Paragon 28®

SURGICAL TECHNIQUE GUIDE

Gorilla® Pilon Fusion Plating System

GORILLA® ANKLE FRACTURE 360™

PRODUCT DESCRIPTION:

Paragon 28® designed the Gorilla® Pilon Fusion Plating System to provide surgeons versatility in fixation selection for pilon fusion procedures.. The system has 6 plate options for anterior and medial fixation of the tibia and talus for a pilon fusion. All circular plate holes accept Ø2.7 mm, Ø3.5 mm and Ø4.2 mm locking and non-locking screws.

A Ø3.5 mm Compact Screw is available in locking and non-locking screws in 10-40 mm lengths to address dense bone in the proximal tibia. The Compact Screw 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 screw into the plate in areas of dense bone.

Instrumentation is included in the Gorilla® Ankle Fracture Plating System that facilitates reduction and fixation of ankle fractures.

CONTENTS:

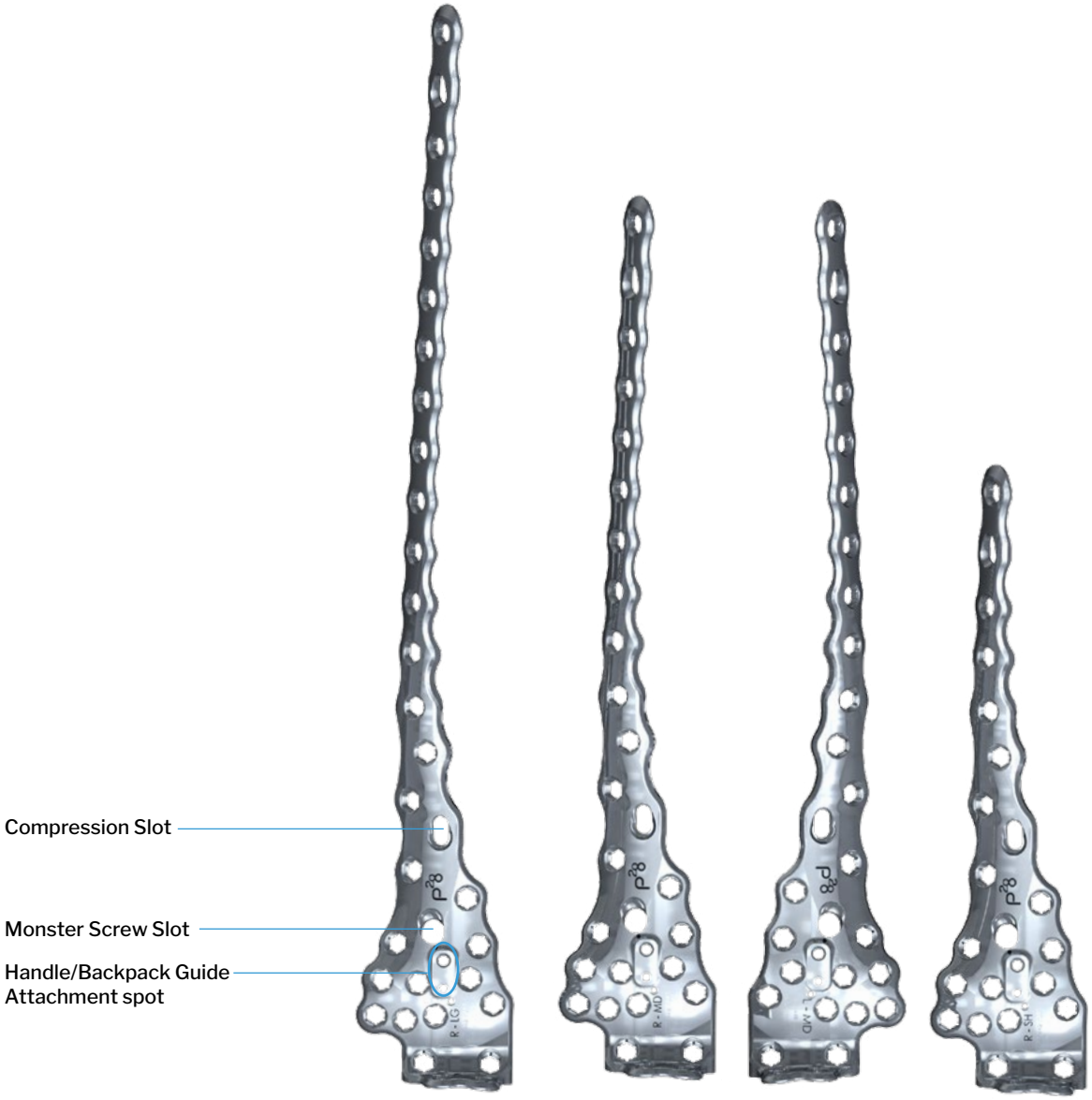
ACKNOWLEDGMENT:

Paragon28® would like to thank Clayton Bettin, M.D., John Kwon, M.D., Eric Moghadamian, M.D., and Aaron Perdue, M.D. for their contribution to the development of the surgical technique guide.

IMPLANT OFFERING:

ANTEROLATERAL PILON FUSION PLATE

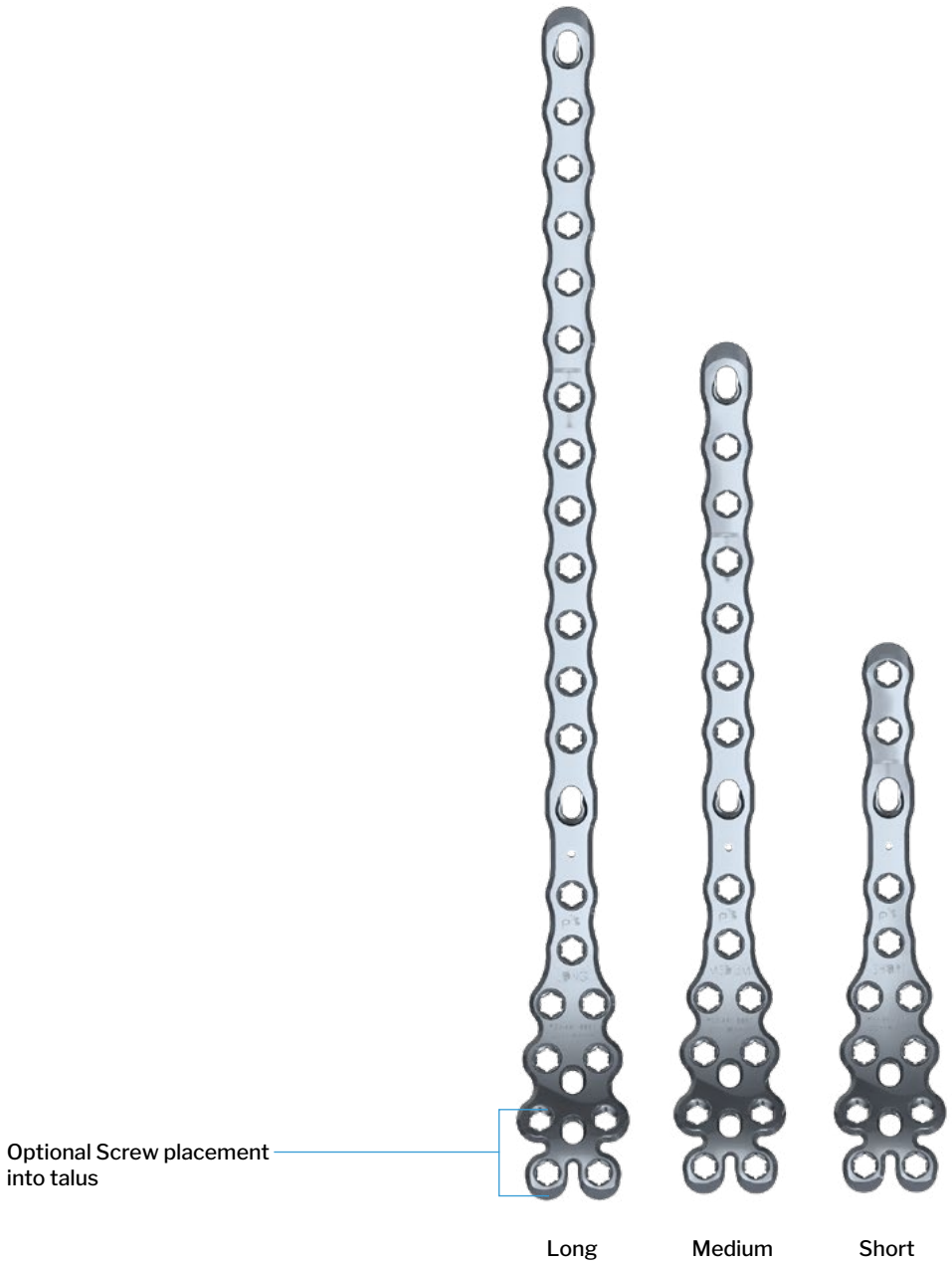
- Offered in 3 sizes –Short, Medium, Long
- Left/Right Specific
- Designed to contour to anterolateral face of distal tibia
- Features optional compression slot and allows for placement of a Ø5.5 Monster® screw through the plate and across the tibiotalar joint
- Compatible with an optional Backpack Guide and Drill Guides that allows nominal trajectory screw placement in the distal cluster



IMPLANT OFFERING:

MEDIAL PILON FUSION PLATE- Supplemental (Use in conjunction with Anterolateral Plate for Pilon Fusion)

- Offered in 3 sizes –Short, Medium, Long
- Universal for left or right
- Designed to contour to medial malleolus and medial tibia
- Compatible with provided plate bending instrumentation for patient specific side contouring along the length of the medial tibia
- Distal portion of the plates allows for optional screw placement from the medial malleolus into the talus



FEATURED INSTRUMENTATION:


Proximal Trocar


Proximal Drill Guide


Assembled Proximal Trocar and Drill Guide

Proximal Screw Driver


Depth Gauge


Reciprocating Rasp (Compatible with Stryker Power System)


King Cobra™ Cartilage Removal Tool


Monster K-wire Guide


K-wire and Drill Guide Assembly


Monster Drill Guide


Backpack Drill Guide

Optional* Backpack Guide


Thread Attachment Rod


Plate Handle


Bone Fenestration Perforator


Curved Bone Fenestration Chisel

NOTE: Additional wires, olive wires, fracture reduction instrumentation, joint preparation instrumentation, plate bending instrumentation and drills/drill guides are offered in the AF360 instrumentation case.

