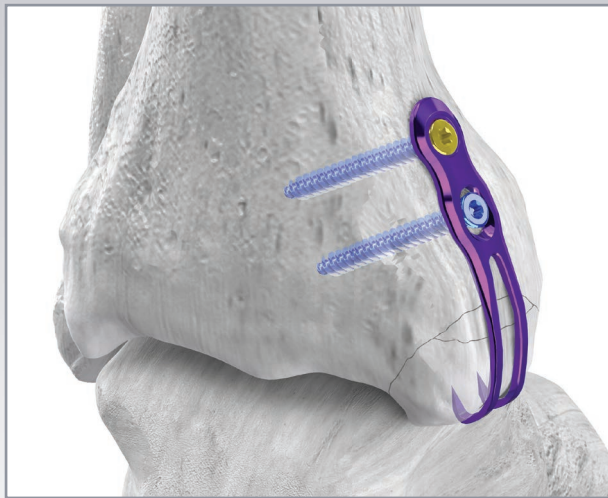


Exclusively foot & ankle **20**
Paragon[®]
ANKLE FRACTURE PLATING SYSTEM



GORILLA[®]
R3CON PLATING SYSTEM

Acknowledgment:

Paragon 28® would like to thank Christopher Zingas, M.D. for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

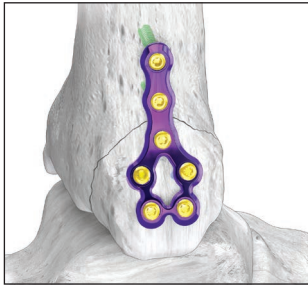
Paragon 28® designed the Gorilla® Ankle Fracture Plating System to allow surgeons versatility in fixation selection for ankle fractures. The system has 52 plate options for fracture fixation of the distal fibula and tibia. While some plating families tend to be more anatomic and directed in their placement, other plates are intended to allow surgeons flexibility in their location. All circular plate holes accept 2.7 mm, 3.5 mm and 4.2 mm locking and non-locking screws. Most plate holes have a built-in recess for placement of a syndesmotic device or to allow a screw that is off-axis to have reduced screw head prominence.

Instrumentation is included in the Gorilla® Ankle Fracture Plating System that facilitates reduction and fixation of ankle fractures. Use of this instrumentation is shown throughout the technique guide within some of the techniques for the 10 plating families. The page number for specific instruments and implant techniques is outlined in the table of contents below.

TABLE OF CONTENTS

FEATURED TECHNIQUE:	PAGE #:
Implants: Plate Families	3-4
Featured System Instrumentation	5
Plate Templates	6
Medial Malleolus Plate	7
Featuring: Placement of Gorilla® Screws	
Straight Fibular Plate	8
Featuring: Use of a Mini-Monster® Solid Screw	
Anatomic Fibular Plate	9-10
Featuring: Syndesmotic Tenaculum Clamp	
Medial Malleolus K-wire Guide	11
Posterior Fibular Plate	12
Featuring: Plate Positioning Tower	
Posteromedial Tibia Plate	13
Trimalleolar Tibia Plate	14
Posterolateral Tibia Plate	15
Straight Fibular Hook Plate	16-17
Featuring: Double Tamp	
Anatomic Fibular Hook Plate	18-19
Featuring: Hook Screw Drill Guide	
Medial Malleolus Hook Plate	20-21
Featuring: Single Tamp	
Indications, Contraindications and Warnings	22-23

ANKLE FRACTURE PLATES



Medial Malleolus Plate

- Plate designed to address vertical shear fractures and medial malleolar osteotomy fixation

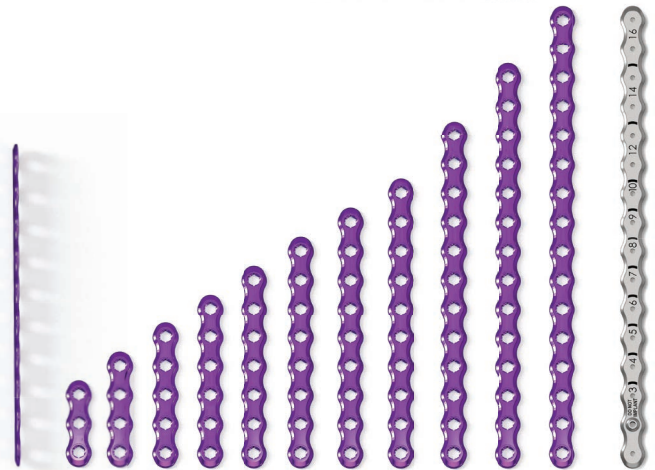
Available in a 7 hole plate and template



Straight Fibular Plate

- Plate optionality and malleability provides a plating solution for a variety of fracture types and patterns

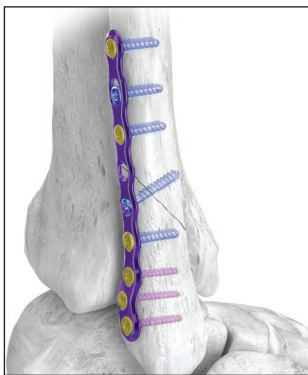
Available in 3-10 hole, 12 hole, 14 hole and 16 hole plates. 16 hole template available



Anatomic Fibular Plate

- Distal screw cluster allows for multiple fixation points in the lateral malleolus

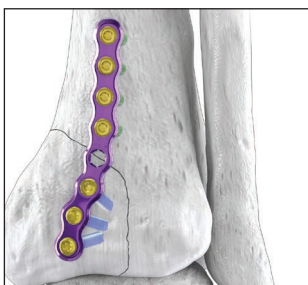
Available in 7 hole, 9 hole, 11 hole, 13 hole and 15 hole right and left side specific plates. 17 hole templates (right and left) available



Posterior Fibular Plate

- Plate optionality provides incision and fracture based configurations for the posterior, posterolateral and lateral fibula

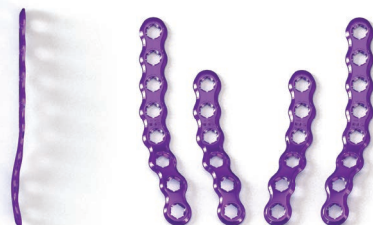
Available in 7 hole, 9 hole and 11 hole alpha and beta plates



Posteromedial Tibia Plate

- Contoured to the posteromedial tibia to treat posterior pilon variant fractures

Available in 6 hole and 8 hole right and left side specific plates



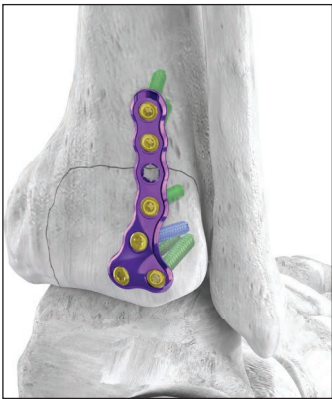
ANKLE FRACTURE PLATES



Trimalleolar Tibia Plate

- Slight concavity allows for plate placement posteriorly on the tibia with little to no bending
- Plate helps guard against superior translation of the posterior tibia fracture fragment in trimalleolar fractures

Available in 3 hole and 4 hole plates



Posterolateral Tibia Plate

- Contoured to the posterolateral tibia to treat posterior pilon variant fractures or large trimalleolar posterior tibia fragments
- Two most distal screw holes are angled superiorly to avoid the dome of the tibial plafond

Available in 5 hole, 6 hole, 7 hole and 8 hole right and left side specific plates



Straight Fibular Hook Plate

- Hooks are designed to support a comminuted lateral malleolus or avulsion fragment

Available in 5 hole and 6 hole plates



Anatomic Fibular Hook Plate

- Distal screw cluster allows for crossing screw placement through hooks to provide support and additional fixation to distal fragment

Available in 5 hole and 6 hole right and left side specific plates



Medial Malleolus Hook Plate

- Intended for fixation of comminuted or small fractures of the medial malleolus that may not be conducive to lag screw fixation

Available in 2 hole and 4 hole plates



FEATURED SYSTEM INSTRUMENTATION



Medial Malleolus K-wire Guide



1.6 x 10 cm Long Olive Wire



Plate Positioning Tower



1.6 x 8 cm Long Olive Wire



Hook Plate Screw Drill Guide



Hook Plate Single Tamp

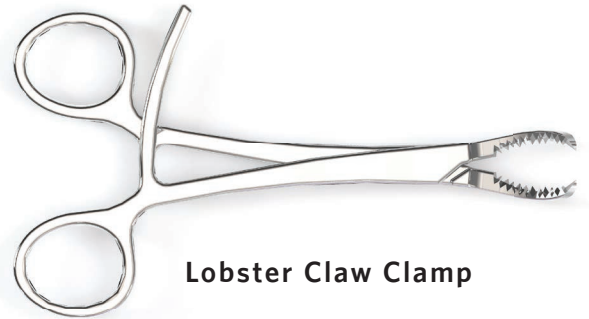


Hook Plate Double Tamp

FRACTURE REDUCTION INSTRUMENTATION



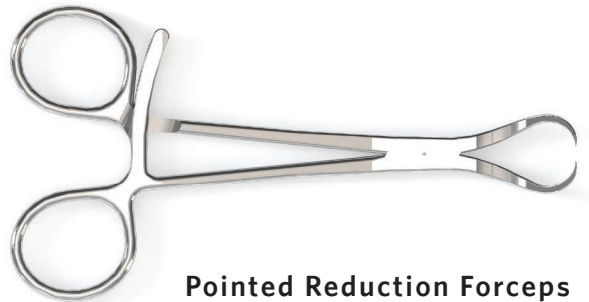
Bone Hook



Lobster Claw Clamp



Tenaculum Clamp



Pointed Reduction Forceps

ADDITIONAL R3CON SCREWS

Additional 3.5 mm R3CON screws are available in the most common lengths for ankle fracture to supplement the screw offering in the Gorilla Case.



