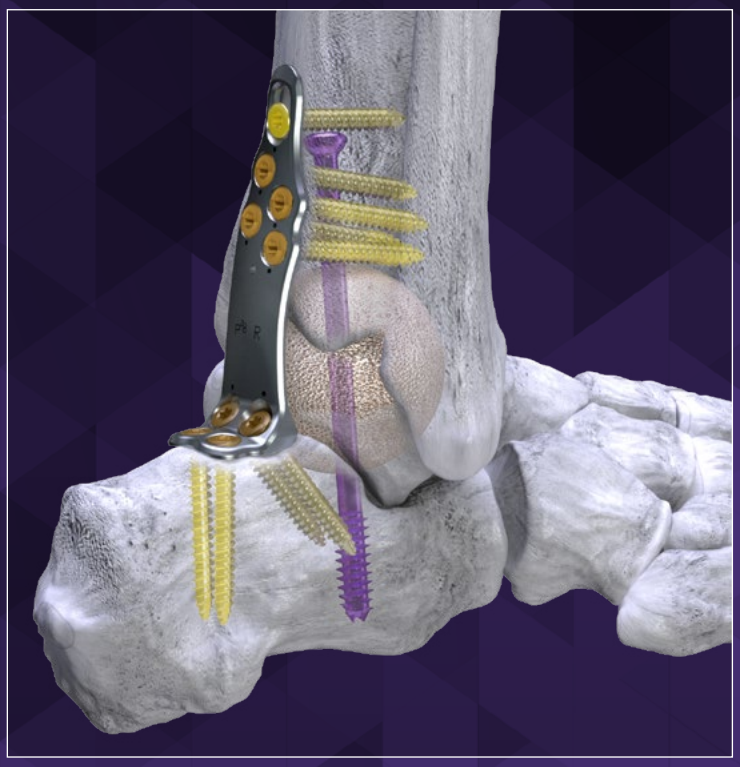
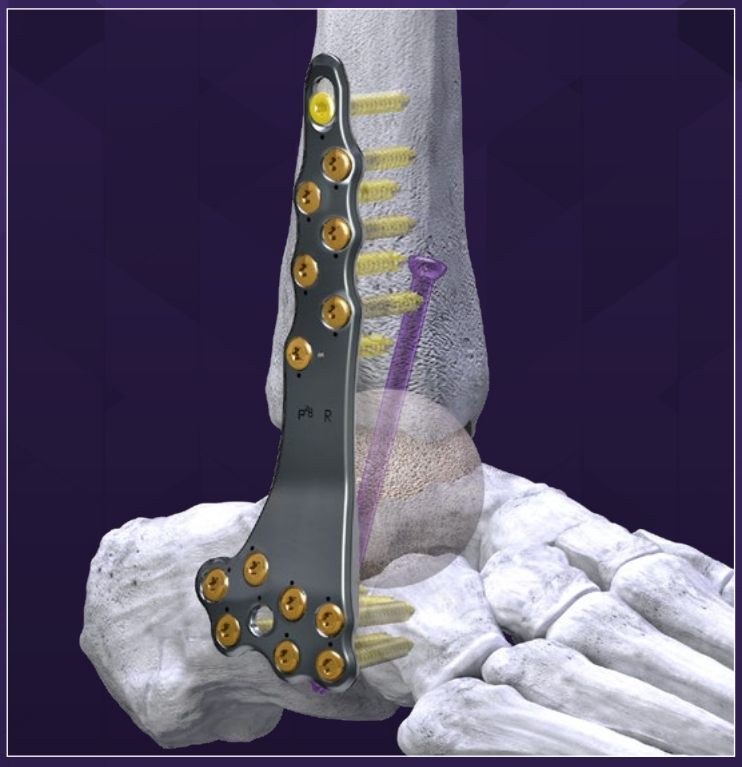
SILVERBACK™
ANKLE FUSION PLATING SYSTEM





SURGICAL TECHNIQUE GUIDE

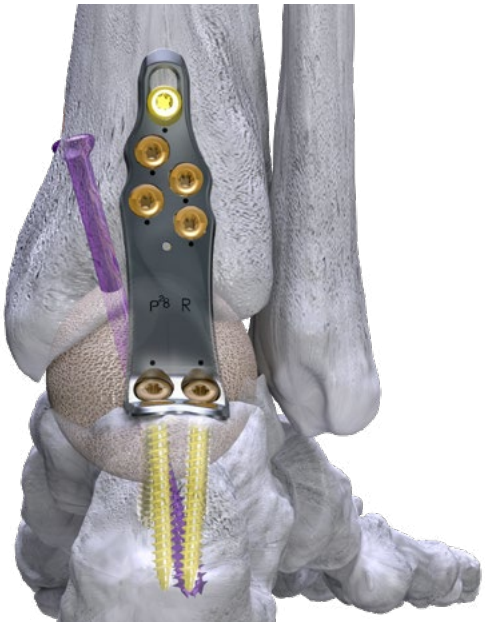
Span Plating System

Exclusively foot & ankle Paragon 28®

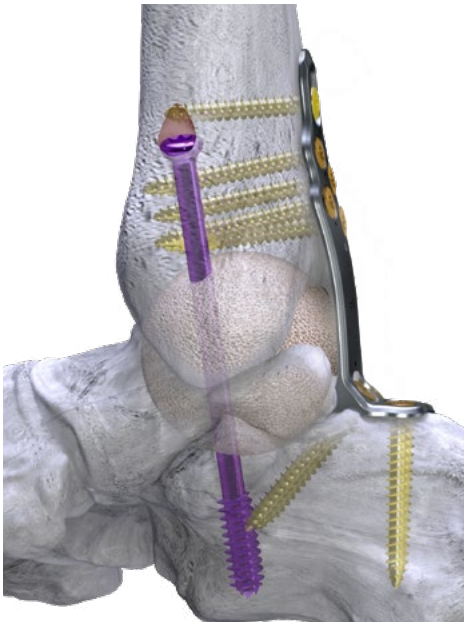
PRODUCT DESCRIPTION

The Paragon 28® Silverback™ Span Plating System provides anterior, lateral, and posterior plates designed to be used in cases where a significant void is present at the ankle joint and/or the talus. Plates may be utilized in combination with an allograft or other hardware to address a bony deficit. A proximal compression slot built into all plates may be used to compress the bone to graft interface. All Span Plates have a single contour and are available in standard and long lengths which offer varying span distances to accommodate different allograft heights required to fill the bone void present. The relatively thinner plate helps to evenly distribute force across the construct and helps guard against stress shielding during healing. The Lateral and Posterior Span Plates accept the Silverback™ Ø4.5 mm and Ø5.2 mm screws to be used for the tibia and calcaneus. The Anterior Span Plates accept Silverback™ Ø4.5 mm and Ø5.2 mm screws in the tibia and talar body and Gorilla® R3CON Ø3.5 mm and Ø4.2 mm screws in the talar neck holes.

