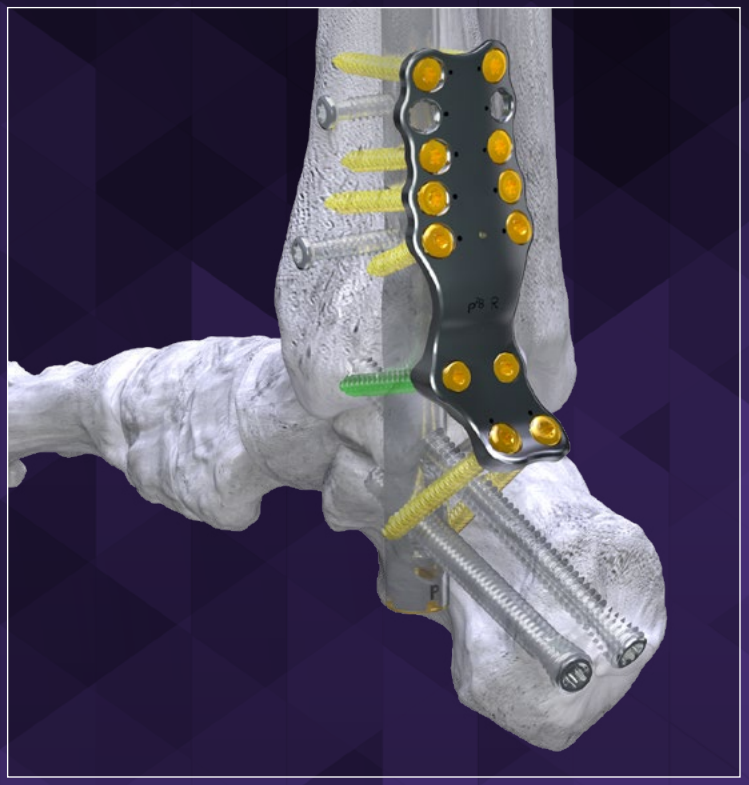
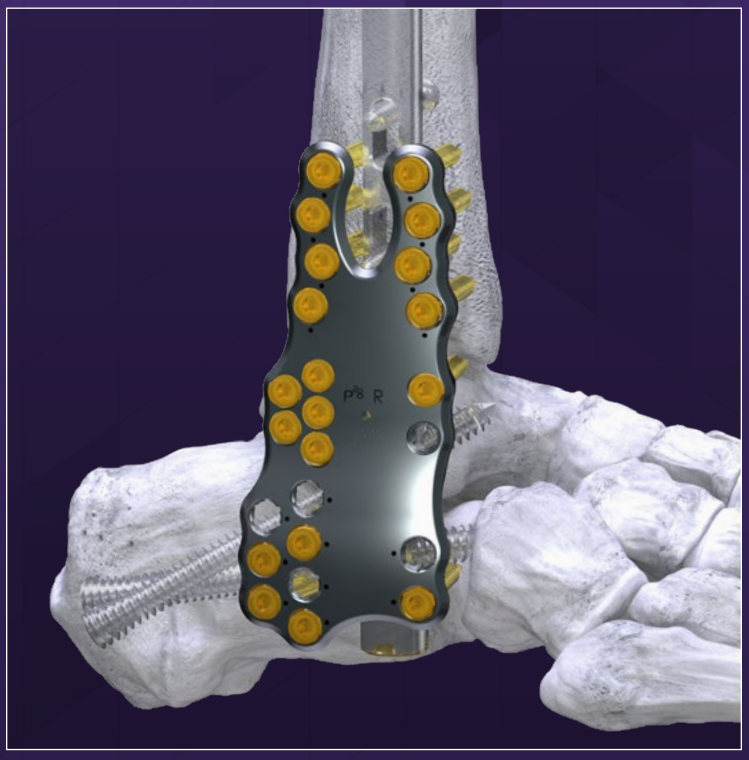
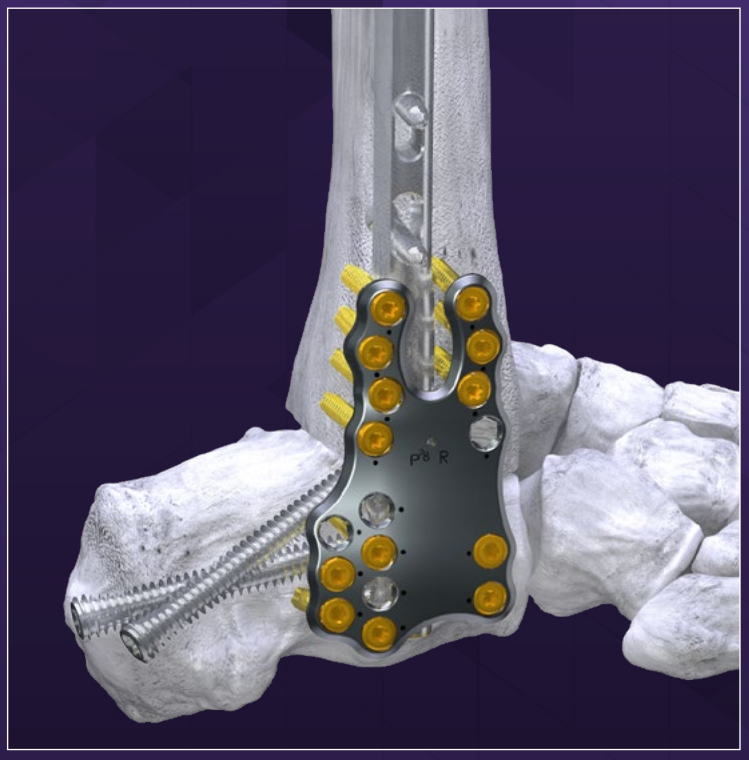
SILVERBACK™
ANKLE FUSION PLATING SYSTEM







SURGICAL TECHNIQUE GUIDE

Straddle Plates

Exclusively foot & ankle Paragon 28®

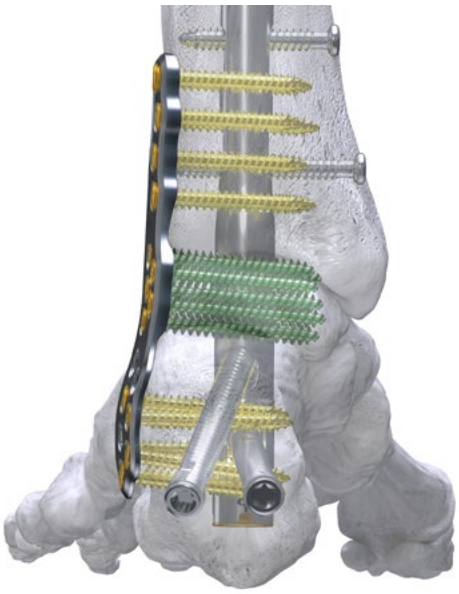
PRODUCT DESCRIPTION

The Paragon 28® Silverback™ Straddle Ankle Fusion Plating System was designed to supplement the Phantom® Hindfoot TTC/TC Nail allow surgeons to create a plate and nail construct for tibiotalocalcaneal (TTC) or tibiocalcaneal (TC) arthrodesis. The Straddle Plate system allows for an anterior, lateral, or posterior approach.

