

Paragon²⁰

a  ZIMMER BIOMET company



 **GORILLA**[®]
R3CON PLATING SYSTEM

SURGICAL TECHNIQUE GUIDE:

Supramalleolar Osteotomy System

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 low profile plate options for osteotomy fixation including an anterior tibial plate, distal medial tibial plate, and a proximal medial tibial plate. The plates also come in standard and long lengths, providing surgeons flexibility for the location of the anterior dome osteotomy, and medial opening and closing osteotomies.

All plates feature a distal screw cluster, which provides flexibility to surgeon preference for screw and plate placement, while maximizing capture of the distal tibia. Each plate features a proximal compression slot in the proximal screw cluster to allow for osteotomy compression through the plate. All plate holes accept 2.7, 3.5, or 4.2 mm locking or non-locking screws or 3.5 mm locking or non-locking compact thread screws. Screws can be inserted off-axis up to 15 degrees in non-compression holes.

The Gorilla Supramalleolar Osteotomy System was designed with instrumentation to facilitate repeatable and controlled anterior dome and medial opening or closing wedge osteotomies. The anterior dome osteotomy drill guides and template provide optionality in the radii for the dome osteotomy in 5 mm increments from 25 to 50 mm and allow for offset drilling to aid completion of the osteotomy. The medial closing wedge guide provides measured correction for the intended wedge to be resected up to 25 degrees or up to 15.5 mm. Cut guides are provided to ensure accuracy of alignment and cuts and aid with biplanar or multiplanar correction. The system also includes a specially shaped PRESERVE SMO allograft wedge which is designed to follow the contours of the metaphyseal region of the distal tibia. The wedge can be shaped intraoperatively to the appropriate height or angle using the provided allograft cutting jig.

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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

SURGICAL CONSIDERATIONS

PATIENT FACTORS TO GUIDE USE OF A SUPRAMALLEOLAR OSTEOTOMY:

- Condition of Ankle Joint:

- Asymmetric ankle joint arthritis
- Medial or lateral gutter arthritis
- Plafond in good condition and minimal talar tilt

- Patient Age:

- Younger patients want to postpone total ankle replacement

- Prior Fusion:

- Such as triple arthrodesis or subtalar arthrodesis

PATIENT CONDITIONS TO HELP DETERMINE SUPRAMALLEOLAR OSTEOTOMY APPROACH:

- Anterior Dome Osteotomy:

- Good condition of anterior skin
- Pre-existing limb length discrepancy requiring minimal shortening
- Simple correction of multiplanar deformities
- Same incision can be used for eventual total ankle replacement, if required

- Medial Closing Wedge Osteotomy:

- Good condition of medial skin
- No or minimal pre-existing limb length discrepancy
- Simple correction of valgus deformity

- Medial Opening Wedge Osteotomy:

- Good condition of medial skin
- Good condition of vasculature that can withstand lengthening
- Simple correction of varus deformity
- Minimal risk of non-union with graft

Varus Deformity



Valgus Deformity



SURGICAL TIPS/PEARLS PER APPROACH

ANTERIOR DOME OSTEOTOMY

- Deformity Correction:

- Versatile translational and rotational correction
- Minimal shortening of limb

- Tibial Osteotomy:

