



SILVERBACK™

ANKLE FUSION PLATING SYSTEM



SURGICAL TECHNIQUE GUIDE

Span Plating System

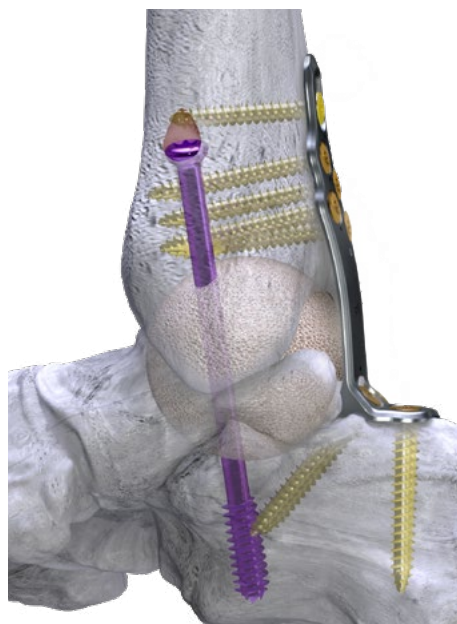
PRODUCT DESCRIPTION

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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SPAN PLATES

Available in Right (shown) and Left Configurations

Anterior Span Plates

Standard



25 mm

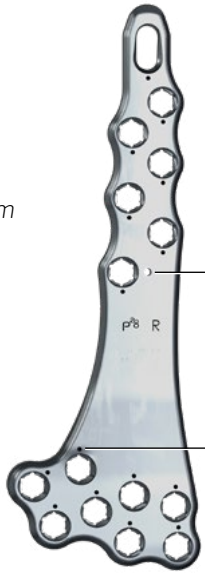
Long



31 mm

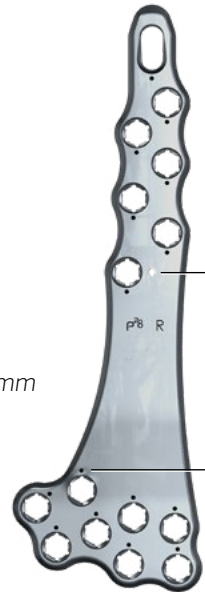
Lateral Span Plates

Standard



38 mm

Long



43 mm

Posterior Span Plates

Standard



25 mm

Long



31 mm

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



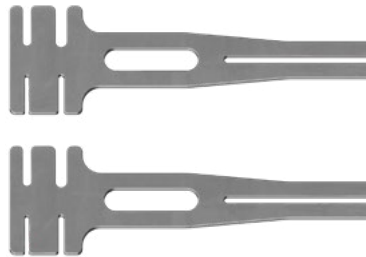
Overdrill Guide



AO Handles



Flat Plate Benders



Threaded Plate Bending Bars



Olive Wire, Short (Smooth and Threaded)



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.