Both the anterior and posterior plates include two forms, a flat and contoured version to help accommodate variations in anatomy. The lateral plates are available in flat TC and TTC versions. The hole sizing allows for Silverback™ Ø4.5 mm and Ø5.2 mm screws to be used in the tibia and calcaneus, while the talar screw holes allow for Gorilla® R3CON Ø3.5 mm and Ø4.2 mm screws. A Ø4.7 mm "Compact" screw is available for the hole sizes in the tibia and calcaneus, which was designed with a smaller thread height to help reduce insertion torque in dense bone. Additionally, single lead bone threads result in a decreased pitch differential between the locking screw head and bone threads to reduce the amount of insertion torque required to lock the Compact screw into the plate in areas of dense bone.

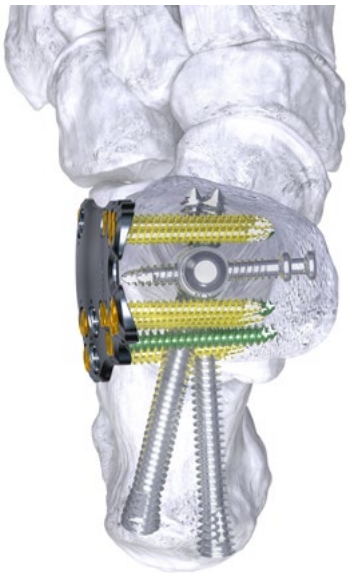
All plate screws have the option to drill on-axis using the Straight / EZ Cone Guide or to drill off-axis up to 15°. The Phantom Hindfoot TTC/TC Nail should be inserted prior to the Straddle Plate placement. The relatively wider plate design accommodates the Phantom TTC/TC Nail which helps evenly distribute force across the construct and guard against stress shielding during healing.

The three images below depict the Lateral Straddle TTC Plate approach to emphasize how the plate "straddles" the Paragon 28 Phantom® Hindfoot TTC/TC Nail.



Posterior view

Lateral view



Axial view

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ANKLE FUSION PLATES

Available in Right (shown) and Left Configurations

Anterior Straddle Plates

Flat

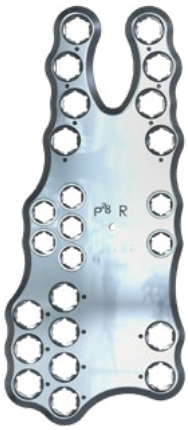
Contoured

Side Profile

Lateral Straddle Plates

17 Hole Tibiocalcaneal

24 Hole Tibiotalocalcaneal



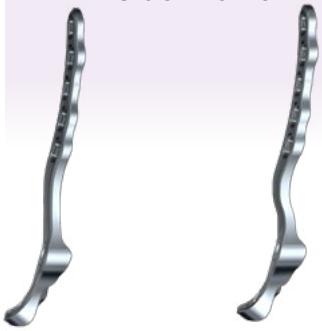
Side Profile

Posterior Straddle Plates

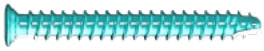
Flat

Contoured

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

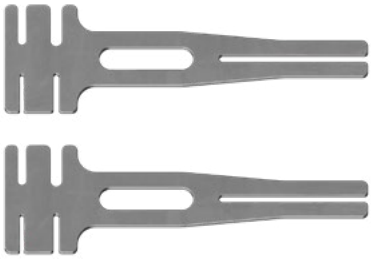
OTHER INSTRUMENTATION

Ø2.5 & Ø3.0 mm K-wire Hindfoot 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

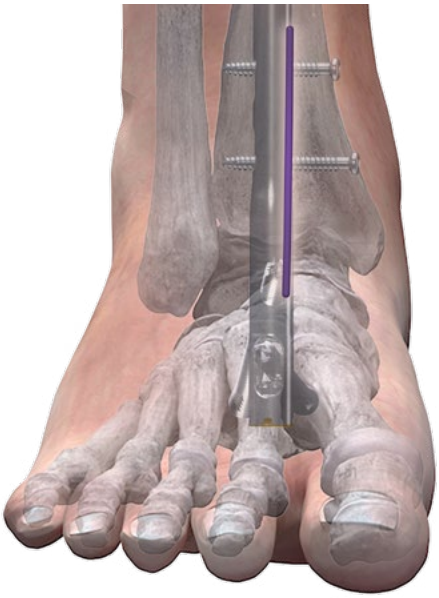
Straight 12 mm Osteotome

Curved 12 mm Osteotome

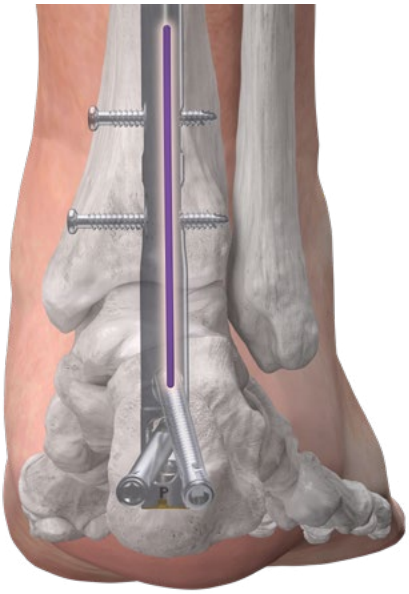
APPROACH

Once the Paragon 28 Phantom Hindfoot TTC/TC Nail System has been implanted using the Surgical Technique Guide (P31-STG-0001), approach the ankle joint through the same incision used for nail joint preparation. If necessary, extend the incision proximal or distal to allow for adequate plate positioning and visualization as shown.

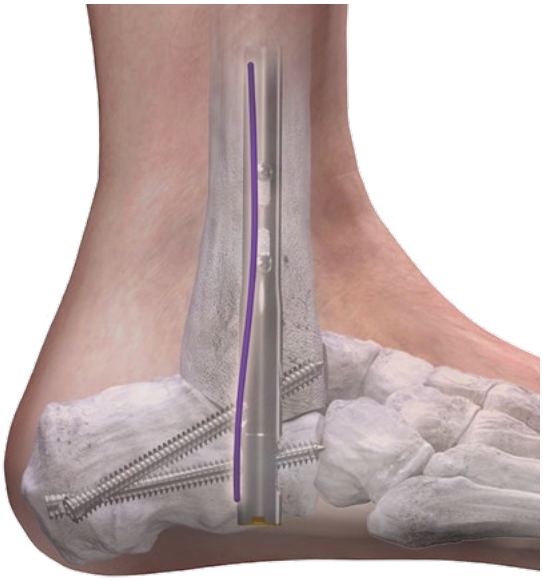
NOTE: After joint preparation and prior to placing the Phantom Hindfoot TTC/TC Nail, it may be helpful to place the intended Straddle Plate over the joints during or after temporary fixation, to ensure appropriate reduction and plate fit prior to placing the nail. The plate can be provisionally fixed to the bone with olive wires, if necessary. The plate should be removed during bone preparation for the nail, as well as during nail placement.