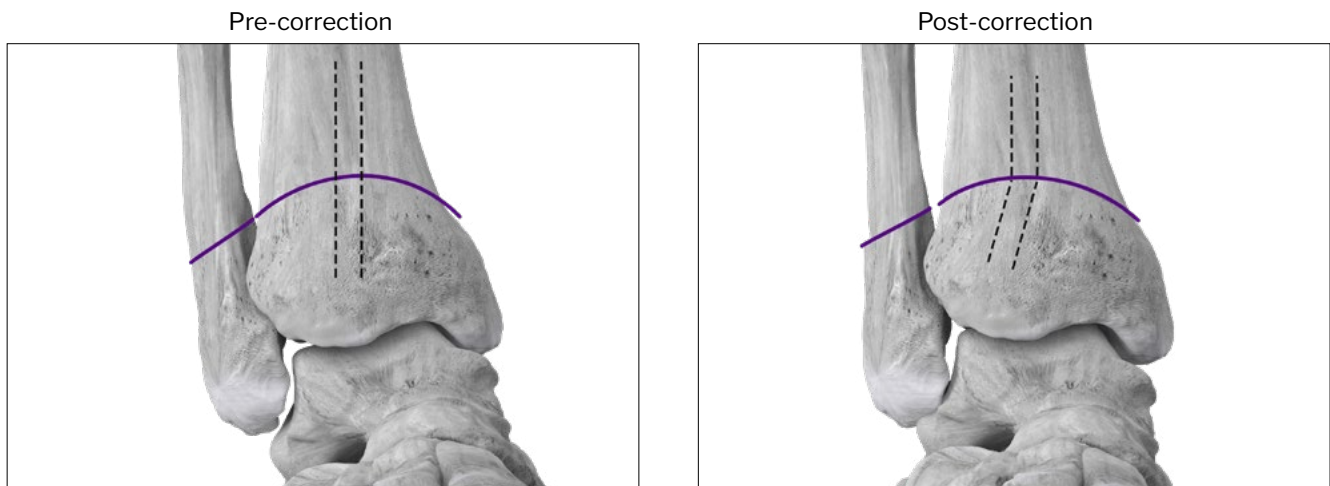
- A malleable retractor should be placed through the incision to protect the tibialis posterior tendon and neurovascular bundle
- Use a bovie to mark the tibia prior to the osteotomy to gauge post-correctional translation (as illustrated)
- Osteotomy should exit lateral tibia just proximal to syndesmosis

- Fibular Osteotomy:

- Should follow arc of tibial osteotomy
- If correcting varus deformity, a small wedge may need to be removed to reduce impingement

- Post Correction Assessment:

- Check axial alignment



Dashed lines represent markings from a bovie to gauge correction. Purple line represents osteotomy

MEDIAL CLOSING WEDGE OSTEOTOMY

- Deformity Correction:

- Useful for valgus deformity

- Tibial Osteotomy:

- Osteotomy will be slightly oblique and angled distally
- Should be completed and stabilized prior to fibular osteotomy

- Fibular Osteotomy:

- Should be oriented distal lateral to proximal medial

- Post Correction Assessment:

- Check axial alignment
- Check for any secondary translational deformity (see next page)



SURGICAL TIPS/PEARLS PER APPROACH

MEDIAL OPENING WEDGE OSTEOTOMY

- Deformity Correction:

- Useful for varus deformity

- Tibial Osteotomy:

- Should be parallel to the joint or slightly oblique if correcting talar tilt
- Avoid breaking lateral hinge in the tibia by cutting the tibia under fluoroscopy
- The hinge can be fenestrated with a small K-wire if needed to weaken it
- If the hinge breaks, consider plating the lateral cortex, if there isn't a concern of a secondary translational deformity

- Fibular Osteotomy:

- Fibular osteotomy should be proximal lateral to distal medial or a small wedge should be removed

- Post Correction Assessment:

- Check axial alignment
- Check for any secondary translational deformity (see below)

Pre-correction



Post-correction



SECONDARY TRANSLATIONAL DEFORMITY

- Assessment:

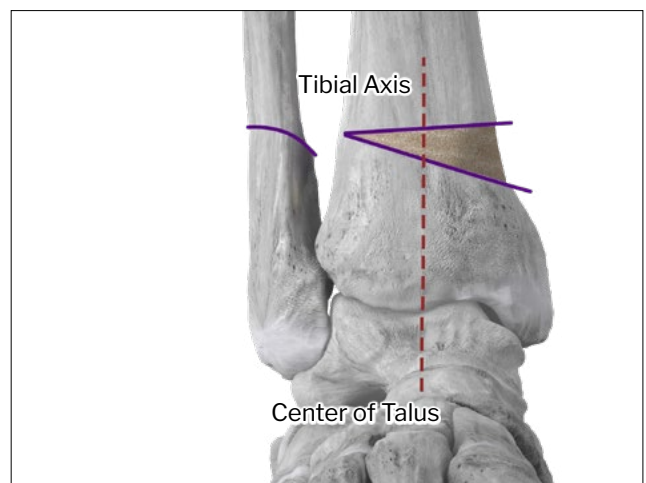
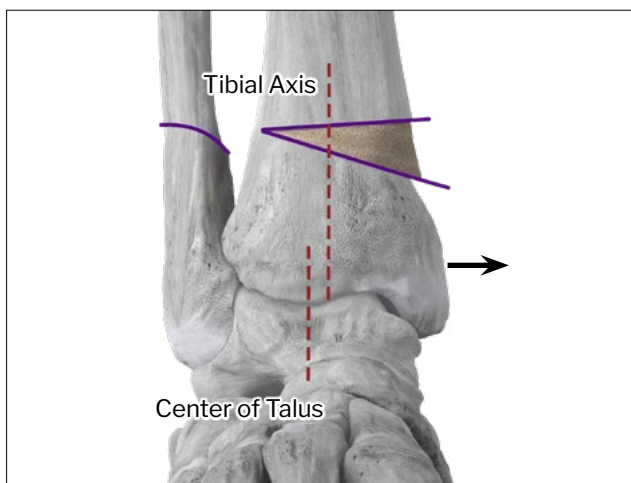
- Distal tibial segment translates from proximal segment during correction
- Tibial axis does not align with center of talus (as illustrated)