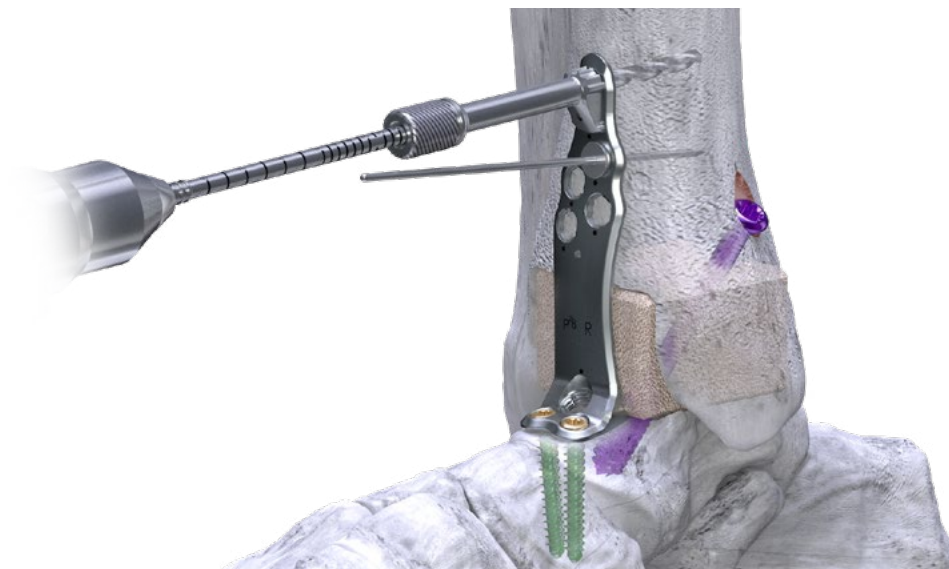


NOTE: It is recommended for all talar screw holes to use the appropriate Locking Drill Guide to achieve on-axis trajectory.

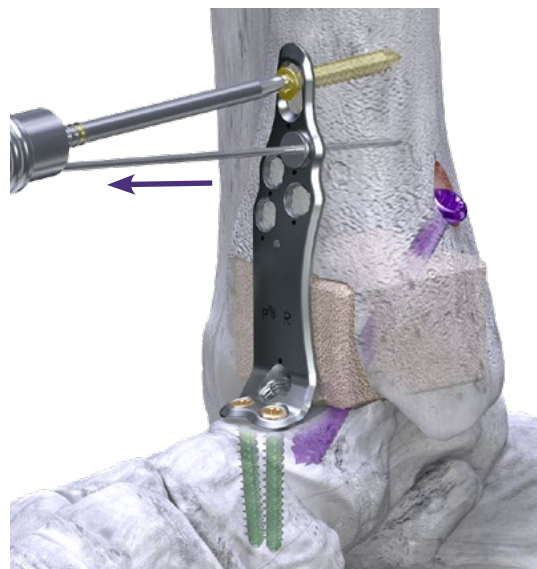


Insert the selected locking or non-locking Ø4.2 mm screw into the talar neck plate hole. Use the provided Driver and Handle to partially seat the first screw. Do not fully seat the first talar screw to avoid toggling of the plate. Remove the Olive Wire from the talus and insert the second talar neck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

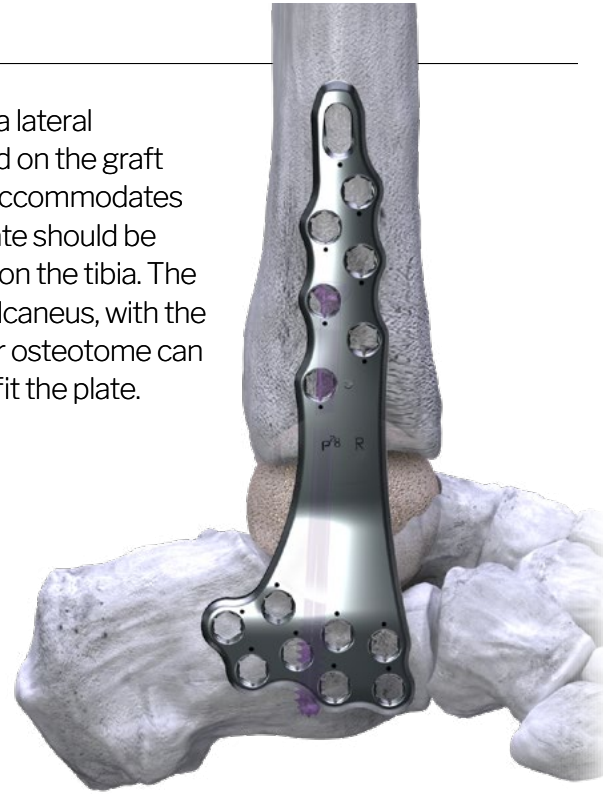
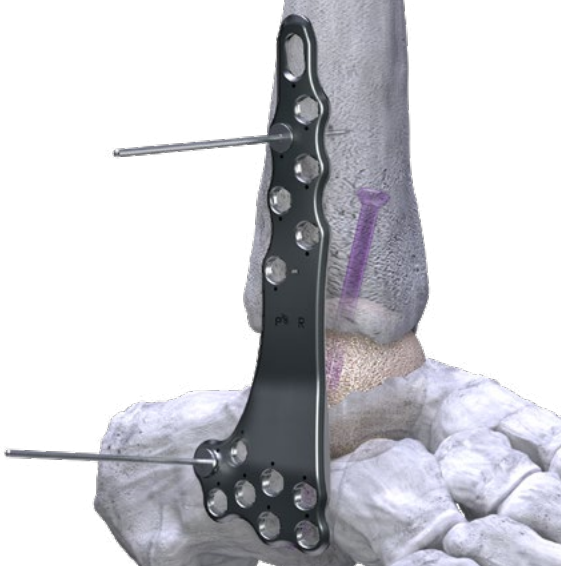


