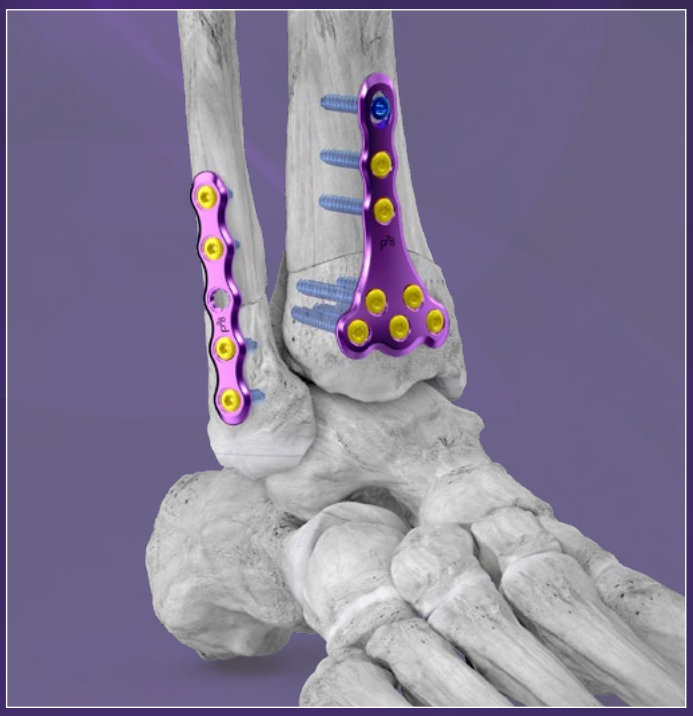
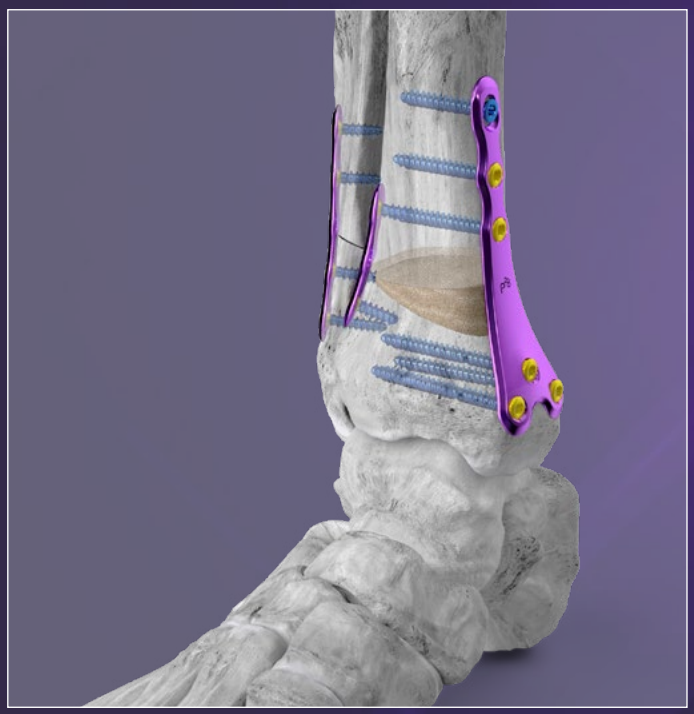
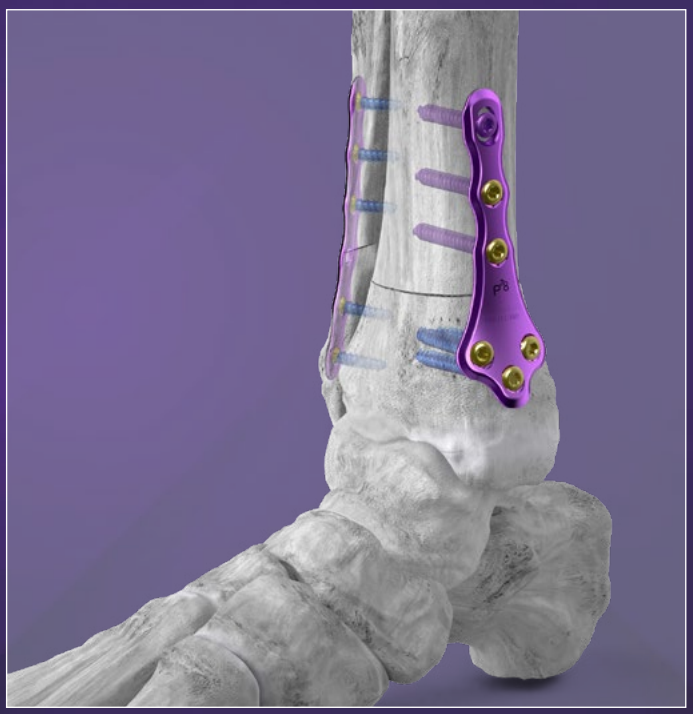
Exclusively foot & ankle

Paragon 28®







GORILLA®

R3CON PLATING SYSTEM

SURGICAL TECHNIQUE GUIDE:

Supramalleolar Osteotomy System

Acknowledgment:
Paragon 28® would like to thank Mark Myerson, MD, Woo-Chun Lee, MD, Cassandra Tomczak, DPM, and Federico Usuelli, MD for their contribution to the development of the Gorilla® Supramalleolar Osteotomy System and the surgical technique guide.

PRODUCT DESCRIPTION

The Gorilla® Supramalleolar Osteotomy System was designed to allow surgeons versatility in plate selection and surgical approach for supramalleolar osteotomies. The system has 6 anatomically contoured plate options for osteotomy fixation, which provides surgeons flexibility for the location of the anterior dome osteotomy, and medial opening and closing osteotomies. The anterior tibial plates feature a 5-hole distal cluster to allow for versatility in screw placement and to maximize capture of the distal anterior tibia. The medial plates feature a 3-hole distal cluster to allow for screw placement in the distal media tibia, while providing flexibility for surgeon preference on location of plate and screw fixation. The circular plate holes accept Ø2.7, Ø3.5, or Ø4.2 mm locking or non-locking screws or Ø3.5 mm locking or non-locking compact thread screws, which can be inserted off-axis up to 15°. A proximal compression slot is present in all plates to allow for osteotomy compression through the plate, if desired. The compression slot accepts Ø2.7 mm, Ø3.5 mm, and Ø4.2 mm non-locking screws, and Ø3.5 mm non-locking compact thread screws.

CONTENTS

PLATE OFFERING

6 PLATES

Anterior Tibia Plates

- Universal for right and left
- Offered in standard and long
  - Standard span length: 13 mm
  - Long span length: 18 mm
- Anatomically contoured to the distal anterior tibia

Distal Medial Tibia Plates

- Universal for right and left
- Offered in standard and long
  - Standard span length: 15 mm
  - Long span length: 25 mm
- Anatomically contoured for the medial malleolus

Proximal Medial Tibia Plates

- Universal for right and left
- Offered in standard and long
  - Standard span length: 15 mm
  - Long span length: 25 mm
- Anatomically contoured for the medial malleolus

- All circular plate holes allow for off-axis screw insertion up to 15°
- All circular plate holes accept Ø2.7 mm, Ø3.5 mm, or Ø4.2 mm locking or non-locking screws or Ø3.5 mm locking or non-locking compact thread screws
- All plates feature a compression slot in the most proximal screw hole, which accepts Ø2.7 mm, Ø3.5 mm, and Ø4.2 mm non-locking screws, and Ø3.5 mm non-locking compact thread screws
- All plates are low profile
  - 1.5 mm thickness throughout all plates
- All plates have chamfered edges to minimize soft tissue irritation
- Distal screw clusters allow for crossing screw placement per surgeon preference
- The span region on all plates accounts for smaller and larger angular adjustments

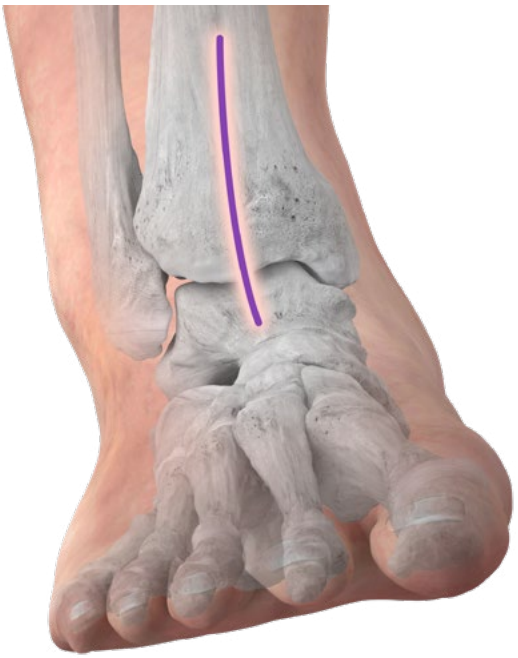
SCREW OFFERING AND INSTRUMENTATION MATRIX

