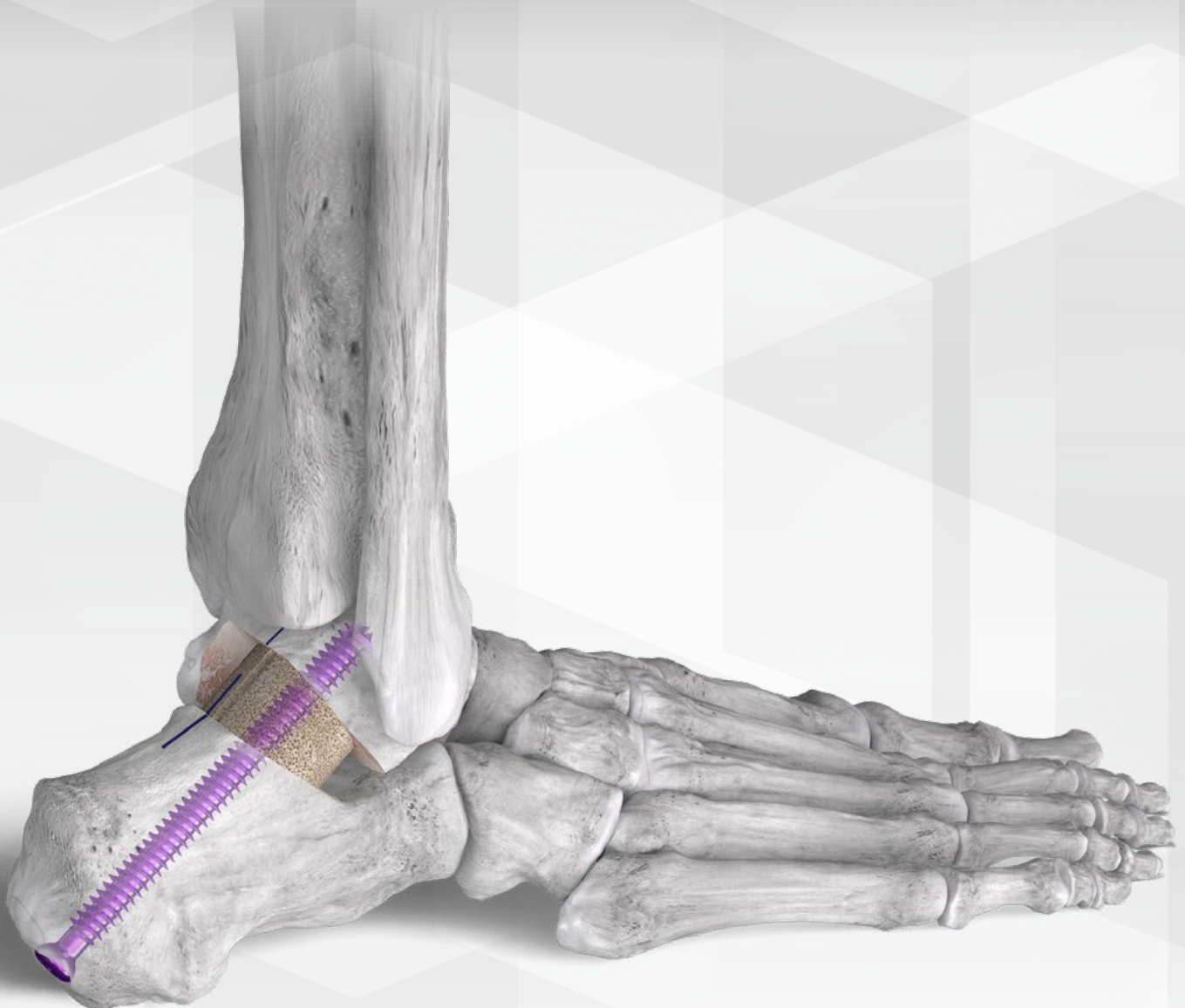


SURGICAL TECHNIQUE GUIDE

PRESERVE™ Subtalar Distraction Arthrodesis Graft

MONSTER™
SCREW SYSTEM

PRESERVE™
BONE GRAFT
SYSTEM



Exclusively foot & ankle **20**
Paragon®

Acknowledgment:

Paragon 28[®] would like to thank Thomas Chang, DPM for his contribution to the surgical technique guide.

