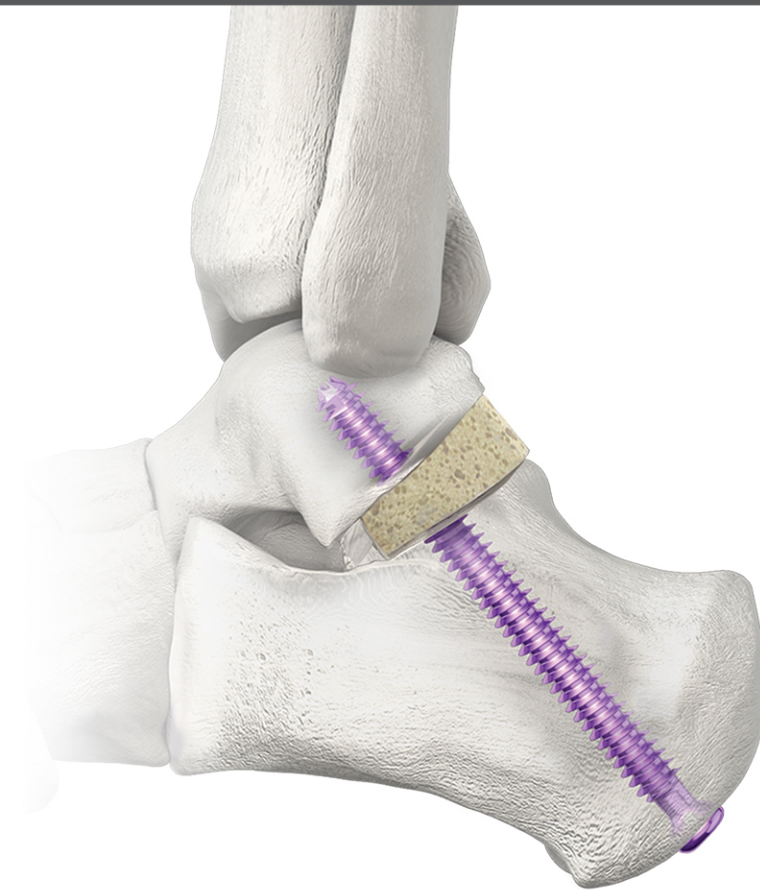




SURGICAL TECHNIQUE GUIDE

SUBTALAR JOINT DISTRACTION ARTHRODESIS



PRESERVE™ Subtalar Distraction Arthrodesis Graft



PRESERVE™
A L L O G R A F T



PRESERVE™
ALLOGRAFT

Surgical Technique Guide

Subtalar Joint Distraction Arthrodesis

Specifically Designed for the Following Conditions:

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**

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 3. 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 4.

Indications, Contraindications and Warnings for the Monster® Screw System are outlined in the Monster® Screw System Surgical Technique Guide (Document P20-STG-0001).

P01-STG-0001 RevD

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Patents: www.paragon28.com/patents

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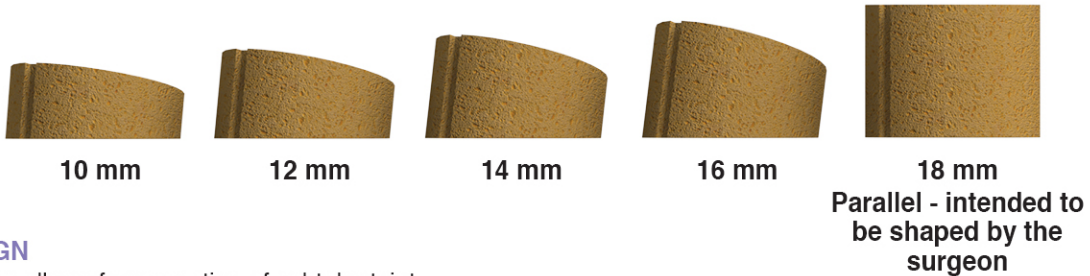
PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon²⁸[®]

www.PARAGON28.com

PRESERVE Subtalar Distraction Arthrodesis Graft

5 Options:



WEDGE DESIGN

- Graft geometry allows for correction of subtalar joint height and calcaneal varus/valgus
- Height and angle of correction are proportional such that more correction can be obtained in cases of severe joint depression
- Allows “dial-in correction” in the frontal and sagittal planes when combined with trials