The images below depict the Posterior Span Plate approach to emphasize how the plate "spans" the allograft.



Posterior view



Medial view

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Acknowledgment:
Paragon 28 would like to thank Mark Myerson, MD for his contribution to the development of the surgical technique guide.

SPAN PLATES

Available in Right (shown) and Left Configurations

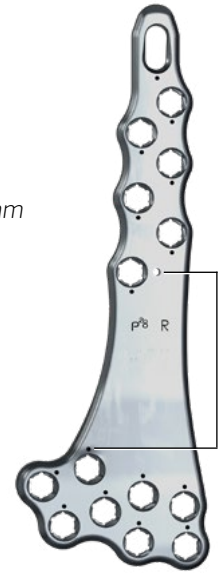
Anterior Span Plates

Standard

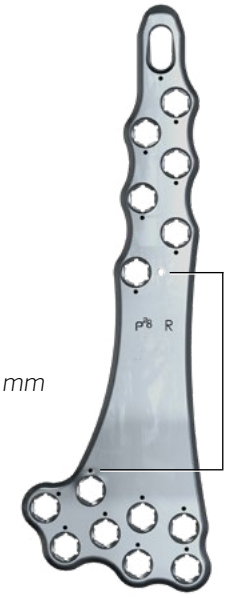
Long

Lateral Span Plates

Standard



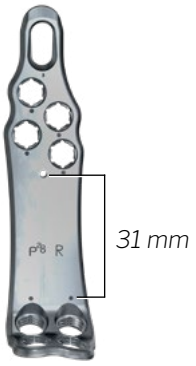
Long



Posterior Span Plates

Standard

Long

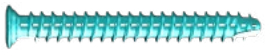
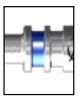


Side Profile

Side Profile

Side Profile

SCREW INSERTION INSTRUMENTS

	Ø3.5 mm R3CON Screws	Ø4.2 mm R3CON Screws	Ø4.5 mm SILVERBACK™ Screws	Ø5.2 mm SILVERBACK™ Screws	Ø4.7 mm SILVERBACK™ Compact Screws
Locking:					
Non-locking:					
Screw Lengths:	14 mm - 30 mm in 2 mm increments	14 mm - 50 mm in 2 mm increments and 55 mm - 60 mm in 5 mm increments			20 mm - 40 mm in 2 mm increments
Drill Size:	Ø2.4 mm 	Ø2.8 mm 	Ø3.1 mm 	Ø3.6 mm 	Ø3.6 mm 
Driver Size:	HX-10 	HX-10 	HX-15 	HX-15 	HX-15 
Locking Drill Guide Size	Ø3.5 mm 	Ø4.2 mm 	Ø4.5 mm 	Ø4.7/Ø5.2 mm 	Ø4.7/Ø5.2 mm 
Centering Drill Guide Size	Ø3.5 mm 	Ø4.2 mm 	Ø4.5 mm 	Ø5.2 mm 	N/A
Compression Slot Drill Guide Size:	N/A	N/A	Ø4.5 mm 	Ø4.7/Ø5.2 mm 	Ø4.7/Ø5.2 mm 
Cone/Straight Easy Guide Size:	Ø3.5 mm 	Ø4.2 mm 	Ø4.5 mm 	Ø4.7/Ø5.2 mm 	Ø4.7/Ø5.2 mm 

Drill

Cone/Straight Easy Guide

Locking Drill Guide

Centering Drill Guide

Compression Slot Drill Guide

Driver

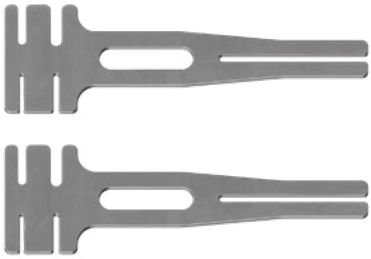
OTHER INSTRUMENTATION

Ø2.5 & Ø3.0 mm Hindfoot Pin Distractor

Overdrill Guide

AO Handles

Flat Plate Benders



Olive Wire, Short (Smooth and Threaded)

Threaded Plate Bending Bars

Olive Wire, Long (Smooth and Threaded)

Ø2.0 x 200 mm K-wire (Smooth and Threaded)

Ø2.5 x 150 mm K-wire (Smooth and Threaded)