PRODUCT DESCRIPTION

The Paragon 28[®] PRESERVE[™] Bone Wedge System was created to deliver pre-contoured, geometrically tapered Grafts. The system was designed to provide an anatomic match to the surgical site as well as density matching to offer strength while allowing incorporation of the Graft. The Paragon 28[®] solution for the Subtalar Joint Distraction Arthrodesis (STDA) procedure includes using a geometrically specific PRESERVE[™] Subtalar Distraction Arthrodesis Graft. Innovative trials are available to assist in selection of the correct Graft size as well as Graft placement in the optimal position.

This surgical technique guide will discuss the patent pending method of using the Paragon 28[®] PRESERVE[™] Subtalar Distraction Arthrodesis Graft, beginning on page 8. Other methods and applications for this Graft can be employed, per surgeon preference. Fixation of the arthrodesis in this surgical technique guide is demonstrated using a Monster[®] 7.0 mm Screw. Alternative methods of fixation can be used for this procedure, at the discretion of the surgeon. The shape of the PRESERVE[™] Subtalar Distraction Arthrodesis Graft allows for “dial-in” correction to restore height of the subtalar joint as well as correction of varus or valgus angulation. Demonstration of this feature begins on page 10.

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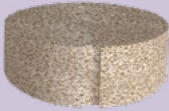


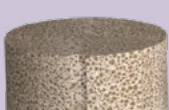
UNIQUE DESIGN FEATURES

Specifically designed for pain in the presence of:

- Post-traumatic subtalar joint arthritis following calcaneal fracture where the posterior facet of the subtalar joint may be depressed and/or inadequate reconstruction of the calcaneus was obtained with or without hindfoot varus
- Calcaneal fracture where the damage to the posterior facet is significant such that primary fusion is indicated
- Loss of calcaneal height unable to be corrected with an isolated subtalar joint fusion
- Stage III or IV posterior tibial tendon dysfunction where adequate height of the subtalar joint cannot be obtained with a standard subtalar joint fusion to correct hindfoot valgus



PRESERVE™ GRAFT OPTIONALITY

Graft Size:	
10 mm	
12 mm	
14 mm	
16 mm	
18 mm Universal (Parallel) • Intended to be shaped by the surgeon	

Wedge Design:

- Restores height to the subtalar joint
- Can correct for calcaneal varus or valgus
- Trial sizer allows ability to “dial-in” correction
- Primary donor sites: distal femur, talus, patella & femoral calcar

Density Matching:

- The primary donor site of PRESERVE™ Subtalar Distraction Arthrodesis Grafts is the distal femur, talus, patella, and femoral calcar-areas of dense bone to allow the wedge to maintain its structure once inserted

Aseptic Processing:

- Hydrogen peroxide bleaching is avoided during processing, with the intent to help preserve the osteoinductivity of the environment in which the Graft is being implanted
- Gamma irradiation is not used during Graft preparation in order to help prevent destruction of the native mechanical advantages of human bone

PRESERVE™ GRAFT INSTRUMENTATION



Trial Size Handle

- The trial sizers mimic the exact size and shape of the 4 pre-cut Graft widths, helping to eliminate the guesswork of which size Graft to use
- The joystick trial sizer handle allows for easy manipulation of the trials, helping to limit surgeon radiation exposure while determining correct size and orientation
- Located in the Allograft Subtalar and Calc-Cuboid Caddy



10 mm Trial



12 mm Trial



14 mm Trial



16 mm Trial

Trial Size Offering

- Available from sizes 10 mm to 16 mm
- 18 mm not available as this Graft is intended to be shaped by the surgeon

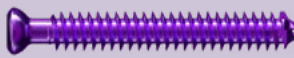

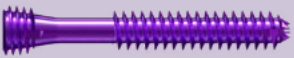






Coin Correction Guide

Helps in alignment of Subtalar Distraction Arthrodesis Graft when placing in joint.




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.
- Split-Flat and 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

Fluoroband™ Guide Wires:

- 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.
 - Available in smooth and threaded options.