CLOSURE

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.

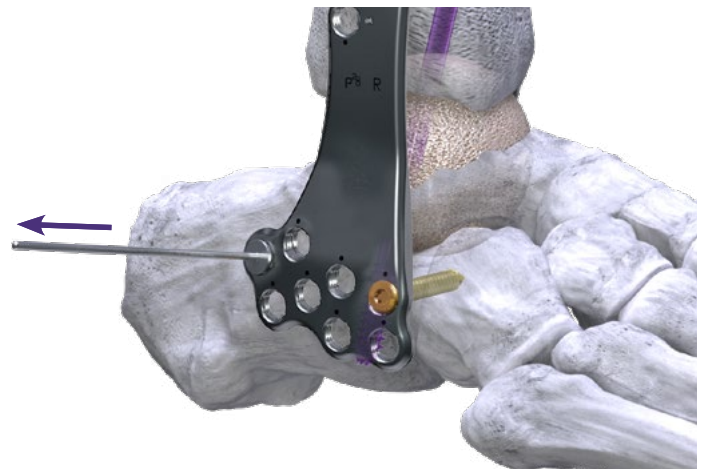
PERMANENT FIXATION – PLATE SCREWS



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.

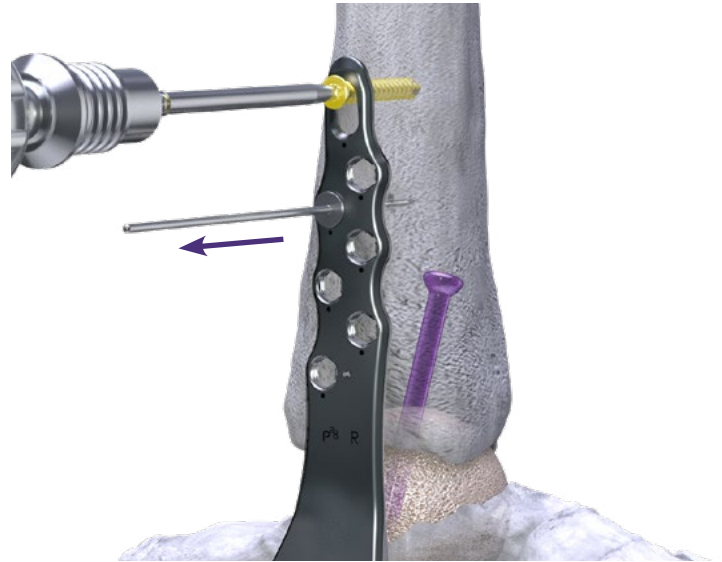


Remove the drill guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw. Remove the Olive Wire from the calcaneus at this time. Per surgeon preference, a second screw may be placed in the calcaneus for additional stability of the plate prior to placing a compression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