BONE PREPARATION INSTRUMENTATION

Oval Burr

Barrel Burr

Bone Fenestration Perforator

Cartilage Removal Tool

Angled Ring Curette

Straight Ring Curette

Angled Curette

Straight Curette

Curved Bone Fenestration Chisel

Straight Bone Fenestration Chisel

Curved 3 mm Osteotome

Straight 6 mm Osteotome

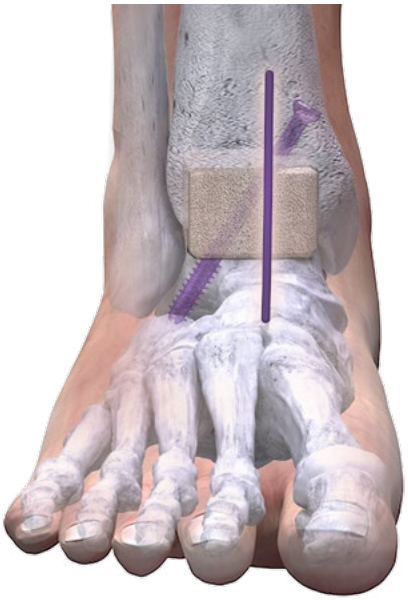
Curved 6 mm Osteotome

Straight 12 mm Osteotome

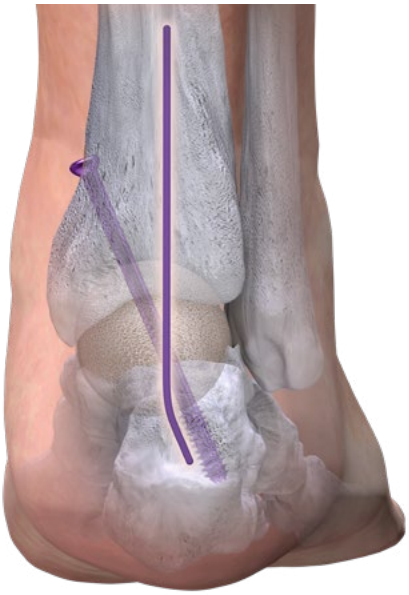
Curved 12 mm Osteotome

APPROACH

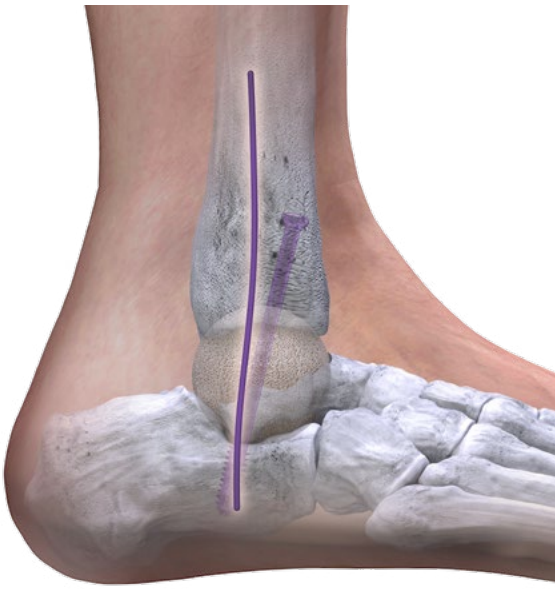
Following the surgeon's preferred method of shaping the structural bone graft and addition of bone healing adjuncts such as mesenchymal stem cells or demineralized bone matrix, the allograft is placed to fill the void of missing bone. It is advised to place at least one or two Monster® crossing screw(s) across the allograft per the Surgical Technique Guide (P20-STG-0001). The use of Monster crossing screw(s) aims to increase the stability of the construct when using an allograft. Approach the ankle joint through the same incision used to place the graft. If necessary, extend the incision proximal or distal to allow for adequate plate positioning and visualization.



Anterior Incision



Posterior Incision

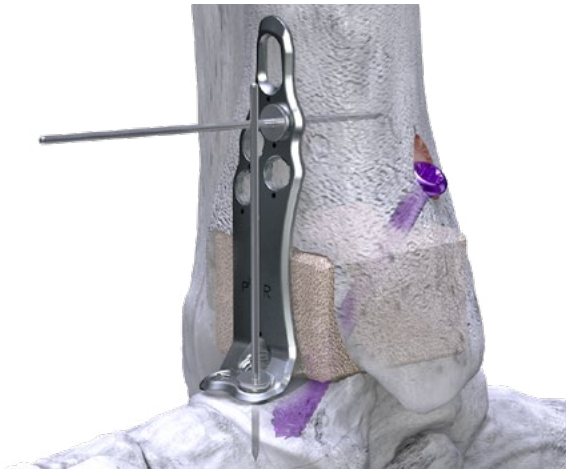


Lateral Incision

ANTERIOR SPAN PLATE PLACEMENT

Following the placement of an allograft and Monster crossing screw(s) using an anterior approach, retrieve the appropriate Anterior TT Span Plate (standard or long) based on the graft height. The difference in span height between the standard and long plates accommodates various allograft heights, with plate selection per surgeon preference. To position the plate, palpate the medial and lateral margins of the talus and center the talar portion of the plate. Ensure that the proximal plate is midline or just lateral to midline.

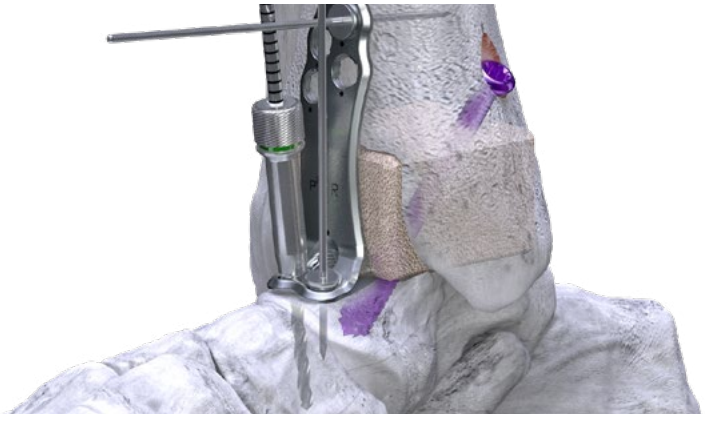
NOTE: In a situation where a surgeon prefers to include the calcaneus in the fusion, a longer Monster crossing screw(s) entering the calcaneus can be used to cross the graft, which may be spherical or cylindrical in shape. A longer screw in the talar body hole may also be used to enter the calcaneus.



Secure the plate to the tibia and talus using a Long Olive Wire in a circular screw hole on the tibia and a Short Olive Wire in the talar neck screw hole. Confirm plate position using fluoroscopy.

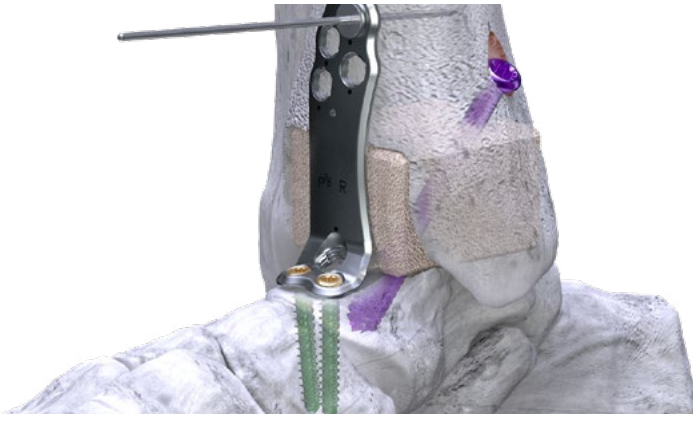
PERMANENT FIXATION - PLATE SCREWS

NOTE: The tibial and talar screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm locking or non-locking screws. A laser etched dot on the plate indicates the plate holes that accept the Ø4.5 mm, Ø4.7 mm, and Ø5.2 mm screws. The technique demonstrates the use of Ø4.5 mm screws for the talar body and Ø4.2 mm screws for the talar neck. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.



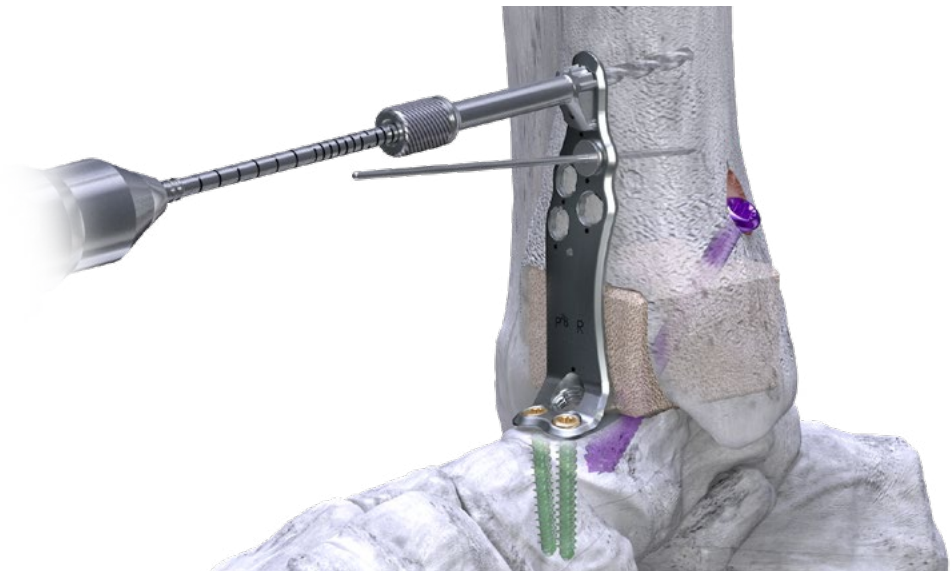
Retrieve the Ø4.2 mm Locking Drill Guide and thread into the talar neck screw hole. Drill, using the Ø2.8 mm Drill. Remove the Ø4.2 mm Locking Drill Guide and measure screw length using the Depth Gauge. Confirm screw projection and length using the Depth Gauge under fluoroscopy, if necessary.