2nd Fluoroband™ is located 32 mm from the tip of the wire

1st Fluoroband™ is located 20 mm from the tip of the wire



MONSTER[®] SCREW INSTRUMENTATION



K-wires



Depth
Gauge



Headed Screw Countersink



Headless Screw Countersink



Drill



Drill Guide



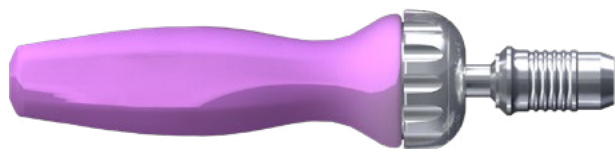
Overdrill



Tap



Driver



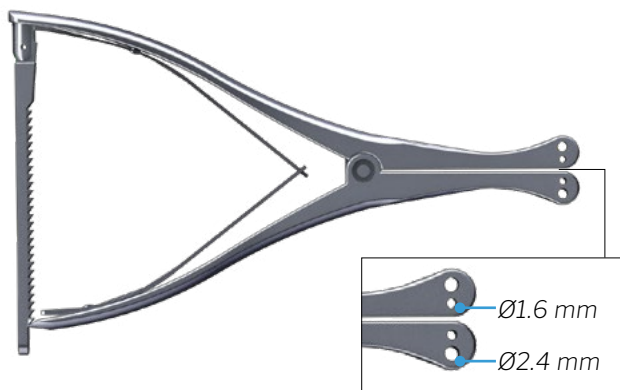
3/16" AO Handle

The 3/16" AO Handle is for use with the Monster[®] Screws from Ø4.5 mm - Ø7.0 mm.



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.

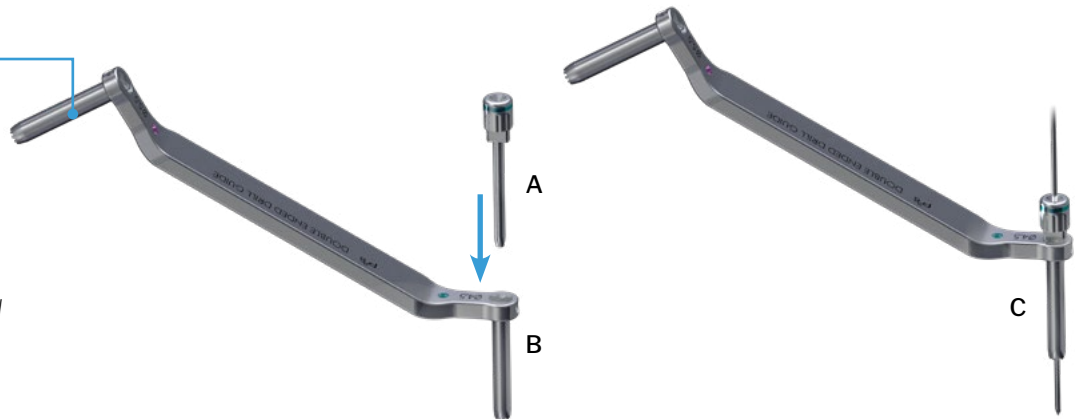


Cleaning Stylet:

MONSTER® SCREW INSTRUMENTATION

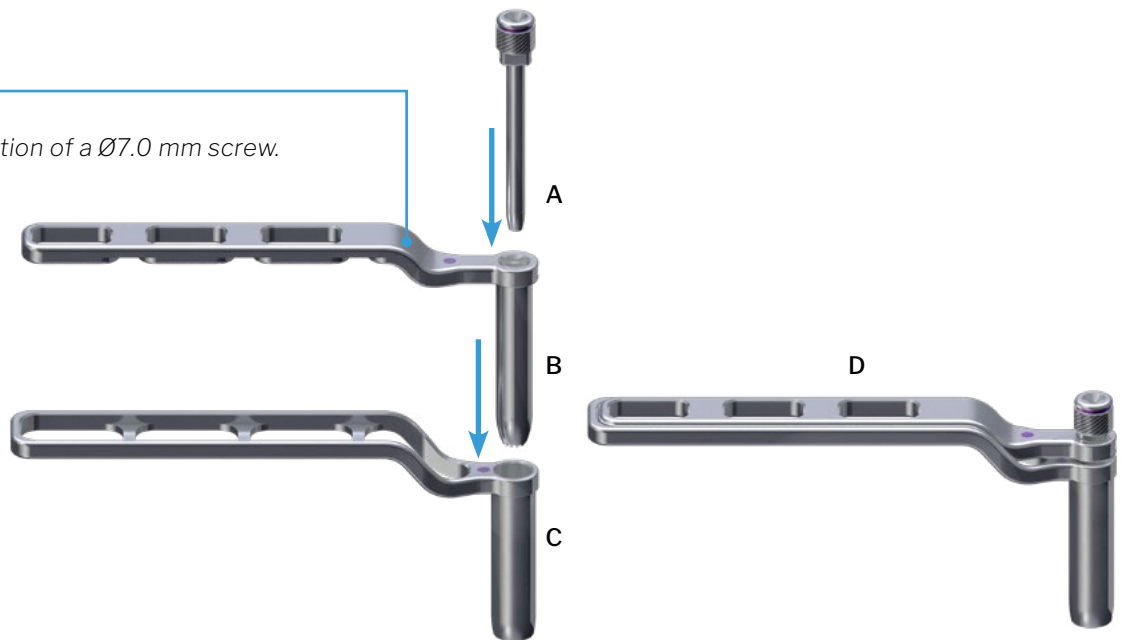
2-in-1 Tissue Protector

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.