- Occurrence:

- The closer the apex of the deformity is the ankle, the greater the likelihood of a translational deformity

- During Surgery:

- Do not plate the lateral cortex if this may occur, such that it can be addressed prior to final implant placement
- The proximal and distal tibial segments should be adjusted until the center of the talus aligns properly with the tibial axis



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:	12 - 30 mm in 2 mm increments	12 mm - 48 mm in 2 mm increments	20 mm - 48 mm in 2 mm increments	20 mm - 34 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
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:	N/A	N/A	N/A	 Ø3.5 mm C

FEATURED INSTRUMENTATION



Locking Drill Guide

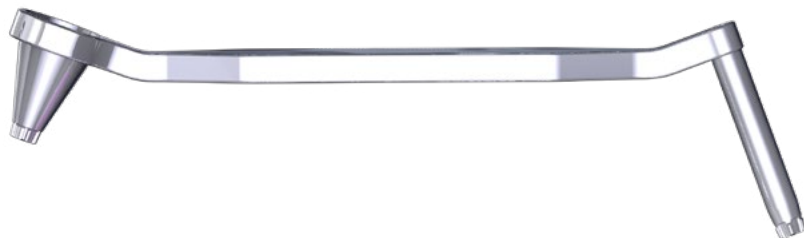


Compression Slot Drill Guide



Drill

- Solid Drill
- Ø2.0 mm, Ø2.4 mm, Ø2.8 mm



Drill Guide

- **Cone Side:** Allows for off-axis drilling of locking screws up to 15° in any direction or 30° total
- **EZ-Guide Side:** Serves as an alternative to the threaded locking drill guide and allows for quick on-axis drilling



Standard Depth Gauge



Large AO Handle



Standard AO Handle



Driver

Ø1.60mm X 10cm Olive Wire, Smooth



Ø1.60mm X 10cm Olive Wire, Threaded



K-wire Ø2.3 x 150 mm



Notched K-wire Ø2.3 x 100 mm



Fluted K-wire Ø2.4 mm x 110 mm

FEATURED INSTRUMENTATION



Threaded Bending Bar
(2 of each included)

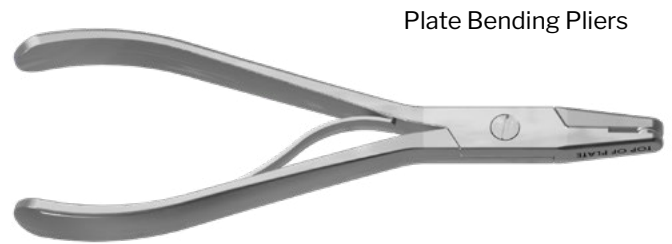


Plate Bending Pliers

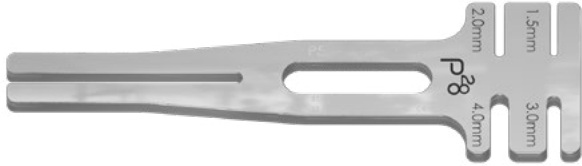


Plate Bending Irons
(2 of each included)