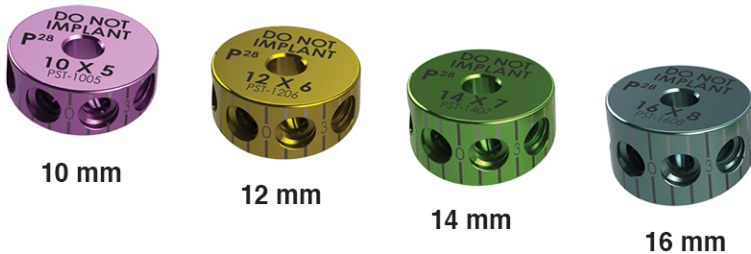
DENSITY MATCHING

- 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

Trial Sizers



Trial Sizer Offering



Trial Sizer Handle



COIN CORRECTION GUIDE

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

- 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

Surgical Technique

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. (A) 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.

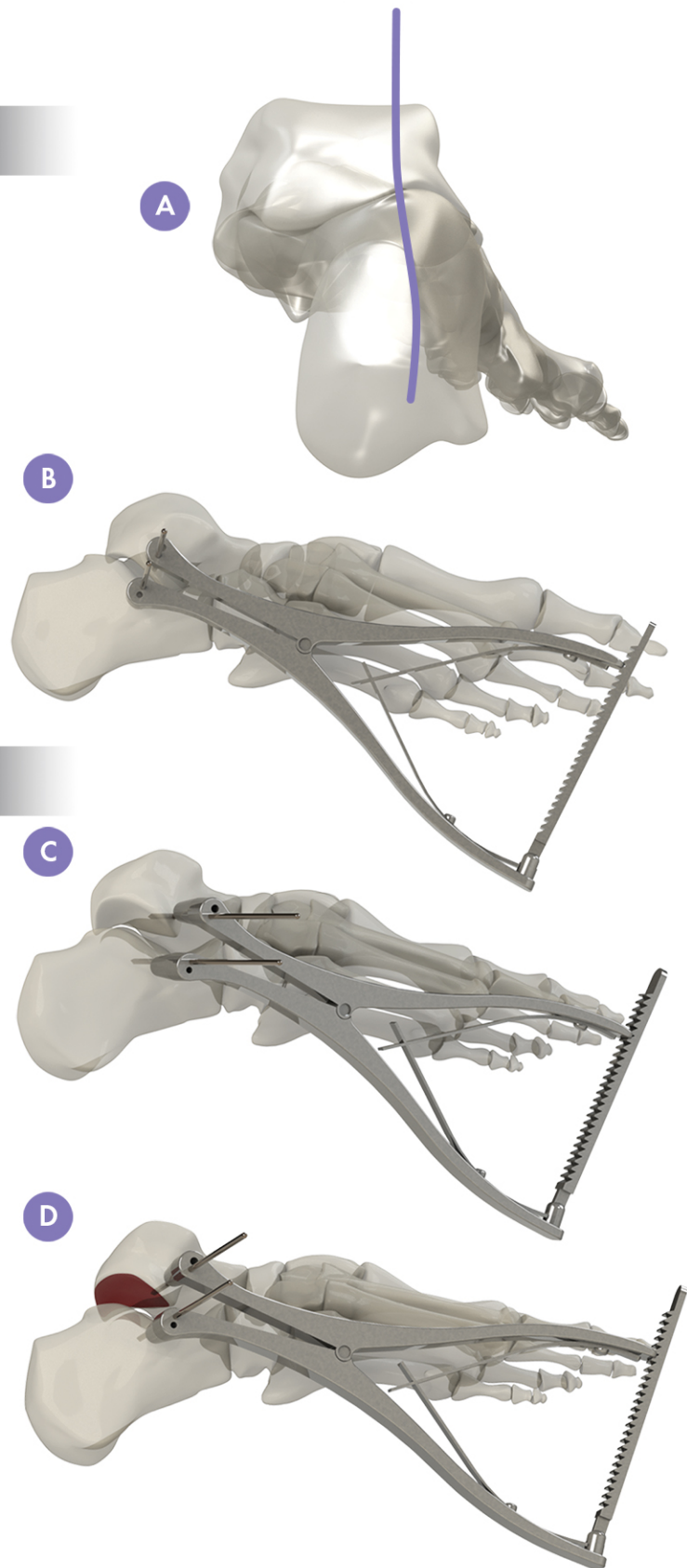
Once the subtalar joint is exposed, the pin distractor can be obtained from the Monster Screw System caddy.