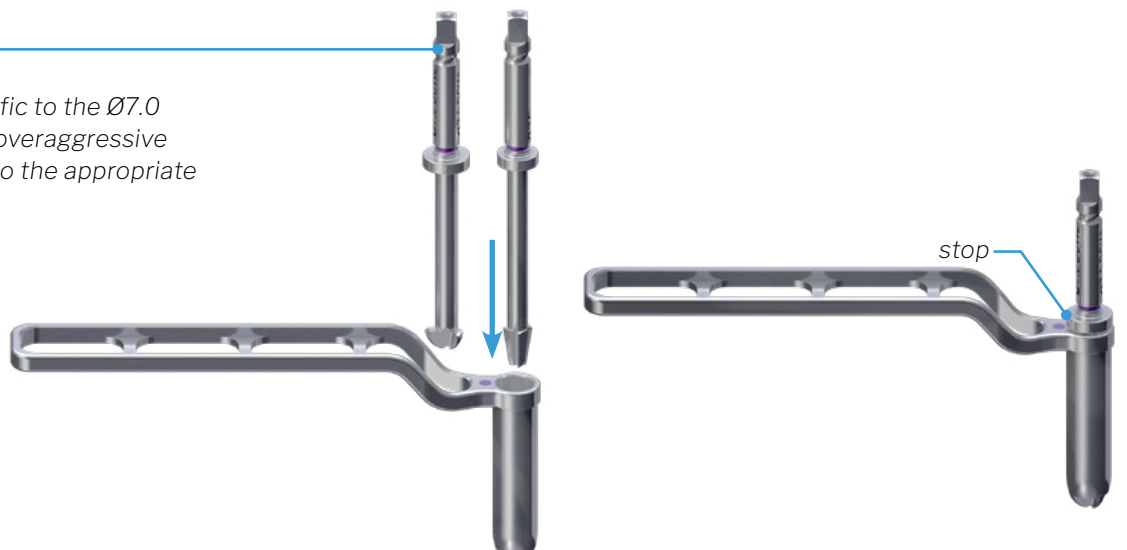
3-In-1 Tissue Protector

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).



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.



INCISION/EXPOSURE

This procedure may be performed alone or in combination with other procedures such as a Dwyer closing wedge osteotomy or lateral displacement osteotomy for varus mal-alignment, a medial displacement calcaneal osteotomy for valgus mal-alignment, or a lateral wall exostectomy.

Hardware removal is recommended to be performed prior to the subtalar joint distraction arthrodesis in cases where the position of existing hardware may interfere with the procedure. A lateral decubitus position with fluoroscopy available is recommended for this procedure.

Several options for incision placement are available for this procedure and are dependent on concomitant procedures, previous incisions, and hardware removal considerations. A posterior linear incision placed lateral to the Achilles tendon is recommended for this procedure, but can be varied according to surgeon preference and patient condition. Dissection is carried down to the subtalar joint directly behind the sural nerve and peroneal tendons with a focus on entering the deep posterior compartment.