SCREW OFFERING AND INSTRUMENTATION MATRIX

	Ø2.7 mm R3CON Screws	Ø3.5 mm R3CON Screws	Ø4.2 mm R3CON Screws	Ø3.5 mm Compact Screws
Locking:				
Non-locking:				
Screw Lengths:	8 mm - 20 mm in 1 mm increments 20 - 54 mm in 2 mm increments 56 mm - 70 mm in 2 mm increments **(Non-locking ONLY)** 70 mm - 75 mm in 5 mm increments **(Non-locking ONLY)**	8 mm - 60 mm in 2 mm increments 60 mm - 70 mm in 5 mm increments 75 mm - 100 mm in 5 mm increments **(Non-locking ONLY)**	8 mm - 60 mm in 2 mm increments 60 mm - 70 mm in 5 mm increments	10 mm - 40 mm in 2 mm increments
Drill Size:	 Ø2.0 mm	 Ø2.4 mm	 Ø2.8 mm	 Ø2.8 mm
Driver Size:	 HX-10	 HX-10	 HX-10	 HX-10
Locking Drill Guide Size:	 Ø2.7mm	 Ø3.5 mm	 Ø3.5 mm C / Ø4.2 mm	 Ø3.5 mm C / Ø4.2 mm
Centering Drill Guide Size:	 Ø2.7mm	 Ø3.5 mm	 Ø4.2 mm	 Ø3.5 mm
Compression Slot Drill Guide Size:	 Ø2.7mm	 Ø3.5 mm	 Ø3.5 mm C/ Ø4.2 mm	 Ø3.5mm C/ Ø4.2 mm
Cone/Straight Easy Guide Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø3.5 mm C/ Ø4.2 mm	 Ø3.5 mm C/ Ø4.2 mm
Tap Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm	 Ø3.5 mm C
OverDrill Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm	 Ø3.5 mm C
Double Ended Drill / Over Drill Guides:	Ø2.0 mm	Ø2.4 mm	Ø2.8 mm	Ø2.8 mm
Drill Sleeve (for use with Double Ended Guide):	Ø2.0 mm Drill / Ø2.7 mm Over Drill	Ø2.4 mm Drill / Ø3.5 mm Over Drill	Ø2.8 mm Drill / Ø4.2 mm Over Drill	Ø2.8 mm Drill / Ø4.2 mm Over Drill

	Ø4.0 mm Mini-Monster Cannulated Screws
Headed, Long Thread:	
Screw Lengths:	24 mm - 50 mm in 2 mm increments 50 mm - 60 mm in 5 mm increments
Drill Size:	Ø2.6 mm
Driver Size:	HX-10
Drill Guide Size:	Ø4.0 mm
Headed Countersink Size:	Ø4.0 mm
Tap Size:	Ø4.0 mm
Over Drill Size:	Ø4.0 mm
Over Drill Guide Size:	Ø4.0 mm
K-wire Size:	Ø1.2 mm x 15 cm

ANTEROLATERAL PILON FUSION PLATE

INCISION

Pre-operative planning should be performed prior to the surgery, including evaluation of soft tissue condition, and review of radiographs and/or advanced imaging to determine approach and internal fixation needs. An anterior (shown) or anterolateral approach is recommended with supine patient positioning, although an anteromedial approach can be utilized depending on fracture morphology. Instrumentation is provided to assist with cartilage removal from the talus and tibia and a fresh scalpel can be used to remove cartilage from small loose articular fracture fragments.

For pilon fractures, it is recommended to restore large metadiaphyseal pieces together with provisional screw and/or wire fixation per surgeon preference.

Reciprocating Rasp

King Cobra™ Cartilage Removal Tool

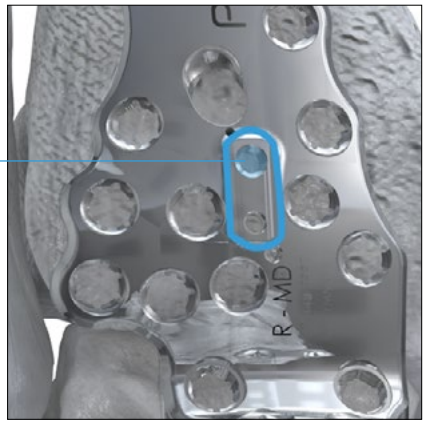
NOTE: Autograft, allograft, or other biologics (e.g. V92) per surgeon preference are recommended to be used before plate placement.

ANTEROLATERAL PILON FUSION PLATE

Plate Handle

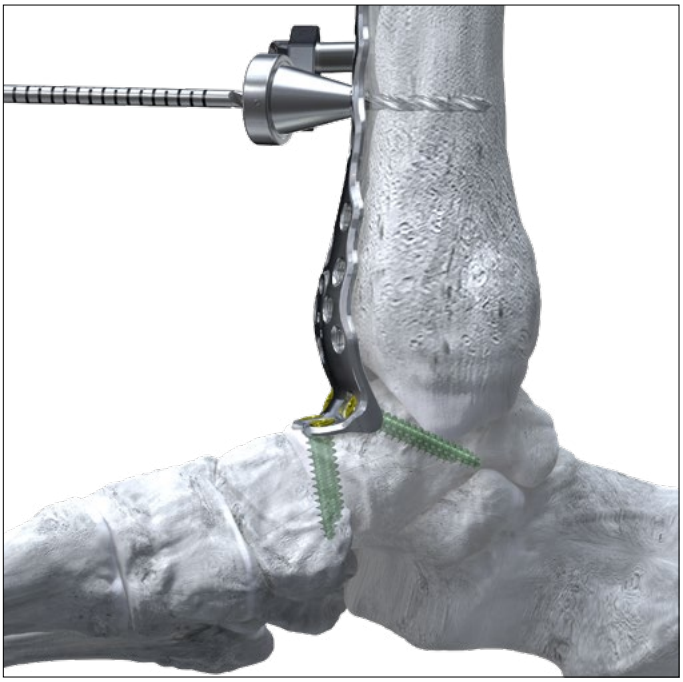
Thread Attachment

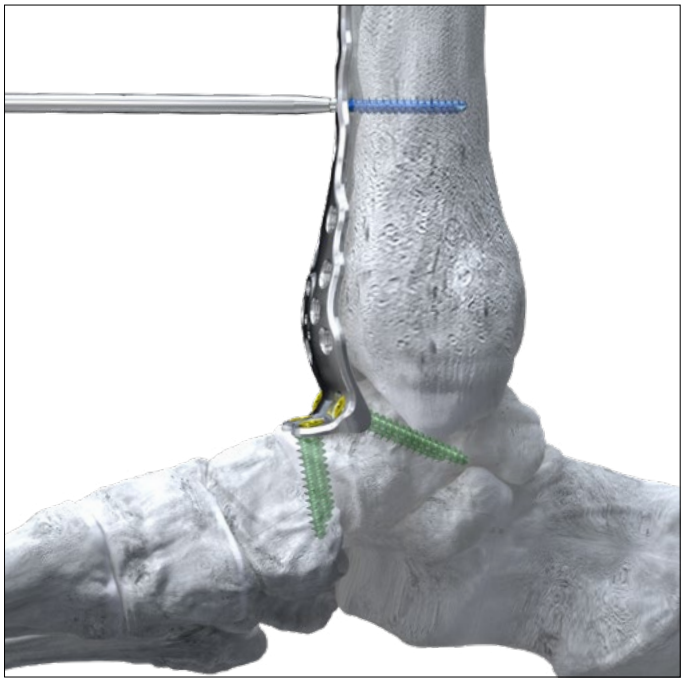
Use the provided instrumentation (Lagenbeck Elevator) to elevate the soft tissues along the length of the anterolateral tibial crest for the intended plate to be used. Retrieve the appropriate length Anterolateral Plate. Attach the handle onto the plate by threading the thread attachment rod through the handle and into the plate. Depending on the approach type, plate size, and/or patient anatomy the handle can be used on the medial or lateral side of the anatomy. When placing the plate, ensure the plate is contacting both the proximal lateral and distal anterior surface of the tibia and is not in floating in the soft tissue. Confirm the plate is positioned appropriately on the talus. Confirm plate placement using fluoroscopy. If provisional fixation of the plate to bone is preferred, olive wires are available to place within the screw holes.