	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	8 mm - 60 mm in 2 mm increments 60 - 70 mm in 5 mm increments 70 - 100 mm in 10 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	 Ø3.5mm C/ Ø4.2mm	 Ø3.5mm C/Ø4.2mm
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

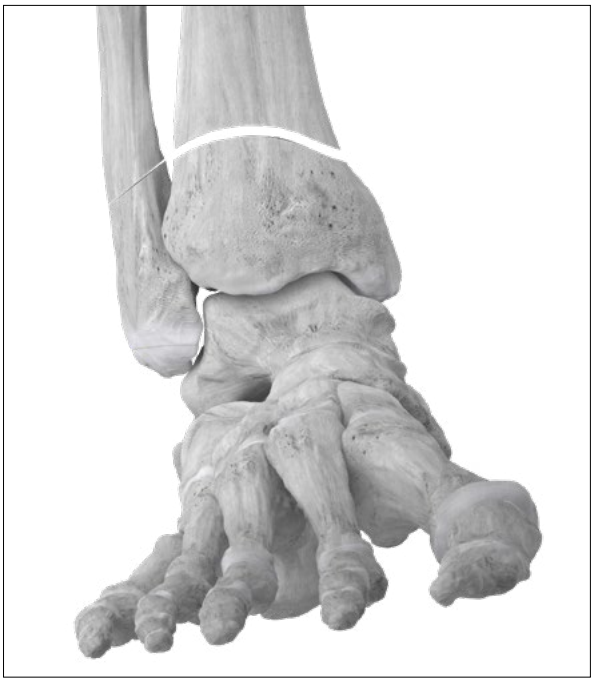
*Only available if shipped with Ankle Fracture 360

INCISION/EXPOSURE

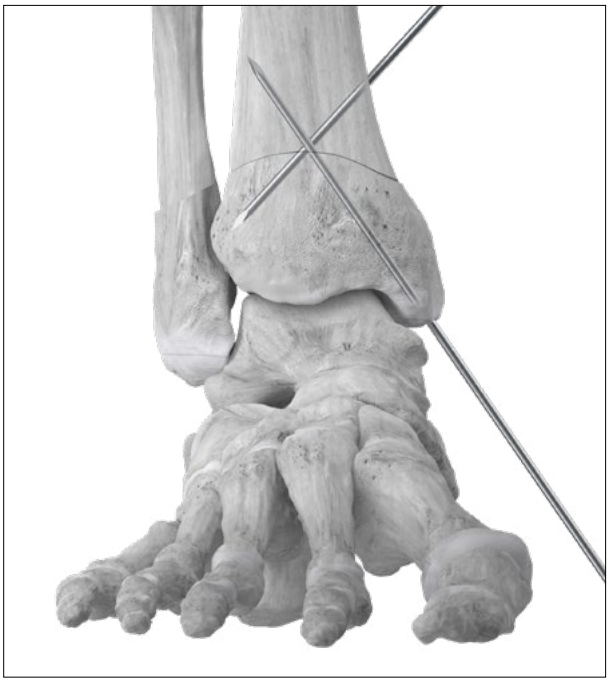
A longitudinal midline incision is made over the anterior distal tibia, splitting the anterior tibialis tendon and extensor hallucis longus (EHL). Continue the incision 2-3 cm past the ankle joint, taking care to avoid violating the ankle joint capsule. Retract the anterior tibialis tendon medially and retract the EHL and neurovascular bundle laterally. If necessary, remove any tibial or talar osteophytes/spurs according to surgeon preference.



OSTEOTOMY AND DEFORMITY CORRECTION



Per surgeon preference, perform a dome osteotomy at the desired height on the tibia and with the appropriate curvature for the correction. If required, create an additional fibular osteotomy that follows the curvature of the tibial osteotomy.

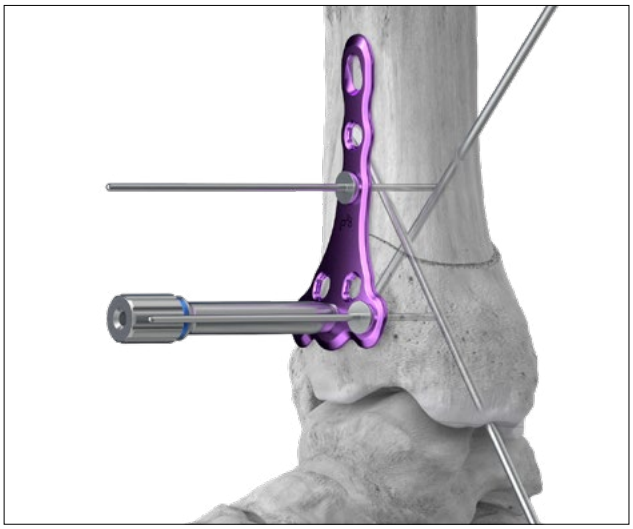


Manually correct the deformity and provisionally fixate the osteotomy with crossing K-wires and confirm correction using fluoroscopy.

Note: *Ø2.3 mm K-wires are available for provisional fixation of the osteotomy. If planning to place a crossing screw across the osteotomy, it is recommended to use the K-wire sized to be the guide wire for the desired crossing screw diameter for provisional fixation.*

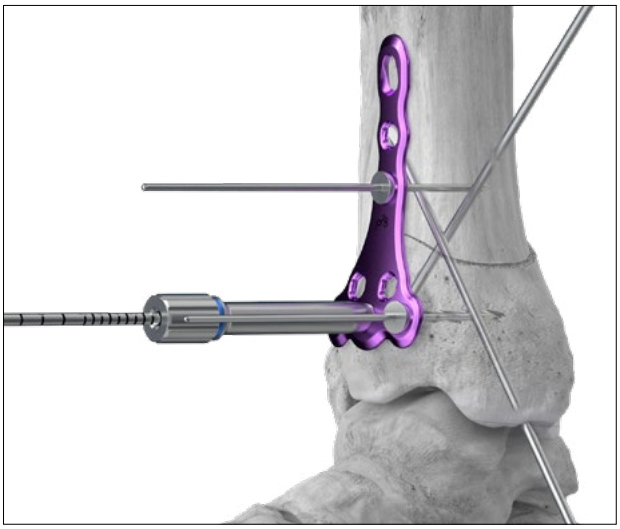
PLATE PLACEMENT AND PERMANENT FIXATION

Note: *If the use of a crossing screw across the osteotomy is preferred, placement of the crossing screw should be performed prior to plating, with screw diameter according to surgeon preference.*



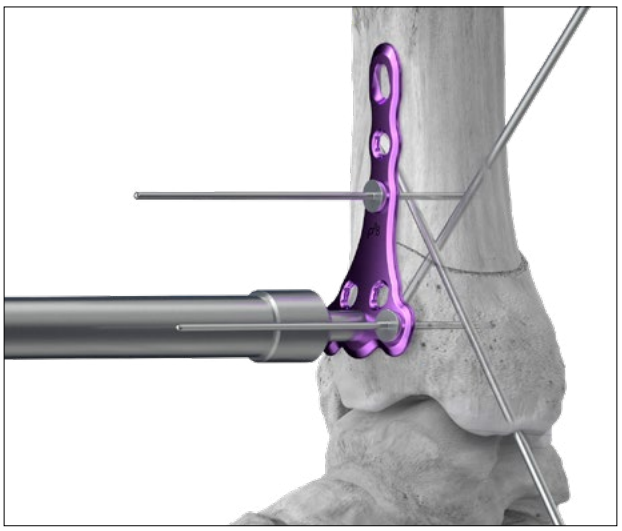
Attach the threaded drill tower to a distal hole on the plate to allow for plate positioning on bone. It is recommended that the spanning region of the plate is centered over the osteotomy. Once the plate is in the desired location, temporarily fixate it to the bone with 2 Olive Wires. Confirm plate position using fluoroscopy.