3.5 mm x 10 mm non-locking screw



3.5 mm x 10 mm locking screw



3.5 mm x 12 mm non-locking screw



3.5 mm x 12 mm locking screw



3.5 mm x 14 mm non-locking screw



3.5 mm x 14 mm locking screw

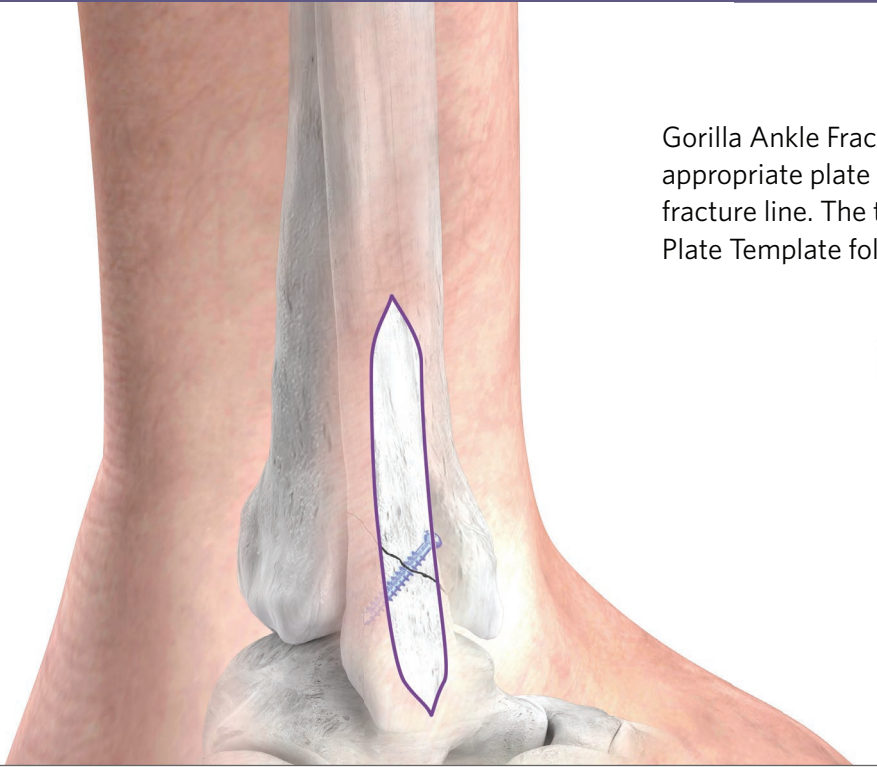


3.5 mm x 16 mm non-locking screw



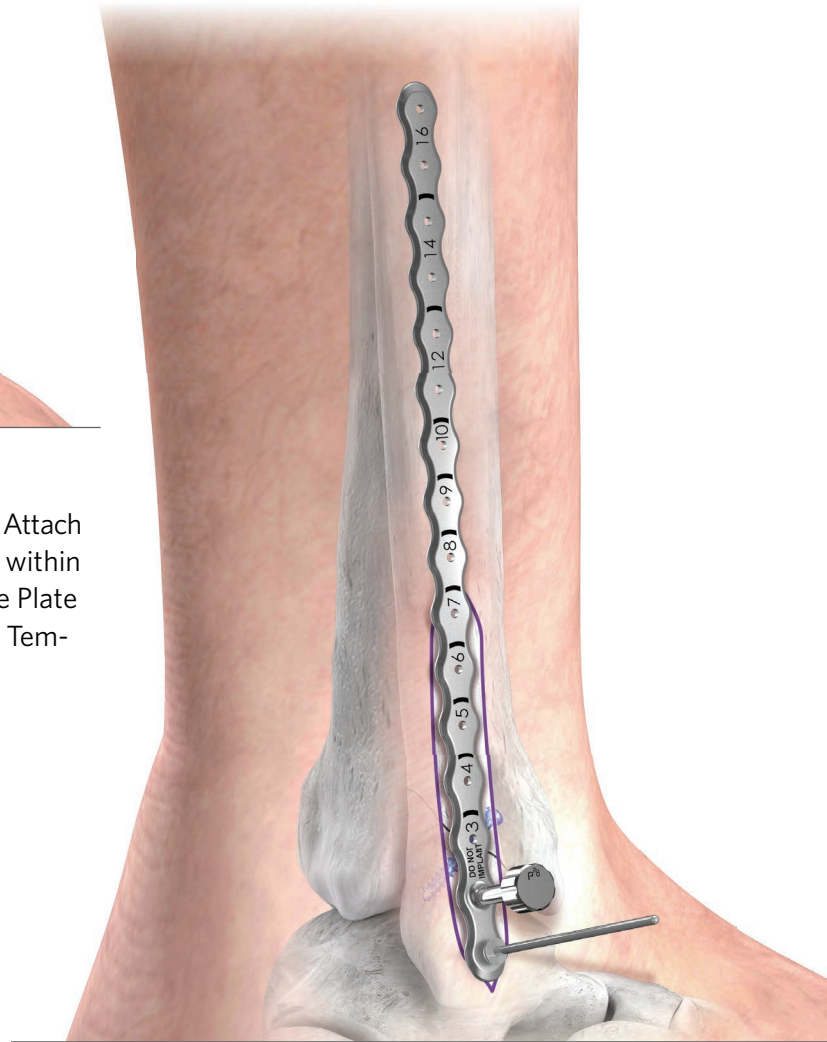
3.5 mm x 16 mm locking screw

PLATE TEMPLATES GORILLA® ANKLE FRACTURE PLATING SYSTEM



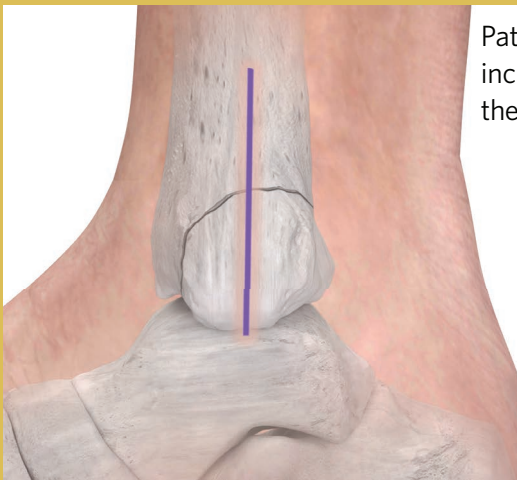
Gorilla Ankle Fracture Plate Templates are intended to assess the appropriate plate length with extracutaneous placement along the fracture line. The technique below shows use of a Straight Fibular Plate Template following lag screw placement in a fibular fracture.

Retrieve the appropriate Plate Template for the fracture type. Attach the Precision Guide Set Screw to the Plate Template by inserting within the raised boss and turning in a clockwise direction. Apply the Plate Template to the surgical site, with the proximal portion of the Template placed extracutaneously, if desired.

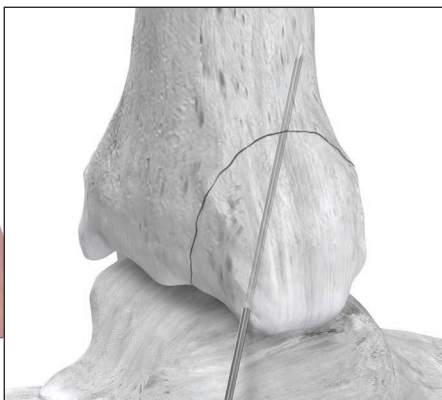


The Plate Templates can be temporarily secured to the surgical site with Ø1.4 mm olive wires, if desired. Select desired plate length based on necessary number of plate holes, which are indicated by the holes along the Template, and/or the laser markings, which identify the lengths of sterile packaged Gorilla plates.

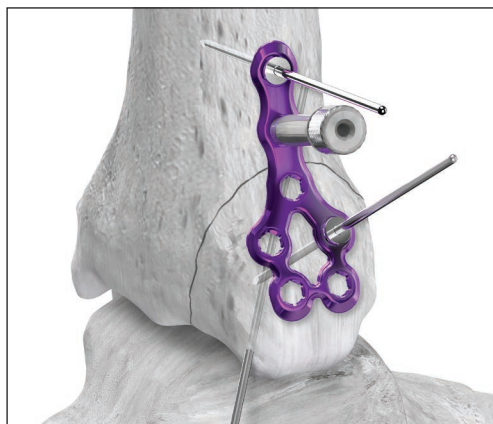
MEDIAL MALLEOLUS PLATE FEATURING: PLACEMENT OF GORILLA® SCREWS



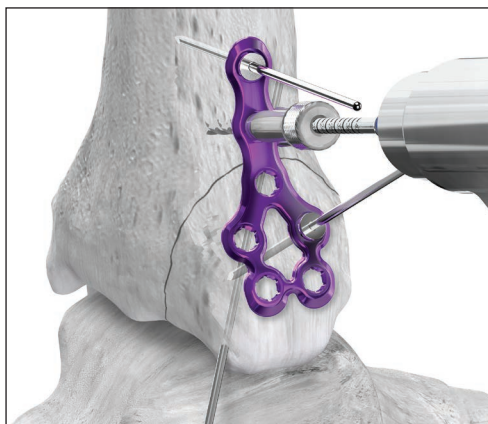
Patient is positioned supine such that the foot is near the end of the table. A longitudinal incision is made over the central aspect of the medial malleolus, appropriately sized for the fracture and plate length. Continue soft tissue dissection until the fracture site is visible.



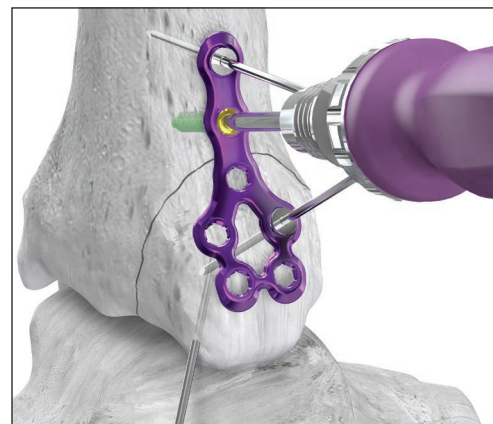
The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forceps or lobster claw clamp, per surgeon preference. Retrieve the Medial Malleolus Plate Template, if desired. The Plate Template can be temporarily secured to the surgical site with olive wires to trial the sterile packaged Medial Malleolus Plate. Template use is described on Page 6.



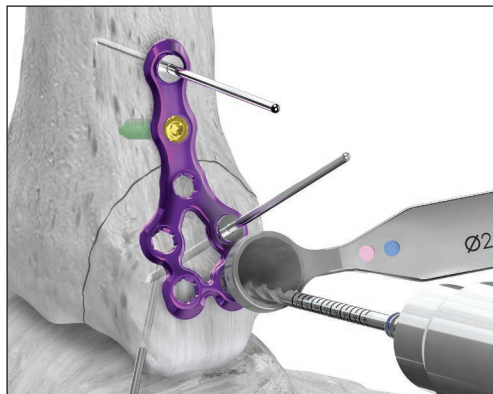
Retrieve the medial malleolus plate. Place a threaded drill tower on the proximal aspect of the plate. Secure the plate to the medial malleolus using 1-2 olive wires. Confirm plate placement using fluoroscopy.



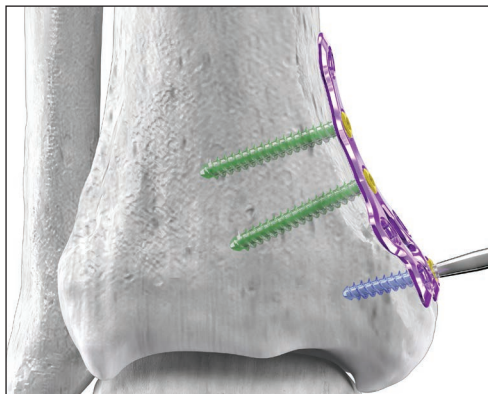
All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Drill through the threaded drill tower using the drill sized for the desired screw diameter. Remove the threaded drill tower.



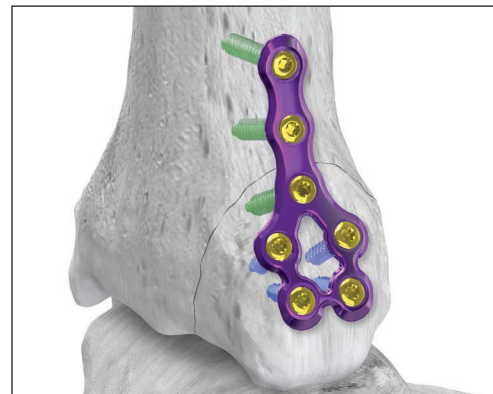
Measure screw length using a depth gauge. Insert the selected screw into the drilled hole in the tibia. Confirm screw position and length using fluoroscopy.



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



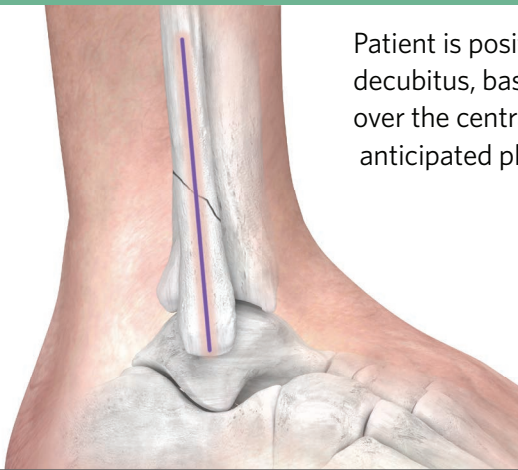
Measure screw length using a depth gauge. Insert the selected screw into the drilled hole in the medial malleolus. Remove olive wires. Repeat the steps above to fill the remaining screw holes. The same steps are used regardless if a locking or non-locking screw is used.



Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

STRAIGHT FIBULAR PLATE FEATURING: USE OF A MINI-MONSTER® SOLID SCREW

Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.



The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forceps or lobster claw clamp, per surgeon preference.

In this instance, a 3.5 mm fully threaded Mini-Monster Solid screw is used as a lag screw across the fracture site prior to plate placement.



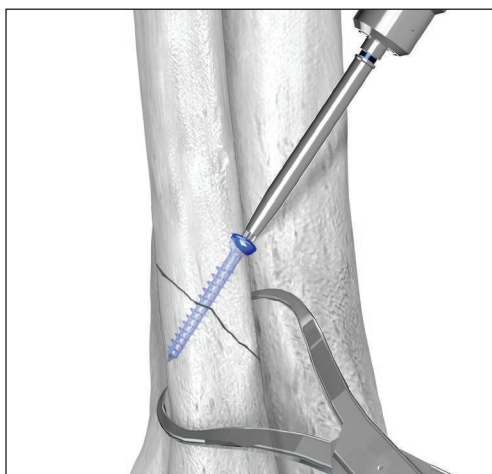
A 1.2 mm K-wire is placed perpendicular to the fracture site, from anterior to posterior. Confirm K-wire position using fluoroscopy.



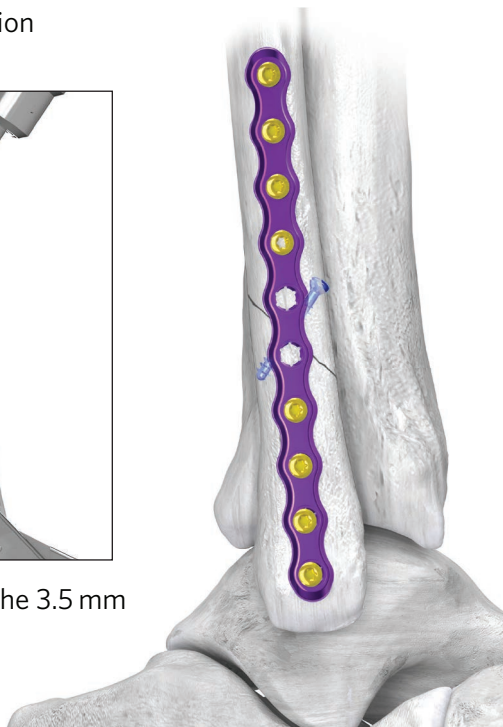
Using the drill, drill bi-cortically over the K-wire, if desired.



Use the overdrill to drill the near cortex of the fibula. Countersink the near cortex. Measure screw length using the provided depth gauge.



Remove the guide wire. Insert the 3.5 mm fully threaded locking screw.



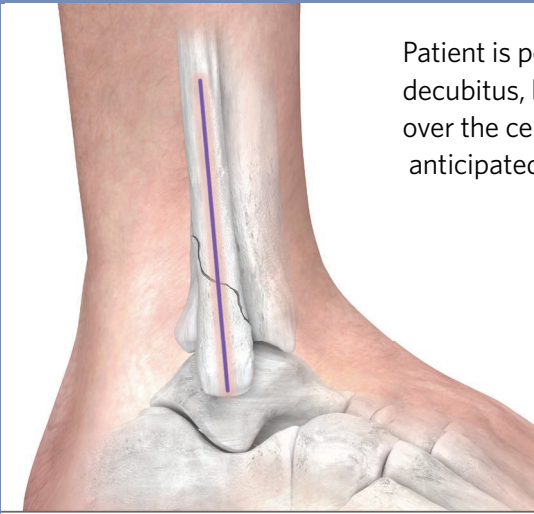
Retrieve the Straight Fibular Plate Template, if desired. The Plate Template can be temporarily secured to the surgical site with olive wires to trial all lengths of the sterile packaged Straight Fibular Plates. Template use is described on Page 6.

Select the appropriate Straight Fibular Plate for the fracture type and size. Olive wires can be used to secure the plate to bone. Confirm plate placement using fluoroscopy. All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Fill desired plate holes with selected screw sizes.

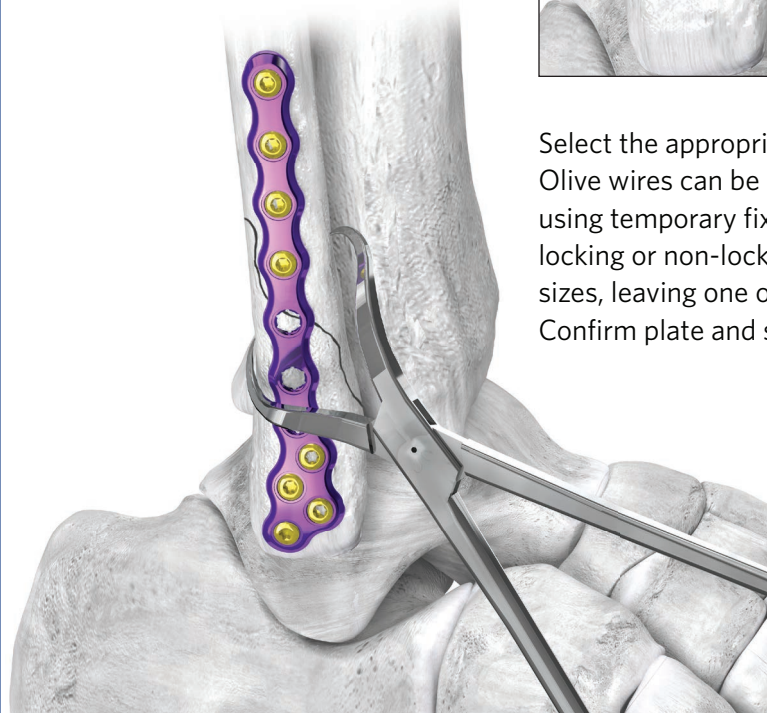
Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

ANATOMIC FIBULAR PLATE FEATURING: SYNDESMOTIC TENACULUM CLAMP

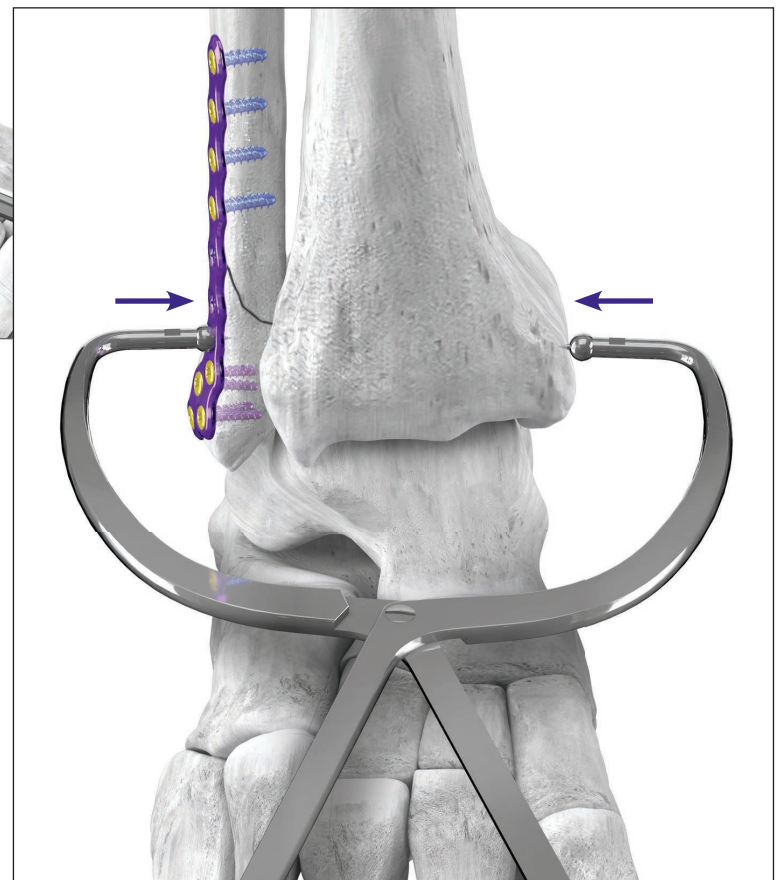
Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.



The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forceps or lobster claw clamp, per surgeon preference. Retrieve the appropriate Anatomic Fibular Plate Template, if desired. The Plate Template can be temporarily secured to the surgical site with olive wires to trial all lengths of the sterile packaged Anatomic Fibular Plates. Template use is described on Page 6.



Select the appropriate Anatomic Fibular Plate for the fracture type and size. Olive wires can be used to secure the plate to bone. Confirm plate placement using temporary fixation. All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Fill desired plate holes with selected screw sizes, leaving one or two screw holes empty for syndesmotic fixation. Confirm plate and screw position using fluoroscopy.



If syndesmotic fixation is necessary, a Syndesmotic Tenaculum Clamp is available to assist in reduction of the syndesmosis. A small stab incision is made over the medial malleolus with blunt dissection carried down to bone. Place the BB-Tak portion of the clamp into the incision and into the lateral malleolus. Reduction of the syndesmosis is performed by closing the handles together and allowing the ratcheting mechanism to maintain position of the clamp once appropriate reduction is achieved.

ANATOMIC FIBULAR PLATE FEATURING: SYNDESMOTIC TENACULUM CLAMP

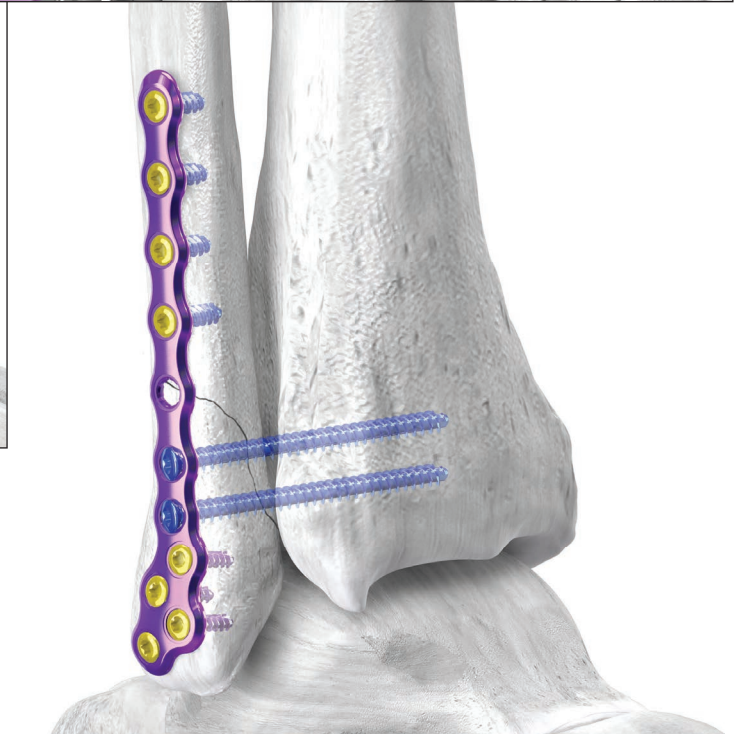


Placement of one or two syndesmotenaculum screws can be performed following reduction of the syndesmosis. A Gorilla R3CON 3.5 mm or 4.2 mm screw is recommended for syndesmotenaculum fixation, and a non-locking screw should be used if greater than 15° of off-axis drilling is performed. Drill 3-4 cortices using the drill for desired screw size.