NOTE: It is recommended for all talar screw holes to use the appropriate Locking Drill Guide to achieve on-axis trajectory.

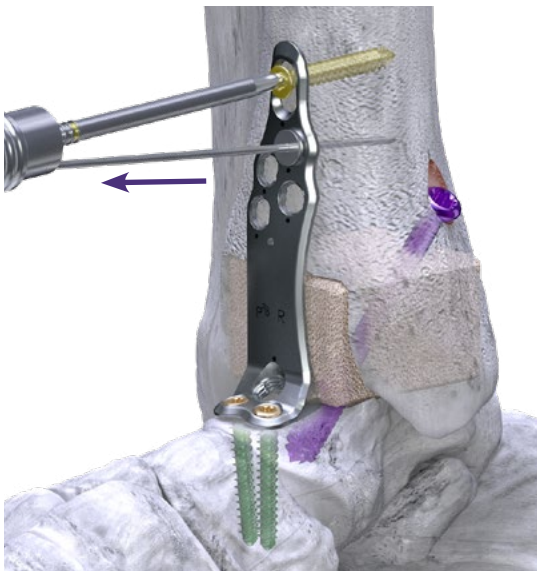


Insert the selected locking or non-locking Ø4.2 mm screw into the talar neck plate hole. Use the provided Driver and Handle to partially seat the first screw. Do not fully seat the first talar screw to avoid toggling of the plate. Remove the Olive Wire from the talus and insert the second talar neck screw as previously described. Completely tighten both of the talar neck screws until fully seated.

PERMANENT FIXATION - PLATE SCREWS

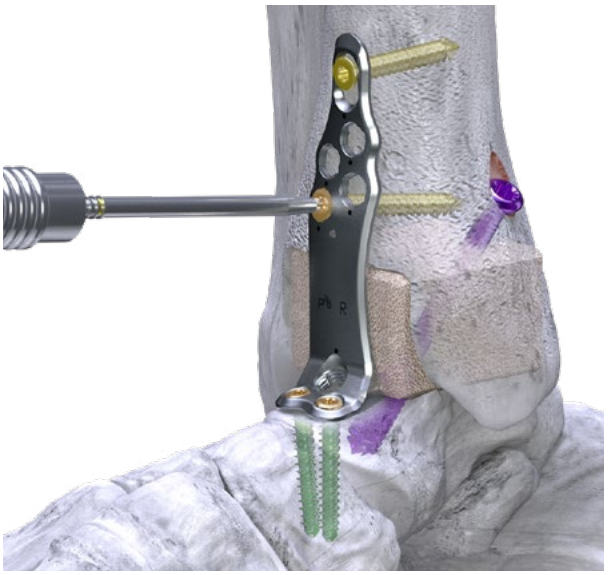


Retrieve the Ø4.5 mm Compression Slot Drill Guide and insert into the tibial compression slot with the arrow pointing towards the tibia-allograft interface. Drill, using a Ø3.1 mm Drill through the Compression Slot Drill Guide. Remove the Compression Slot Drill Guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm non-locking screw.

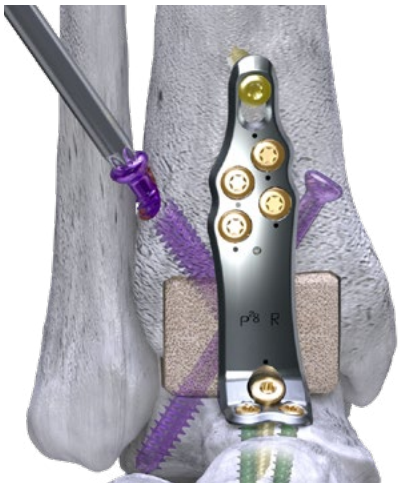


Remove Olive Wire. Fully seat the compression screw at this time.

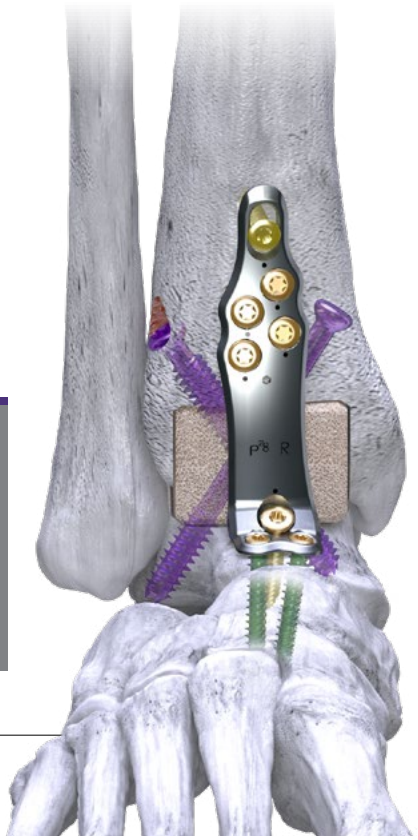
NOTE: Alternatively, the circular holes in the tibia may be filled first with locking or non-locking screws. In this situation, when placing the compression slot screw, point the Compression Slot Drill Guide arrow away from the tibia-allograft interface.



Complete screw placement for the remaining tibia and talar body screw holes by using the technique previously described for the Ø4.5mm locking or non-locking screws, as per surgeon preference. Confirm screw lengths and placement using fluoroscopy.



NOTE: An additional fully threaded crossing screw may be placed through the tibia-allograft interface from lateral to medial for enhanced stability. The fully threaded crossing screw should be inserted anteriorly to the fibula.