ANTEROLATERAL PILON FUSION PLATE

After temporarily securing the plate position with olive wires and confirming position, unthread and remove the handle from the plate. Continue with drilling and placing appropriately sized screws according to surgeon preference in the distal portion of the plate.





ANTEROLATERAL PILON FUSION PLATE

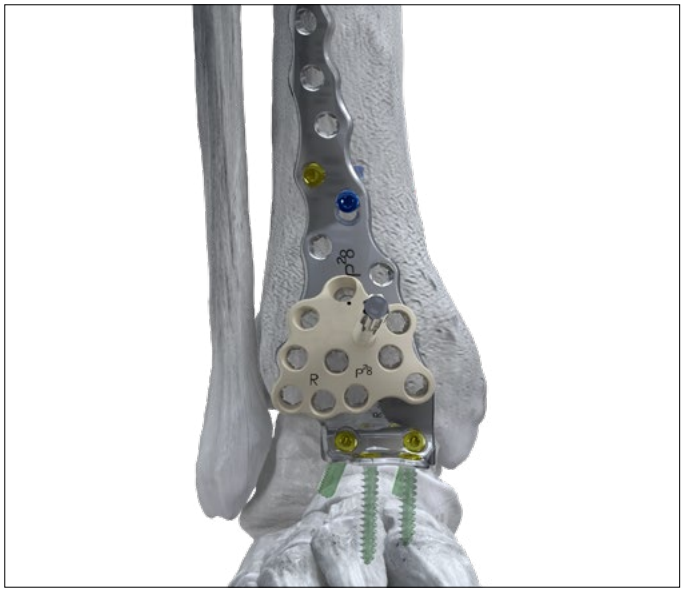
OPTIONAL BACKPACK GUIDE USE

If using the optional Backpack Guide, it can be attached to the plate using the same threaded attachment rod as used with the handle. Place the Backpack drill guide into the Backpack Guide to guide drills at a nominal trajectory with respect to the plate using the backpack drill guides.

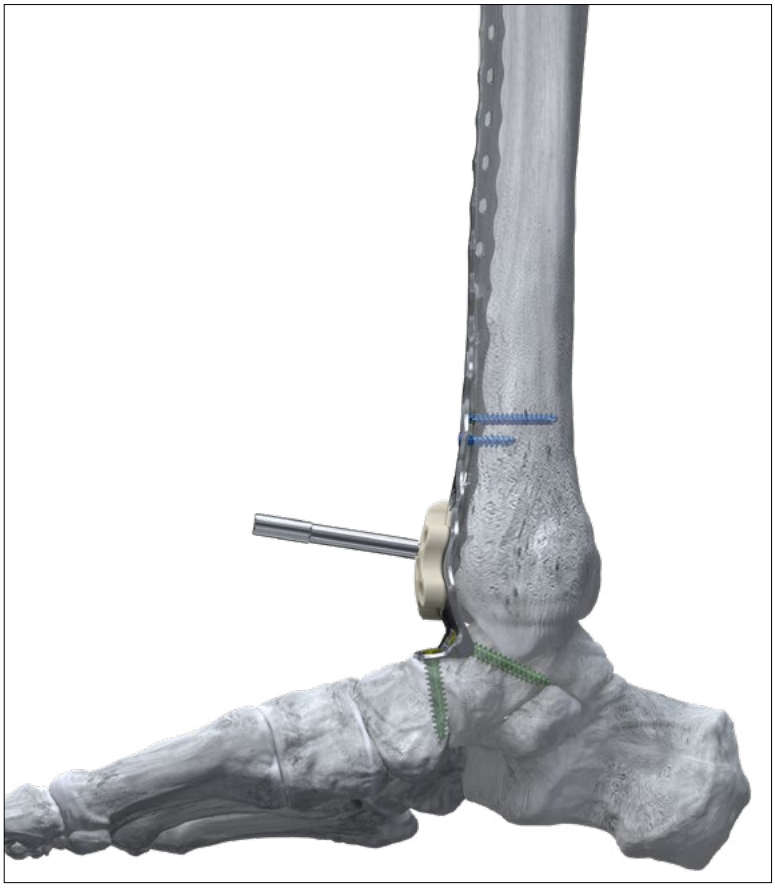
Backpack Guide

Thread Attachment

Backpack Drill Guide



NOTE: When measuring screw length through the backpack guide, remove the drill guides and use provided pilon fusion depth gauge.



Monster Screw Hole

ANTEROLATERAL PILON FUSION PLATE

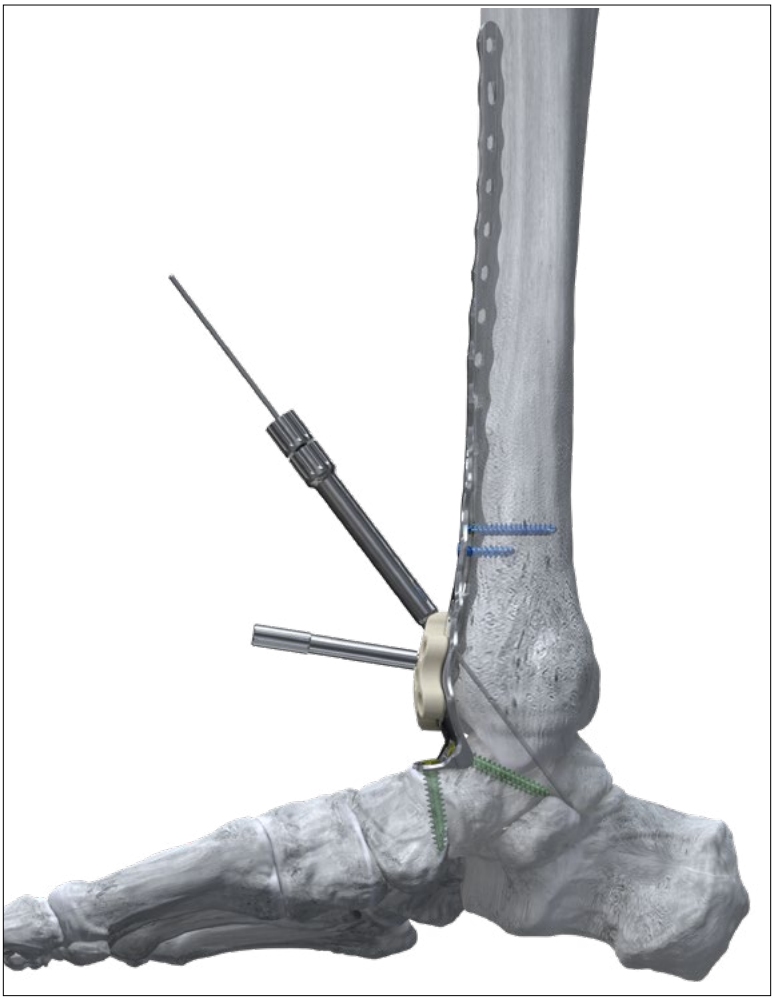
Monster K-Wire Guide

Monster Drill Guide

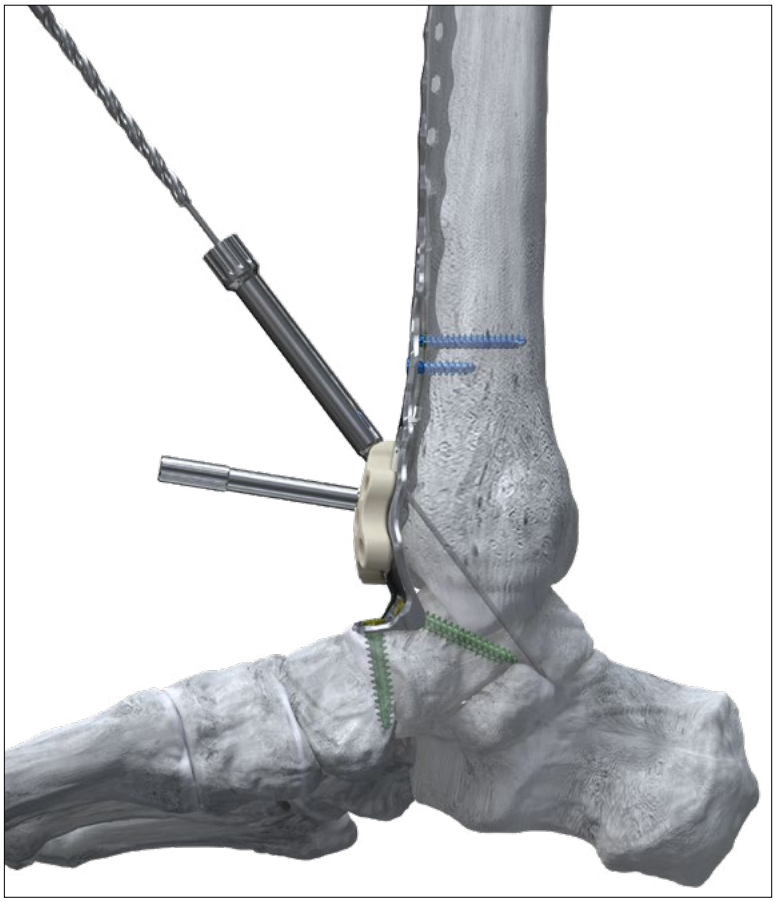
Assembled Monster K-Wire and Drill Guide