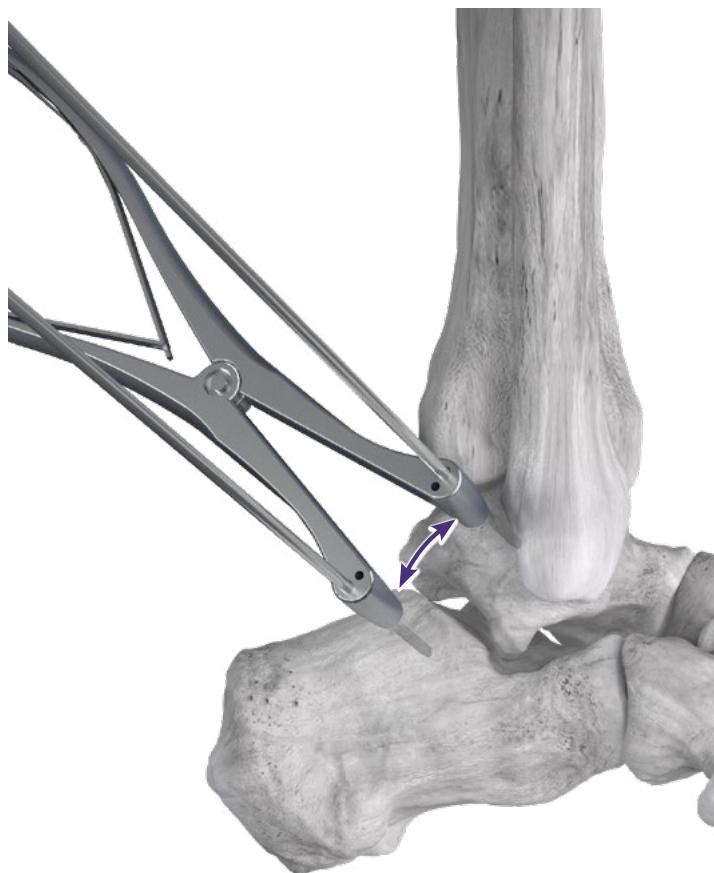


JOINT PREPARATION

The subtalar joint should be exposed such that adequate visualization of the posterior facet is achieved. Release the calcaneofibular ligament and mobilize the peroneal tendons, sural nerve and flexor hallucis longus tendon to retract them away from the surgical site.

Once the subtalar joint is exposed, the Hindfoot Distractor can be obtained from the Monster Screw System caddy.

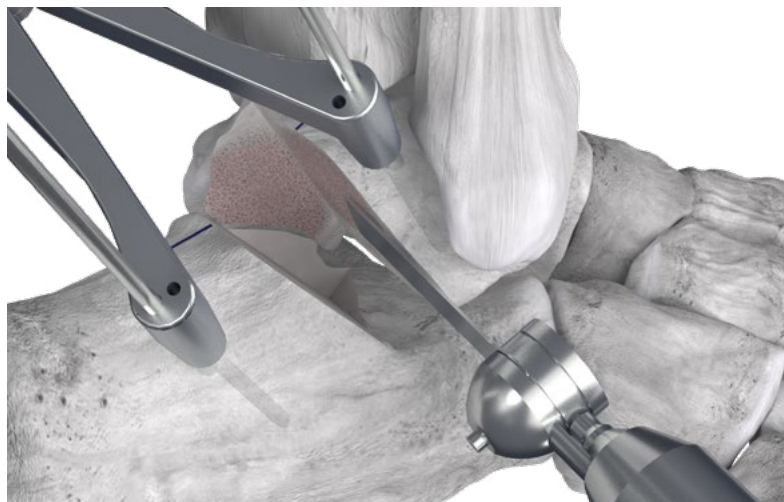
Place the Hindfoot Distractor on either side of the subtalar joint and secure with K-wires. Distract the subtalar joint.



JOINT PREPARATION

Cartilage resection should be performed on either side of the posterior facet of the subtalar joint. Resection of cartilage off of the anterior and middle facets may be performed at this time, if preferred, generally through a second incision.

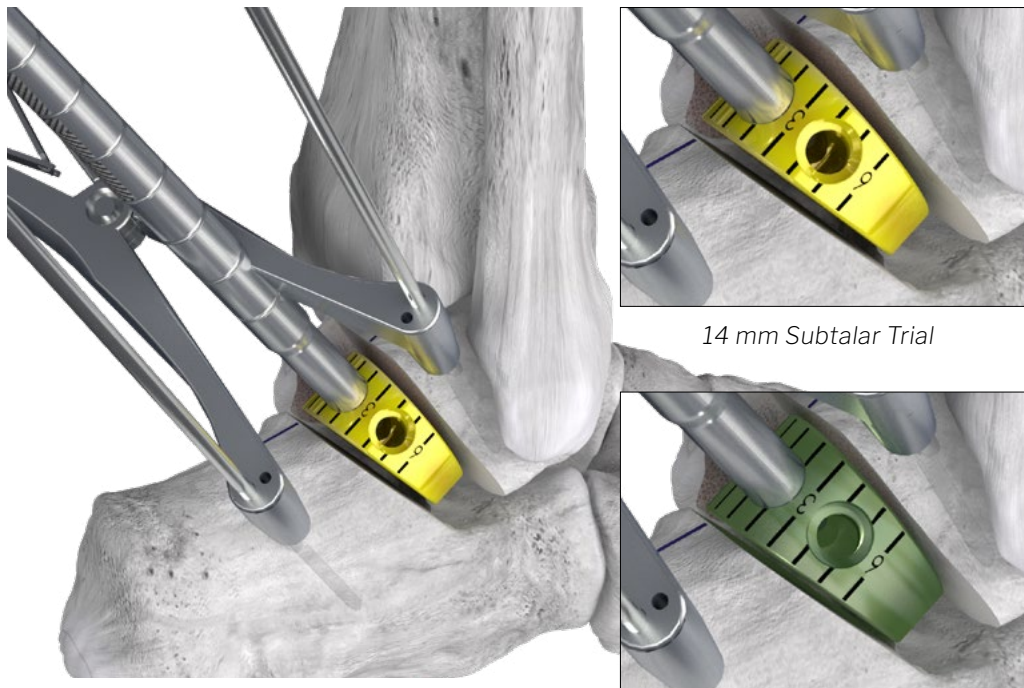
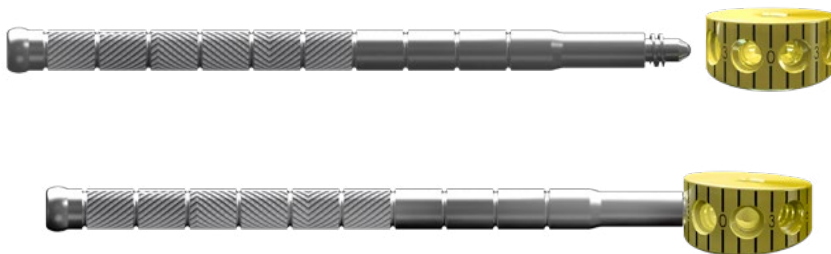
Subchondral drilling of the bone surfaces can be performed at this time.