Note: *All circular plate holes accept Ø2.7, Ø3.5, or Ø4.2 mm locking or non-locking screws and Ø3.5 mm locking or non-locking compact thread screws.*

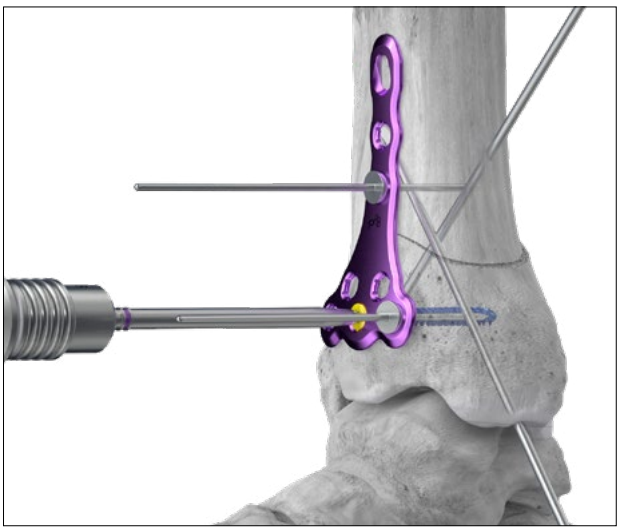


Drill through the drill guide with the appropriately sized drill for the desired screw diameter.

Note: *For more information and instructions on the use of Paragon28's Gorilla® plates and screws, please refer to the Gorilla® R3CON Surgical Technique Guide: P51-STG-0001.*

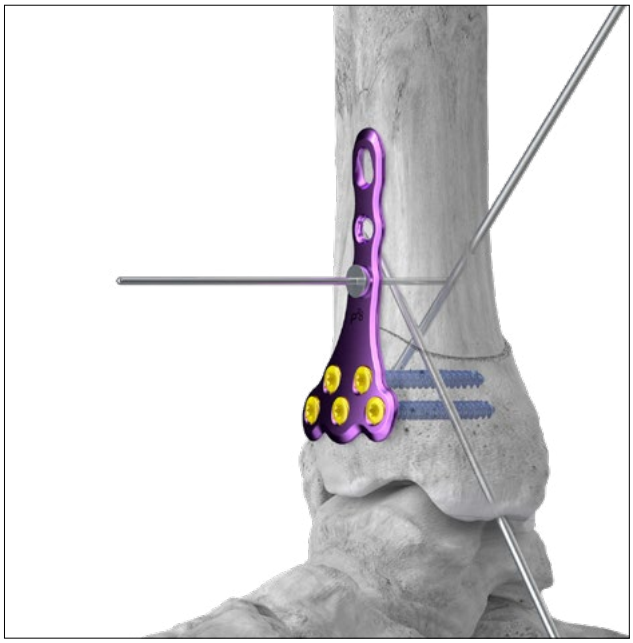


Measure screw length using the provided depth gauge.

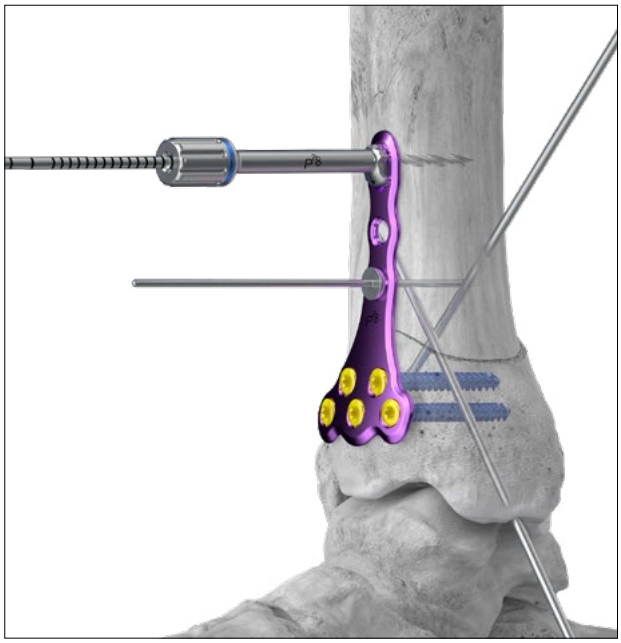


Attach the driver to a provided handle. Insert the appropriate length screw using the driver by inserting it into the screw head and turning the screw clockwise until seated.

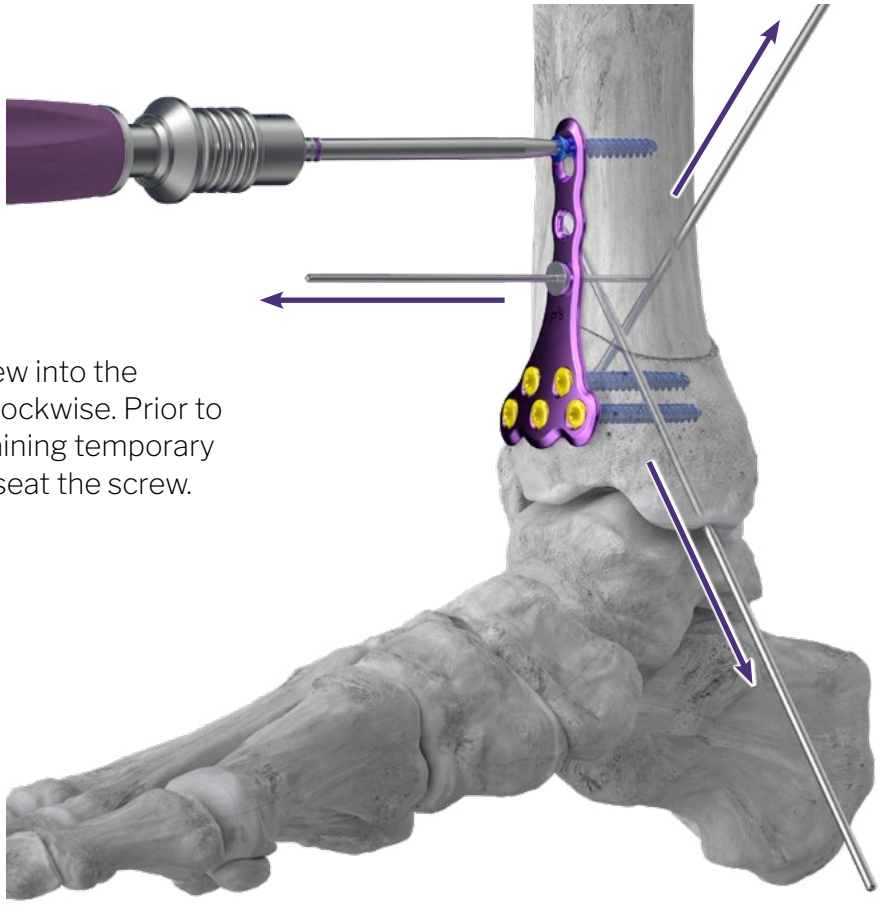
PLATE PLACEMENT AND PERMANENT FIXATION



Repeat the same steps of drilling, measuring, and screw insertion for the remaining holes in the distal cluster of the anterior plate, removing any temporary fixation Olive Wires in the distal portion to allow for screw placement.



For the compression slot, insert the compression slot drill guide into the compression slot, with the arrow on the guide pointing toward the osteotomy to create a drill hole at the proximal end of the slot. Drill through the drill guide using the drill for the desired screw diameter.



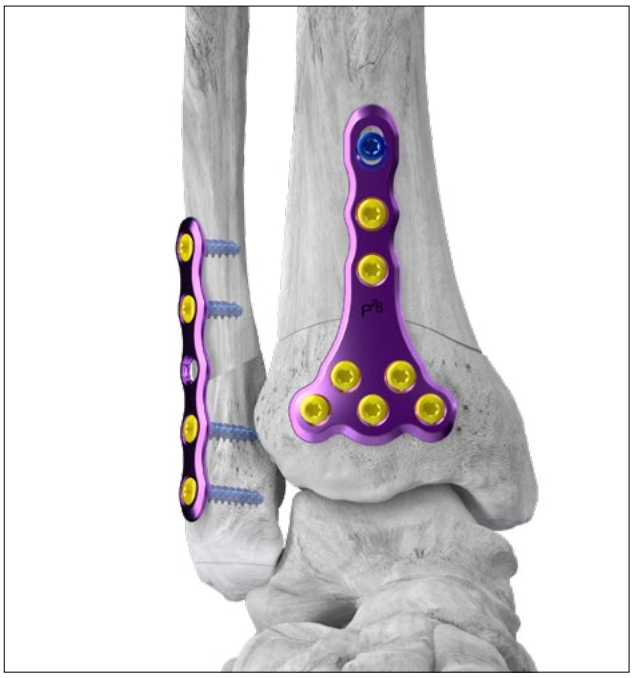
Use the provided driver to insert the screw into the compression slot by turning the screw clockwise. Prior to fully seating the screw, remove any remaining temporary fixation wires and then continue to fully seat the screw.