Measure screw length using a depth gauge. Insert the selected screw. Confirm screw length and placement using fluoroscopy. Remove the syndesmotenaculum clamp to allow space to place a second syndesmotenaculum screw.



Repeat steps above if placing a second syndesmotenaculum screw.

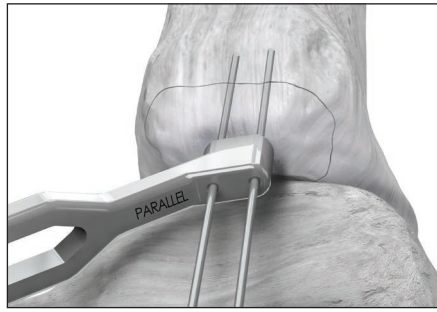


Confirm plate and screw placement using fluoroscopy. Proceed to incision closure and adjunctive procedures at this time.

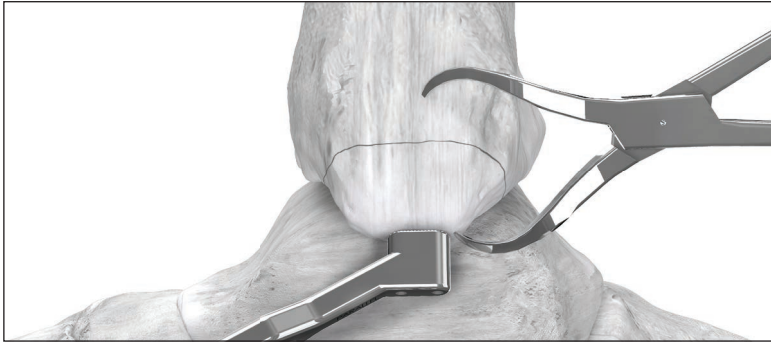
MEDIAL MALLEOLUS K-WIRE GUIDE

For medial malleolus fractures that require screw fixation only, the Medial Malleolus K-wire Guide allows for K-wire placement that is parallel or converging, depending on surgeon preference. Both sides of the K-wire Guide are designed to allow for 4.0 mm or smaller Mini-Monster screws to be inserted into the medial malleolus without colliding.

Parallel K-wire Guide



Converging K-wire Guide



After fracture reduction and temporary fixation of the fracture, retrieve the Medial Malleolus K-wire Guide. Position the selected side (Parallel or Converging) against the distal aspect of the medial malleolus at the desired K-wire entry position.

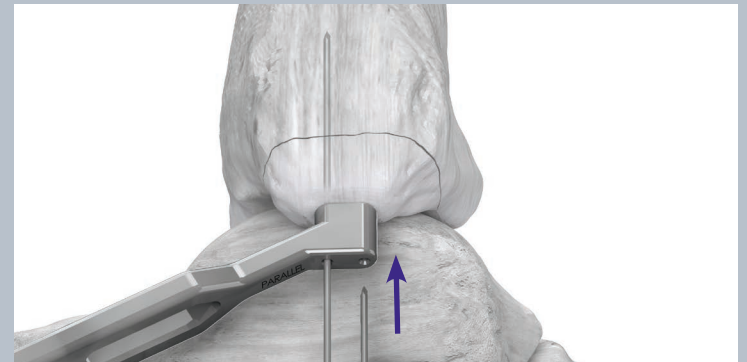


Insert two K-wires into the guide and confirm K-wire placement using fluoroscopy.

NOTE:



Alternatively, a single K-wire can be placed freehand into the medial malleolus using fluoroscopy.



If position of wire is appropriate after checking under fluoroscopy, the K-wire Guide can be slid over the original wire such that the empty hole is anterior or posterior to the original K-wire. The second K-wire is then placed.



Using standard cannulated screw insertion techniques, place two 4.0 mm partially threaded Mini-Monster screws into the medial malleolus.

Confirm position and length of screws using fluoroscopy. Remove K-wires serving as temporary fixation. Proceed to incision closure and adjunctive procedures at this time.

POSTERIOR FIBULAR PLATE FEATURING: PLATE POSITIONING TOWER



Posterior or posterolateral plate placement can be achieved through a lateral or a posterior incision. Incision placement and patient positioning may be dependent on fibular fracture pattern and the presence and extent of a tibial fracture and planned fixation.

A lateral incision (shown) may require supine or lateral decubitus patient position with the foot near the end of the table. For a posterior incision, the patient is positioned in the lateral decubitus position or prone, per surgeon preference. Soft tissue dissection is carried down until the fracture site is visible. Retract the peroneal tendons to allow for plate and screw placement.

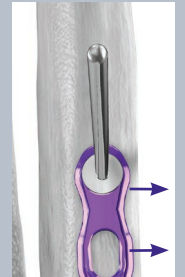
NOTE: The Plate Positioning Tower helps the surgeon to place olive wires through the plate holes in the fibula that are centered, allowing the plate to stay in the intended position on this narrow bone. When olive wires are placed that are not perfectly centered, the plate can shift to meet the olive wire.



Plate positioning tower



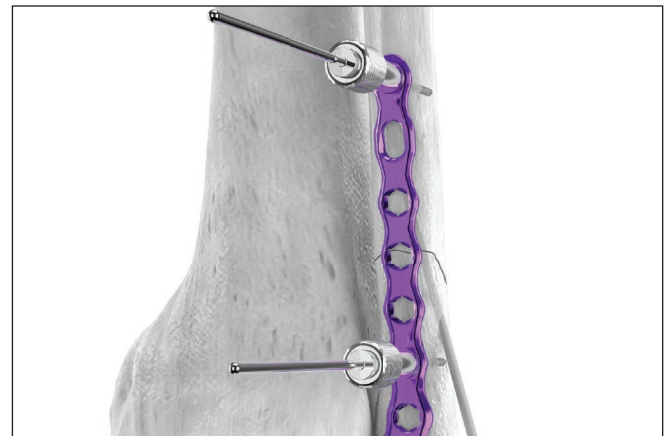
Olive wire not centered



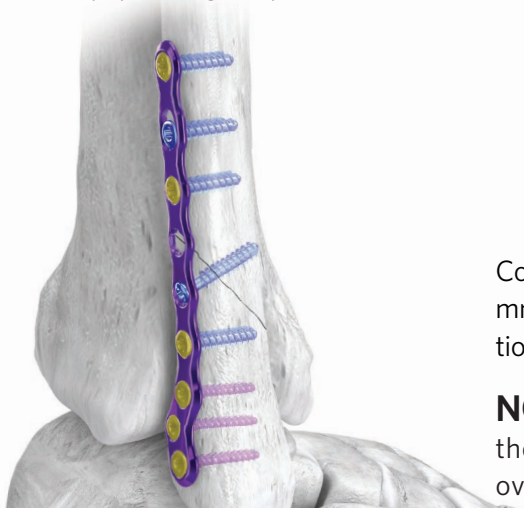
Result in plate shifting



The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.



Select the appropriate Posterior Fibular Plate for the fracture type and size. Affix the plate positioning tower to the plate at the proximal aspect. Retrieve a long olive wire. Use the long olive wire through the plate positioning tower to temporarily fix the plate to the fibula, while maintaining intended plate position. A second plate positioning tower and long olive wire can be used distally to temporarily secure the plate to bone.

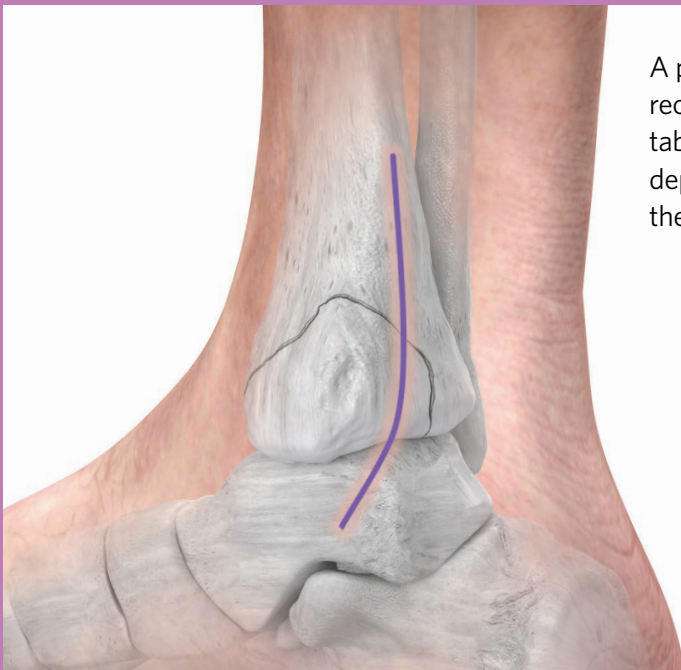


Confirm plate placement using fluoroscopy. All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws, with the exception of the compression slot, which only accepts non-locking screws.

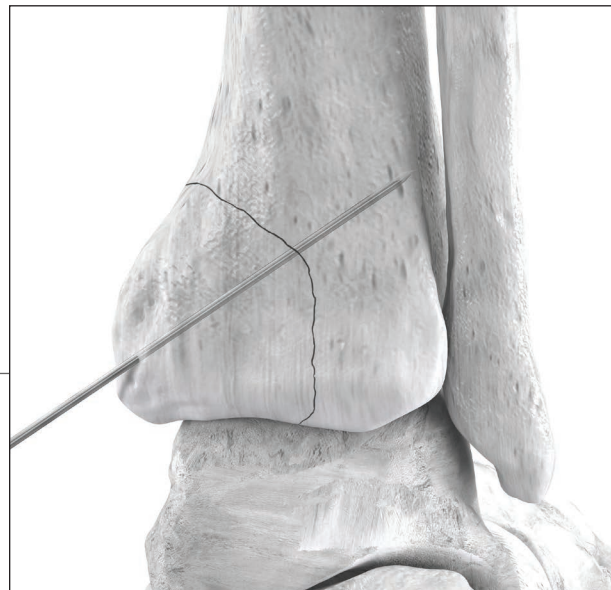
NOTE: A lag screw can be placed across the fracture through the plate in this instance. A non-locking screw can be used with overdrilling of the near cortex. Fill remaining plate holes.

Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

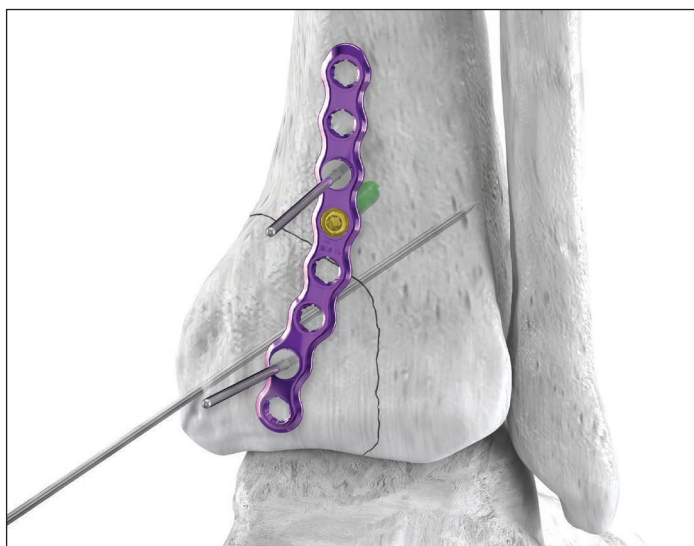
POSTEROMEDIAL TIBIA PLATE



A posteromedial approach for use with the posteromedial tibia plate is recommended. Prone patient positioning with the foot near the end of the table is recommended. The soft tissue interval for deep dissection will be dependent on fracture pattern. Soft tissue dissection is carried down until the fracture site is visible.