Flat Tamp



Curved Tamp

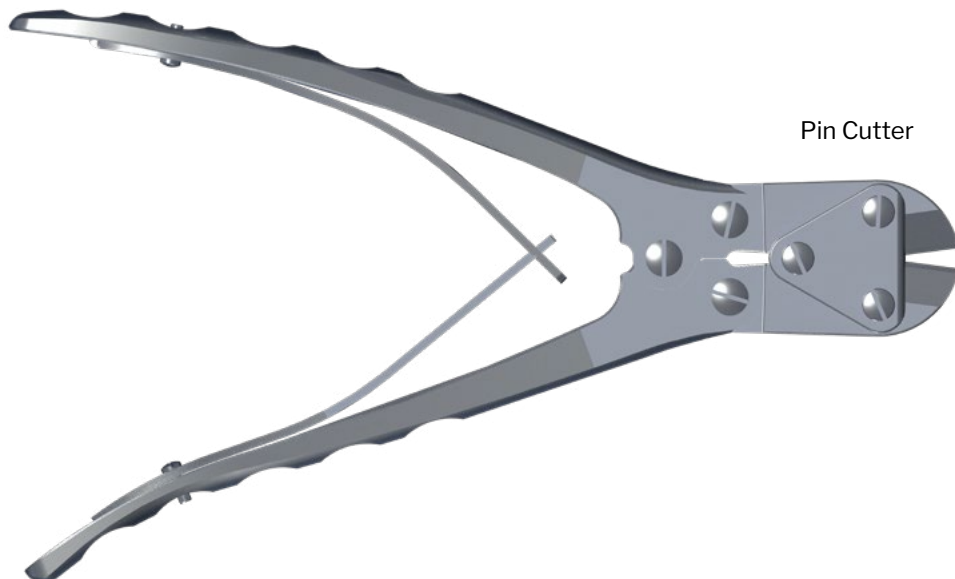


Hintermann Distractor

- Sized for foot and ankle applications
- Smaller holes accept up to Ø1.6 mm K-wires
- Larger holes accept up to Ø2.3 mm K-wires