PLATE PLACEMENT AND PERMANENT FIXATION

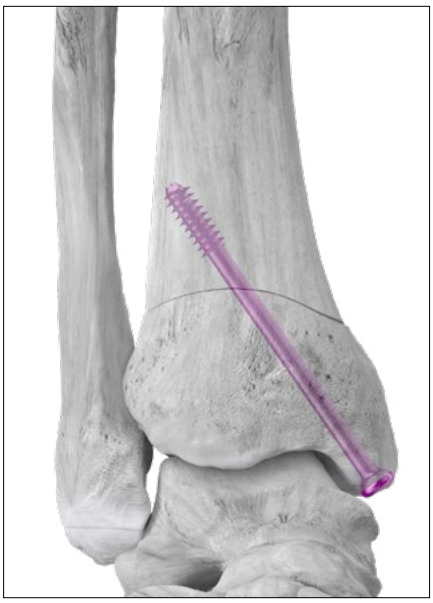
Place screws as previously described into any remaining screw holes. Confirm final plate position and screw lengths using fluoroscopy.

If a fibula osteotomy was created during deformity correction, fibula plates are available to allow for permanent fixation of the fibula.

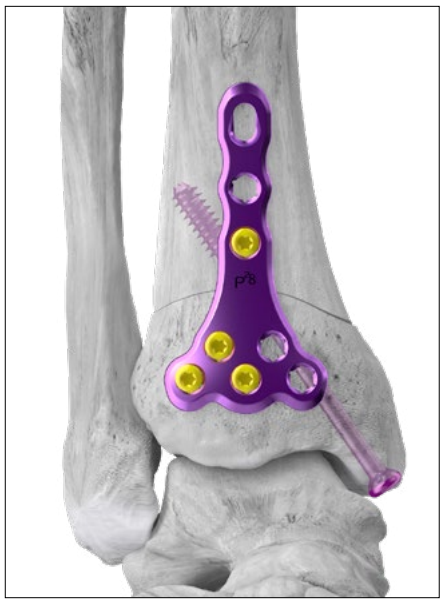
Note: *For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-0008.*



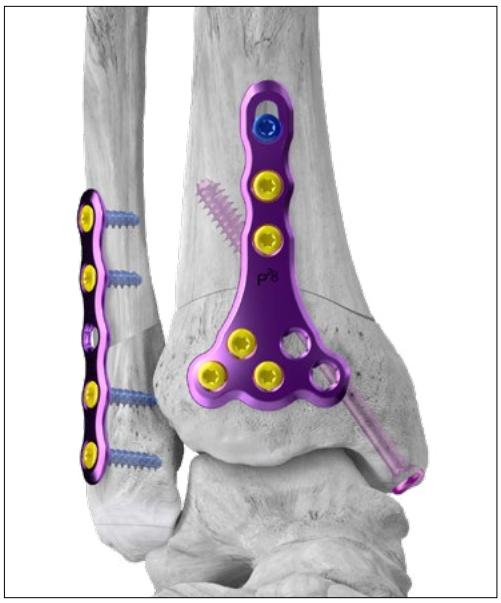
ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-0001).



When a crossing screw is used, plate holes in the distal cluster may be filled first, followed by the most distal screw hole proximal to the osteotomy. Follow steps as previously described for plate screw placement.

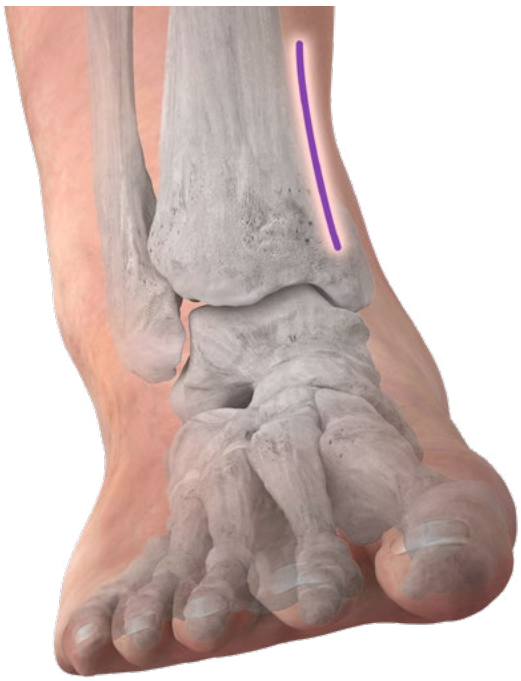


In placing a screw in the compression slot where a crossing screw across the osteotomy is already placed, position the compression slot drill guide such that the arrow faces away from the osteotomy to allow for distal screw placement in the slot.

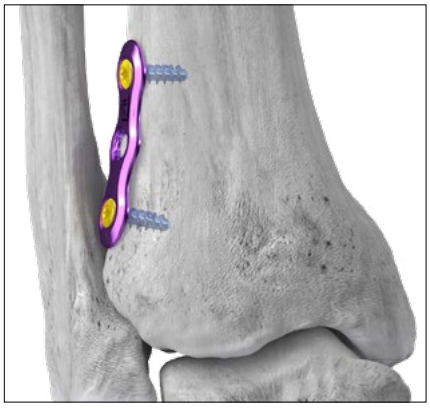
If a fibula osteotomy was performed, place a fibula plate as previously described. Confirm plate position and screw lengths using fluoroscopy.

INCISION/EXPOSURE

A longitudinal medial incision is made at the level of the planned osteotomy and is appropriately sized for the osteotomy and plate size. Dissection is carried down to the medial tibia to expose the bone surface.



OSTEOTOMY AND DEFORMITY CORRECTION



If preferred, the lateral cortex of tibia can be preemptively plated at the level of the planned osteotomy to help keep the lateral cortex of the tibia intact while performing the opening wedge osteotomy.

Note: *For more information and instructions on the use of Paragon28's Gorilla® plates and screws, please refer to the Gorilla® R3CON Surgical Technique Guide: P51-STG-0001.*

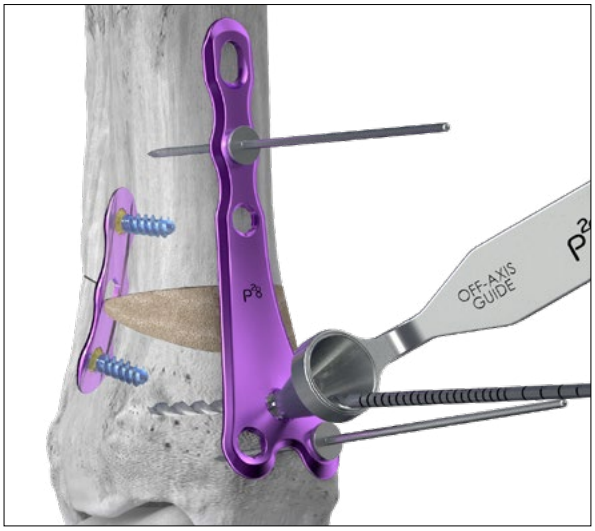
Perform a transverse tibial osteotomy at the correct height according to surgeon preference. Take care to avoid violating the lateral cortex of the tibia during the osteotomy. If required, create an oblique fibular osteotomy depending on the deformity being corrected and according to surgeon preference.

Distract the tibial osteotomy according to surgeon preference and insert the appropriately sized autograft or allograft wedge.

PLATE PLACEMENT AND PERMANENT FIXATION

Position the plate on the bone such that the spanning region of the plate is centered over the osteotomy. Once the desired position is achieved, provisionally fixate the plate with 2 Olive Wires. Confirm plate position using fluoroscopy.

Note: *If the use of a crossing screw across the osteotomy is preferred, placement of the crossing screw should be performed prior to plating, with screw diameter according to surgeon preference.*

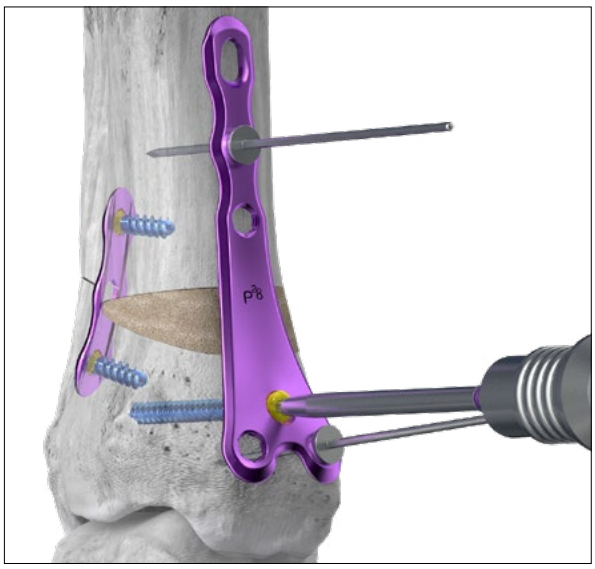


If longer distal plate screws are desired, the EZ Cone Drill Guide can direct the drill up to 15° off axis to allow for screws to be placed more parallel to the ankle joint, thus allowing for longer lengths. Use the appropriately sized drill and drill a hole at the desired angle for the intended screw.