Place the pin distractor on either side of the subtalar joint and secure with K-wires. (B) Distract the subtalar joint. (C)

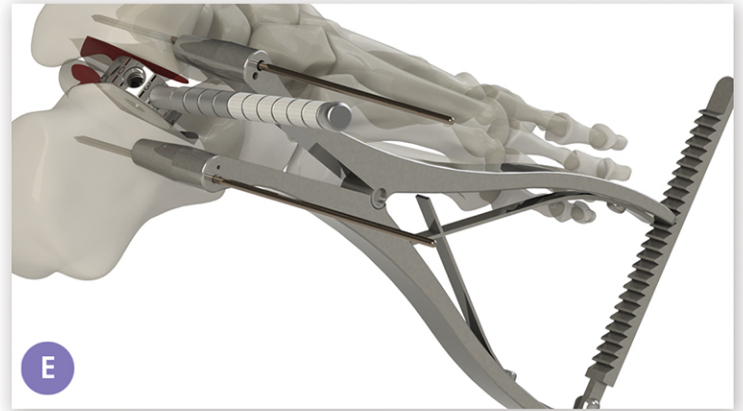
Cartilage resection should be performed on either side of the posterior facet of the subtalar joint. Resection of cartilage off of the anterior and middle facets may be performed at this time, if preferred, generally through a second incision. (D)

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

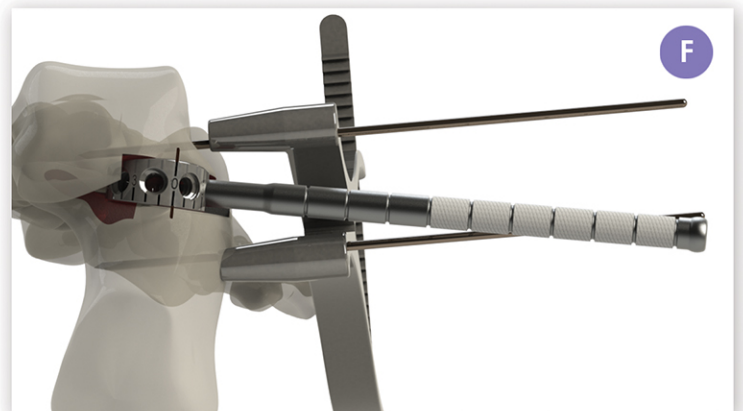


DETERMINING GRAFT SIZE AND POSITION

The pin 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 "0") should be oriented posteriorly. Introduce the trial sizer into the subtalar joint, centering the graft within the posterior facet. (E)