PERMANENT FIXATION – PLATE SCREWS

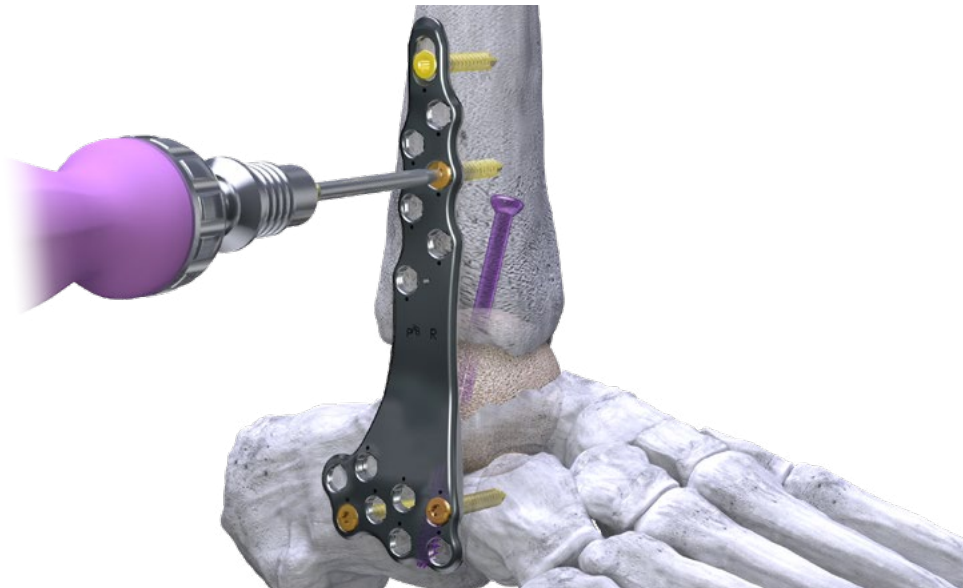


Retrieve the Ø4.5 mm Compression Slot Drill Guide and insert into the tibial compression slot with the arrow pointing toward the tibia-allograft interface. Drill, using a Ø3.1 mm Drill through the Compression Slot Drill Guide.



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.

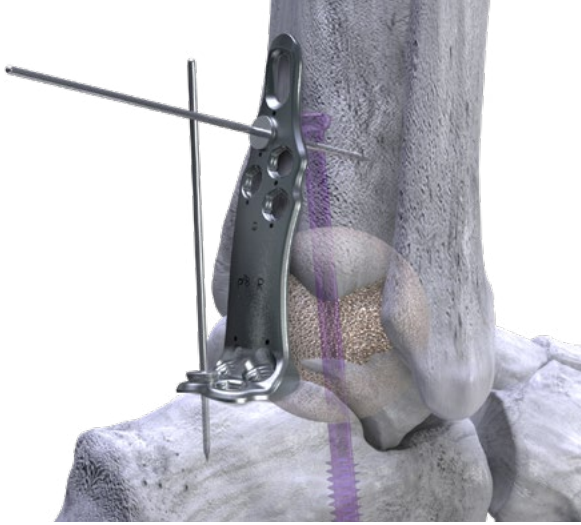
CLOSURE

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.

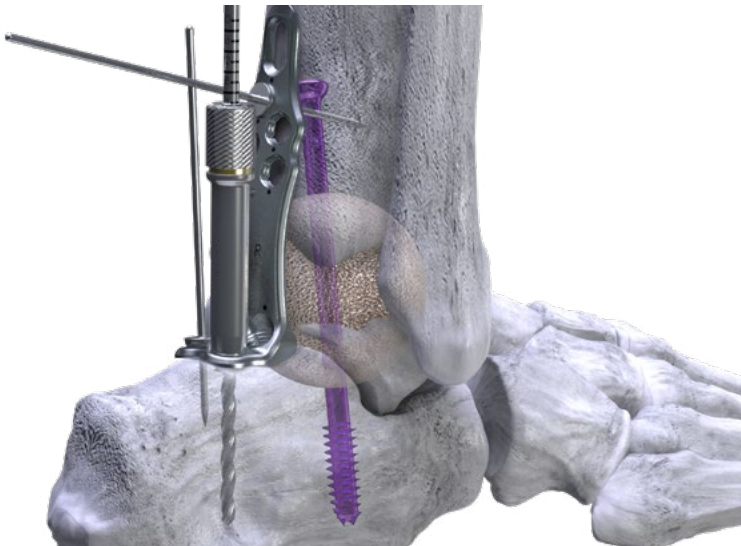


Secure the plate to the tibia and calcaneus using a Long Olive Wire in a calcaneal screw hole and a Long Olive Wire in a circular screw hole of the tibia, per surgeon preference. Confirm plate position using fluoroscopy.