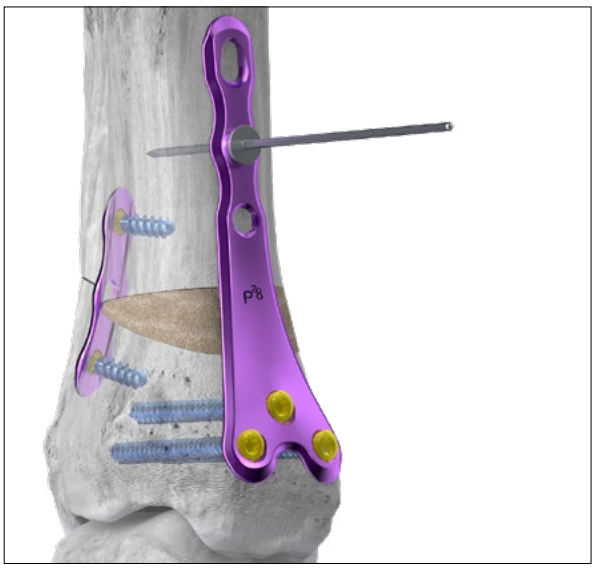
Note: *All circular plate holes accept Ø2.7, Ø3.5, or Ø4.2 mm locking or non-locking screws and Ø3.5 mm locking or non-locking compact thread screws.*

Measure screw length using the provided depth gauge.

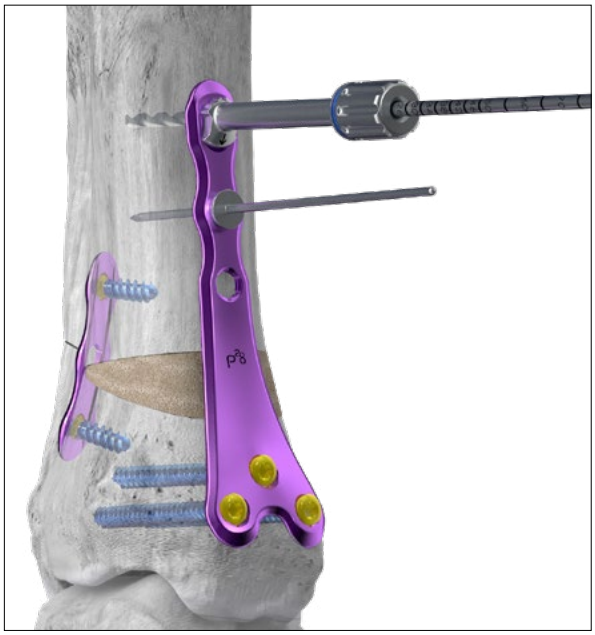
PLATE PLACEMENT AND PERMANENT FIXATION



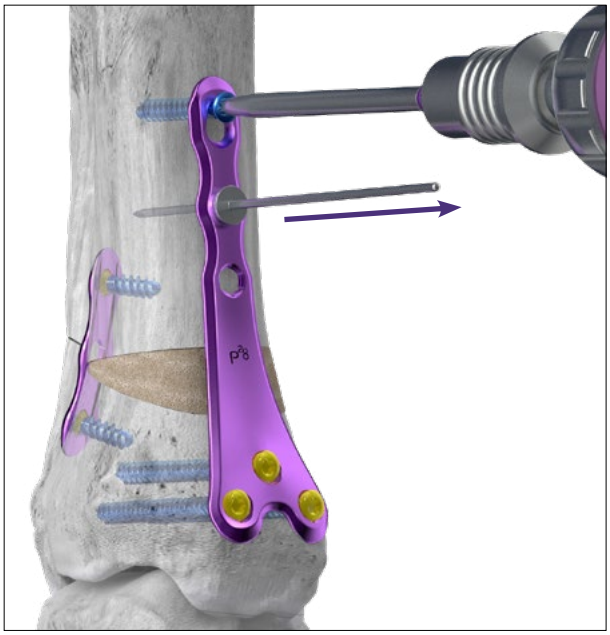
Attach the driver to a provided handle. Insert the appropriate length screw using the driver by inserting it into the screw head and turning the screw clockwise until seated.



Repeat the same steps of drilling, measuring, and screw insertion for the remaining holes in the distal cluster of the plate, removing any temporary fixation Olive Wires in the distal portion to allow for screw placement.



For the compression slot, insert the compression slot drill guide into the compression slot, with the arrow on the guide pointing toward the osteotomy to create a drill hole at the proximal end of the slot. Drill through the drill guide using the drill for the desired screw diameter.

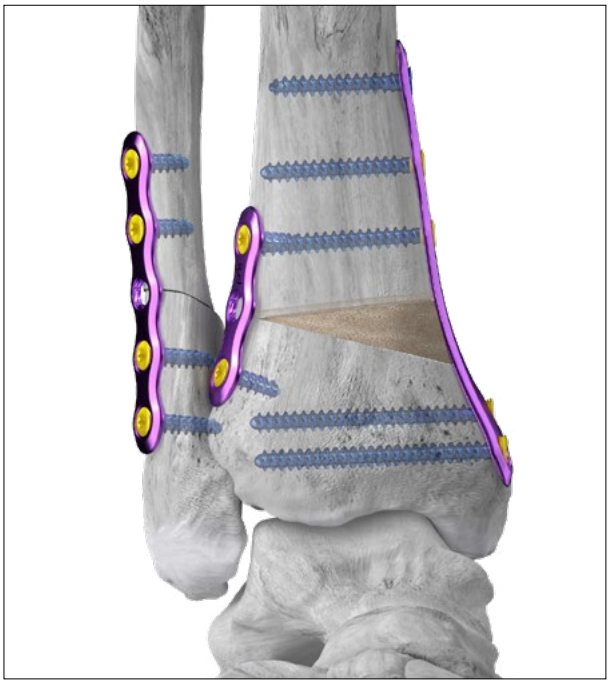


Use the provided driver to insert the screw into the compression slot by turning the screw clockwise. Prior to fully seating the screw, remove any remaining temporary fixation wires and then continue to fully seat the screw.

PLATE PLACEMENT AND PERMANENT FIXATION

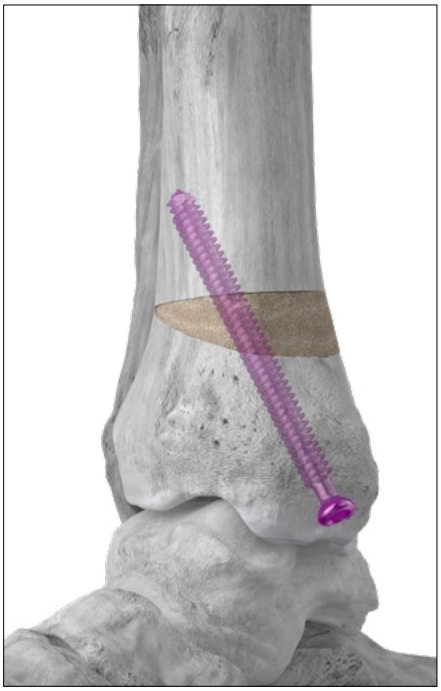
Place screws as previously described into any remaining screw holes. Confirm final plate position and screw lengths using fluoroscopy.

If a fibula osteotomy was created during deformity correction, fibula plates are available to allow for permanent fixation of the fibula.

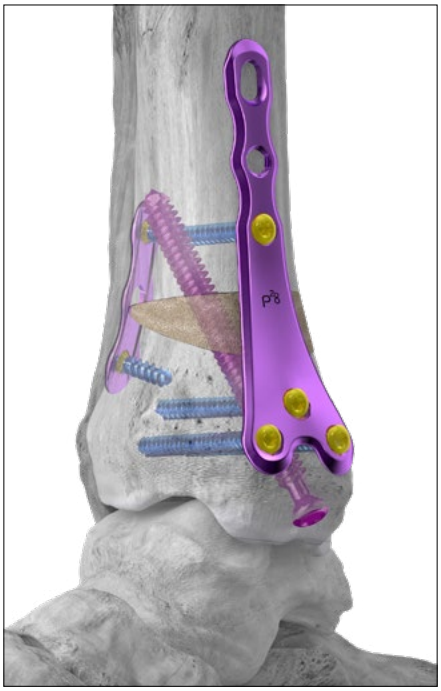


Note: *For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-0008.*

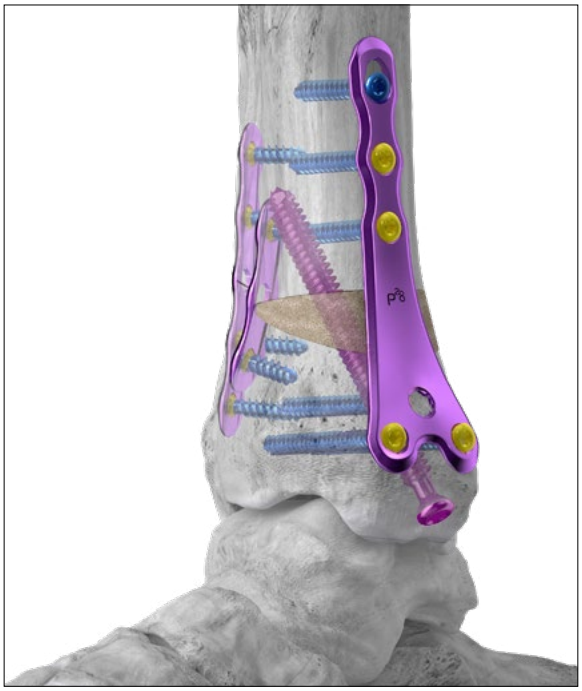
ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-0001).