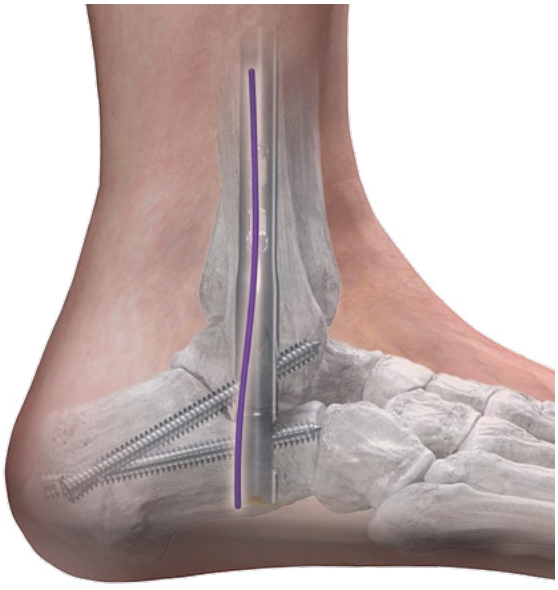
Anterior Incision



Posterior Incision



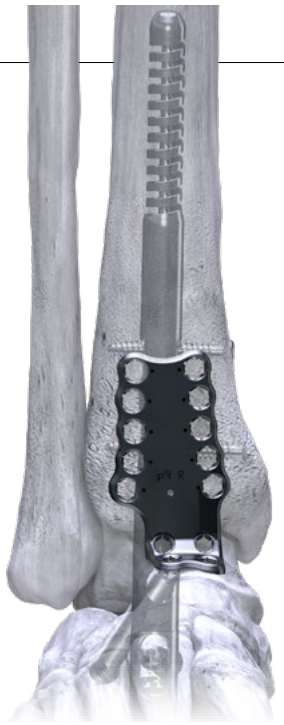
Lateral TC Incision



Lateral TTC Incision

ANTERIOR STRADDLE PLATE PLACEMENT

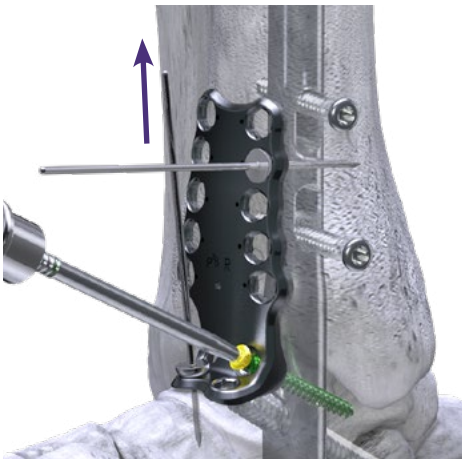
Following Phantom Hindfoot TTC/TC Nail placement using an anterior approach, retrieve the appropriate Anterior Straddle Plate (flat or contoured) based on the patient's anatomy. To position the plate, palpate the medial and lateral margins of the talus and center the talar portion of the plate. Ensure that the proximal plate is midline or just lateral to midline. The nail should be located at the central aspect of the plate. Debride any irregular surface or remaining osteophytes at the joint that may interfere with plate fit.



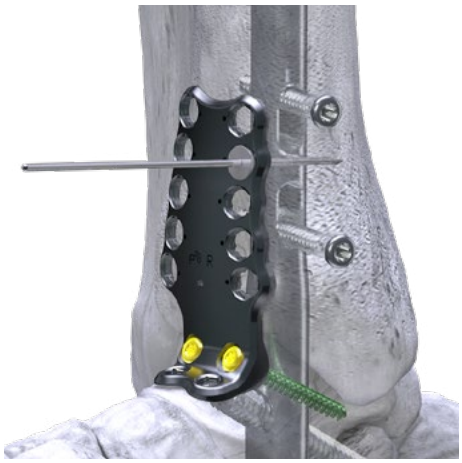
Secure the plate to the tibiotalar joint using a Long Olive Wire in the tibia and a Short Olive Wire in one of the talar neck screw holes. Confirm plate position using fluoroscopy.

PERMANENT FIXATION - PLATE SCREWS

Retrieve the Ø4.2 mm Threaded Drill Guide and thread into the talar body screw hole, opposite the medial or lateral Olive Wire in the talar neck screw hole. Drill, using the Ø2.8 mm Drill. Remove the Ø4.2 mm Threaded Drill Guide and measure screw length using the Depth Gauge. Confirm screw projection and length using the Depth Gauge under fluoroscopy (not shown).



Insert the selected locking or non-locking Ø4.2 mm screw into the plate hole using the provided Driver and Handle. Do not fully tighten the screw until the second talar body screw is secure, to prevent toggling of the plate. Remove the Olive Wire in the talar neck hole.



Insert a second Ø4.2 mm screw into the second talar body screw hole using the same procedure previously described. Complete tightening and seating of both talar body screws. Confirm screw length and placement using fluoroscopy.

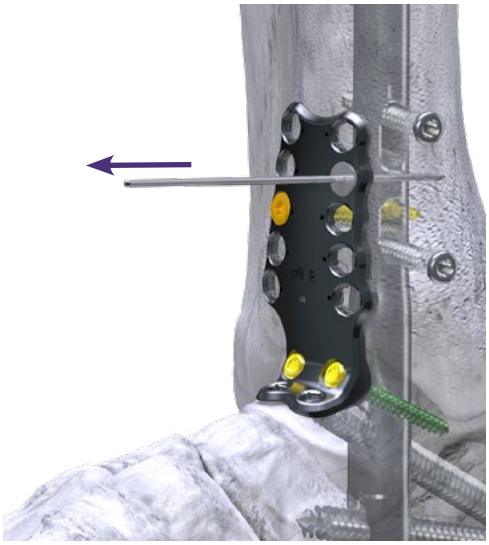
NOTE: The talar screw holes accept Ø3.5 mm or Ø4.2 mm non-locking and locking screws. Ø4.2 mm screws are recommended for this area, except in the case of a small patient. The use of Ø4.2 mm screws is demonstrated in this technique. When using Ø3.5 mm screws, use the appropriate instrumentation as described on page 4.

PERMANENT FIXATION - PLATE SCREWS

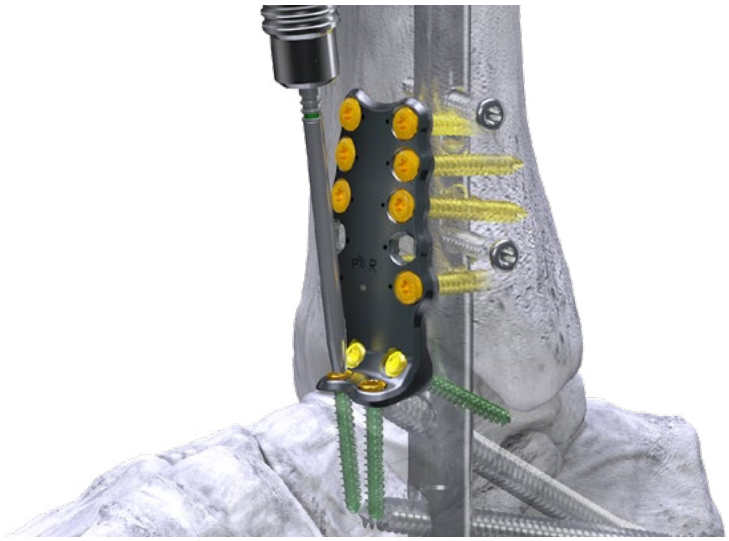
NOTE: The tibial screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm locking or non-locking screws. A laser etched dot on the plate indicates the plate holes that accept the Ø4.5 mm, Ø4.7 mm, and Ø5.2 mm screws. The technique demonstrates the use of the Ø4.5 mm screws. When using the Ø4.7 mm or Ø5.2 mm screws,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

Retrieve the Ø4.5 mm Threaded Drill Guide and insert into one of the circular screw holes on the tibia. Drill, using a Ø3.1 mm Drill through the Threaded Drill Guide.