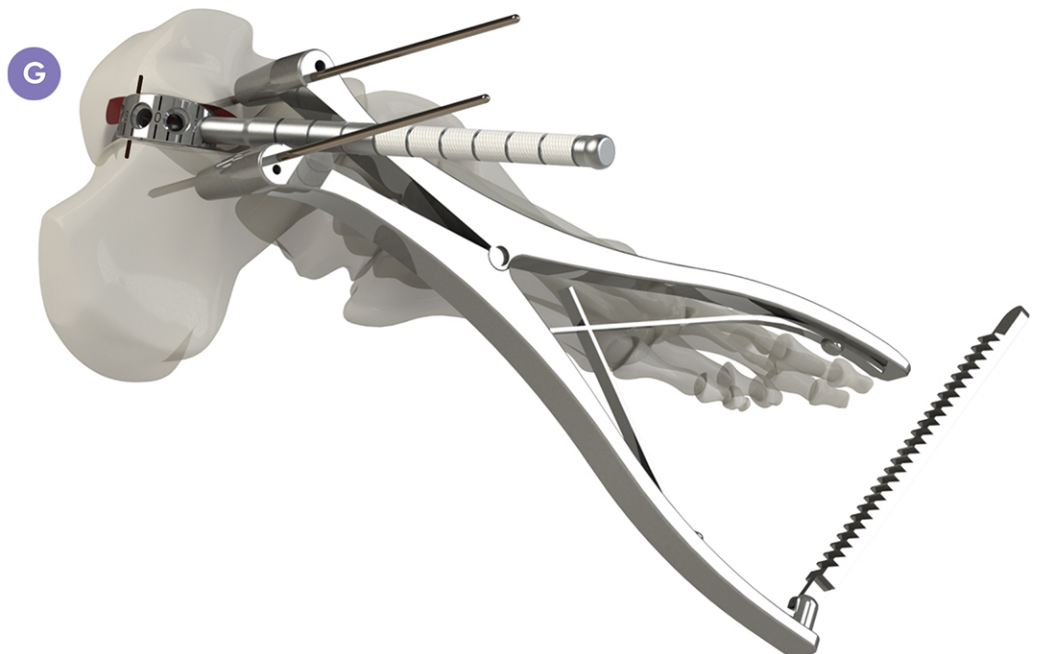


Remove the smallest trial sizer if it does not snugly fit into the subtalar joint (as shown in Fig. E). Replace with the next largest trial sizer until appropriate calcaneal height is achieved. Orient the tallest portion of the sizer posteriorly and the handle attached laterally. Make a score on the bone using a marker or bovie at the "zero" marker on the trial. (F)



The toothed arm of the pin 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. (G)

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.



The score was made at the 2nd line to the left of the "0" mark.

Surgical Technique

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. (H)

Insert the graft such that the score at the subtalar joint is aligned with the score on the graft. (I)

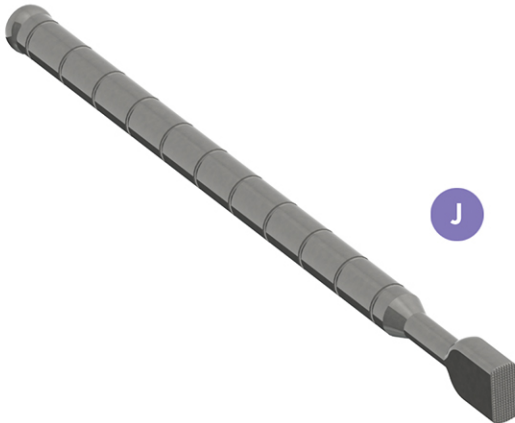
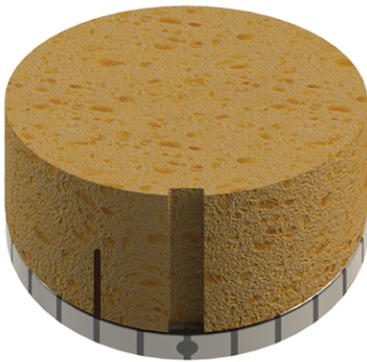
Use the bone tamp (J) to fully seat the graft. (K)

Confirm reduction using fluoroscopy.



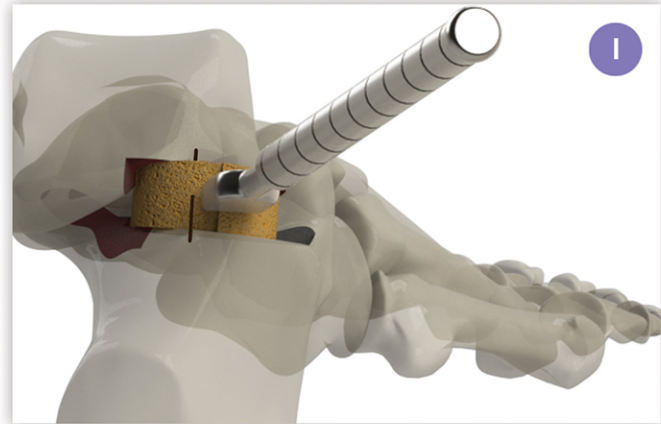
H

The score is made at the 2nd line to the left of the "0" mark.