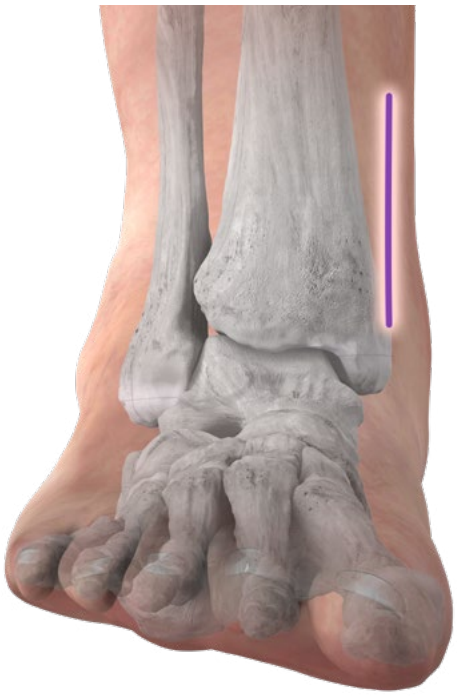
When a crossing screw is used, plate holes in the distal cluster may be filled first, followed by the most distal screw hole proximal to the osteotomy. Follow steps as previously described for plate screw placement.



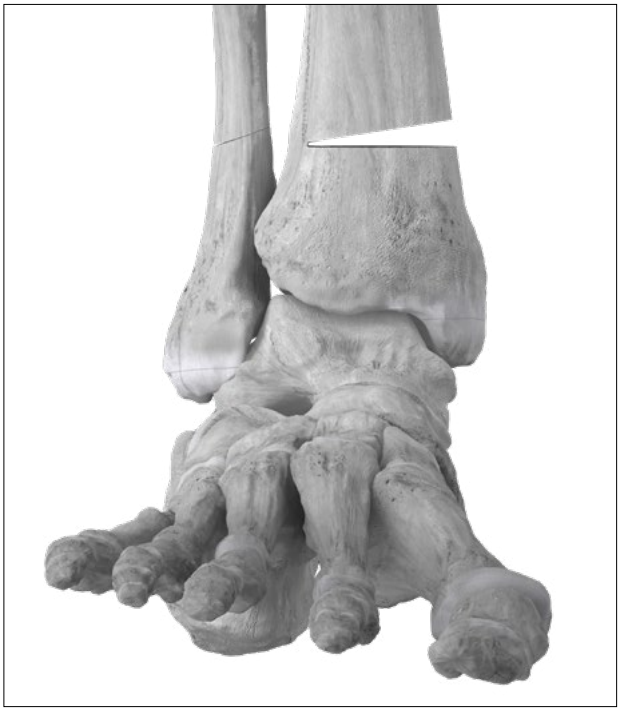
In placing a screw in the compression slot where a crossing screw across the osteotomy is already placed, position the compression slot drill guide such that the arrow faces away from the osteotomy to allow for distal screw placement in the slot. If a fibular osteotomy was performed, place a fibula plate as previously described. Confirm plate position and screw lengths using fluoroscopy.

INCISION/EXPOSURE

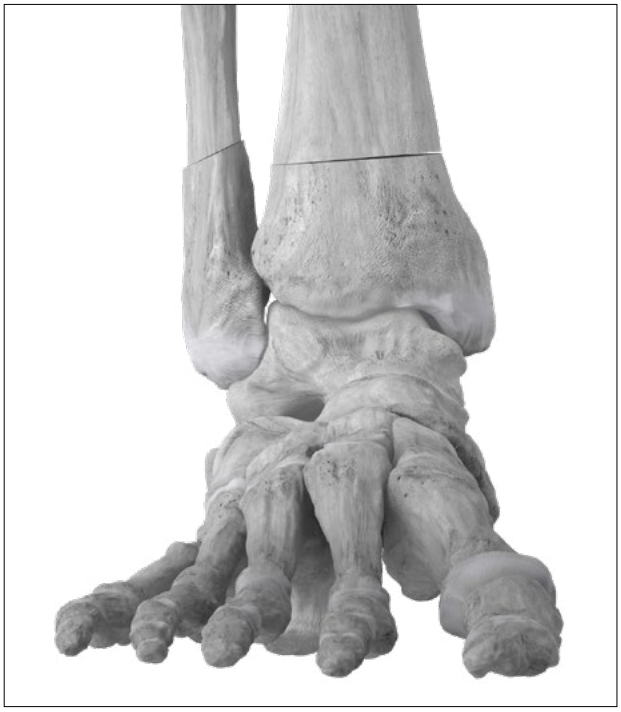
A longitudinal medial incision is made at the level of the planned osteotomy and is appropriately sized for the osteotomy and plate size. Dissection is carried down to the medial tibia to expose the bone surface.



OSTEOTOMY AND DEFORMITY CORRECTION



Perform a closing wedge tibial osteotomy at the correct height according to surgeon preference. Take care to avoid violating the lateral cortex of the tibia during the osteotomy. If required, create an oblique fibular osteotomy depending on the deformity being corrected and according to surgeon preference



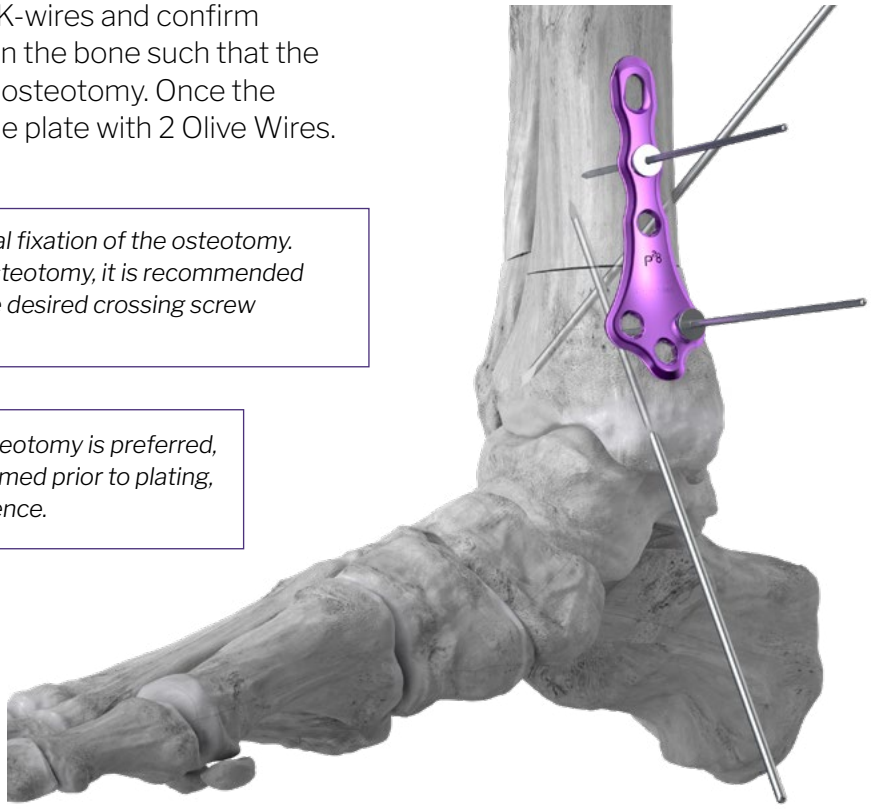
Manually correct the deformity.