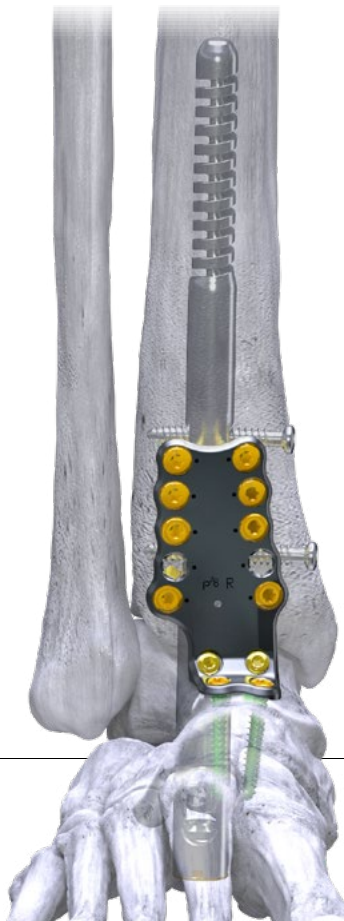
Remove the Threaded Drill Guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw.



Remove the Long Olive Wire. Insert the remaining tibial screws using the technique previously described for Ø4.5 mm screws. Confirm screw lengths and placement using fluoroscopy.



Insert two Ø4.2 mm screws into the talar neck holes using the same procedure previously described. Confirm all screw lengths and positions using fluoroscopy.



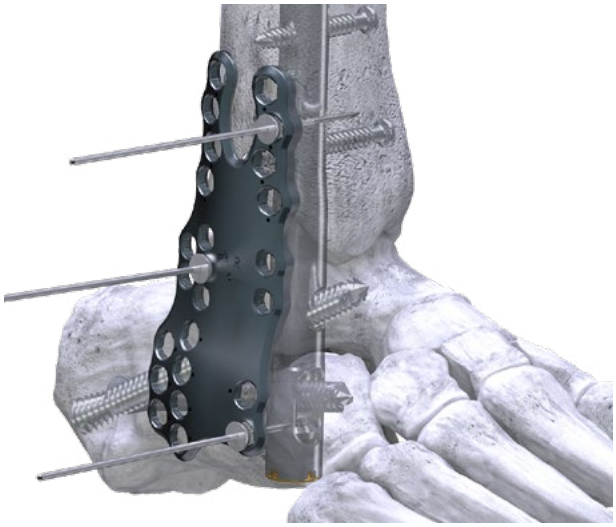
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

LATERAL TTC PLATE PLACEMENT

Following Phantom Hindfoot TTC/TC Nail placement using a lateral approach, ensure appropriate fibular resection by aligning the Lateral Tibiotalocalcaneal Straddle Plate over the lateral subtalar and tibiotalar joints. Perform additional fibula resection if interfering with the superior aspect of the plate.

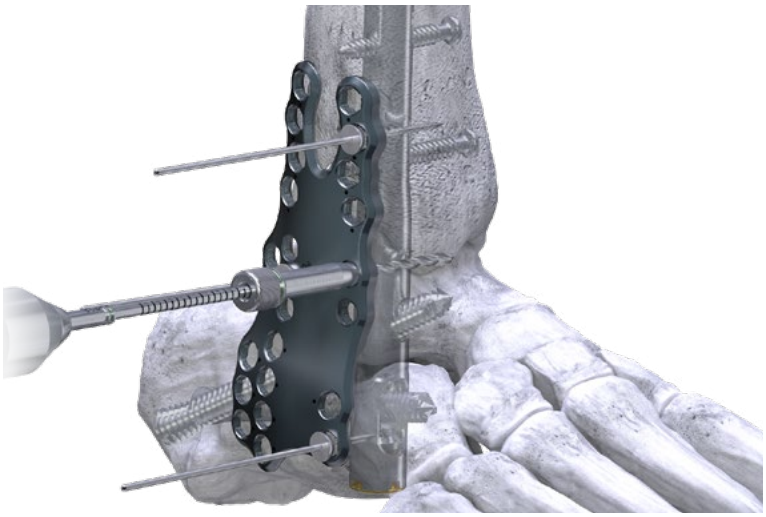
Resection of osteophytes or prominent bone such as the lateral talar process may be necessary to ensure proper plate fit. The plate should be positioned such that the proximal aspect is centered from anterior to posterior on the tibia, with the plate holes "straddling" the nail, if possible. Align the anterior and posterior talar hole clusters such that they straddle the nail, while avoiding the tibiotalar and subtalar joints, if possible. Position the calcaneal holes over the lateral calcaneus. If necessary, a saw can be used to smooth the bone surfaces to fit the contour of the plate.



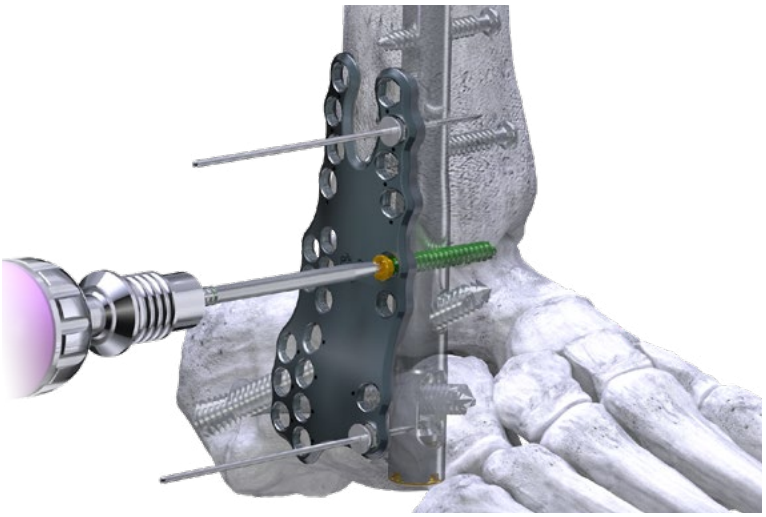
Secure the plate to the lateral aspect of the foot and distal tibia using a Long Olive Wire in a circular tibial hole and two Short Olive Wires, one in the talus and one in the calcaneus, as shown. Confirm plate position using fluoroscopy.

NOTE: The talar screw holes accept Ø3.5 mm or Ø4.2 mm non-locking and locking screws. The use of Ø4.2 mm screws is demonstrated in this technique. When using the Ø3.5 mm screws, use the appropriate instrumentation as described on page 4.

PERMANENT FIXATION – PLATE SCREWS

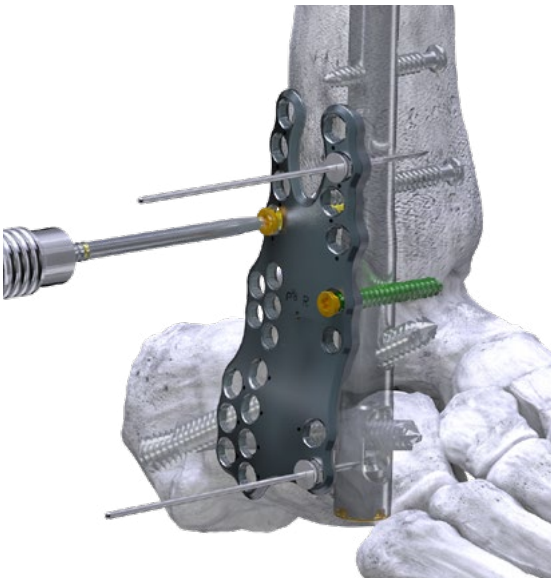


Retrieve the Ø4.2 mm Threaded Drill Guide and thread into a talar body screw hole. Drill, using the Ø2.8 mm Drill. Remove the Ø4.2 mm Threaded Drill Guide and measure screw length using the Depth Gauge.