Ø1.60 mm x 15 cm Smooth K-Wire

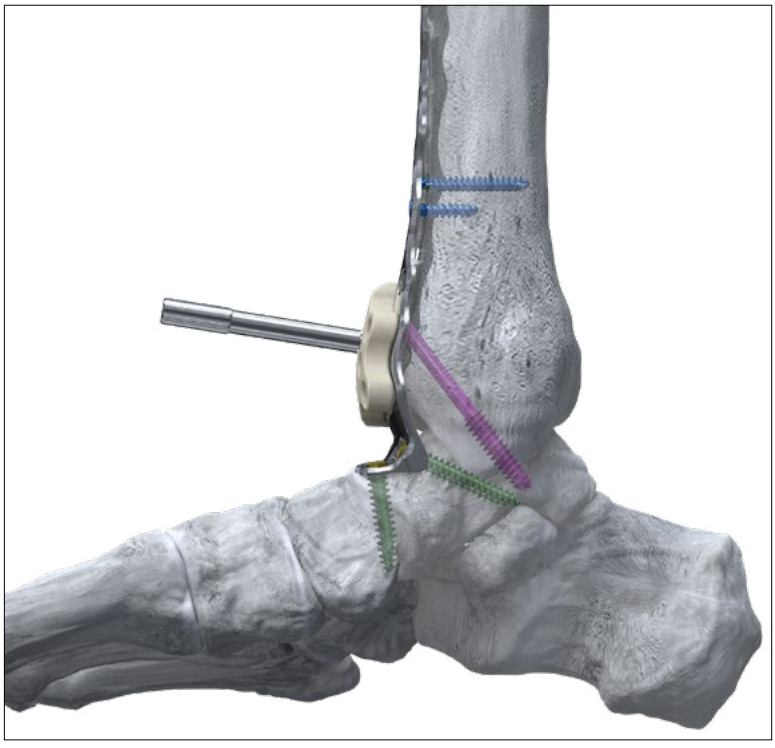
For placement of a Monster® screw through the plate and across the tibiotalar joint, assemble the Monster K-wire and Drill Guide. Place the assembled guide into the Monster screw hole in the Backpack Guide on the plate. Place a Ø1.6 K-wire through the guide and advance the wire to the desired termination point based on surgeon preference. If the K-wire trajectory is not appropriate for patient anatomy, remove the wire and guides and continue with freehand placement of the wire and screw using Monster® instrumentation.



ANTEROLATERAL PILON FUSION PLATE

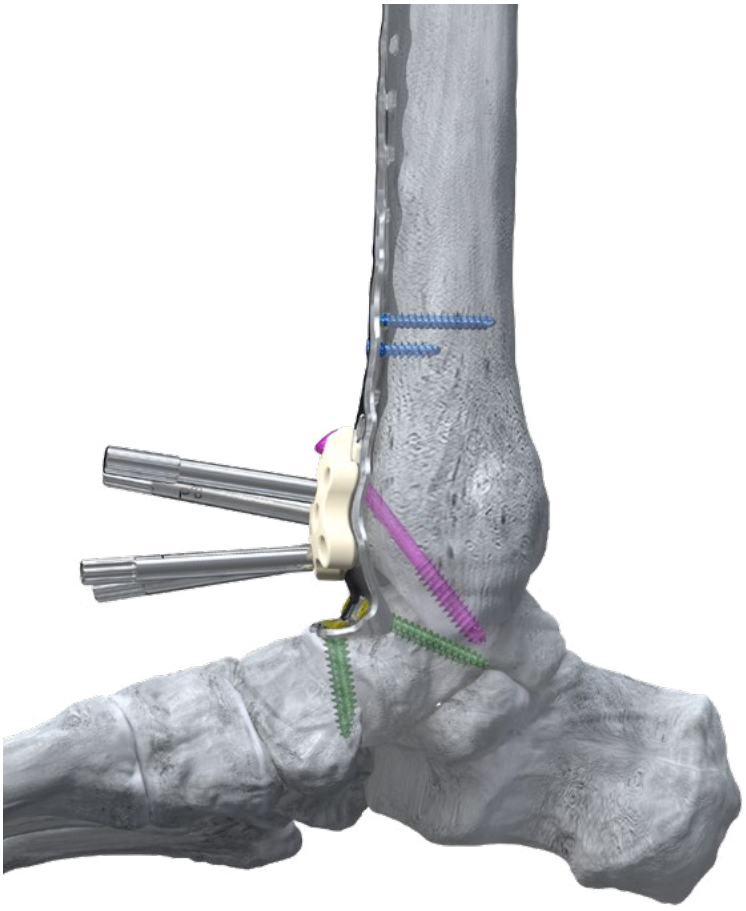


Remove the K-wire guide and drill over the K-wire with the Ø3.5 mm cannulated drill or remove the K-wire and K-wire Guide and drill with a solid 3.5 mm drill to the intended termination point.

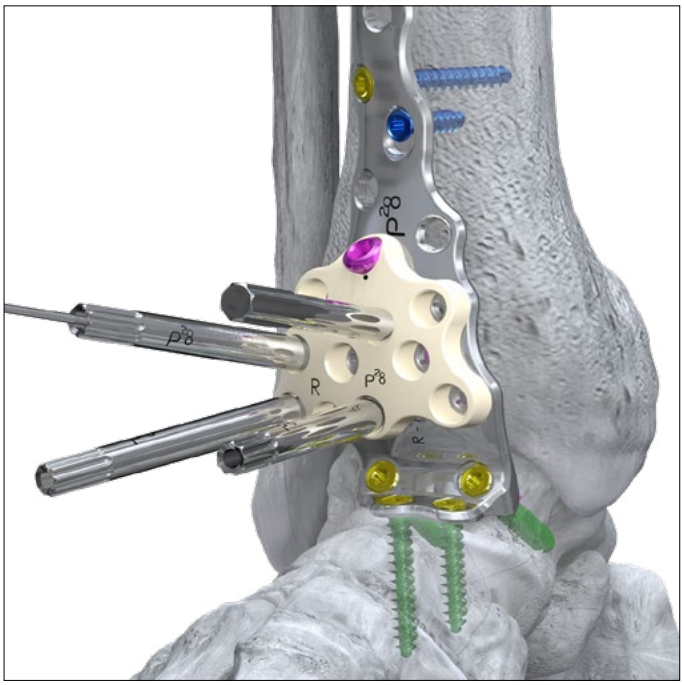


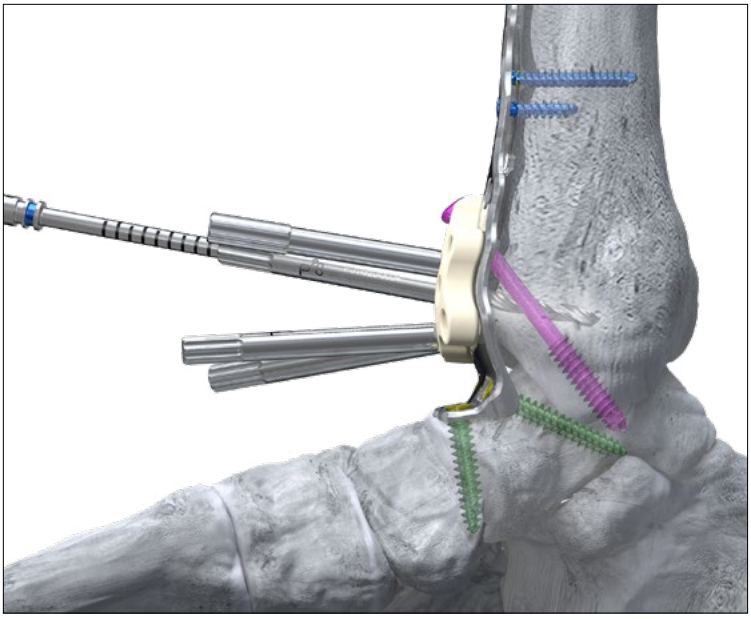
Remove the drill and drill guide and place the appropriate length Monster screw (partial or fully threaded per surgeon preference) through the plate and in to the talus. Confirm screw position and trajectory using fluoroscopy

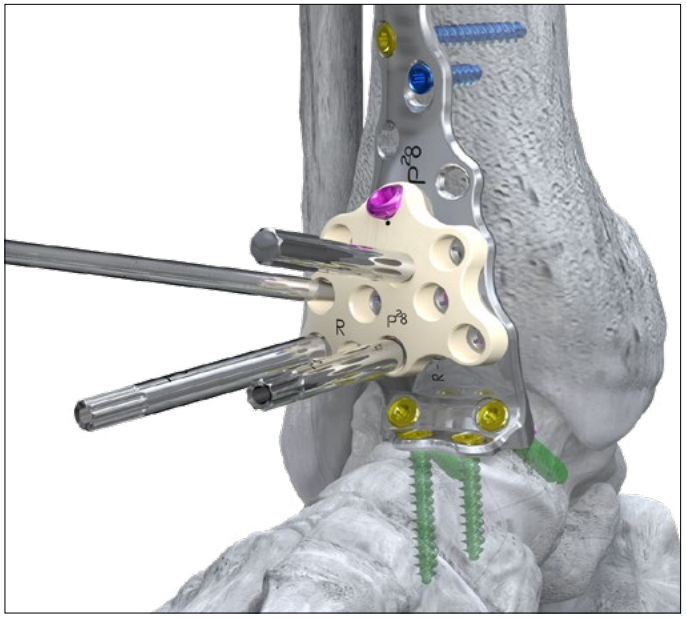
ANTEROLATERAL PILON FUSION PLATE



The drill guides should press fit into the backpack guide. Drill through the drill guides with the appropriately sized drills for the intended screw diameter to be used. Measure screw length based on the markings on the drill or measure using the provided depth gauge.