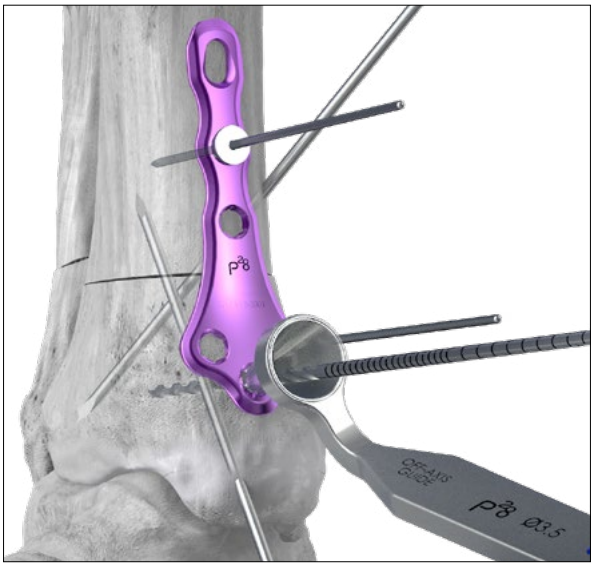
PLATE PLACEMENT AND PERMANENT FIXATION

Provisionally fixate the osteotomy with crossing K-wires and confirm correction using fluoroscopy. Position the plate on the bone such that the spanning region of the plate is centered over the osteotomy. Once the desired position is achieved, temporarily fixate the plate with 2 Olive Wires. Confirm plate position using fluoroscopy.

Note: *Ø2.3 mm K-wires are available for provisional fixation of the osteotomy. If planning to place a crossing screw across the osteotomy, it is recommended to use the K-wire sized to be the guide wire for the desired crossing screw diameter for provisional fixation.*

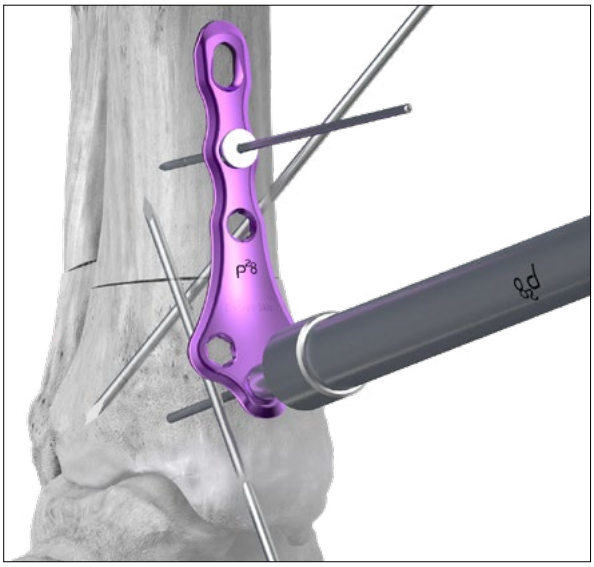
Note: *If the use of a crossing screw across the osteotomy is preferred, placement of the crossing screw should be performed prior to plating, with screw diameter according to surgeon preference.*





If longer distal plate screws are desired, the EZ Cone Drill Guide can direct the drill up to 15° off axis to allow for screws to be placed more parallel to the ankle joint, thus allowing for longer lengths. Use the appropriately sized drill and drill a hole at the desired angle for the intended screw.

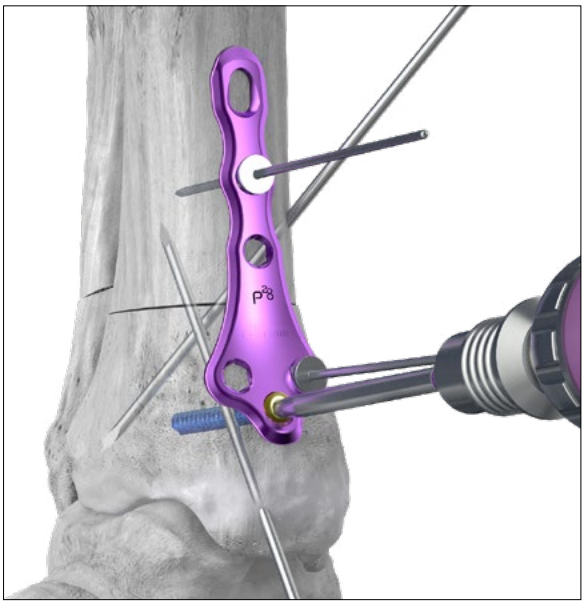
Note: *All circular plate holes accept Ø2.7, Ø3.5, or Ø4.2 mm locking or non-locking screws and Ø3.5 mm locking or non-locking compact thread screws.*



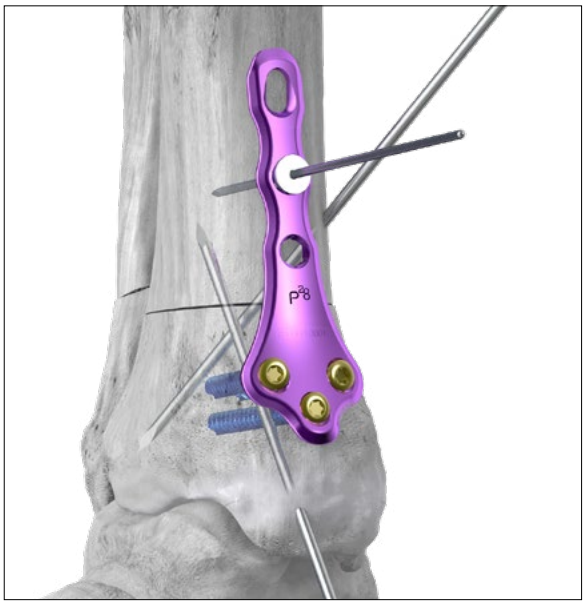
Measure screw length using the provided depth gauge.

Note: *For more information and instructions on the use of Paragon28's Gorilla® plates and screws, please refer to the Gorilla® R3CON Surgical Technique Guide: P51-STG-0001.*

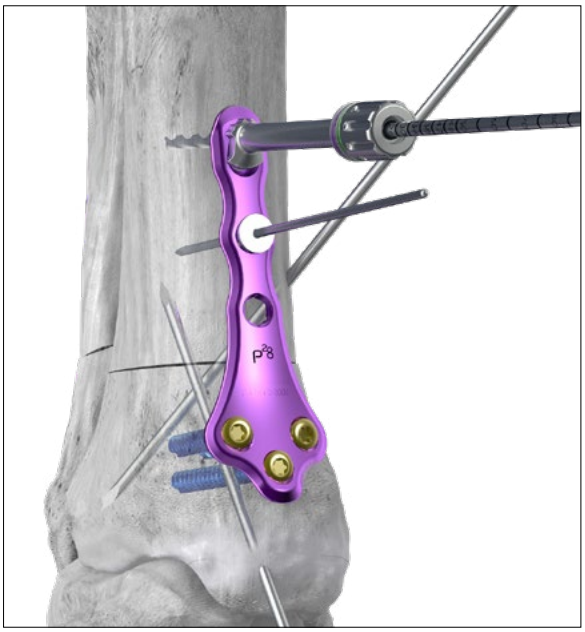
PLATE PLACEMENT AND PERMANENT FIXATION



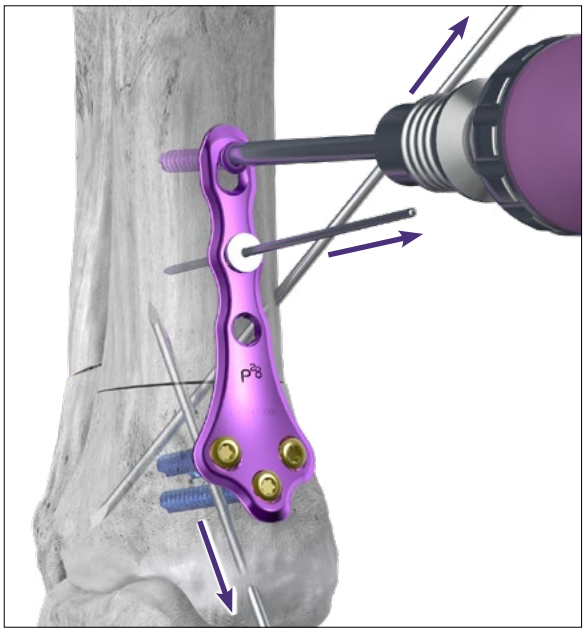
Attach the driver to a provided handle. Insert the appropriate length screw using the driver by inserting it into the screw head and turning the screw clockwise until seated.



Repeat the same steps of drilling, measuring, and screw insertion for the remaining holes in the distal cluster of the plate, removing any temporary fixation Olive Wires in the distal portion to allow for screw placement.



For the compression slot, insert the compression slot drill guide into the compression slot, with the arrow on the guide pointing toward the osteotomy to create a drill hole at the proximal end of the slot. Drill through the drill guide using the drill for the desired screw diameter.