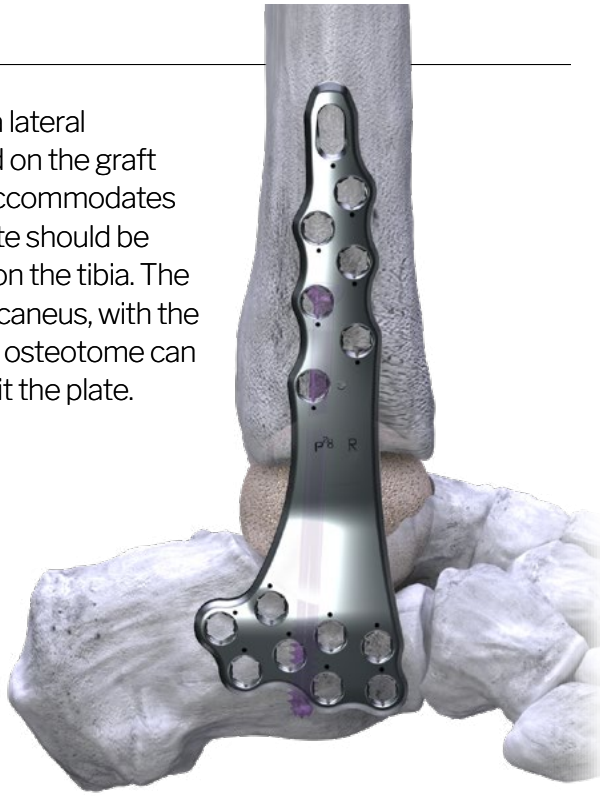


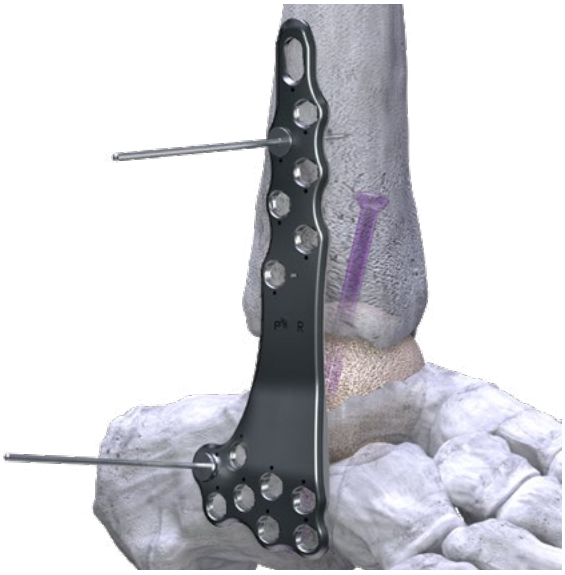
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

LATERAL SPAN PLATE PLACEMENT

Following the placement of an allograft and Monster crossing screw(s) using a lateral approach, retrieve the appropriate Lateral Span Plate (standard or long) based on the graft height. The difference in span height between the standard and long plates accommodates various allograft heights, with plate selection per surgeon preference. The plate should be positioned such that the superior plate is centered from anterior to posterior on the tibia. The posterior calcaneal holes are aligned inferior to the superior surface of the calcaneus, with the anterior holes just posterior to the calcaneocuboid joint. If necessary, a saw or osteotome can be used to smooth the bone surface of the distal tibia or calcaneus to better fit the plate.

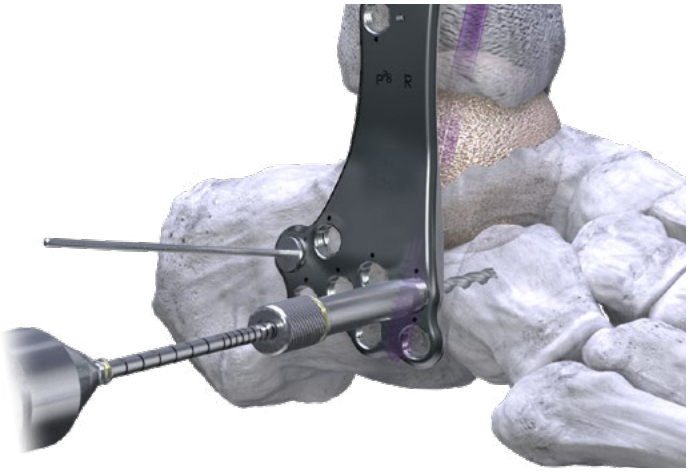




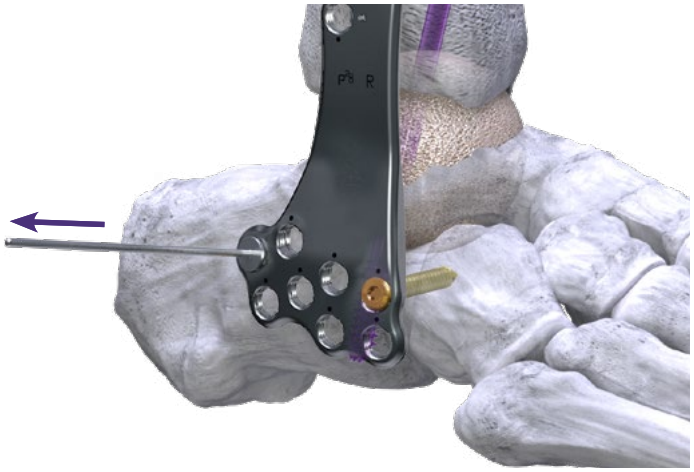
Secure the plate to the lateral aspect of the tibia and calcaneus using a Long Olive Wire in a circular tibial hole and a Long Olive Wire in the calcaneus, as shown. Confirm plate position using fluoroscopy.

PERMANENT FIXATION – PLATE SCREWS

NOTE: The tibial and calcaneal screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm locking or non-locking screws. A laser etched dot on the plate indicates the plate holes that accept the Ø4.5 mm, Ø4.7 mm, and Ø5.2 mm screws. The technique demonstrates use of the Ø4.5 mm screws. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.

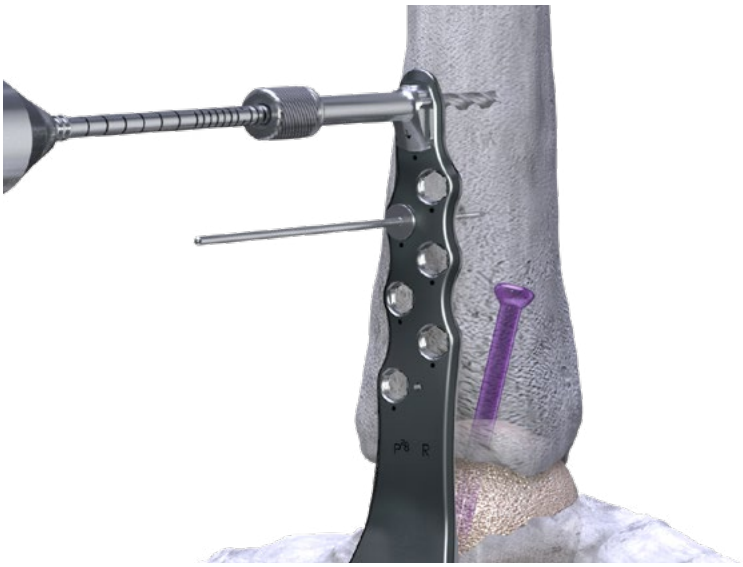


Retrieve a Ø4.5 mm Threaded or Cone/Straight Easy Guide for a Ø4.5 mm screw, and secure to a preferred calcaneal screw hole. Drill, using a Ø3.1 mm Drill through the selected drill guide.