Remove the drill guide and place the selected screw into the drilled hole. Repeat the steps of drilling and screw placement for remaining plate holes based on surgeon preference.

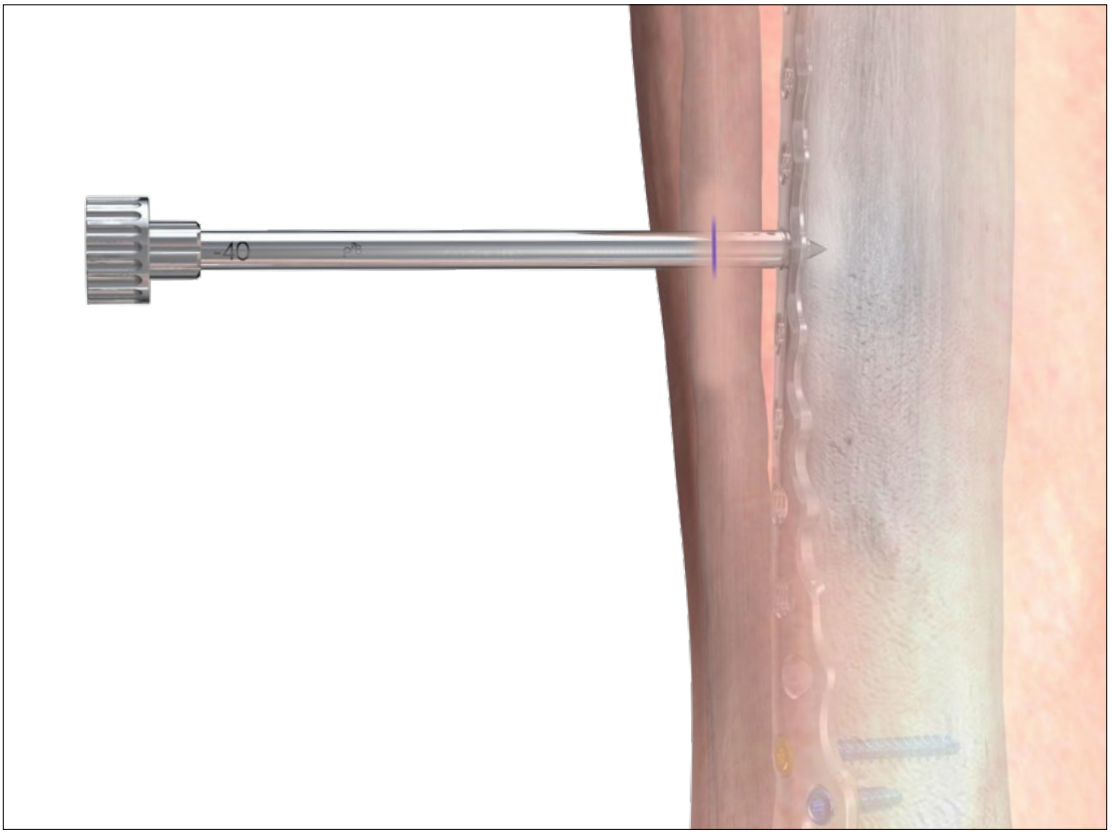
ANTEROLATERAL PILON FUSION PLATE

For placement of the proximal lateral screws on the plate, use fluoroscopy to locate the plate screw holes and make a stab or open incision at the intended locations. A trocar and drill guide are available to help assist with minimizing soft tissue disruption for screw placement. After using the trocar to reach bone, and thread the drill guide into the plate.

Trocar

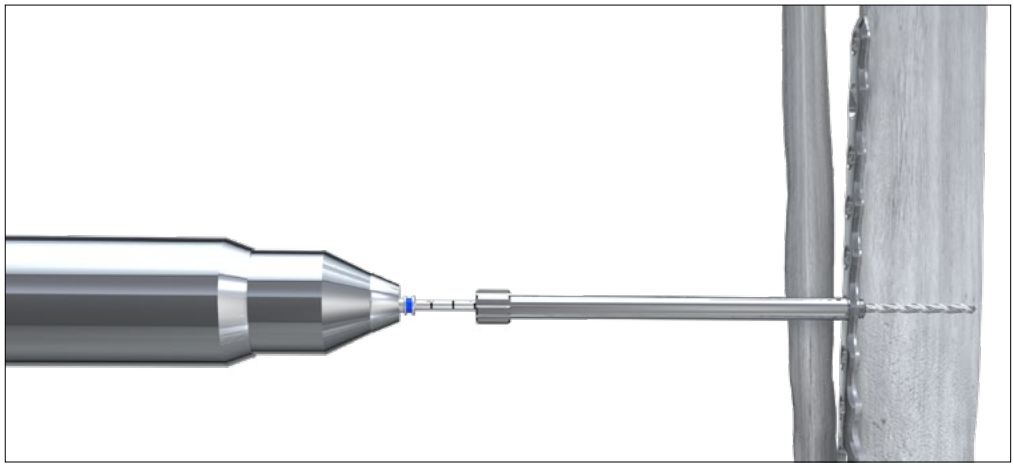
Drill Guide

Assembled Trocar, and Drill Guide



ANTEROLATERAL PILON FUSION PLATE

If using the trocar with the drill guide, remove the trocar and drill through the drill guide using the calibrated drill for the appropriately sized screw to be used.



NOTE: When measuring through the drill guide with an AF360 drill, subtract 40 mm from the measured length.

Remove the drill guide and continue with placement of remaining proximal lateral screws according to surgeon preference.

MEDIAL PILON FUSION PLATE

A Medial Plate is offered to provide additional fixation and strength to the plating construct. **It is recommended to use the medial pilon plate along with the anterolateral plate and not as the only plate used.**

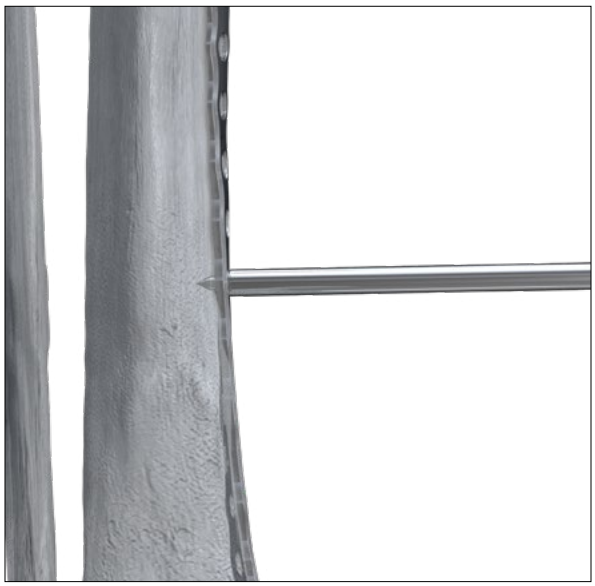
Make a longitudinal incision over the central aspect of the medial malleolus, appropriately sized for the fracture and plate length. Continue soft tissue dissection until the fusion site is visible. Use the provided Langenbeck elevator to elevate soft tissues along the length of the medial tibia for the intended plate being used.

Retrieve the appropriate length Medial Plate. Slide the plate under the soft tissues and along the bone to the appropriate position. It may be necessary to use the provided plate bending instrumentation to adjust the bend of the proximal portion of the plate to better fit patient anatomy. If provisional fixation of the plate to bone is preferred, olive wires are available to place within the screw holes or within the K-wire/Olive Wire holes in the plate. Confirm plate placement using fluoroscopy. Proceed with drilling and placement of screws along length of the plate according to surgeon preference and fracture pattern. .

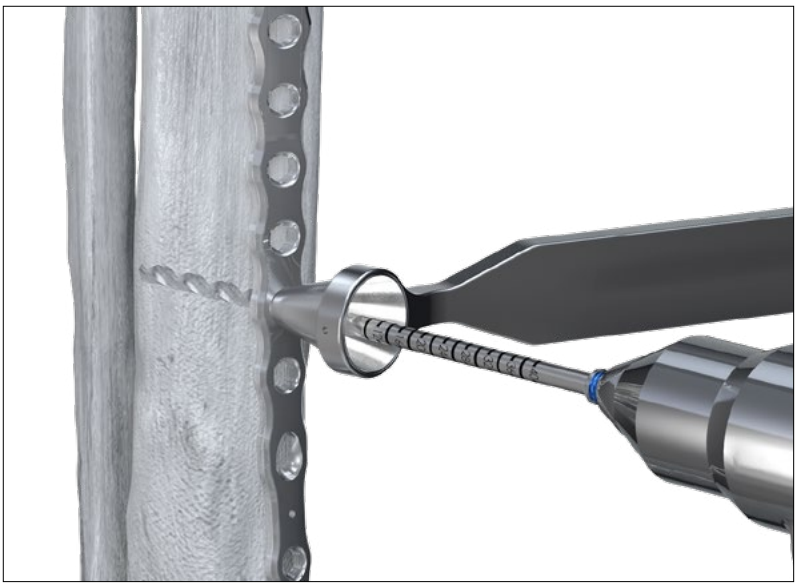
NOTE: The plates should not extend to the same spot, but overlap to minimize stress risers proximally.