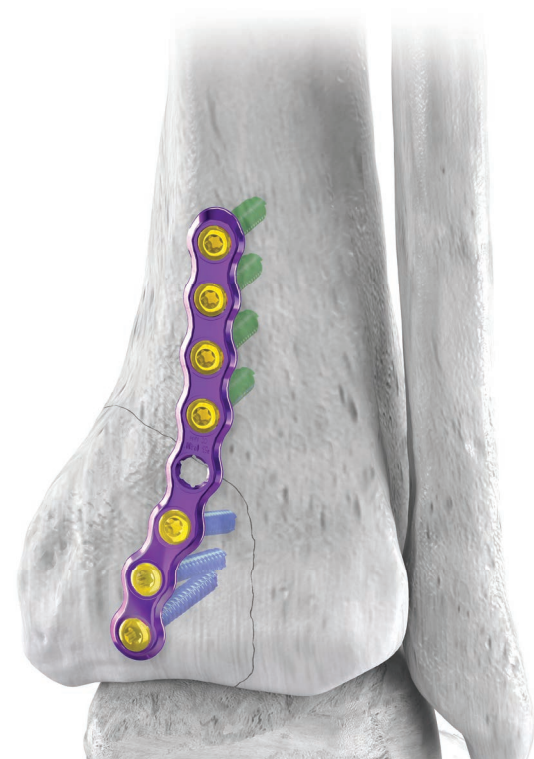
The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire or clamp, per surgeon preference.



Select the appropriate Posteromedial Tibia Plate for the fracture type and size. Temporarily fix the plate to the posterior tibia by placing 1-2 olive wires.

Confirm plate placement using fluoroscopy.

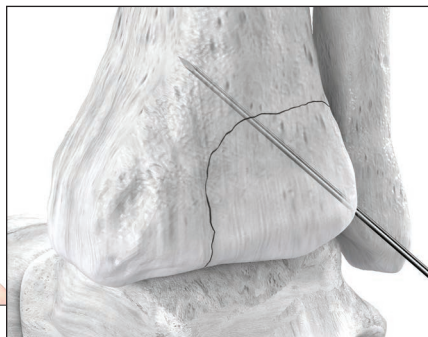
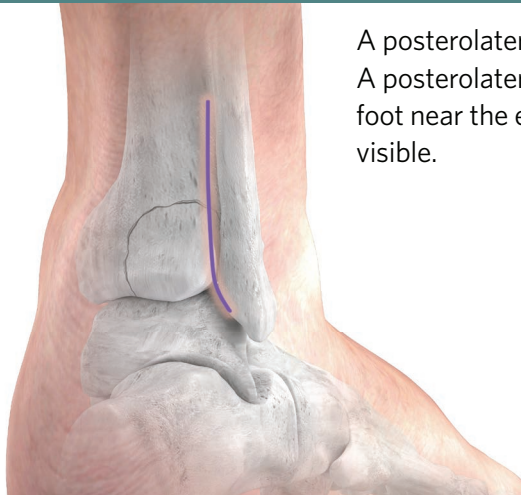
All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Place a proximal plate screw above the fracture to secure the plate to the bone.



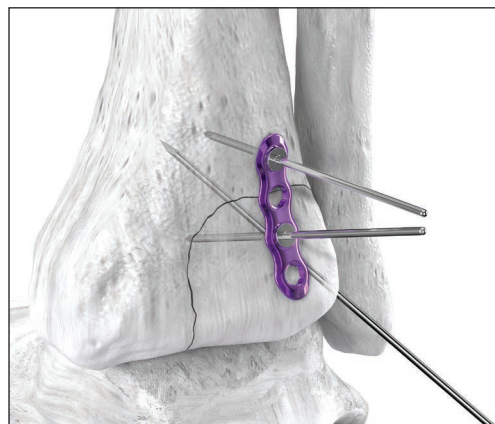
Continue screw placement into desired screw holes. Confirm plate and screw placement using fluoroscopy. Proceed to additional fracture fixation, incision closure or adjunctive procedures at this time.

TRIMALLEOLAR TIBIA PLATE

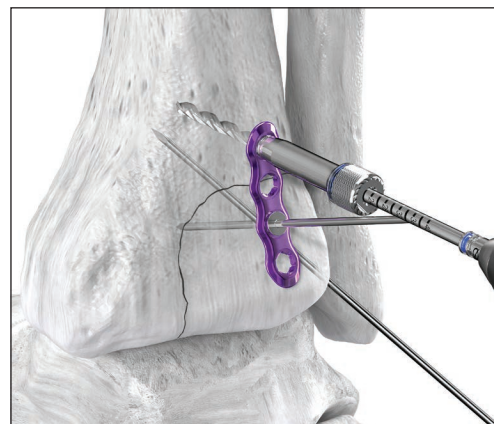
A posterolateral approach for posterior malleolar fixation using a plate is typically used. A posterolateral incision may require a lateral decubitus or prone patient position with the foot near the end of the table. Soft tissue dissection is carried down until the fracture site is visible.



The fracture site is cleared and refreshed. It is important to preserve the Posterior Inferior Tibiofibular Ligament (PITFL) attachment to the fracture fragment. Fracture reduction is performed and temporary stabilization is achieved using a K-wire or clamp, per surgeon preference.



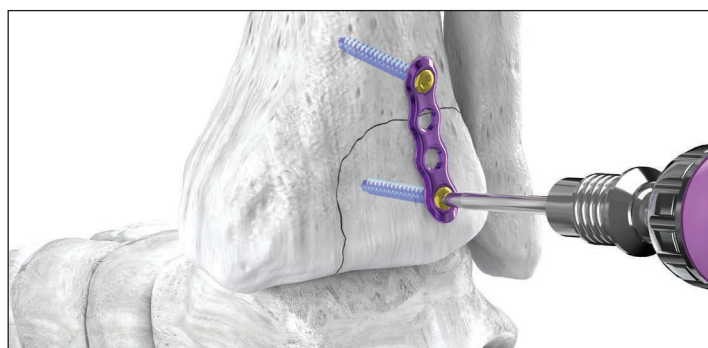
Select the 3 or 4 hole Trimalleolar Plate appropriate for the fracture type and size. Temporarily fix the plate to the posterior malleolus by placing 1-2 olive wires. Confirm plate placement using fluoroscopy.



All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Drill for the desired screw diameter in the proximal hole to anchor the plate proximally and allow the plate to assist in fracture reduction while placing the distal screws.



Depending on plate placement, the distal screw(s) may require off-axis drilling in a superior direction to avoid drill contact with the dome of the tibial plafond. The cone end of the EZ/Cone Guide can be used to limit drilling to 15° in any direction. Drill for the desired screw diameter.



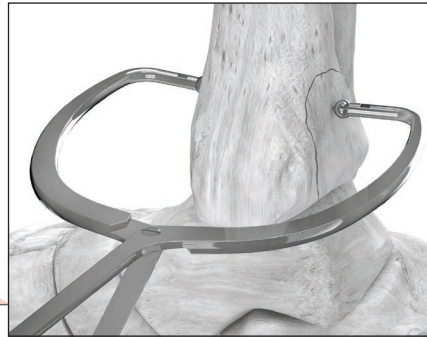
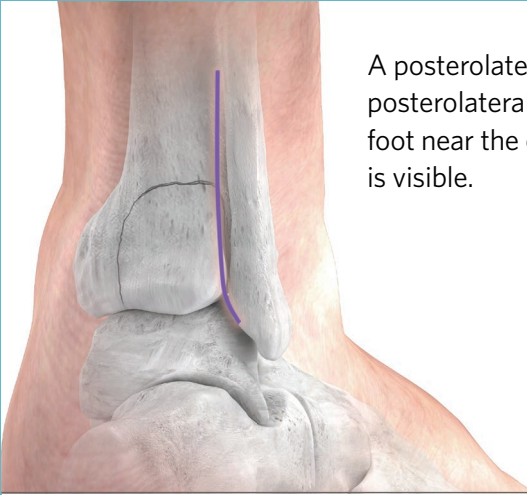
Measure screw length using a depth gauge. Insert the selected screw into the drilled hole.



Repeat the steps above to fill the remaining screw holes. The same steps are used regardless if a locking or non-locking screw is used. Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

POSTEROLATERAL TIBIA PLATE

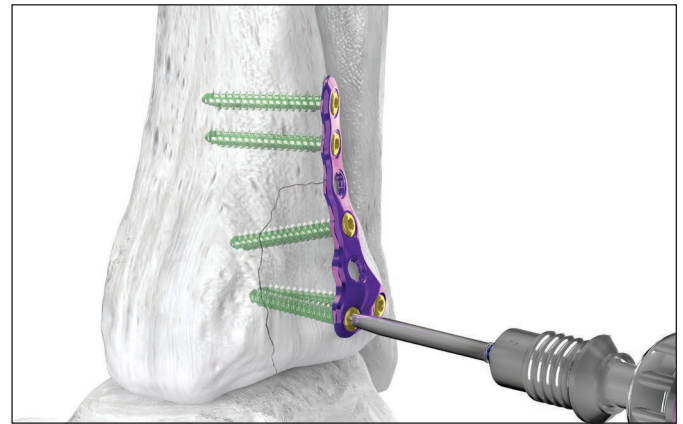
A posterolateral approach for use with the posterolateral tibia plate is recommended. A posterolateral incision will require a lateral decubitus or prone patient position with the foot near the end of the table. Soft tissue dissection is carried down until the fracture site is visible.



The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire or clamp, per surgeon preference.



Select the appropriate Posterolateral Tibia Plate for fracture type and size. Temporarily fix the plate to the posterior malleolus by placing 1-2 olive wires. Confirm plate placement using fluoroscopy.



All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. The distal two screw holes are tapped such that the screws, when placed on-axis, are directed superiorly away from the dome of the tibial plafond. If additional proximal angulation is desired, the cone end of the EZ/Cone guide can be used during drilling.

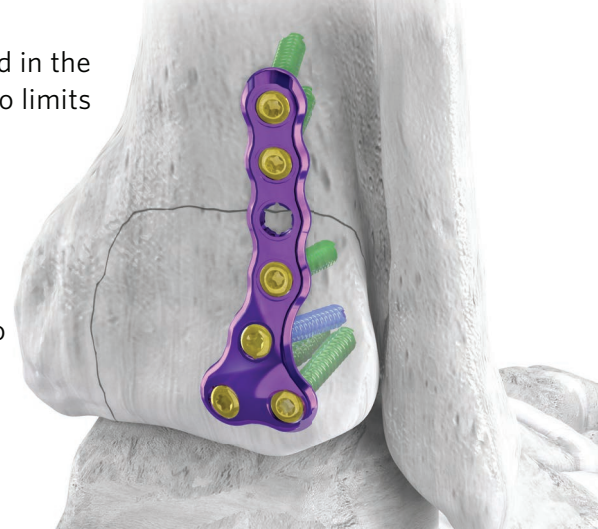
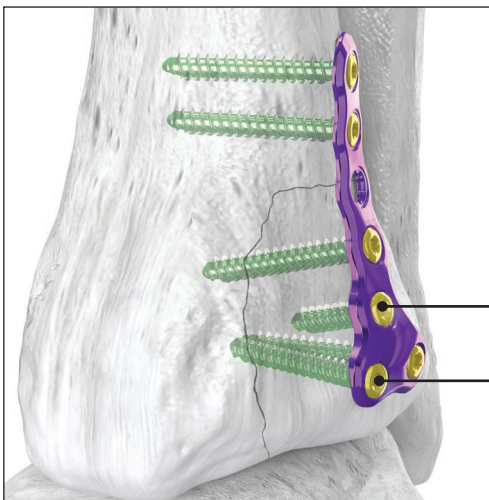
NOTE: If 4.2 mm screws are used in the two most distal screw holes (Holes 1 & 2), a short 4.2 mm screw (≤ 18 mm) must be used in the screw hole above it (Hole 3) to avoid screw collision; however, a full length 3.5mm (or smaller) screw diameter can be used.