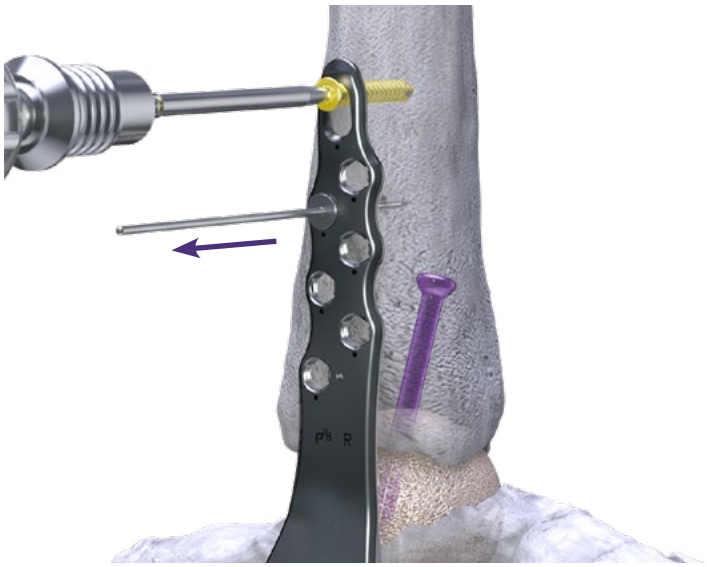


Remove the drill guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw. Remove the Olive Wire from the calcaneus at this time. Per surgeon preference, a second screw may be placed in the calcaneus for additional stability of the plate prior to placing a compression screw.

PERMANENT FIXATION – PLATE SCREWS

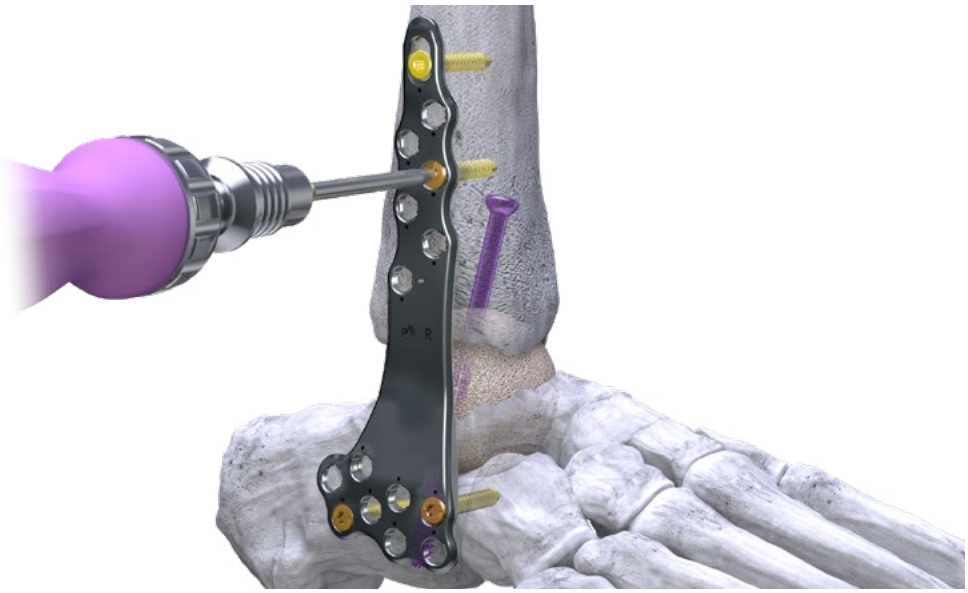


Retrieve the Ø4.5 mm Compression Slot Drill Guide and insert into the tibial compression slot with the arrow pointing toward the tibia-allograft interface. Drill, using a Ø3.1 mm Drill through the Compression Slot Drill Guide.

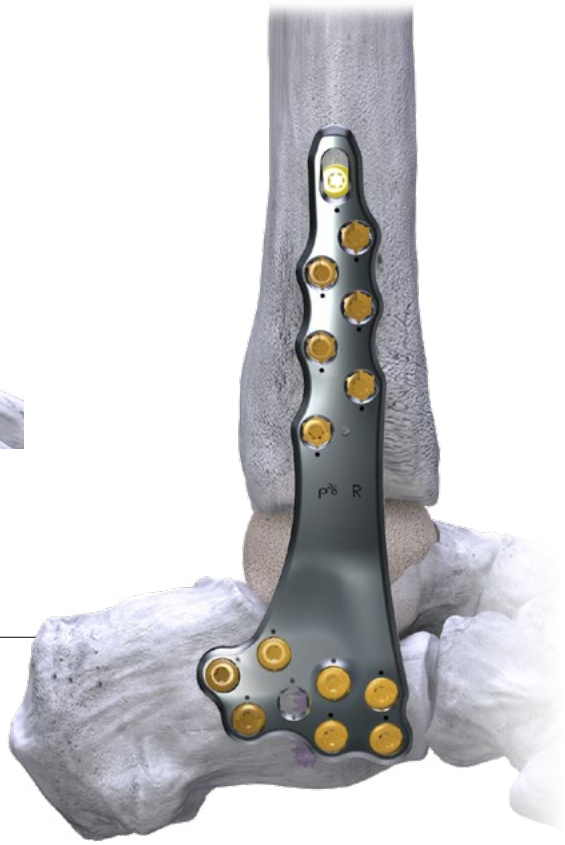


Remove the Compression Slot Drill Guide and measure screw length using the Depth Gauge. Insert and fully seat a Ø4.5 mm non-locking screw into the tibia. Remove the Olive Wire at this time.

NOTE: Alternatively, the circular holes may be filled first with locking or non-locking screws. In this situation, when placing the compression slot screw, point the Compression Slot Drill Guide away from the tibia-allograft interface.



Complete screw placement for the remaining screw holes by using the technique previously described for the Ø4.5mm locking or non-locking screws, as per surgeon preference. Confirm screw lengths and placement using fluoroscopy.

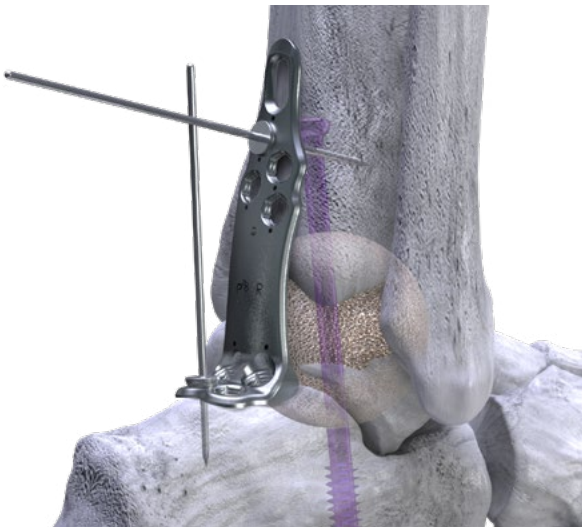


CLOSURE

Proceed to incision closure or concomitant procedures at this time.