Insert the selected screw into the plate hole using the provided Driver and Handle. To help prevent toggling of the plate, it may be beneficial to wait to fully seat the initial 2-3 screws placed into plate holes, to allow for even seating of the plate across the talus, tibia and calcaneus. Remove the Short Olive Wire from the talus.

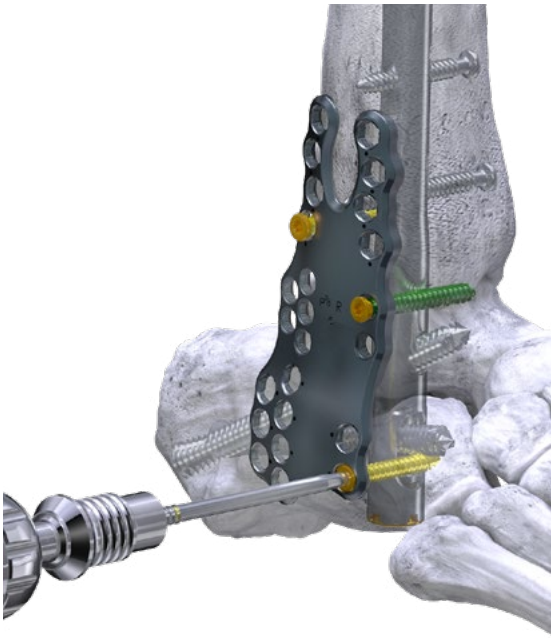
PERMANENT FIXATION – PLATE SCREWS



Retrieve the Ø4.5 mm Threaded Drill Guide and insert into a tibial circular hole. Drill, using a Ø3.1 mm Drill through the Threaded Drill Guide. Remove the Threaded Drill Guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw but do not fully seat.

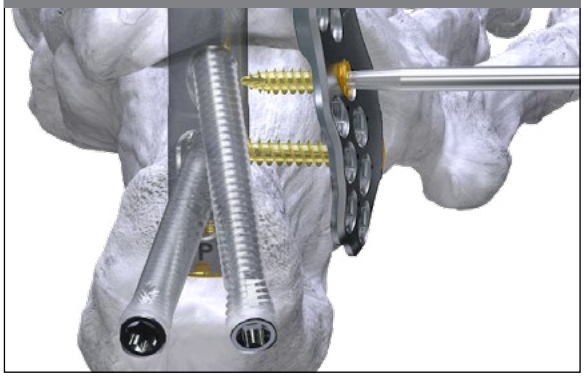
NOTE: Screw placement within the talus may be limited in cases of diseased or eroded tali.

NOTE: The tibial and calcaneal screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm 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 instructions provided below are for Ø4.5 mm screws. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.

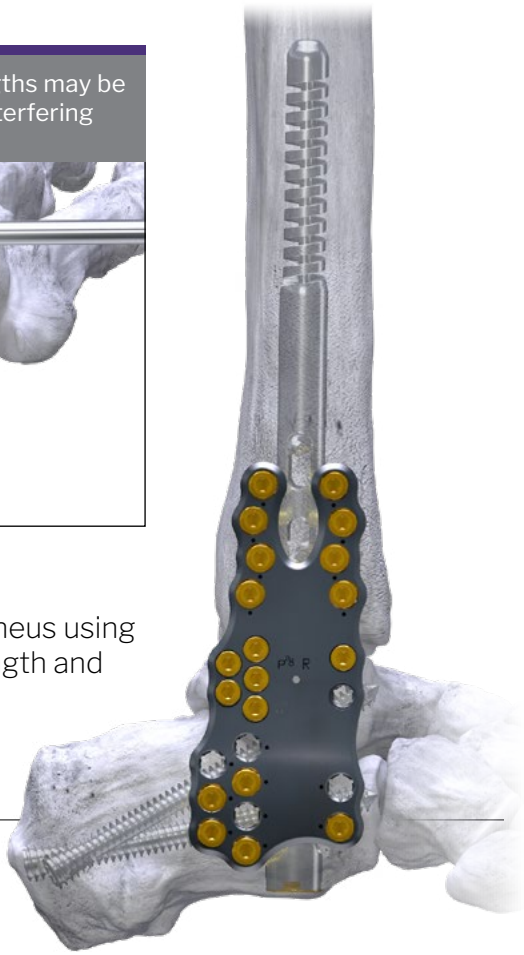


Retrieve a Threaded or Cone/Straight Easy Guide for a Ø4.5 mm screw, and secure to a preferred calcaneal screw hole. Drill, using a Ø3.1 mm Drill through the selected drill guide. Remove the drill guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw. At this time, it may be advantageous to seat all three screws, alternating between the screws in the talus, tibia, and calcaneus to evenly bring the plate into optimum contact with bone. Remove any Olive Wires at this time.

NOTE: Shorter screws lengths may be used as needed to avoid interfering with the Phantom Nail.



Complete screw placement in the tibia, talus, and calcaneus using the techniques previously described. Confirm screw length and position using fluoroscopy.



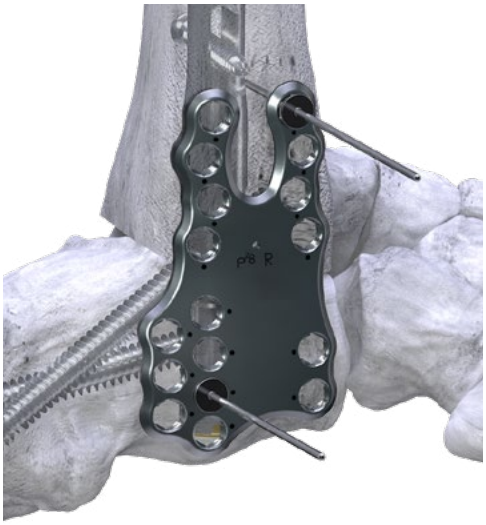
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

LATERAL TC PLATE PLACEMENT

Following Phantom Hindfoot TTC/TC Nail placement using a lateral approach, ensure appropriate fibular resection by aligning the Lateral Tibiocalcaneal Straddle Plate over the lateral tibiocalcaneal joint. Perform additional fibula resection if interfering with the superior aspect of the plate.

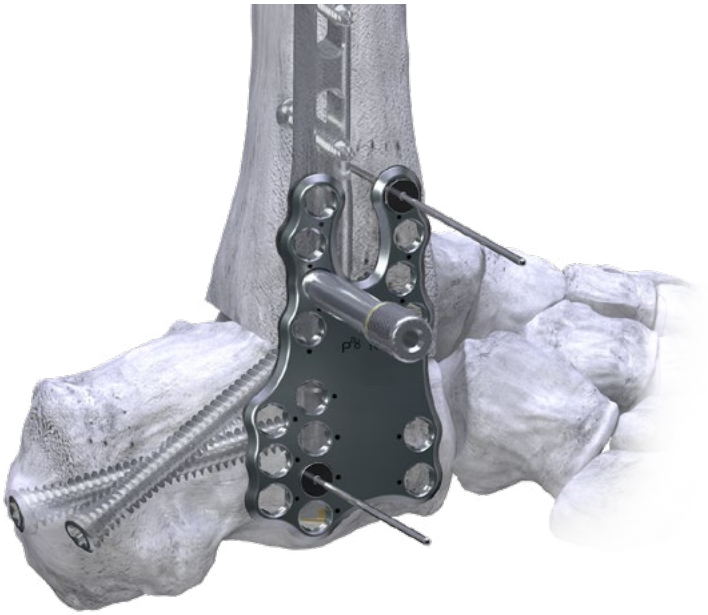
Resection of osteophytes or prominent bone such as the lateral talar process may be necessary to ensure proper plate fit. The plate should be positioned such that the proximal aspect is centered from anterior to posterior on the tibia, with the plate holes "straddling" the nail, if possible. Align the anterior and posterior talar hole clusters such that they straddle the nail, while avoiding the tibiotalar and subtalar joints, if possible, while positioning the calcaneal holes over the lateral calcaneus. If necessary, a saw can be used to smooth the bone surfaces to fit the contour of the plate.