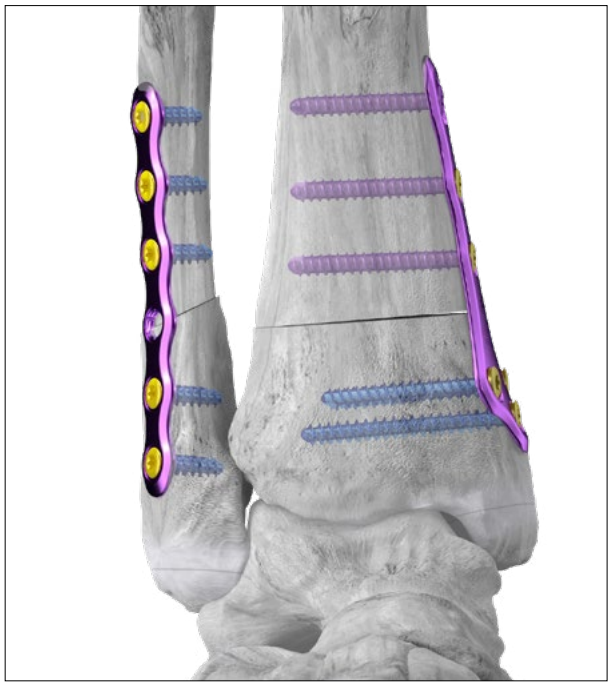


Use the provided driver to insert the screw into the compression slot by turning the screw clockwise. Prior to fully seating the screw, remove any remaining temporary fixation wires and then continue to fully seat the screw.

PLATE PLACEMENT AND PERMANENT FIXATION

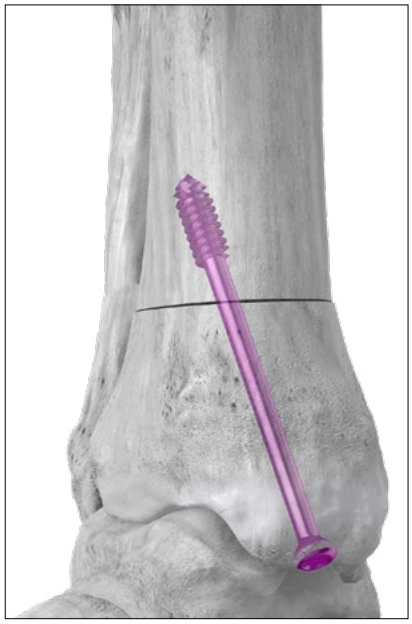
Place screws as previously described into any remaining screw holes. Confirm final plate position and screw lengths under fluoroscopy.

If a fibula osteotomy was created during deformity correction, fibula plates are available to allow for permanent fixation of the fibula.



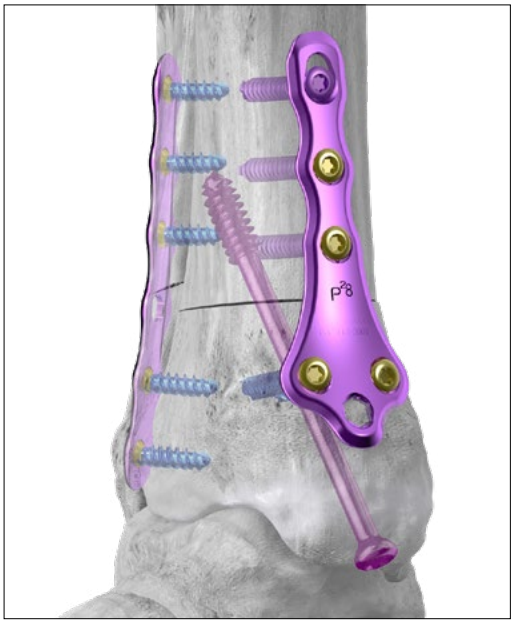
Note: *For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-0008.*

ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-0001).

When a crossing screw is used, plate holes in the distal cluster may be filled first, follow by the most distal screw hole proximal to the osteotomy. Follow steps as previously described for plate screw placement.

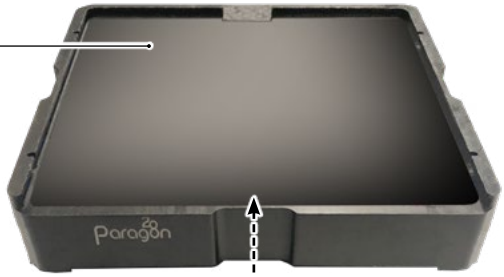


In placing a screw in the compression slot where a crossing screw across the osteotomy is already placed, position the compression slot drill guide such that the arrow faces away from the osteotomy to allow for distal screw placement in the slot.
If a fibular osteotomy was performed, place a fibula plate as previously described. Confirm plate position and screw lengths using fluoroscopy.

GORILLA® CADDY AND CASE SYSTEM

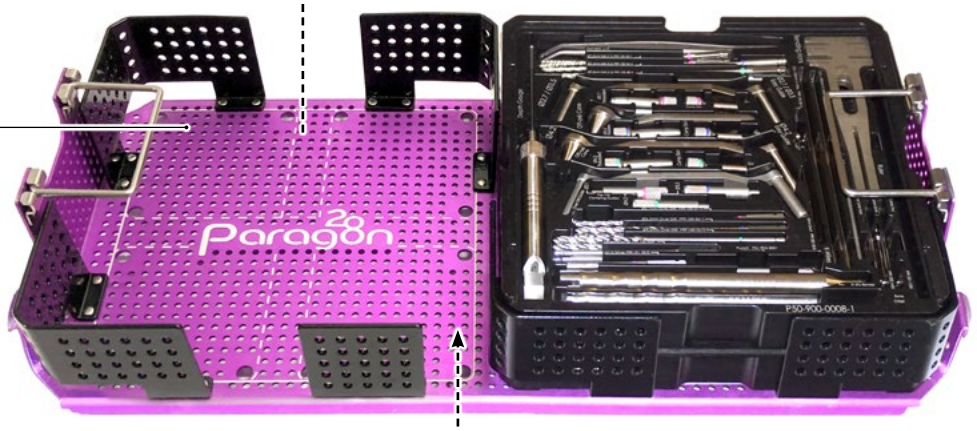
GORILLA® SUPRAMALLEOLAR OSTEOTOMY SYSTEM PLATE CADDY

The Gorilla® Supramalleolar Osteotomy Plate Caddy contains the standard and long Anterior Tibia, Distal Medial Tibia, and Proximal Medial Tibia Plate options. The caddy also contains Gorilla® Ankle Fracture 3, 4, or 5 hole Straight Fibular Plates. It also comes with Gorilla® Ankle Fracture 7 or 9 hole left and right Anatomic Fibular Plates. Smooth and threaded Olive Wires are also included in this Caddy.



GORILLA® R3CON INSTRUMENT CADDY

Drills, Drill guides, Centering Guides, Olive Wires, Plate Benders, Drivers, K-wires and a Depth Gauge are located in the Gorilla® R3CON Instrument Caddy.



GORILLA® SCREW CADDY

GORILLA® CASE

MINI-MONSTER® SCREW CADDY

The Gorilla® Case can accommodate one Mini-Monster® Screw Caddy if a Ø2.0 mm, Ø2.5 mm, Ø3.0 mm Ø3.5 mm or Ø4.0 mm cannulated screw is needed during a case.

GORILLA® R3CON INSTRUMENTS

The Caspar Compression/Distraction device, osteotomes, baby Bennet retractors, bone reduction clamps, periosteal elevator, cartilage removal device, pin distractor and handles are located at the bottom of the Gorilla® Case.

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

INDICATIONS FOR USE (GORILLA®)

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

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

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

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

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

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

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

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

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

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

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.

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

INDICATIONS FOR USE (MONSTER®)

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Fractures and Osteotomies

- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
- Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
- Talar fractures
- Ankle fractures
- Navicular fractures
- Fractures of the fibula, malleolus, and calcaneus
- Metatarsal and phalangeal osteotomies
- Weil osteotomy
- Calcaneal osteotomy

Hallux Valgus Correction

- Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Arthrodesis/Deformity Correction

- 1st MTP arthrodesis
- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint arthrodesis
- Talonavicular arthrodesis
- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Fusion resulting from neuropathic osteoarthopathy (Charcot) such as:

- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

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GORILLA®
R3CON PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

P51-STG-0014 RevA [2022-11-18]

Paragon 28, Inc.
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Englewood, CO 80112 USA
(855) 786-2828

DISCLAIMER

The purpose of the Gorilla® Supramalleolar Osteotomy System Surgical Technique Guide is to demonstrate use of the Gorilla® Plates in the Gorilla® Supramalleolar Osteotomy 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.