POSTERIOR SPAN PLATE PLACEMENT

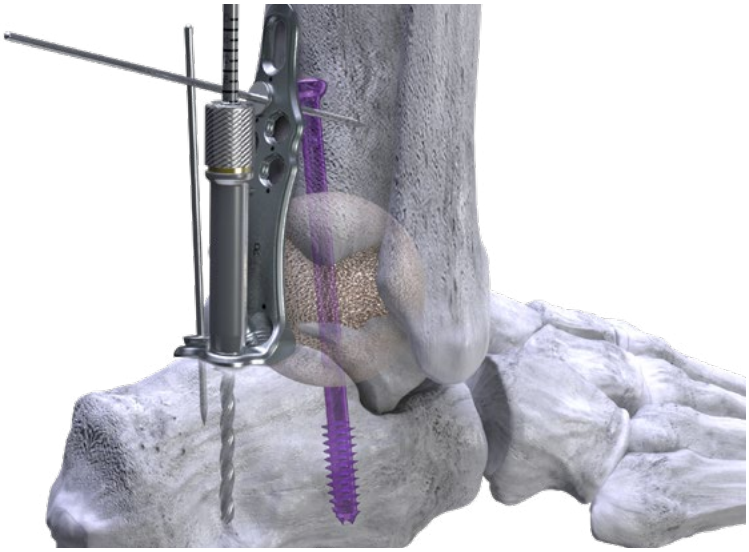
Following the placement of an allograft and Monster crossing screw(s) using a posterior approach, retrieve the appropriate Posterior Span Plate (standard or long) based on the graft height. The difference in span height between the standard and long plates accommodates various allograft heights, with plate selection per surgeon preference. To position the plate, ensure that the superior plate is midline or just lateral to midline on the tibia and that the inferior aspect of the plate is centered over the superior calcaneus.



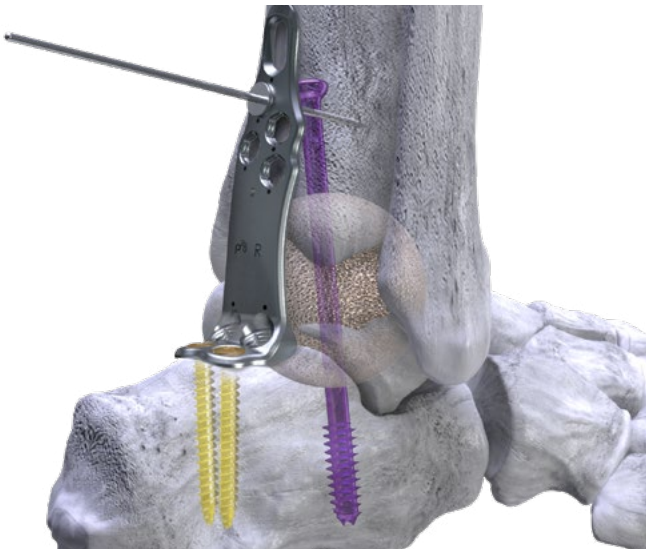
Secure the plate to the tibia and calcaneus using a Long Olive Wire in a calcaneal screw hole and a Long Olive Wire in a circular screw hole of the tibia, per surgeon preference. Confirm plate position using fluoroscopy.

PERMANENT FIXATION – PLATE SCREWS

NOTE: The tibial and calcaneal screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm locking or non-locking screws. A laser etched dot on the plate indicates the plate holes that accept the Ø4.5 mm, Ø4.7 mm, and Ø5.2 mm screws. The technique demonstrates the use of the Ø4.5 mm screws. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.



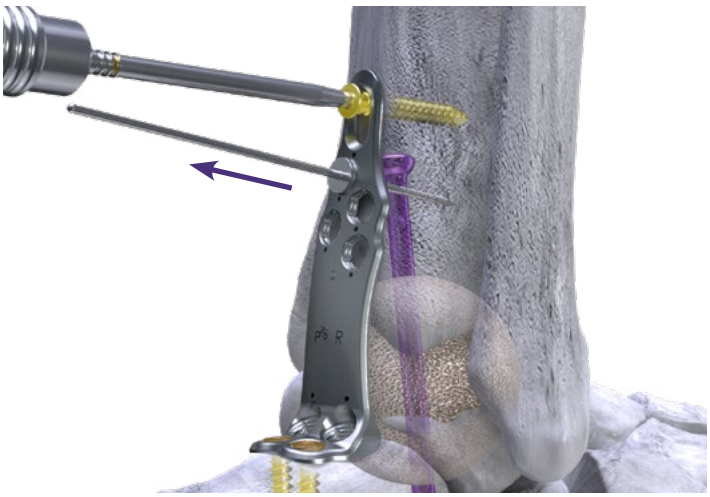
Retrieve a Ø4.5 mm Locking Drill Guide and thread into the preferred posterior calcaneal screw hole. Drill, using a Ø3.1 mm Drill through the selected drill guide.



Remove the drill guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw. Do not fully seat the screw to avoid toggling of the plate. Remove the calcaneal Olive Wire and repeat process for the other posterior calcaneal screw hole. Fully seat screws at this time.

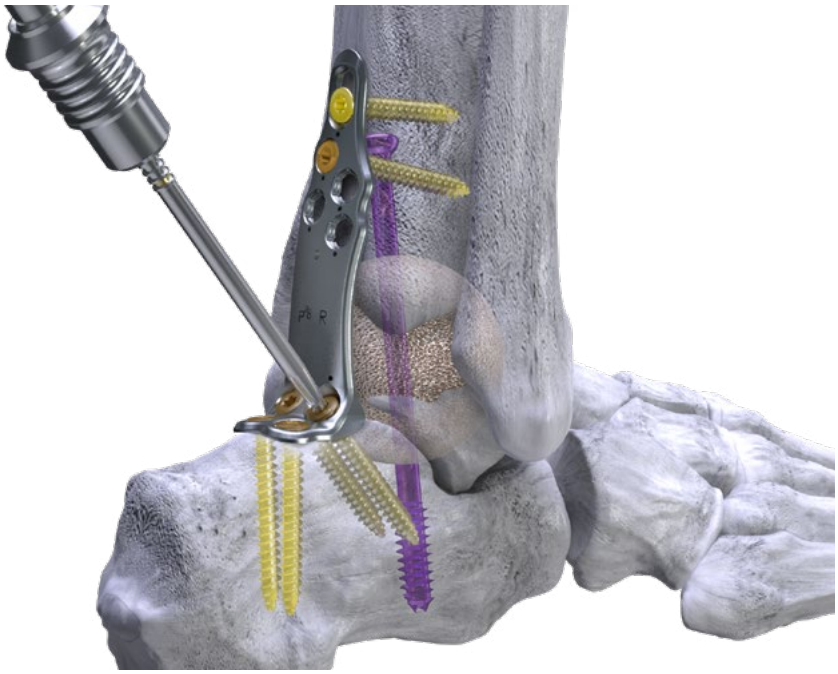
PERMANENT FIXATION – PLATE SCREWS

Retrieve the Ø4.5 mm Compression Slot Drill Guide and insert into the tibial compression slot with the arrow pointing toward the tibia-allograft interface. Drill, using a Ø3.1 mm Drill through the Compression Slot Drill Guide.