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.

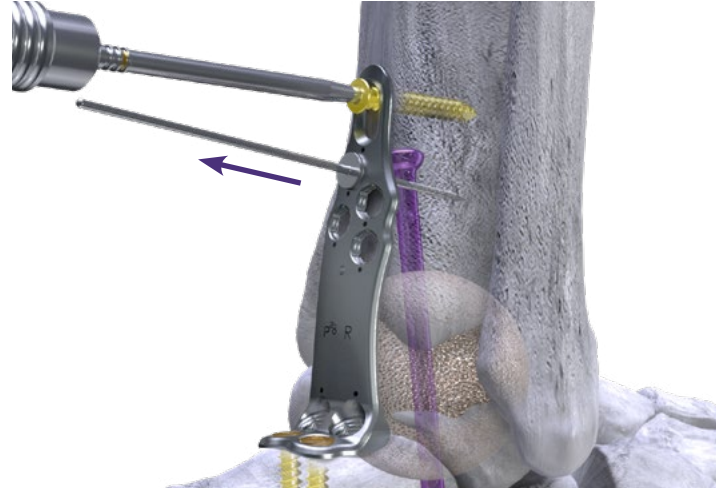


Remove the drill guide and measure screw length using the Depth Gauge. Insert a Ø4.5 mm locking or non-locking screw. Do not fully seat the screw to avoid toggling of the plate. Remove the calcaneal Olive Wire and repeat process for the other posterior calcaneal screw hole. Fully seat screws at this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

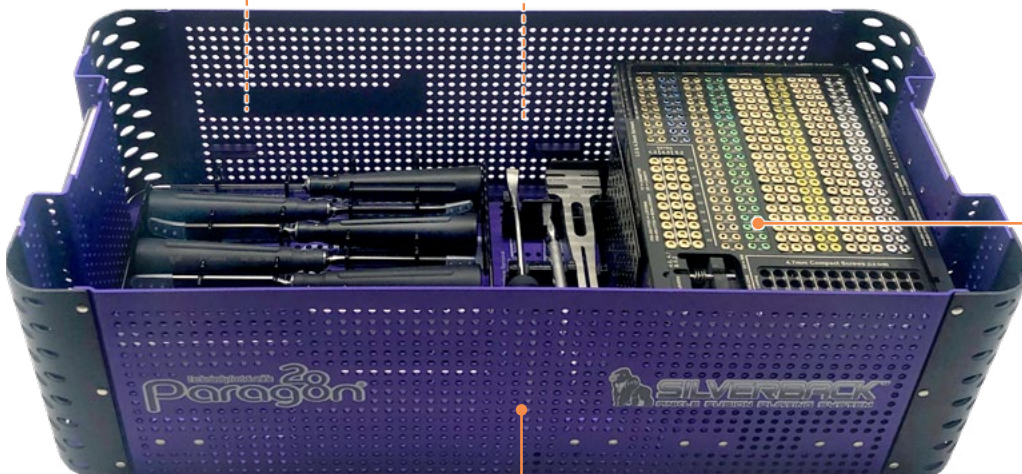
Silverback™ K-wire and Olive Wire Caddy

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™ 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.

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

INSTRUCTIONS FOR USE: BABY GORILLA®/GORILLA® PLATING SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Baby Gorilla®/Gorilla® Plating System are contained in the Instructions for Use document of the Baby Gorilla®/Gorilla® Plating System P51-IFU-3001.

A patient with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Name/Identification of Device	Paragon 28® Baby Gorilla®/Gorilla® Plating System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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

INSTRUCTIONS FOR USE: MONSTER®/MINI-MONSTER® SCREW SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Monster® Screw System are contained in the Instructions for Use document of the Monster® Screw System P20-IFU-3001.



A patient with the Paragon 28® Monster® Screw System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Monster® Screw System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 20 mm
If information about a specific parameter is not included, there are no conditions associated with that parameter.	



SILVERBACK™
ANKLE FUSION PLATING SYSTEM



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Paragon²⁸

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