DETERMINING GRAFT SIZE AND POSITION

The Hindfoot Distractor should be set to hold the subtalar joint open to an appropriate height. Select the trial sizer that most appropriately fits in this opening. The handle can be screwed into any hole in the sizer; however, it is encouraged to place the handle in a hole that allows the handle to be as central as possible within the incision. This allows for maximal joy-sticking of the handle.

The tallest portion of the sizer (marker "O") should be oriented posteriorly. Introduce the trial sizer into the subtalar joint, centering the Graft within the posterior facet.



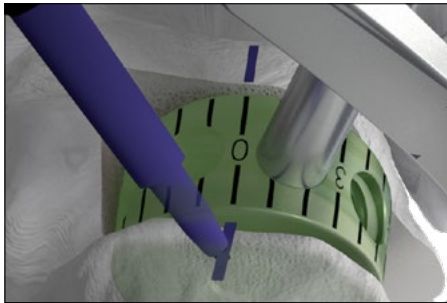
14 mm Subtalar Trial

16 mm Subtalar Trial

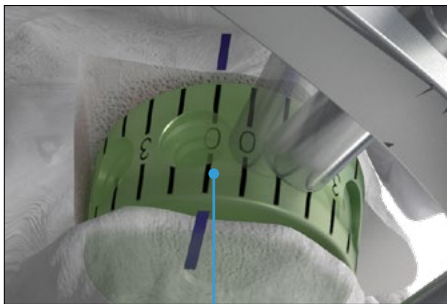
Remove the smallest trial sizer if it does not snugly fit into the subtalar joint. Replace with the next largest trial sizer until appropriate calcaneal height is achieved.