NOTE: The distal portion of the plate can be bent with provided instrumentation to better fit the shape of the medial malleolus and/or tibia. A slight external rotation bend from proximal to distal should help the plate sit along the length of the tibia.

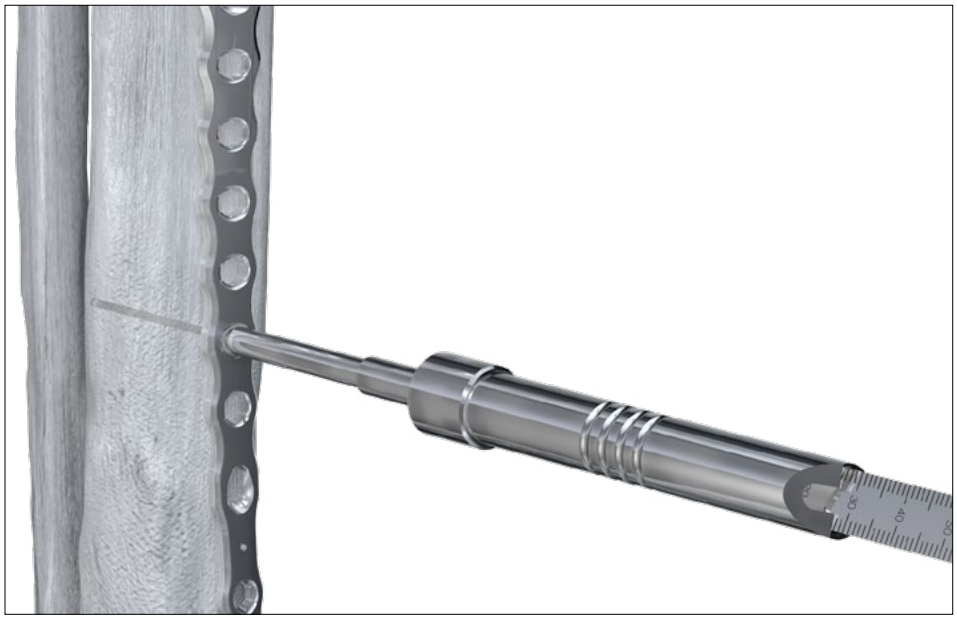
MEDIAL PILON FUSION PLATE

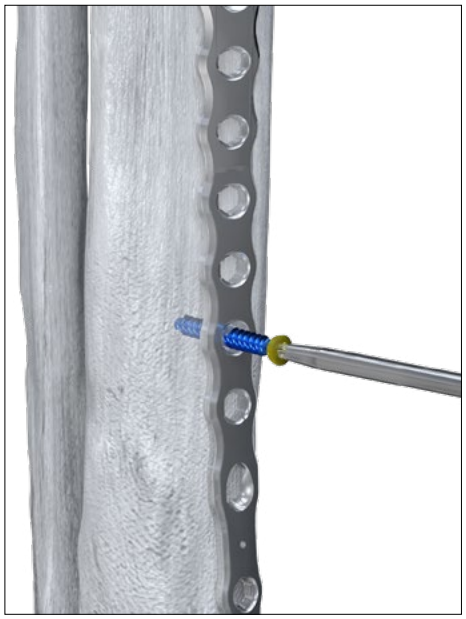


All plate holes accept Ø2.7 mm, Ø3.5 mm or Ø4.2 mm locking or non-locking screws. Drill through the provided drill guides using the drill sized for the desired screw diameter.



Locking screws have the ability to be placed off-axis 15° in any direction. The cone end of the Easy Cone Drill Guide can be used to limit drilling to 15° in any direction. Drill in desired direction.



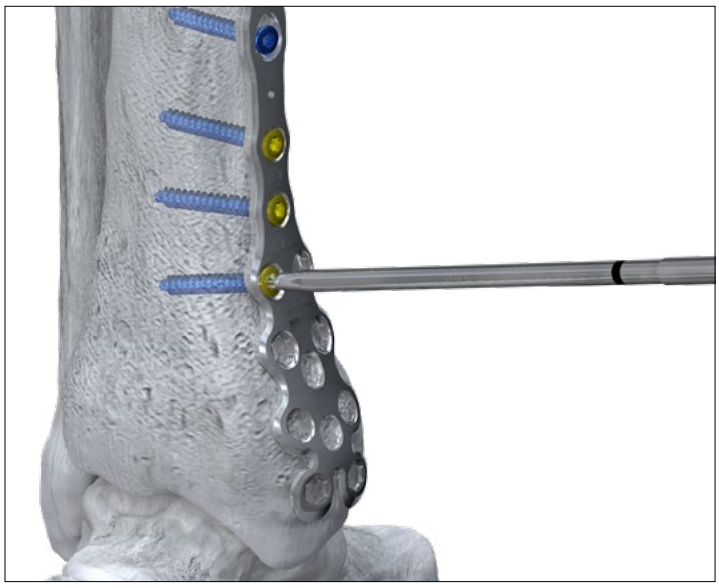


Measure screw length using a depth gauge. Insert the selected screw into the drilled hole in the tibia. Confirm screw position and length using fluoroscopy.

NOTE: Using a washer with a 3.5 compact or a 4.2 non locking screw may allow additional compression of the plate down to bone.

Refer to pages 14-15 for use of the drill guide and trocar for placement of proximal screws where the plate is under the soft tissue.

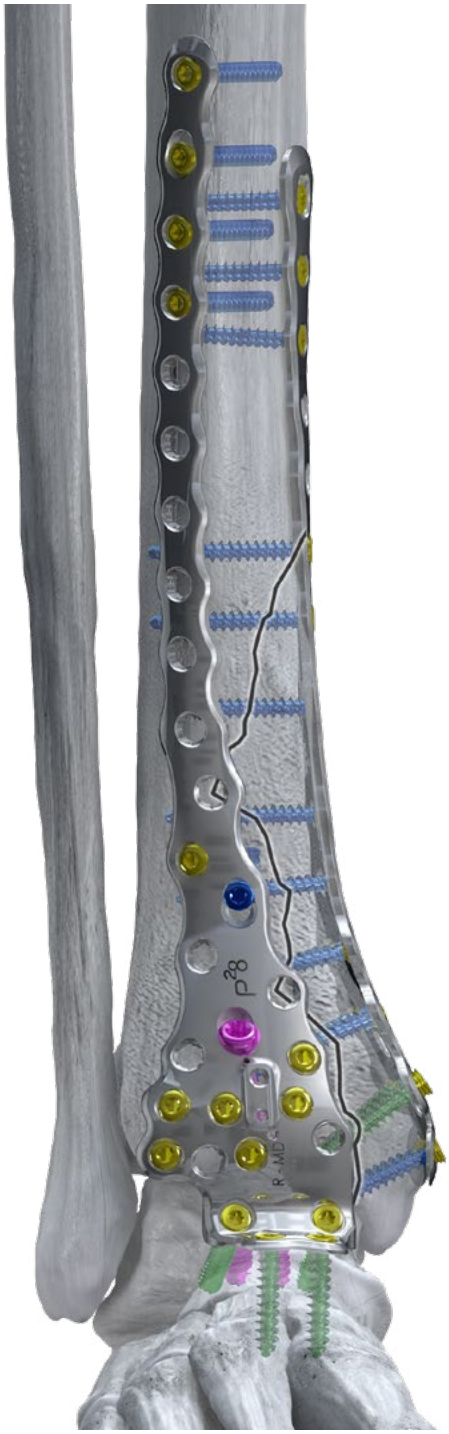
MEDIAL PILON FUSION PLATE



Continue with drilling and placement of screws along the length of the plate according to surgeon preference. If additional compression through the plate and into the talus is preferred, the screws in the two most distal rows can be angled to be placed into the talus.

MEDIAL PILON FUSION PLATE

Confirm plate and screw placement using fluoroscopy. Proceed to incision closure.