Remove the Compression Slot Drill Guide and measure screw length using the Depth Gauge. Insert and fully seat a Ø4.5 mm non-locking screw. Remove Olive Wire from the tibia at this time.

NOTE: Alternatively, the circular holes may be filled first with locking or non-locking screws. In this situation, when placing the compression screw, point the Compression Slot Drill Guide away from the tibia-allograft interface.



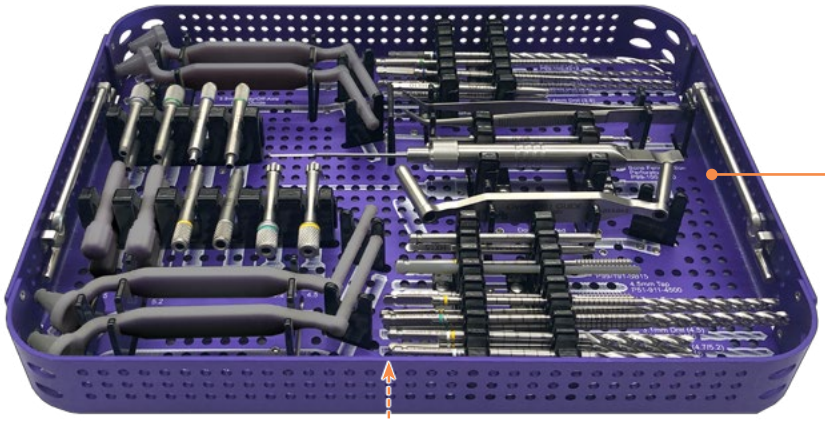
Complete screw placement for the remaining screw holes by using the technique previously described for the Ø4.5mm locking or non-locking screws, as per surgeon preference. Confirm screw lengths and placement using fluoroscopy.

CLOSURE

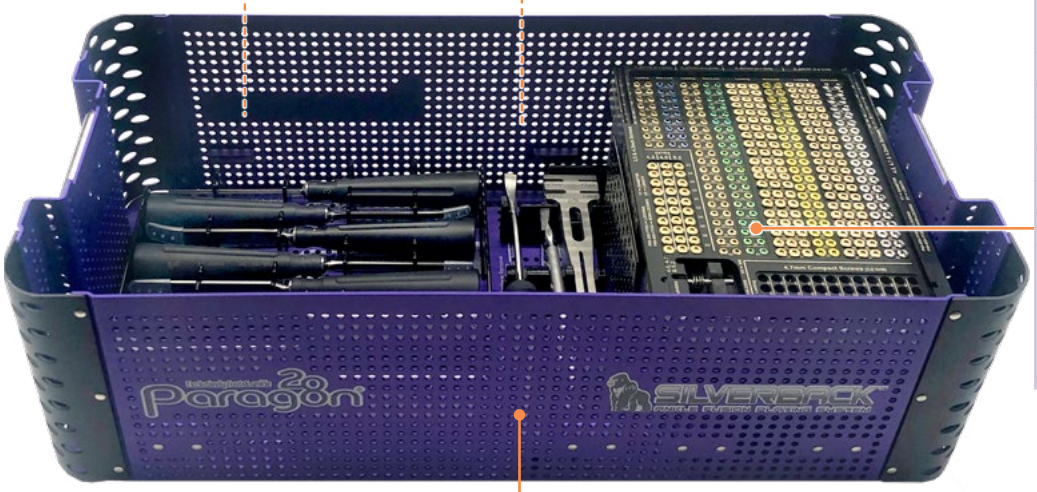
Proceed to incision closure or concomitant procedures at this time.

Silverback™ Span Plate Caddy
Standard and long Anterior, Lateral and Posterior Plates are located within the Span Plate Caddy.

Silverback™ K-wire and Olive Wire Caddy
Smooth and threaded K-wires and Olive Wires and a ruler are located within the K-wire and Olive Wire Caddy.



Silverback™ Instrument Tray
All drill guides, drills, overdrills, taps, Drivers, forceps and a Depth Gauge are located within the Silverback Instrument Tray.



Silverback™ Screw Caddy
The Silverback screw length options for locking and non-locking screws:

3.5 mm	2 mm increments, 14-30 mm
4.2 mm	2 mm increments, 14-50 mm
4.2 mm	5 mm increments, 55-60 mm
4.5 mm	2 mm increments, 14-50 mm
4.5 mm	5 mm increments, 55-60 mm
5.2 mm	2 mm increments, 14-50 mm
5.2 mm	5 mm increments, 55-60 mm

The Silverback compact screw length options are as follows:

4.7 mm	2 mm increments, 20-40 mm

Silverback™ Case Base
Handles, plate bending instrumentation and joint preparation instrumentation including curettes, osteotomes, Chisels and a Cartilage Removal Tool are located at the bottom of the Silverback Instrument Case.

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

INDICATIONS FOR USE (Gorilla®)

The Baby Gorilla®/Gorilla® Bone Plates and Bone Screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric patients. Specific examples include:

Forefoot:
- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:
- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

Ankle:
- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiotalar Joint Arthrodesis
- Tibiocalcaneal Arthrodesis
- Supramalleolar Osteotomy
- Fibular Osteotomy

First metatarsal osteotomies for hallux valgus correction including:
- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron/Austin)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:
- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot:
- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:
- Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking, titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

CONTRAINDICATIONS

Use of the Baby Gorilla®/Gorilla® Plating 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

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

to dislodged particles

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS (continued)

- 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®, Inc. 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®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. 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 plate or 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.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION

The Baby Gorilla®/Gorilla® Plating 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 Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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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
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- The presence of tumors
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- 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

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  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.**

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SILVERBACK™
ANKLE FUSION PLATING SYSTEM

GORILLA®
R3CON PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P51-STG-0013 RevB [2022-01-15]

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DISCLAIMER

The purpose of the SILVERBACK™ Span Plate Surgical Technique Guide is to demonstrate the optionality and functionality of the SILVERBACK™ Span Plating System and Gorilla® R3CON Plating System. Although variations in placement and use of the SILVERBACK™ Span Plates can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.