DETERMINING GRAFT SIZE AND POSITION

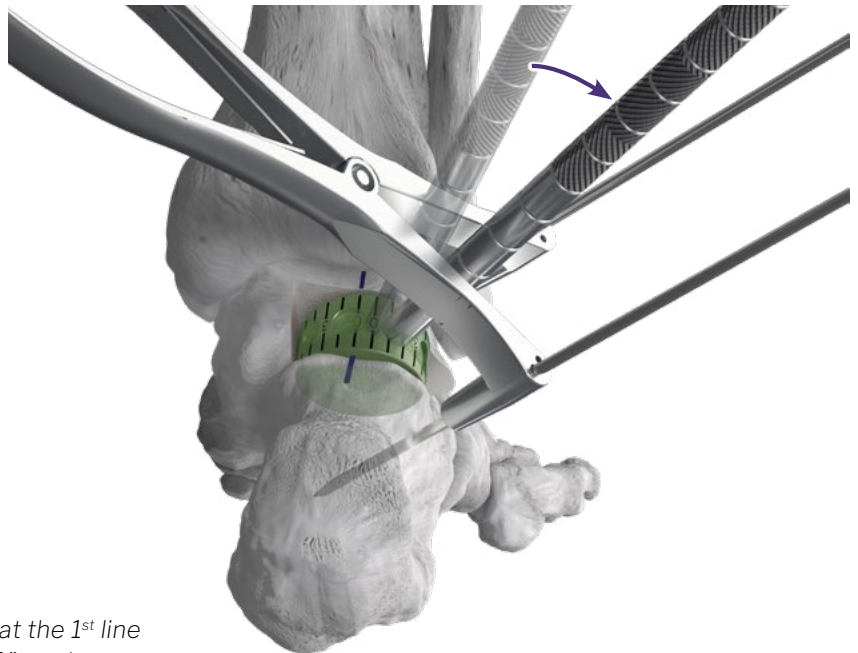
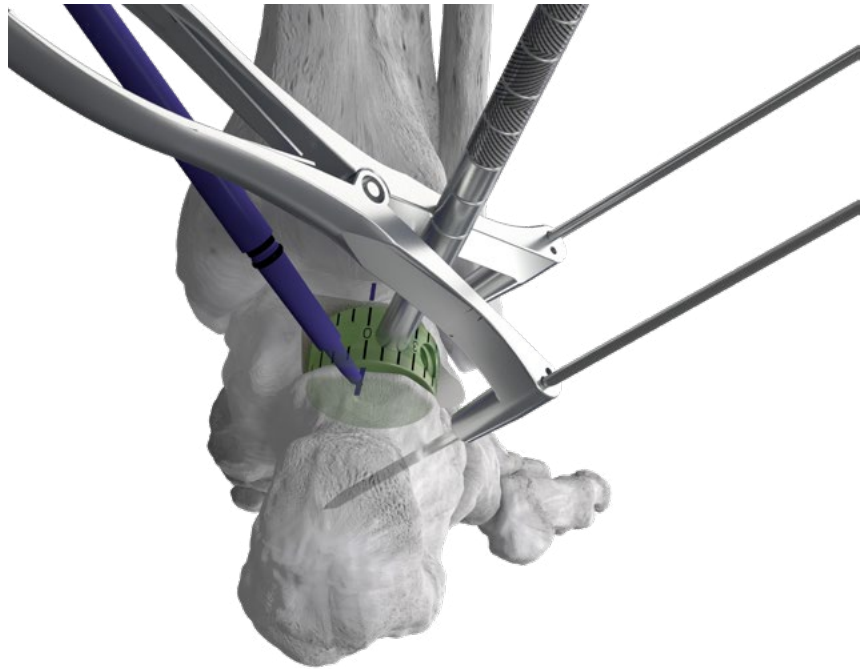
Orient the tallest portion of the sizer posteriorly and the handle attached laterally. Make a score on the bone using a marker or bovie at the “zero” marker on the trial.



The toothed arm of the Hindfoot Distractor can be opened up once the correctly sized trial sizer is inserted. This will allow “dial-in” varus/valgus correction of the calcaneus. Rotate the trial sizer medial or lateral until correct varus or valgus orientation of the calcaneus is achieved. Once appropriate height and orientation of the calcaneus is achieved using the sizer, make a note of the number located at the score.



The score aligned at the 1st line to the left of the “0” mark.



Select the Graft size corresponding with the final trial sizer used. Hydrate the Graft in normal sterile saline for 5 minutes. If platelet rich protein, blood, bone marrow aspirate, or other osteogenic medium is being used to improve Graft incorporation, apply following hydration in normal sterile saline.

16 mm Preserve® Subtalar Graft

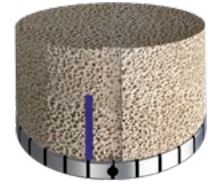
GRAFT INSERTION



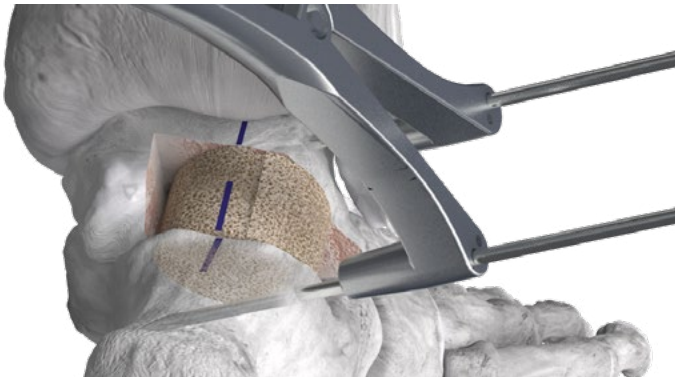
Obtain the Subtalar Coin Correction Guide from the Allograft Subtalar and Calc-Cuboid Caddy.