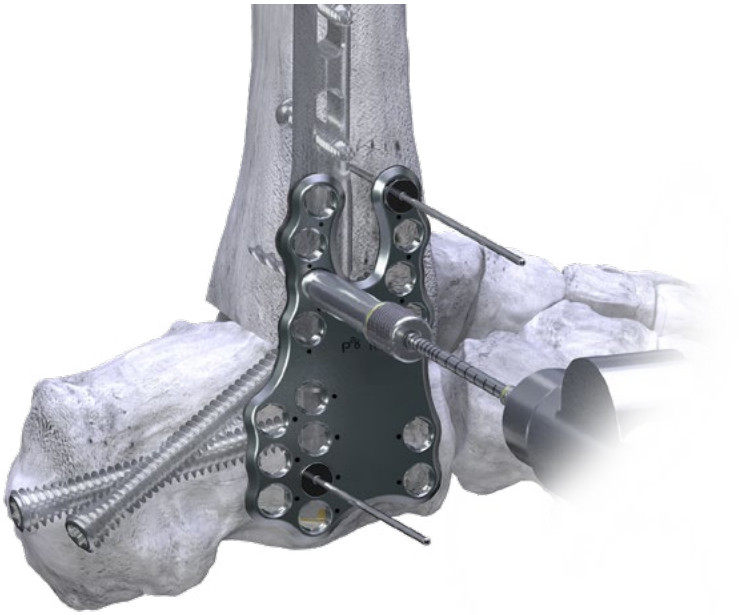
Secure the plate to the lateral aspect of the tibiocalcaneal joint using a Long Olive Wire in a circular tibial hole and a Short Olive Wires in the calcaneus, as shown. Confirm plate position using fluoroscopy.

NOTE: The tibial and calcaneal screw holes accept Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm 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 instructions provided below are for Ø4.5 mm screws. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.

PERMANENT FIXATION – PLATE SCREWS

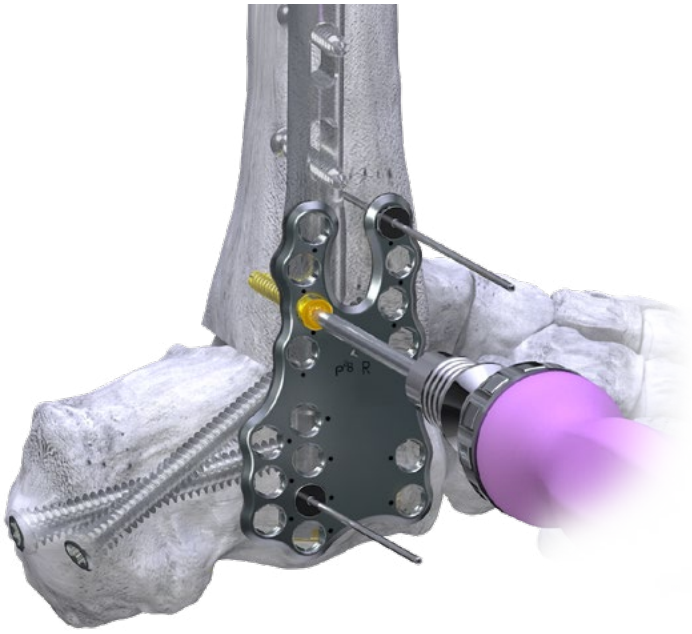


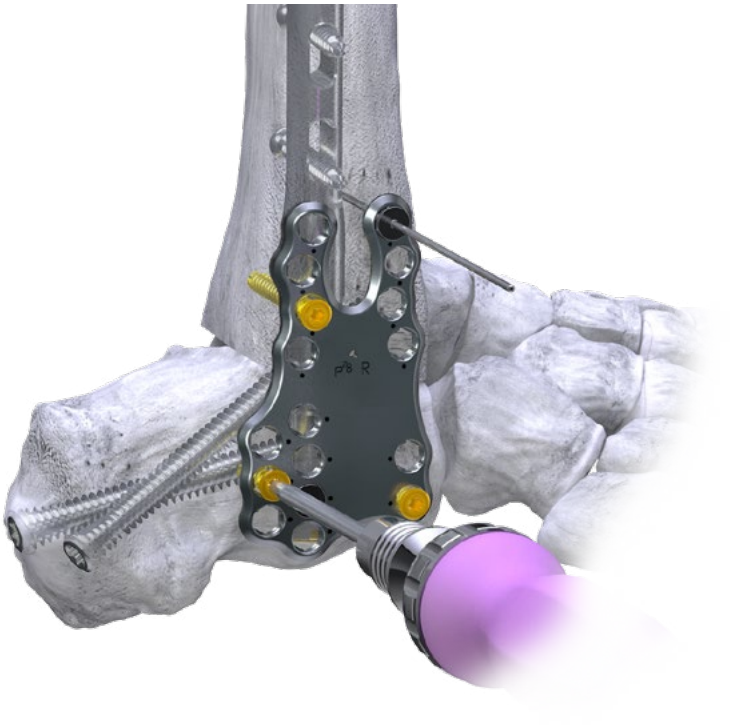
Retrieve the Ø4.5 mm Threaded Drill Guide and insert into the tibial circular hole.



Drill, using a Ø3.1 mm Drill through the Threaded Drill Guide. Remove the Threaded Drill Guide and measure screw length using the Depth Gauge.

PERMANENT FIXATION – PLATE SCREWS

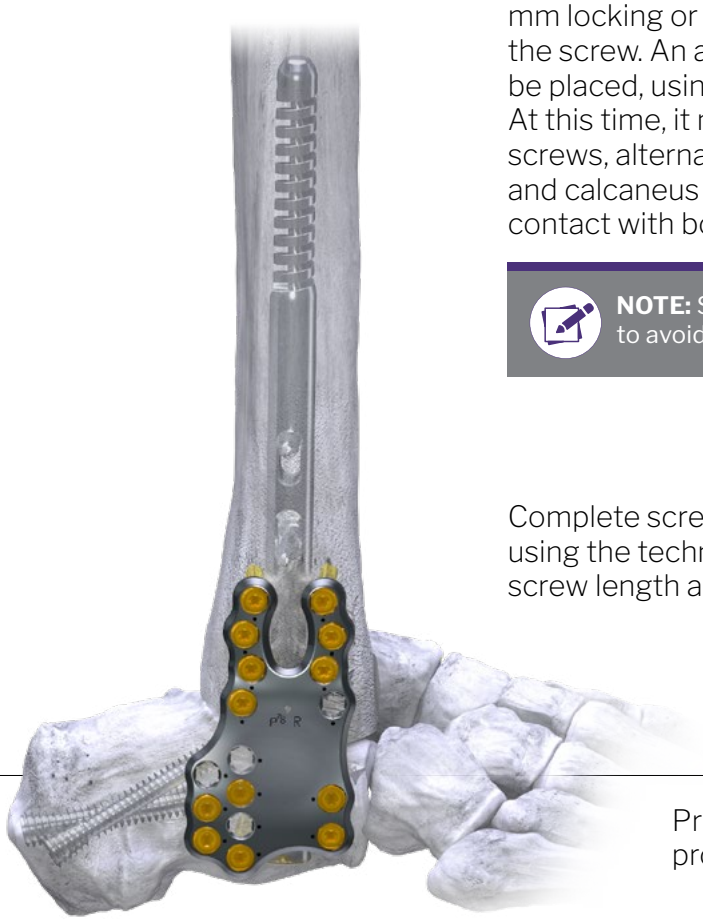




Insert a Ø4.5 mm, Ø4.7 mm, or Ø5.2 mm locking or non-locking screw, per surgeon preference. Do not fully seat the tibial screw until a second screw has been placed in the calcaneus to avoid toggling of the plate.