If 3.5 mm screws or smaller are used in the three distal screw holes, there are no limits on screw lengths.

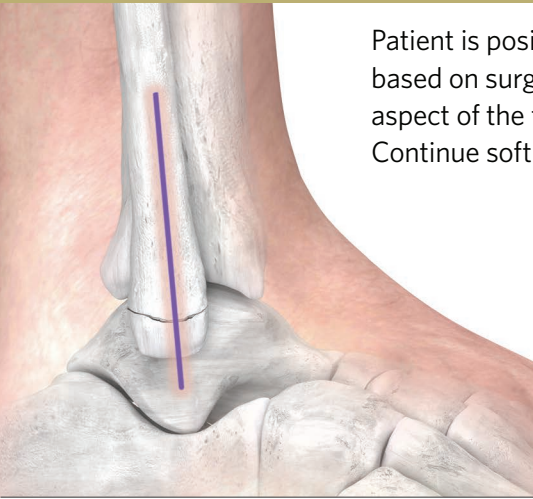
Hole 3

Holes 1 and 2

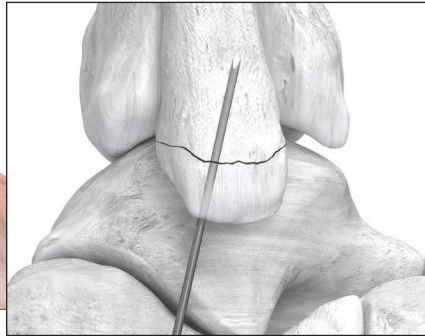
Upon placing all screws in the plate into desired screw holes, confirm screw position and lengths using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.



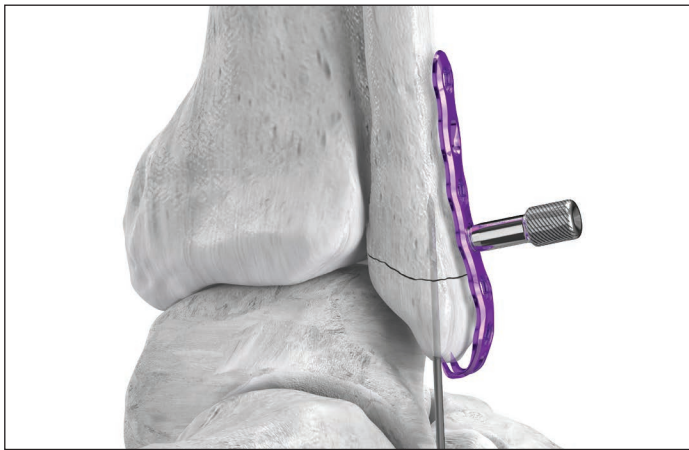
STRAIGHT FIBULAR HOOK PLATE FEATURING: DOUBLE TAMP



Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.

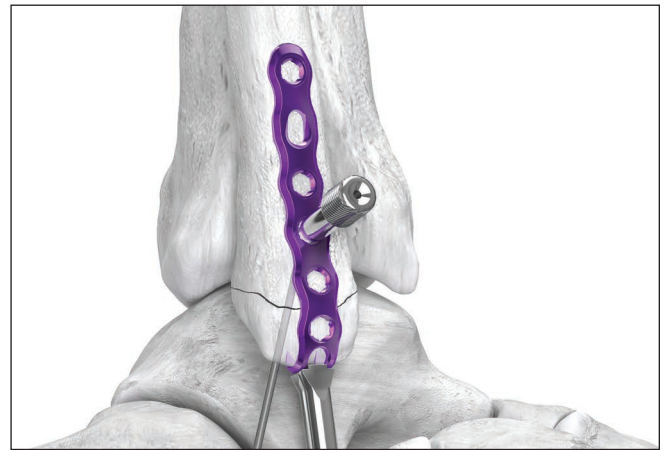


The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forceps or lobster claw clamp, per surgeon preference.

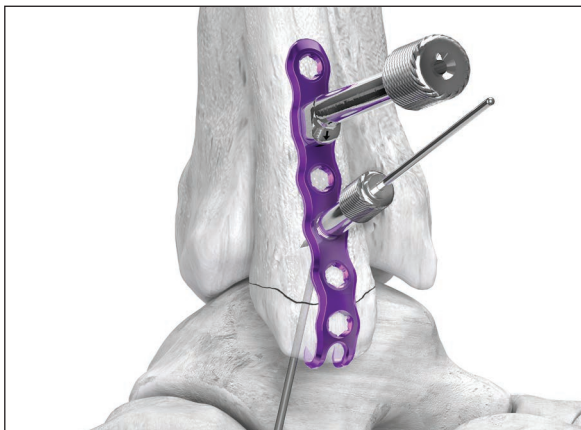


Select the appropriate Straight Fibular Hook Plate for fracture type and size. Attach a plate positioning tower to the plate to assist with plate placement.

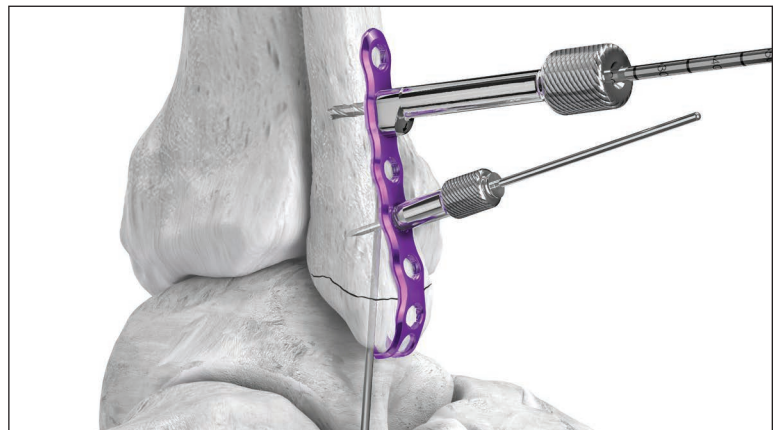
NOTE: If pre-drilling of the hooks is desired for a patient with a hard bone or for a severely comminuted fracture, 2.0 mm K-wires can be retrieved from the Gorilla Instrument Caddy to use for pre-drilling.



Place plate onto bone, allowing the hooks to engage the distal tip of the fibula. Retrieve the double tamp. Press the double tamp against the two hooks of the plate and tap the end with a mallet until the hooks have engaged the distal tip of the fibula.

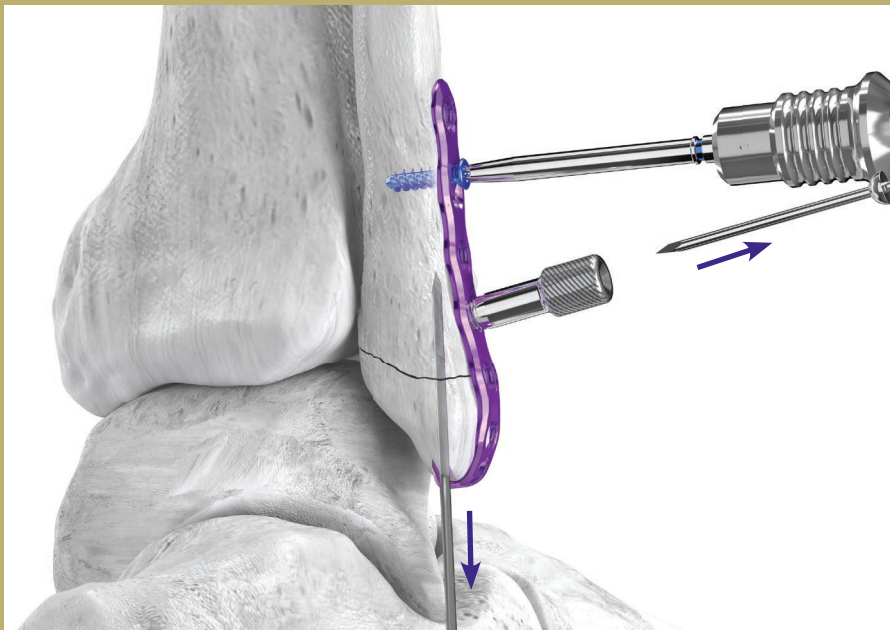


Insert a long olive wire into the plate positioning tower. A compression drill guide is placed in the compression slot with the arrow pointing toward the fracture.



Drill using the drill for desired screw diameter. Measure screw length using a depth gauge.

STRAIGHT FIBULAR HOOK PLATE FEATURING: DOUBLE TAMP



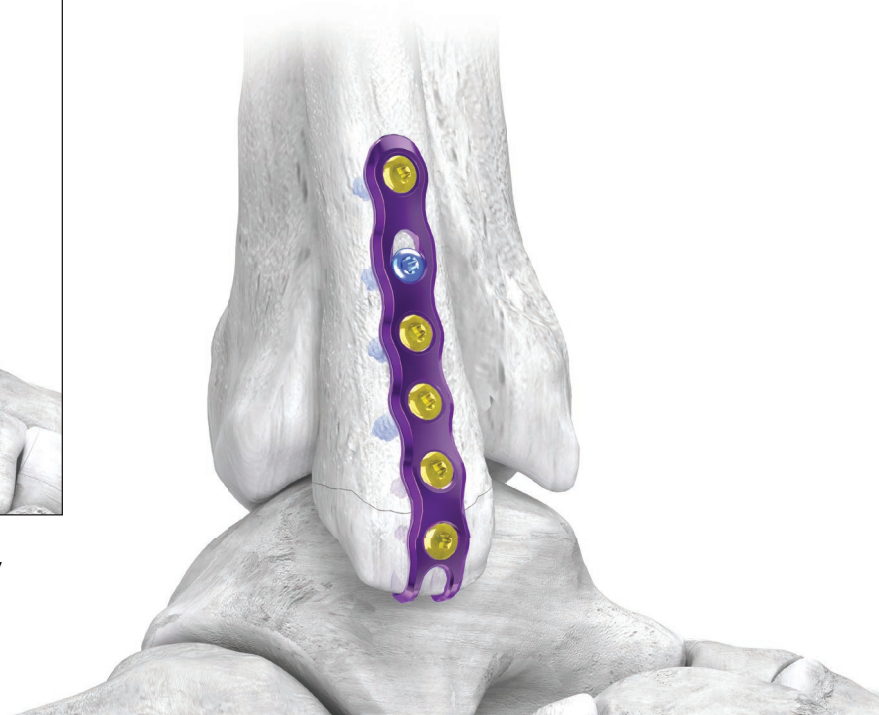
Insert the selected non-locking screw into the plate hole. Remove the long olive wire and the K-wire serving as temporary fixation prior to the screw head making contact with the plate.



NOTE: If adequate compression of the fracture site is not achieved or if plate seating is not adequate with placement of the screw in the compression slot, back out the compression screw at least one quarter turn. Tamp the plate hooks using the double hook tamp to seat the plate on the distal fibula.