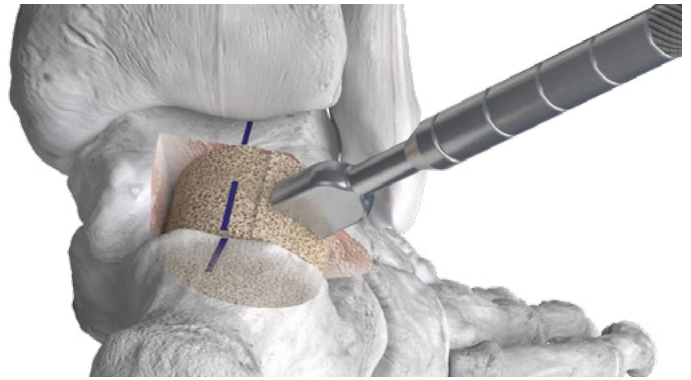
Place the hydrated PRESERVE Subtalar Distraction Arthrodesis Graft on the Subtalar Coin Correction Guide with the vertical indentation mark on the Graft lined up with the zero mark on the coin.



Using the marker or bovie, make a score on the Graft that corresponds to the number where the score was made on the bone of the talus and/or calcaneus.



Insert the Graft such that the score at the subtalar joint is aligned with the score on the Graft.



Use the bone tamp to fully seat the Graft. Confirm reduction using fluoroscopy.

TEMPORARY FIXATION MONSTER SCREW

Obtain the Ø2.3 mm K-wire from the Monster Ø7.0mm SlimLine Case or Monster Screw System Midfoot/Hindfoot Set.

Insert the Ø2.3 mm K-wire into the posterior aspect of the heel above the weight bearing surface. Continue insertion into the calcaneus, across the Graft, and into the talus. Confirm positioning using fluoroscopy.



PERMANENT FIXATION MONSTER SCREW



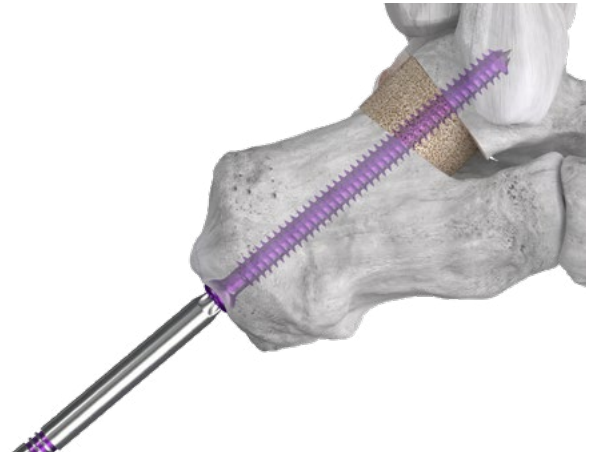
When using a headed Ø7.0 mm Monster Screw, countersinking is recommended. Insert the countersink over the guide wire and perform the countersinking.



Drill over the K-wire into the Talus. Tapping can be performed at this time, if desired.



Measure the screw length using the Depth Gauge.



Insert the screw over the K-wire until the head is flush with the bone. Confirm position with fluoroscopy before removing the K-wire.



TIP: A second Ø7.0 mm Monster Screw can be inserted in the same general direction to potentially improve stability and create a stronger construct.

CLOSURE

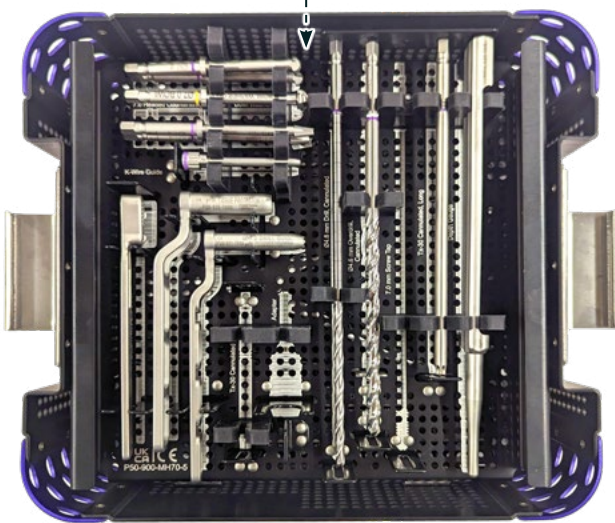
Proceed to incision closure or concomitant procedures at this point.



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 X 80 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 X 65 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
P20-570-074S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 74 mm	Single-use
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P20-570-087S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 78 mm	Single-use
P20-570-080S	Monster® Cannulated, Short Thread Screw, Headless, 7.0 X 80 mm	Single-use
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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
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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.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



PRESERVETM


BONE GRAFT
SYSTEM

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Paragon 28, Inc. 
14445 Grasslands Dr.
Englewood, CO 80112 USA
(855) 786-2828

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.