Retrieve a 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, without fully seating the screw. An additional tibia or calcaneal screw can be placed, using the technique previously described At this time, it may be advantageous to seat the screws, alternating between the screws in the tibia and calcaneus to evenly bring the plate into optimum contact with bone. Remove any Olive Wires at this time.

NOTE: Shorter screws lengths may be use as needed to avoid interfering with the Phantom Nail.



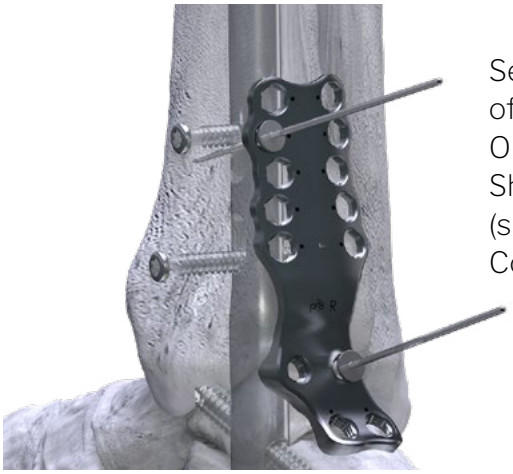
Complete screw placement in the tibia and calcaneus using the techniques previously described. Confirm screw length and position using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

POSTERIOR TTC PLATE PLACEMENT

Following Phantom Hindfoot TTC/TC placement using a posterior approach, resection of osteophytes or prominent bone may be necessary to ensure proper plate fit. Retrieve the appropriate Posterior Straddle Plate (flat or contoured) based on the patient's anatomy. To position the plate, center the talar portion of the plate on the talus, while ensuring that the proximal plate is midline or centered over the nail. The distal plate should be centered over the superior calcaneus and brought inferiorly to contact the bone surface. Debride any irregular surface or remaining osteophytes at the joint that may interfere with plate fit.

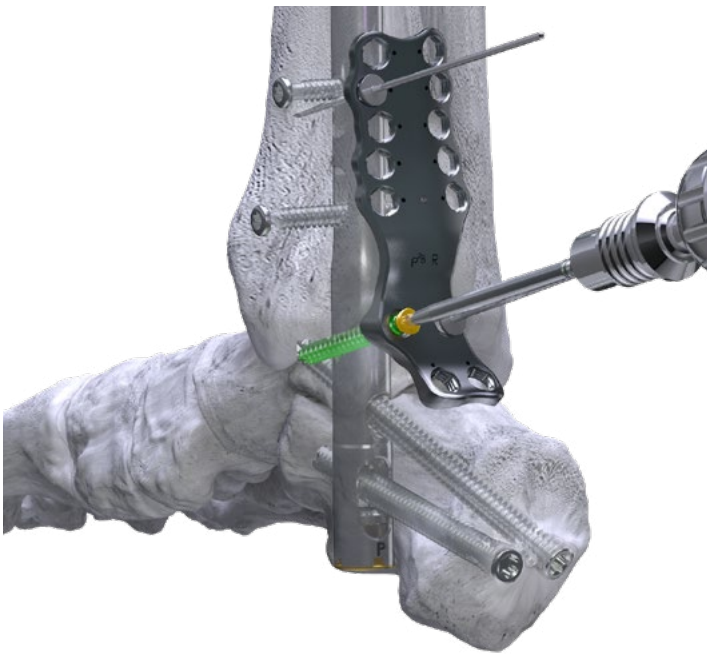


Secure the plate to the posterior aspect of the tibiotalocalcaneal joint using a Long Olive Wire in a circular tibial hole and a Short Olive Wire in the medial or lateral (shown) talar hole, per surgeon preference. Confirm plate position using fluoroscopy.

PERMANENT FIXATION – PLATE SCREWS

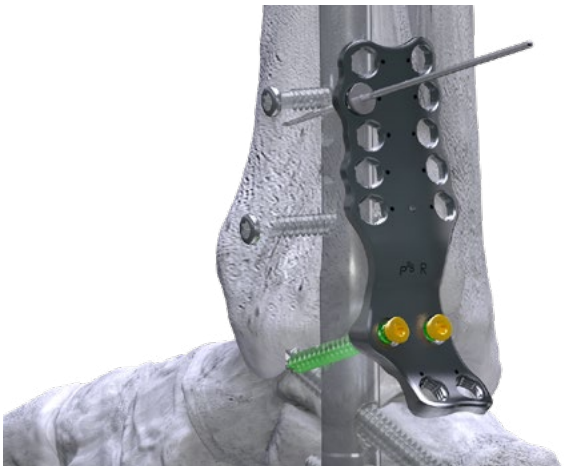
Retrieve the Ø4.2 mm Threaded Drill Guide and thread into the talar screw hole. Drill, using the Ø2.8 mm Drill.

NOTE: The talar screw holes accept Ø3.5 mm or Ø4.2 mm non-locking and locking screws. The use of Ø4.2 mm screws is demonstrated in this technique. When using the Ø3.5 mm screws, use the appropriate instrumentation as described on page 4.



Remove the Ø4.2 mm Threaded Drill Guide and measure screw length using the Depth Gauge. Insert the selected screw into the plate hole using the Driver and Handle. Do not fully tighten the talar screws to prevent toggling of the plate.

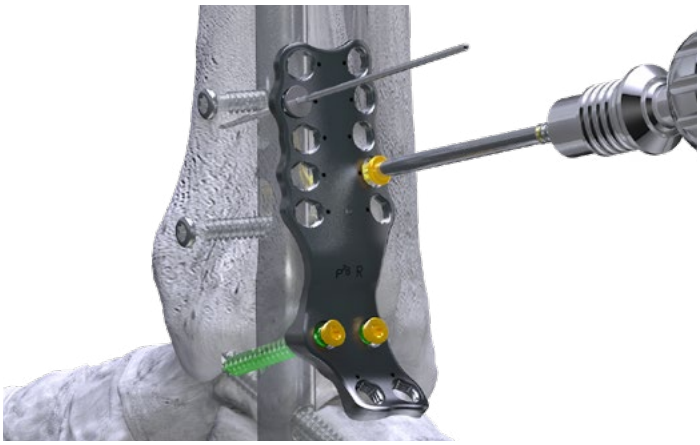
PERMANENT FIXATION – PLATE SCREWS



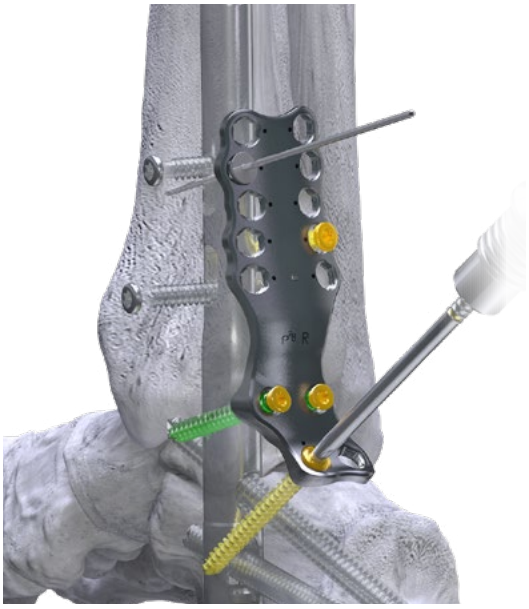
Remove the adjacent Olive Wire from the lateral talar body. Insert the remaining locking or non-locking talar screw, per surgeon preference. To help prevent toggling of the plate, it may be beneficial to wait to fully seat the initial 3-4 screws placed into plate holes, to allow for even seating of the plate across the talus, tibia and calcaneus.