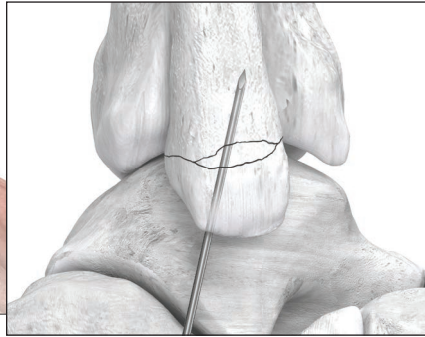
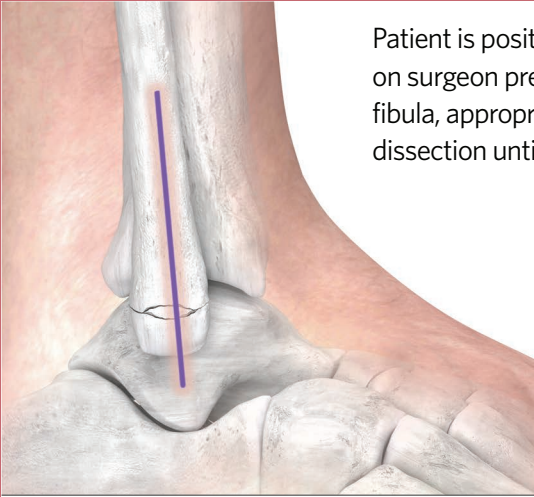
While maintaining pressure on the hooks with the tamp, tighten and fully seat the compression screw in the compression slot once better hook position is achieved.



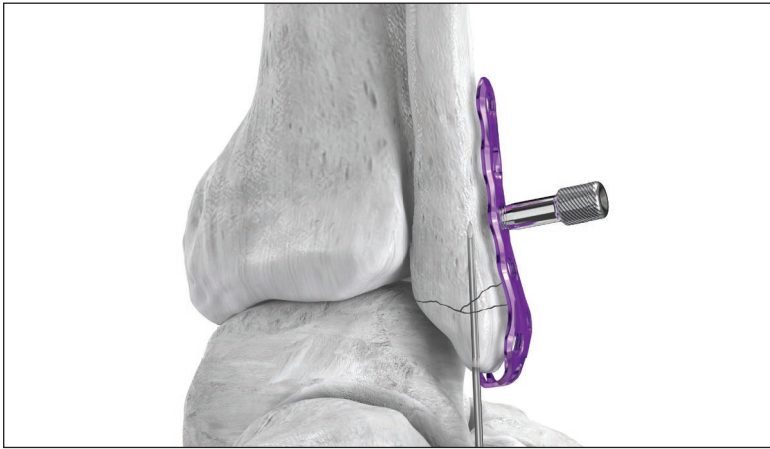
All remaining plate hole accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Fill the remaining plate screw holes as desired. Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

ANATOMIC FIBULAR HOOK PLATE FEATURING: HOOK SCREW DRILL GUIDE

Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.

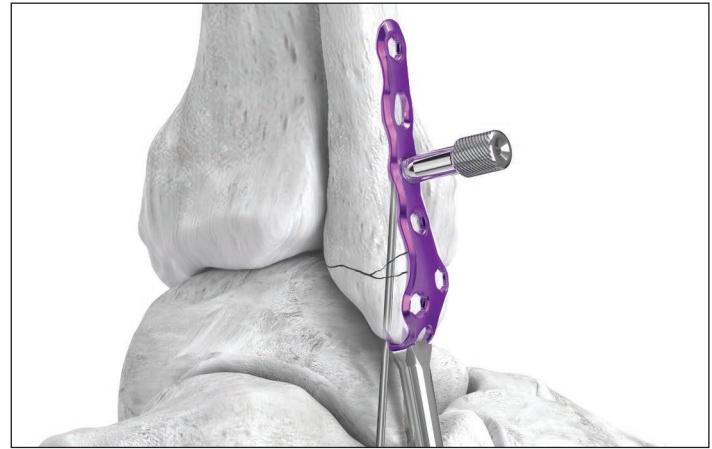


The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.

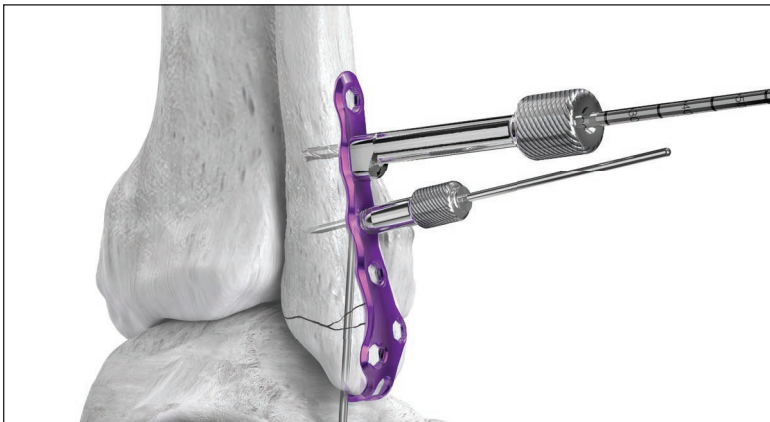


Select the appropriate Anatomic Fibular Hook Plate for fracture type and size. Attach a plate positioning tower to the plate to assist with plate placement.

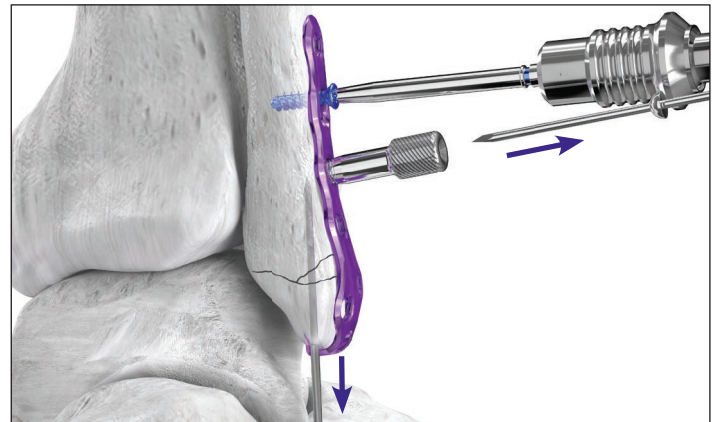
NOTE: If pre-drilling of the hooks is desired for a patient with a hard bone or for a severely comminuted fracture, 2.0 mm K-wires can be retrieved from the Gorilla Instrument Caddy to use for pre-drilling.



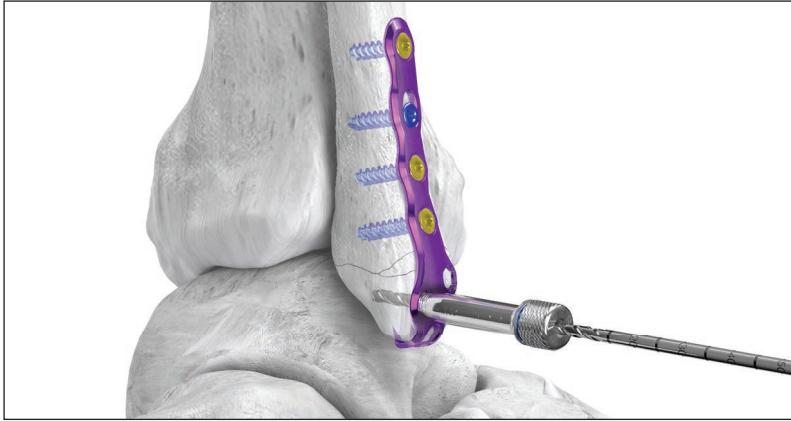
Place plate onto bone, allowing the hooks to engage with the distal tip of the fibula. Retrieve the double tamp. Press the double tamp against the two hooks of the straight plate and tap the end with a mallet until the hooks have engaged the distal tip of the fibula.



Insert a long olive wire into the plate positioning tower. A compression drill guide is placed in the compression slot with the arrow pointing toward the fracture. Drill using the drill for desired screw diameter. Measure screw length using a depth gauge.



Insert the selected non-locking screw into the plate hole. Remove the long olive wire and the K-wire serving as temporary fixation prior to the screw head making contact with the plate.



All remaining plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Fill the remaining plate screw holes as desired. It is recommended to use the threaded drill guide and 3.5 mm or smaller screws when drilling for the distal two screws to avoid interference if a screw is used in between the hooks.



Confirm plate and screw placement using fluoroscopy, if desired.

OPTIONAL SCREW FIXATION



If screw placement between the hook screws is desired for fracture fragment fixation or additional stability of the fracture, retrieve the hook screw drill guide. Place the hook screw drill guide in between the hooks on the plate.

NOTE: If a 4.2 mm hook screw is used, a 3.5 or smaller distal plate screw should be used to avoid screw interference .

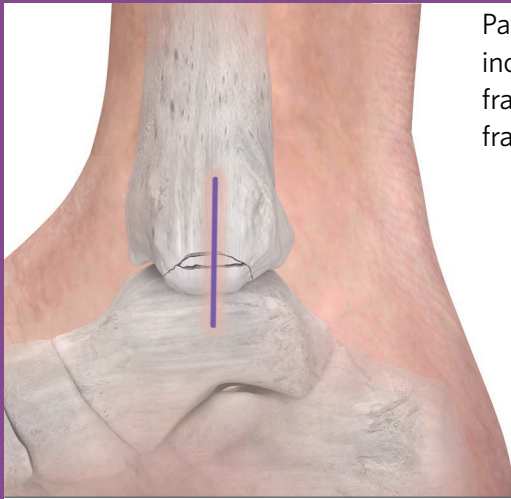


Drill through the hook screw drill guide using the drill for desired screw diameter. Measure for screw length using the depth gauge.

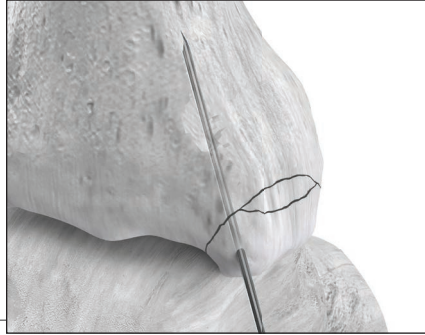
Insert the selected screw between the hooks. Check screw and plate position using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.



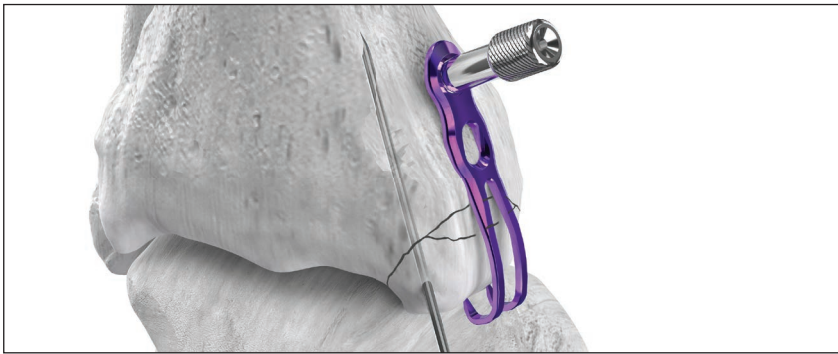
MEDIAL MALLEOLUS HOOK PLATE FEATURING: SINGLE TAMP



Patient is positioned supine such that the foot is near the end of the table. A longitudinal incision is made over the central aspect of the medial malleolus, appropriately sized for fracture access and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.