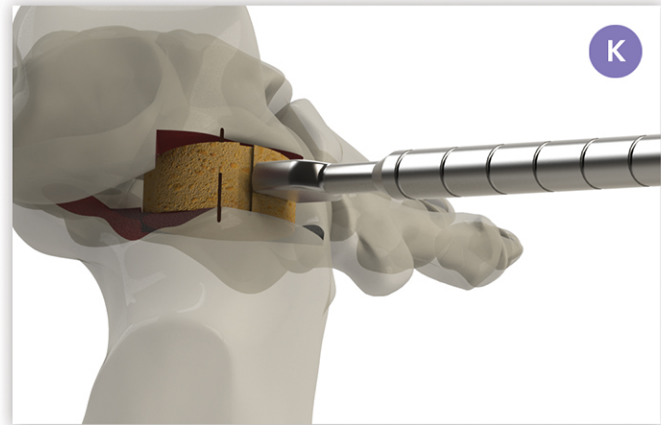


J

I



K



Surgical Technique

TEMPORARY FIXATION

A 2.3 mm K-wire is selected from the Monster Screw System Midfoot/Hindfoot Set.

The 2.3 mm K-wire is inserted into the posterior aspect of the heel above the weight bearing surface. Continue insertion into the calcaneus, across the graft, and into the talus. Position is confirmed using fluoroscopy. (L)



PERMANENT FIXATION

A fully threaded, headed 7.0 mm Monster Screw is recommended for fixation of the graft and subtalar joint to maintain correction and provide fixation without providing excessive compression across the graft.

Drilling is performed over the guide wire. (M) Tapping can be performed at this time, if desired.

When using a headed 7.0 mm Monster screw, countersinking is recommended. The countersink is inserted over the guide wire and countersinking is performed. (N)

The screw length is measured using the Monster depth gauge.

The screw is inserted with position and length confirmed using fluoroscopy before removing the guide wire. (O) (P)

TIP: A second 7.0 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.

Product Information

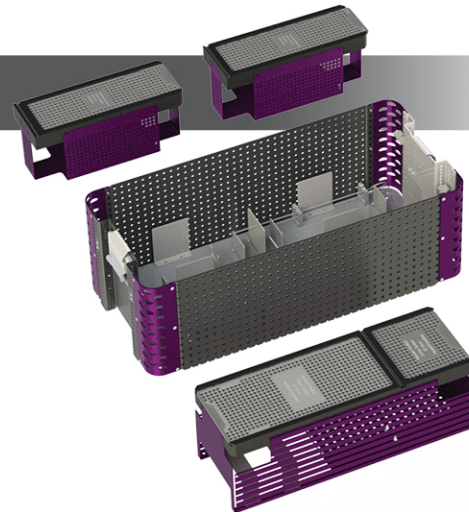
ALLOGRAFT SUBTALAR AND CALC-CUBOID CADDY



The Calc Cuboid and Subtalar Caddy contains the 4 trials for the PRESERVE™ Subtalar Distraction Arthrodesis Grafts. The Subtalar Coin Correction Guide and bone tamp are contained in this caddy as well.

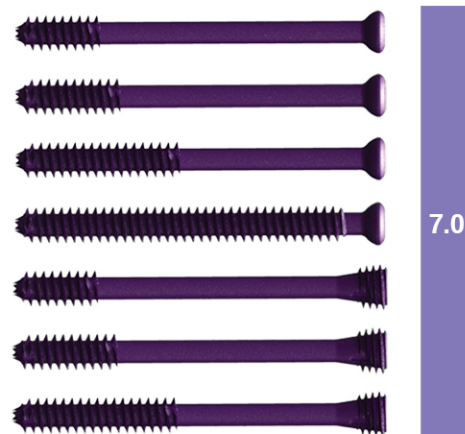
MONSTER® HINDFOOT CADDY

The Monster® Screw System Hindfoot Set contains the instrumentation for insertion of a 4.5 mm, 5.5 mm, or 7.0 mm headed or headless Monster screw. The pin distractor is located at the bottom of this caddy. Caddies for the 4.5 mm, 5.5 mm, and 7.0 mm screws are also included in this set.



7.0 mm MONSTER® SCREW SIZE CHART

7.0 mm	Headed	Part Threaded - Short	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Part Threaded - Med	2 mm increments, 40-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Part Threaded - Long	2 mm increments, 44-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Fully Threaded	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Short	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Med	2 mm increments, 44-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Long	2 mm increments, 72-90 mm; 5 mm increments, 60-70 mm and 95-130 mm



SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Refer to www.paragon28.com/ifu 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.