NOTE: The tibial and calcaneal screw holes accept Ø4.5, Ø4.7 mm, or Ø5.2 mm 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 instructions provided below are the Ø4.5 screws. When using the Ø4.7 mm or Ø5.2 mm screws, use the appropriate instrumentation as described on page 4.

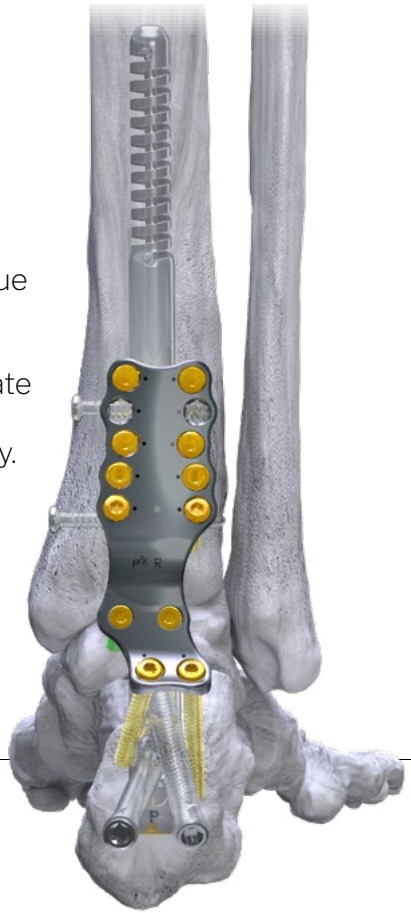
Retrieve the Ø4.5 mm Threaded Drill Guide and insert into the tibial circular hole. Drill, using a Ø3.1 mm Drill through the Threaded Drill Guide. Measure screw length using the Depth Gauge.



Insert a Ø4.5 mm locking or non-locking screw, but do not fully seat.



Insert a Ø4.5 mm locking or non-locking screw in the calcaneus using the technique previously described. Seat all screws in an alternating fashion, to allow maximum plate contact with bone. Fill remaining plate screw holes, as desired. Confirm screw position and placement using fluoroscopy.

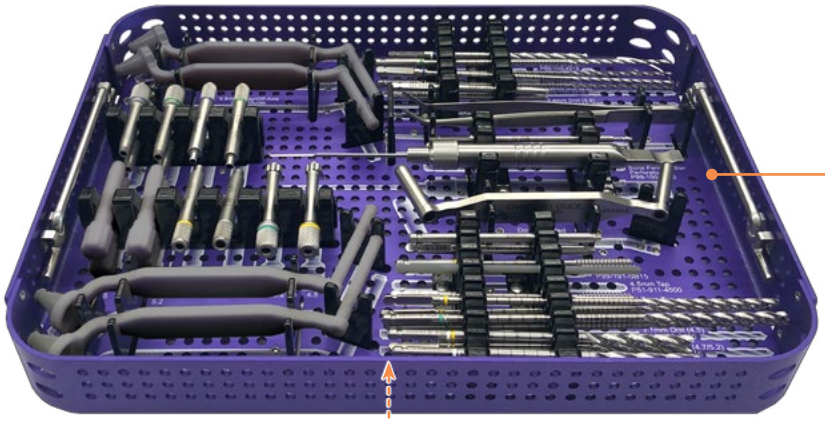


CLOSURE

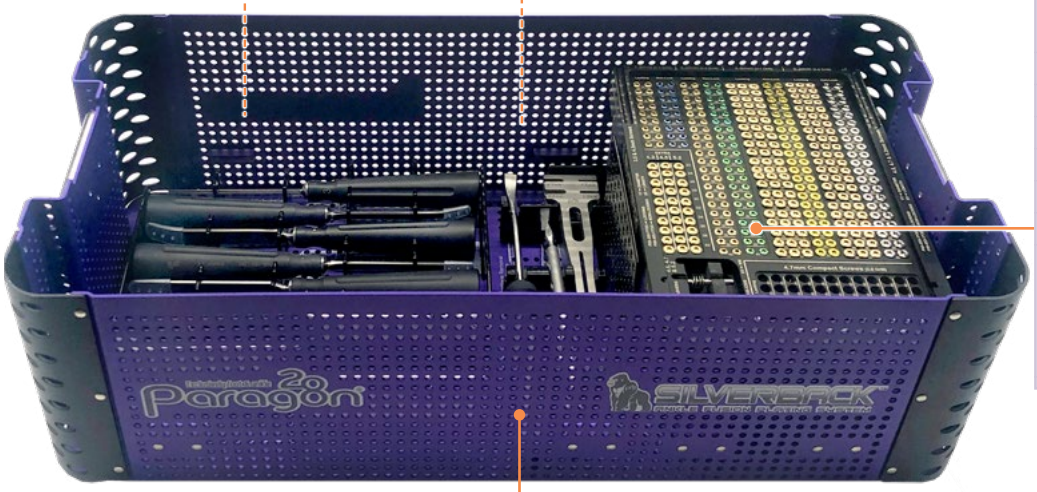
Proceed to incision closure or concomitant procedures at this time.

Silverback™ Straddle Plate Caddy
Flat and contoured Anterior and Posterior Plates as well as Lateral TC and TTC Plates are located within the Straddle Plate Caddy. The caddy also contains Ø4.2, Ø4.5 and Ø5.2 mm locking and non-locking screws in lengths of 10 and 12 mm.

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: BABY GORILLA®/GORILLA® PLATING SYSTEM

The 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, distal fibula, talus, and calcaneus. The system can be used in both adult and pediatric patients.

In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, 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 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®, 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.
- Patient risk as a result of the Baby Gorilla®/Gorilla® Plating System in the MR environment has been minimized.
- **Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.**
- **Do not implant the instruments.**

MR SAFETY INFORMATION

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

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

INDICATIONS FOR USE: MONSTER® SCREW SYSTEM

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

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
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WARNINGS AND PRECAUTIONS

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- 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 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.

SILVERBACK™
ANKLE FUSION PLATING SYSTEM

GORILLA®
R3CON PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P51-STG-3012 Rev A [2023-02-10]

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DISCLAIMER

The purpose of the SILVERBACK™ Straddle Plate Surgical Technique Guide is to demonstrate the optionality and functionality of the SILVERBACK™ Ankle Fusion Plating System and Gorilla® R3CON Plating System. Although variations in placement and use of the SILVERBACK™ Straddle 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.