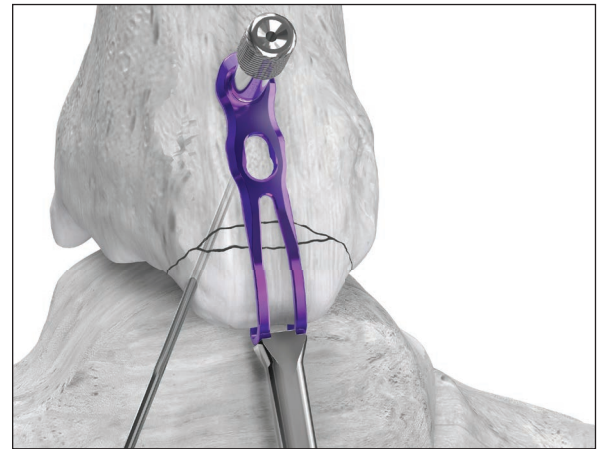


The fracture site is cleared and refreshed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.



Select the appropriate Medial Malleolus Hook Plate for fracture type and size. Attach a plate positioning tower to the hole adjacent the compression slot to assist with plate placement. Press the plate onto bone, allowing the hooks to engage the distal tip of the medial malleolus.

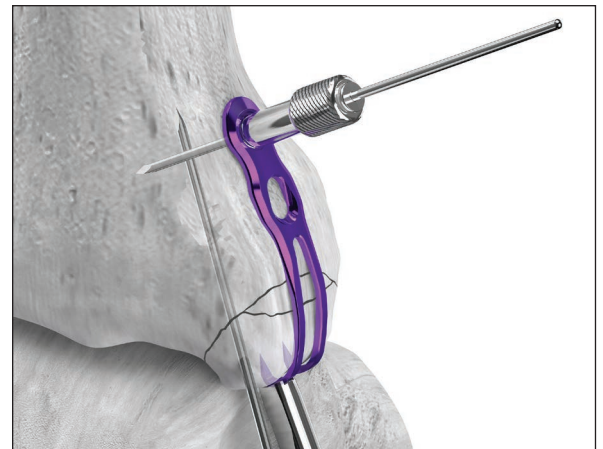
NOTE: If pre-drilling of the hooks is desired for a patient with a hard bone or for a severely comminuted fracture, 2.0 mm K-wires can be retrieved from the Gorilla Instrument Caddy to use for pre-drilling.



Retrieve the double tamp and press against the two hooks. Tap the end with a mallet until the hooks have engaged the medial malleolus.

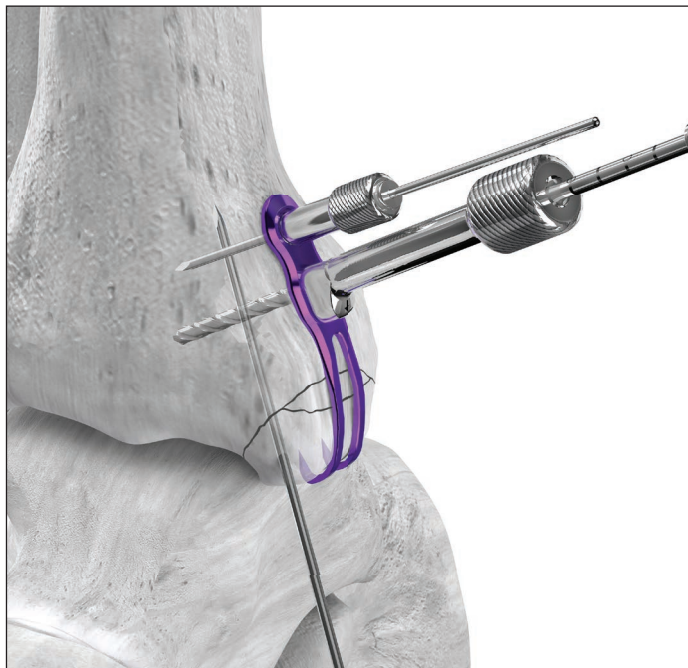


NOTE: : If a single hook needs tamping to oppose the bone or assist in straightening the plate, place the single tamp over the hook that requires additional tamping. Use a mallet to strike the single tamp such that plate positioning is improved.



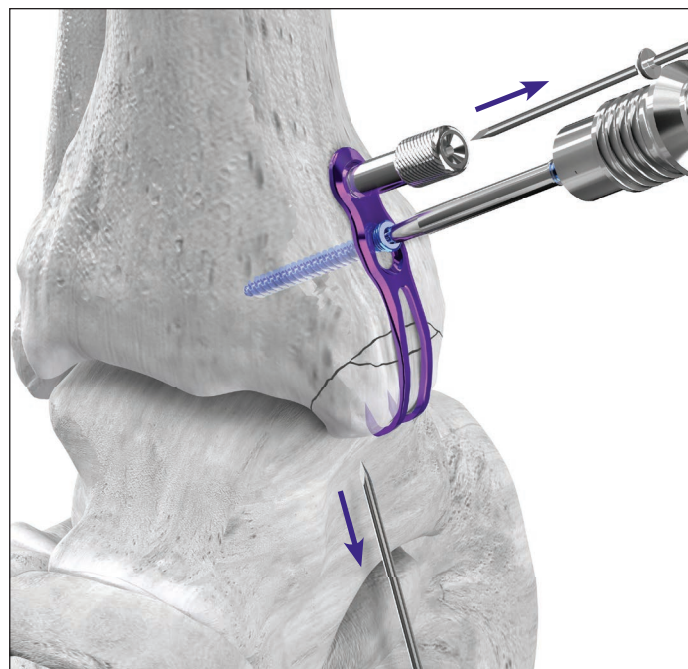
Insert a long olive wire into the plate positioning tower to maintain plate position.

MEDIAL MALLEOLUS HOOK PLATE FEATURING: SINGLE TAMP

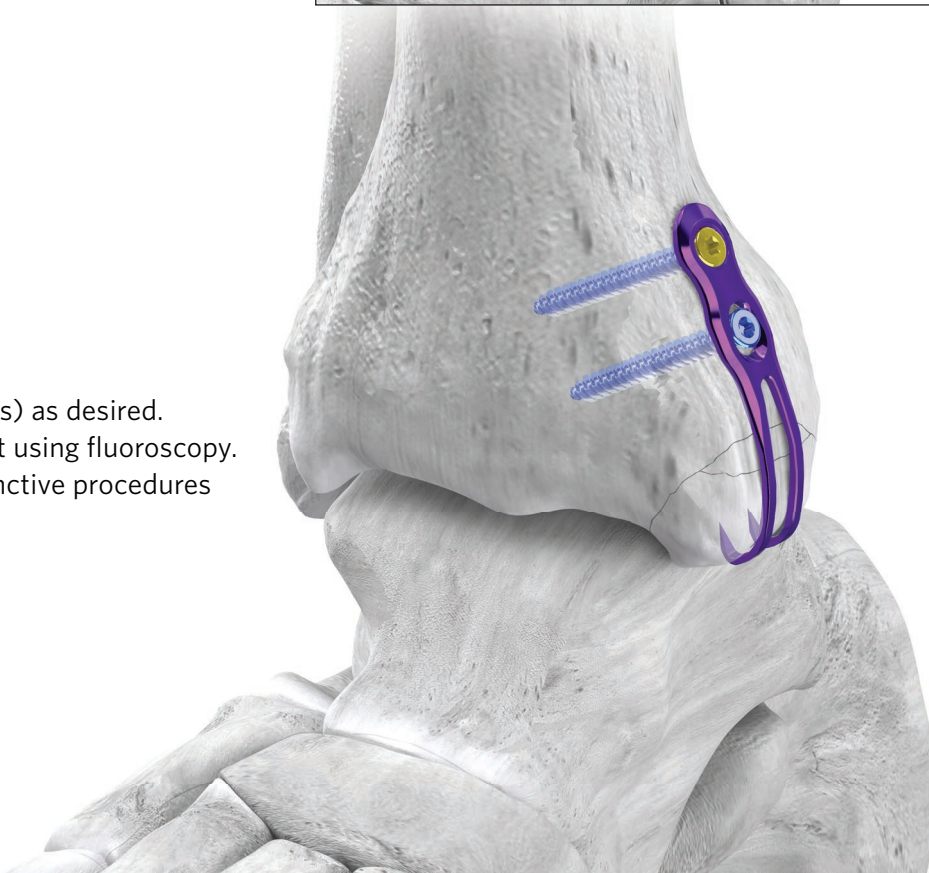


A compression drill guide is placed in the compression slot with the arrow pointing toward the fracture. Drill using the drill for desired screw diameter. The compression slot accepts 2.7 mm, 3.5 mm or 4.2 mm non-locking screws, while the remaining plate hole(s) accept locking or non-locking screws.

Measure screw length using a depth gauge. Insert the selected non-locking screw length into the plate hole. Prior to the screw head making contact with the plate, remove the long olive wire and the K-wire serving as temporary fixation.



Fill the remaining plate screw hole(s) as desired. Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.



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

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

The bone plates and bone screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in bone reconstruction/osteotomies, arthrodesis/joint fusion, and fracture repair/fracture fixation of the foot and ankle, appropriate for the size of the device.

System(s)	Indications	Intended Population(s)
Gorilla Plating System Plates and Bone Screws in Diameters: 2.7 mm, 3.5 mm, and 4.2 mm	The Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Baby Gorilla Plating System Plates and Bone Screws in Diameters: 2.0 mm and 2.5 mm	The Baby Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot for: - Bone Reconstruction/Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Silverback Plating System Plates and Bone Screws in Diameters: 4.5 mm, 4.7 mm, 5.2 mm	The Silverback plates and bone screws of the Gorilla plating System are indicated for use in the ankle for: - Arthrodesis/Joint fusion	Adult Patients
R3LEASE Stabilization System Solid Screws and Washers in 3.9 mm Diameter	The R3LEASE Stabilization Screws of the Gorilla Plating System are indicated for use in the ankle for: - Fracture repair/fracture fixation	Adult Patients
Non-locking Screws and Washers Diameters: 2.0 mm, 2.5 mm, 2.7 mm, 3.5 mm, 4.2 mm, 4.5 mm, 4.7 mm, 5.2 mm, and 5.5 mm	The Non-Locking Bone Screws and Washers of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients

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

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

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

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Patient risk as a result of the Baby Gorilla[®]/Gorilla[®] Plating System in the MR environment has been minimized.
- **Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla[®]/Gorilla[®] Plating System.**
- **Do not implant the instruments.**

MR SAFETY INFORMATION

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

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

INDICATIONS FOR USE: MONSTER® SCREW SYSTEM

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

CONTRAINDICATIONS

Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

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

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

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

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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- 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 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 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.

GORILLA[®]

R3CON PLATING SYSTEM

ANKLE FRACTURE PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle **28**
Paragon[®]


www.PARAGON28.com

P51-STG-1008 RevE (2022-07-10)

™Trademarks and ®Registered Marks of Paragon 28®, Inc.

© Copyright 2022 Paragon 28®, Inc. All rights reserved.

Patents: www.paragon28.com/patents

Paragon 28, Inc. 
14445 Grasslands Dr.
Englewood, CO 80112
(855) 786-2828

 2797

Paragon 28 Medical Devices Trading Limited
First Floor Block 7 Beckett Way
Park West Business Park
Dublin 12
D12 X884
Ireland
+353 (0) 1588 0350

DISCLAIMER

The purpose of the Gorilla® Ankle Fracture Surgical Technique Guide is to demonstrate the optionality and functionality of the Ankle Fracture Plating System implants and instrumentation in the Gorilla® R3CON Plating System. Although various methods can be employed for these procedures, 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.