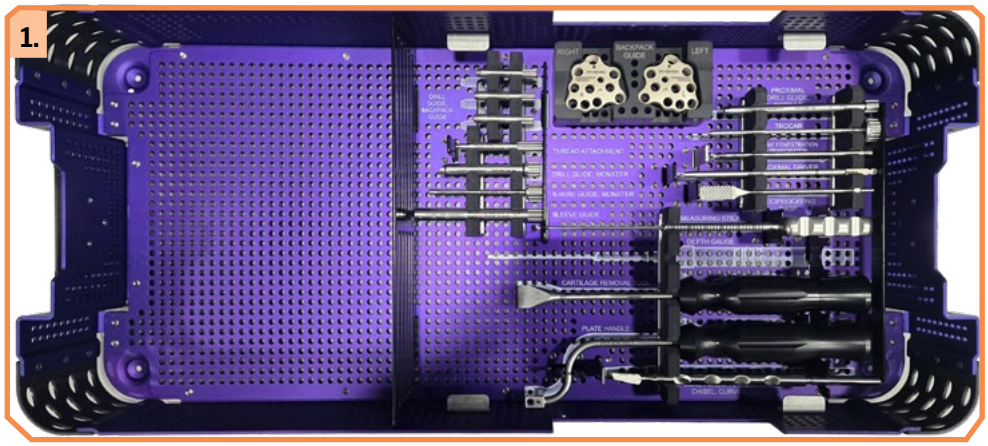
REMOVAL

Use provided drivers to remove all plate screws and any crossing screws. Remove the plate and confirm removal of all plates and screws under fluoroscopy.

INSTRUMENT CASE:

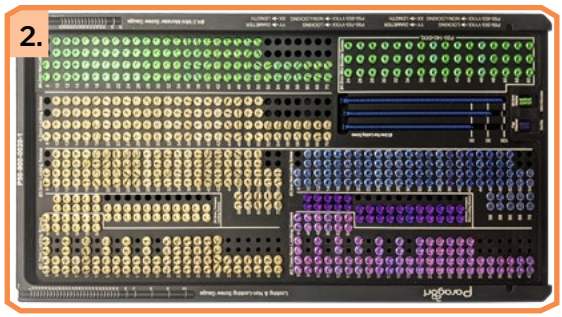
1 . GORILLA® PILON FUSION CADDY

The Gorilla® Ankle Pilon Fusion Caddy contains the right and left anterolateral plates, Medial plates, Trocar, Drill Guide, Monster Drill and K-wire Guides, Backpack Guide, Backpack Drill Guides, Thread Attachment, Handle, Drill Guide, Curved Bone Fenestration Chisel, King Cobra™ Cartilage Removal Tool, Reciprocating Rasp, and Bone Fenestration Perforator are also included in this caddy.



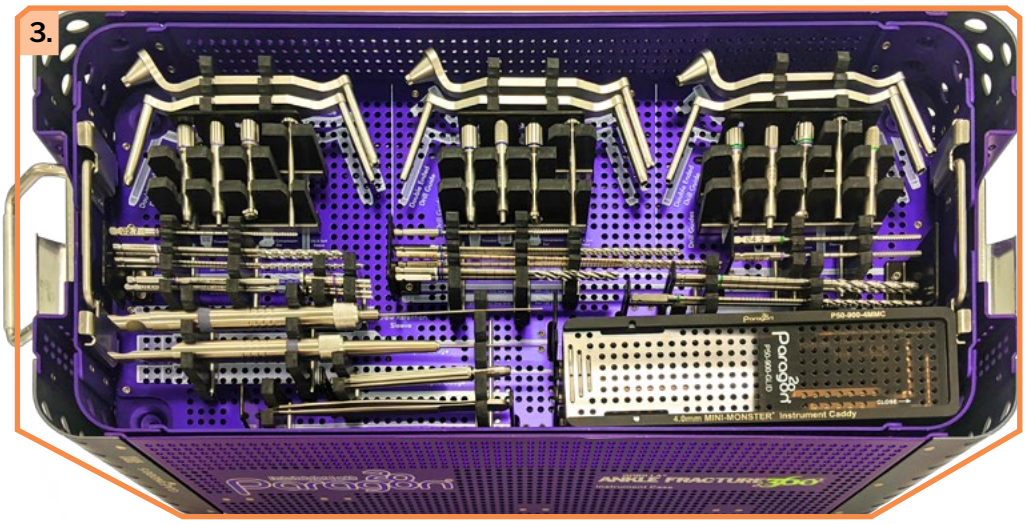
2 . ANKLE FRACTURE 360™ SCREW CADDY

The Ankle Fracture 360™ Screw Caddy accommodates Ø2.7 mm, Ø3.5 mm and Ø4.2 mm R3CON Locking and Non-locking Screws. As well as Gorilla R3CON Ø3.5 mm Compact Locking and Non-locking screws and Ø4.0 mm Mini Monster Screws.



3 . GORILLA® ANKLE FRACTURE 360™ INSTRUMENT TRAYS

Drills, drill guides, centering guides, taps, drivers, plate bending instrumentation, K-wires, olive wires, handles and Ø4.0 Mini Monster Instrumentation.

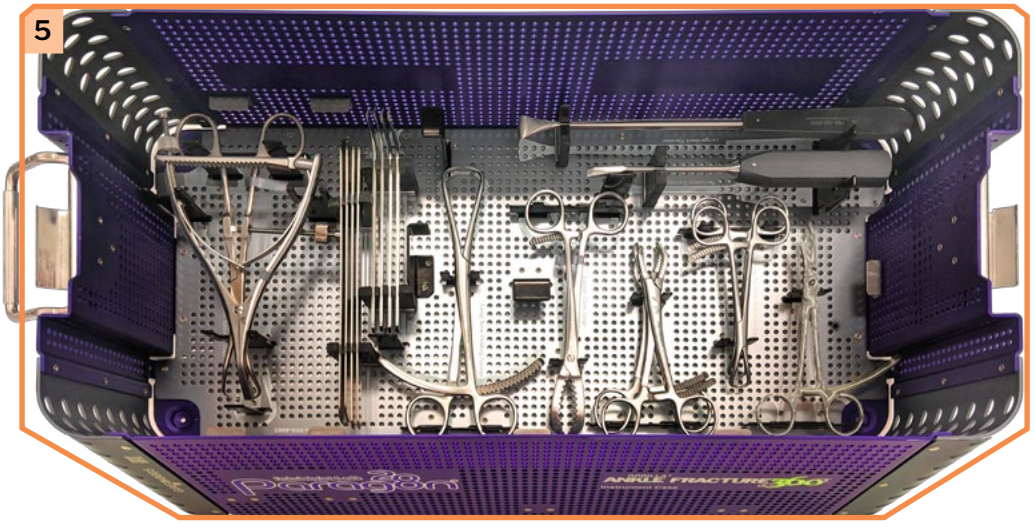


4. ADDITIONAL GORILLA® CADDIES

Drills, drill guides, centering guides, taps, drivers, plate bending instrumentation, K-wires, olive wires, handles and Ø4.0 Mini Monster Instrumentation.

5. ANKLE FRACTURE 360™ INSTRUMENT CASE

Reduction clamps, joint preparation instrumentation and retractors are located at the bottom of the Ankle Fracture 360 Instrument Case Base.



Caddy Contents

INSTRUMENT CASE:

Part #	Description	Quantity	Use
P53-440-L001	Pilon Fusion Plate, Anterolateral, Short, Left	1	Single-use
P53-440-L002	Pilon Fusion Plate, Anterolateral, Medium, Left	1	Single-use
P53-440-L003	Pilon Fusion Plate, Anterolateral, Long, Left	1	Single-use
P53-440-R001	Pilon Fusion Plate, Anterolateral, Short, Right	1	Single-use
P53-440-R002	Pilon Fusion Plate, Anterolateral, Medium, Right	1	Single-use
P53-440-R003	Pilon Fusion Plate, Anterolateral, Long, Right	1	Single-use
P53-441-0001	Pilon Fusion Plate, Medial, Short	1	Single-use
P53-441-0002	Pilon Fusion Plate, Medial, Medium	1	Single-use
P53-441-0003	Pilon Fusion Plate, Medial, Long	1	Single-use
P51-926-1001	Trocar	1	Reusable
P51-926-1003	Drill Guide	1	Reusable
P51-926-2001	Monster Drill Guide	1	Reusable
P51-926-1005	Proximal Driver	1	Reusable
P51-926-2002	Monster K-Wire Guide	1	Reusable
P51-926-4001	King Cobra Cartilage Removal Tool	1	Reusable
P51-926-5001	Backpack Guide, Right	1	Reusable
P51-926-5002	Thread Attachment	1	Reusable
P51-926-5003	Backpack Guide, Left	1	Reusable
P51-926-5004	Backpack Drill Guide	3	Reusable
P51-926-6001	Insertion Handle	1	Reusable
P51-926-7001	Reciprocating Rasp	1	Single-use
P51-926-8001	Depth Gage	1	Reusable
P99-150-0135	Bone Fenestration Chisel, Curved	1	Reusable
P99-100-2010	Bone Fenestration Perforator	1	Single-Use

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - SCREW CADDY

Part #	Description	Use
P50-353-27[08-54]	R3CON Locking Screw, Ø2.70 x 8-54 mm	Single-use
P50-453-27[08-75]	R3CON Non-Locking Screw, Ø2.70 x 8-75 mm	Single-use
P50-353-35[08-70]	R3CON Locking Screw, Ø3.50 x 8-70 mm	Single-use
P50-453-35[08-00]	R3CON Non-Locking Screw, Ø3.50 x 8-100 mm	Single-use
P50-353-42[08-70]	R3CON Locking Screw, Ø4.20 x 8-70 mm	Single-use
P50-453-42[08-70]	R3CON Non-Locking Screw, Ø4.20 x 8-70 mm	Single-use
P50-853-35[10-40]	Gorilla, R3CON, Non-Locking Screw, Compact Thread, Ø3.50 x 10-40 mm	Single-use
P50-753-35[10-40]	Gorilla, R3CON, Locking Screw, Compact Thread, Ø3.50 x 10-40 mm	Single-use
P20-140-0[24-60]L	Mini Monster Ø4.0 X 24-60 mm Headed Screw, Long Thread	Single-use
P20-040-DW00	Ø4.0 Flat Washer, Mini Monster	Single-use

