65 mm	Single-use
P20-570-070M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 70 mm	Single-use
P20-570-072M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 72 mm	Single-use
P20-570-074M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 74 mm	Single-use
P20-570-076M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 76 mm	Single-use
P20-570-078M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 78 mm	Single-use
P20-570-080M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 80 mm	Single-use
P20-570-082M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 82 mm	Single-use
P20-570-084M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 84 mm	Single-use
P20-570-086M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 86 mm	Single-use
P20-570-088M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 88 mm	Single-use
P20-570-090M	Monster® Cannulated, Medium Thread Screw, Headless, 7.0 X 90 mm	Single-use
P20-570-040S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 40 mm	Single-use
P20-570-042S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 42 mm	Single-use
P20-570-044S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 44 mm	Single-use
P20-570-046S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 46 mm	Single-use
P20-570-048S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 48 mm	Single-use
P20-570-050S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 50 mm	Single-use
P20-570-055S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 55 mm	Single-use
P20-570-060S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 60 mm	Single-use
P20-570-065S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 65 mm	Single-use
P20-570-070S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 70 mm	Single-use
P20-570-072S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 72 mm	Single-use
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P20-570-080S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 80 mm	Single-use
P20-570-082S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 82 mm	Single-use
P20-570-084S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 84 mm	Single-use
P20-570-086S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 86 mm	Single-use
P20-570-088S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 88 mm	Single-use
P20-570-090S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 90 mm	Single-use

IMPLANTS

Part #	Description	Use
P20-570-060L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 60 mm	Single-use
P20-570-065L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 65 mm	Single-use
P20-570-070L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 70 mm	Single-use
P20-570-072L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 72 mm	Single-use
P20-570-074L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 74 mm	Single-use
P20-570-078L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 78 mm	Single-use
P20-570-080L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 80 mm	Single-use
P20-570-082L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 82 mm	Single-use
P20-570-084L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 84 mm	Single-use
P20-570-086L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 86 mm	Single-use
P20-570-088L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 88 mm	Single-use
P20-570-090L	Monster® Cannulated, Long Thread Screw, Headless, 7.0 X 90 mm	Single-use

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

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

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.

MONSTER™ SCREW SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

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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.