*See page 6 for detailed screw size offerings

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - WIRE CADDY

Part #	Description	Use
P99-150-0005	P28, K-Wire Hole Gauge & Ruler, SS	Reusable
P99-192-1615	Ø1.60 mm x 15 cm Smooth, K-Wire	Single-use
P99-192-2015	Ø2.0 mm x 15 cm Smooth, K-Wire	Single-use
P99-192-2020	Ø2.0 mm x 20 cm Smooth, K-Wire	Single-use
P99-193-1615	Ø1.60 mm x 15 cm Threaded, K-Wire	Single-use
P99-193-2015	Ø2.0 mm x 15 cm Threaded, K-Wire	Single-use
P99-193-2020	Ø2.0 mm x 20 cm Threaded K-Wire	Single-use
P99-200-1406	Ø1.40 mm x 6 cm Olive Wire, Smooth	Single-use
P99-201-1406	Ø1.40 mm x 6 cm Olive Wire, Threaded	Single-use
P99-250-1608	Ø1.60 mm X 8 cm Olive Wire, Smooth, 316 LVM	Single-use
P99-250-1610	Ø1.60 mm X 10 cm Olive Wire, Smooth, 316 LVM	Single-use
P99-251-1608	Ø1.60 mm X 8 cm Olive Wire, Threaded, 316 LVM	Single-use
P99-251-1610	Ø1.60 mm X 10 cm Olive Wire, Threaded, 316 LVM	Single-use

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - INSTRUMENT TRAYS

Part #	Description	Use
P51-900-1004	Gorilla R3CON, Drill Guide, Ø2.7 Threaded, Locking, SS, Long	Reusable
P51-900-1005	Gorilla R3CON, Drill Guide, Ø3.5 Threaded, Locking, SS, Long	Reusable
P51-900-1006	Gorilla R3CON, Drill Guide, Ø4.2 Threaded, Locking, SS, Long	Reusable
P51-901-5027	Gorilla R3CON, Drill Guide, EZ Cone Ø2.7 mm, Long	Reusable
P51-901-5035	Gorilla R3CON, Drill Guide, EZ Cone Ø3.5 mm, Long	Reusable
P51-901-5042	Gorilla R3CON, Drill guide, EZ Cone Ø4.2 mm, Long	Reusable
P51-902-1004	Gorilla R3CON, Drill Guide, Centering, Ø2.7 mm, SS, Long	Reusable
P51-902-1005	Gorilla R3CON, Drill Guide, Centering, Ø3.5 mm, SS, Long	Reusable
P51-902-1006	Gorilla R3CON, Drill Guide, Centering, Ø4.2 mm, SS, Long	Reusable

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - INSTRUMENT TRAYS

Part #	Description	Use
P51-902-1008	Gorilla R3CON, Drill Guide, Centering, Ø3.5 mm Compact, SS, Long	Reusable
P51-903-3004	Gorilla, R3CON, Drill Guide, Compression Slot, Ø2.7, Long	Reusable
P51-903-3005	Gorilla, R3CON, Drill Guide, Compression Slot, Ø3.5, Long	Reusable
P51-903-3006	Gorilla, R3CON, Drill Guide, Compression Slot, Ø4.2, Long	Reusable
P51-905-2027	Gorilla R3CON, Drill/Over Drill Guide, Double Ended, Ø2.0 / Ø2.7, SS	Reusable
P51-905-2027-03	Gorilla R3CON, Ø2.7 mm Drill Sleeve	Reusable
P51-905-2435	Gorilla R3CON, Drill/Over Drill Guide, Double Ended, Ø2.4 / Ø3.5, SS	Reusable
P51-905-2435-03	Gorilla R3CON, Ø3.5 mm Drill Sleeve	Reusable
P51-905-2842	Gorilla R3CON, Drill / Over Drill Guide, Double Ended, Ø2.8 / Ø4.2, SS	Reusable
P51-905-2842-03	Gorilla R3CON, Ø4.2 mm Drill Sleeve	Reusable
P51-913-2027	Gorilla R3CON, Drill/Over Drill Guide, Double Ended, Ø2.0 / Ø2.7, SS	Reusable
P51-913-2027-03	Gorilla R3CON, Ø2.7 mm Drill Sleeve	Reusable
P51-913-2435	Gorilla R3CON, Drill/Over Drill Guide, Double Ended, Ø2.4 / Ø3.5, SS	Reusable
P51-913-2435-03	Gorilla R3CON, Ø3.5 mm Drill Sleeve	Reusable
P51-913-2842	Gorilla R3CON, Drill / Over Drill Guide, Double Ended, Ø2.8 / Ø4.2, SS	Reusable
P51-913-2842-03	Gorilla R3CON, Ø4.2 mm Drill Sleeve	Reusable
P51-900-2002	Gorilla, Ankle Fracture, Threaded Positioning Tower	Reusable
P51-910-1001	Gorilla, Plate Bender, Threaded Bending Bar, SS	Reusable
P51-910-1002	Gorilla, Plate Bender, Bending Irons, SS	Reusable
P51-910-1003	Gorilla, Plate Bending Pliers	Reusable
P51-911-2700	Gorilla Tap, Double Lead, Ø2.7 mm	Reusable
P51-911-3500	Gorilla Tap, Double Lead, Ø3.5 mm	Reusable
P51-911-3501	Gorilla Tap, Compact Thread, Ø3.5 mm	Reusable
P51-911-4200	Gorilla Tap, Double Lead, Ø4.2 mm	Reusable
P99-100-2013	P28, Drill, Gorilla Ø2.0 x 13 cm, Solid, A/O, SS	Reusable
P99-100-2416	P28, Drill, Gorilla Ø2.4 x 16 cm, Solid A/O, SS	Reusable
P99-100-2418	P28, Drill, Gorilla, Ø2.8 x 18 cm, Solid, A/O, SS	Reusable
P99-100-2713	P28, Drill, Gorilla Ø2.7 x 110 mm, Solid, A/O, Overdrill, SS	Reusable
P99-100-2816	P28, Drill, Gorilla, Ø2.8 x 16 cm, Solid, A/O, SS	Reusable
P99-100-3513	P28, Drill, Gorilla Ø3.5 x 110 mm, Solid, A/O, Overdrill, SS	Reusable
P99-100-4214	P28, Drill, Gorilla Ø4.2 x 120 mm, Solid, A/O, Overdrill, SS	Reusable
P99-191-AF10	Gorilla, R3CON, Long, Driver, Solid, HX10 x 83 mm, SS	Reusable
P99-000-AOLG	Mini-AO, Ratchet Handle, Purple, Large	Reusable
P99-000-AOMN	Mini-AO, Ratchet Handle, Purple	Reusable
P99-150-0001	P28, Screw Forceps, Ti	Reusable
P99-150-0013	Sharp Tip Bone Reduction Clamp	Reusable
P99-150-0017	Lobster Claw Clamp	Reusable
P99-150-0051	8 mm, Mini Hohmann Retractor	Reusable
P99-150-0052	16 mm, Mini Hohmann Retractor	Reusable
P99-150-0083	Webber Spin Down Clamp	Reusable

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - INSTRUMENT TRAYS

Part #	Description	Use
P99-150-0111	P28, Depth Gauge Plate Screw, 90 mm, SS	Reusable
P99-150-0112	P28, Percutaneous Depth Gauge, SS	Reusable
P99-150-0113	Large, Lobster Claw Clamp	Reusable
P99-150-0114	Lamina Spreader	Reusable
P99-150-0133	Syndesmotic Clamp	Reusable
P99-150-0134	Malleolar Reduction Clamp	Reusable
P99-150-1013	(Long) Bone Holding Forceps	Reusable
P99-150-2003	Langenbeck Elevator	Reusable
P99-150-2004	Periosteal Elevator	Reusable
P99-157-0810	Ribbon Retractor 1.0" X 8"	Reusable
P99-157-0850	Ribbon Retractor 0.5" X 8"	Reusable
P99-191-SL10	Screw Retention Sleeve	Reusable
P99-150-0038	Tenaculum Clamp	Reusable

Indications, Contraindications and Warnings

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 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.
- 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.

Indications, Contraindications and Warnings

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

CONTRAINDICATIONS (CONTINUED)

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.

MR SAFETY INFORMATION

The Monster® Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Monster® Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

NOTES:

Exclusively foot & ankle

www.Paragon28.com

GORILLA®
ANKLE FRACTURE 360™

SURGICAL TECHNIQUE GUIDE

Gorilla® Pilon Fusion System

P51-STG-0015 RevA [2025-07-28]

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Exclusively foot & ankle
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Disclaimer:
The purpose of the Gorilla® Pilon Fusion Plating System Surgical Technique Guide is to demonstrate use of the Gorilla® Pilon Fusion in the Gorilla® Pilon Fusion Plating System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.