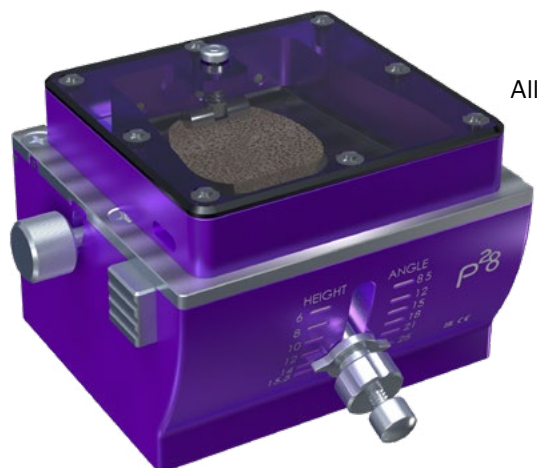


Lamina Spreader



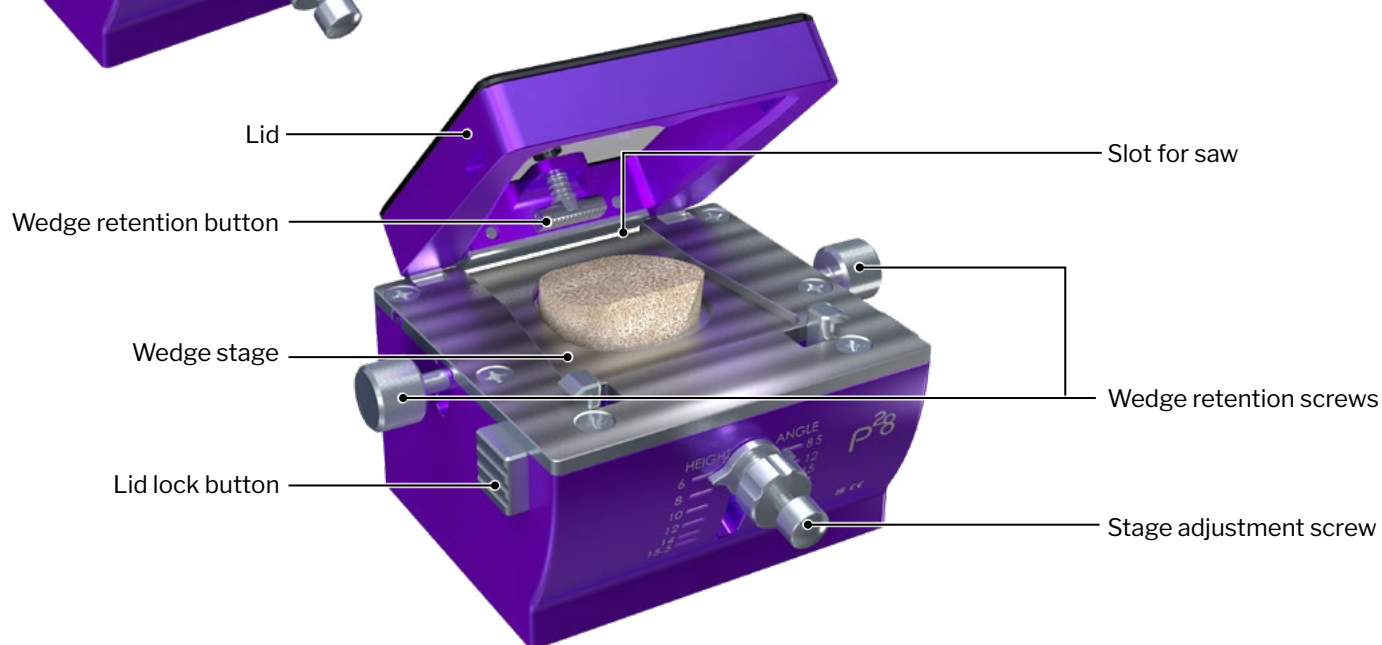
Pin Cutter

FEATURED INSTRUMENTATION



Allograft Cutting Jig

- Designed to aid in shaping the SMO Allograft Wedge to provide intended correction



Anterior Drill Guide Template

- Designed to aid planning and alignment of anterior dome osteotomy

Anterior Drill Guide Inserts

- Offered in several different radii to provide optionality in guiding anterior dome osteotomy
- Each Insert has a Side A and a side B with offset holes, allowing for offset drilling

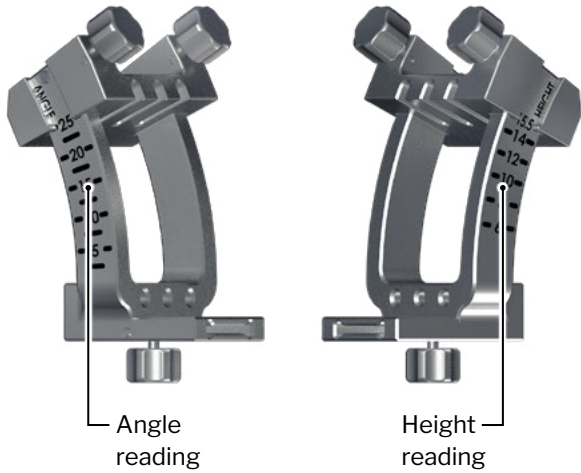
Side A



Side B

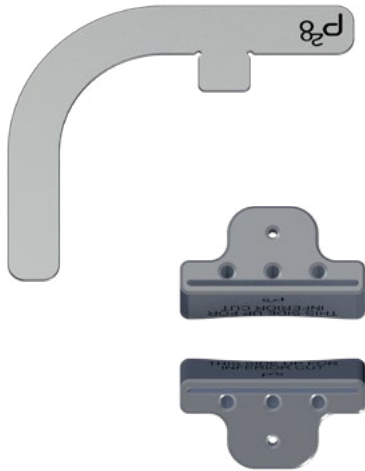


FEATURED INSTRUMENTATION



Medial Sextant Jig

- Designed to aid alignment and provide sizing information for medial closing wedge osteotomy
- One side provides measurements for the angle of wedge to be resected and the other side provides height measurements of the wedge to be resected



Angelwing

- Designed to aid sagittal alignment for anterior and medial approaches



Medial Cut Guide

- Designed to aid cut alignment for medial opening and closing wedge osteotomies

PREPARATION INSTRUMENTATION



8 mm Hohmann Retractors

- 2 of each included



16 mm Hohmann Retractors

- 2 of each included



Periosteal Elevator



6 mm Straight Osteotome



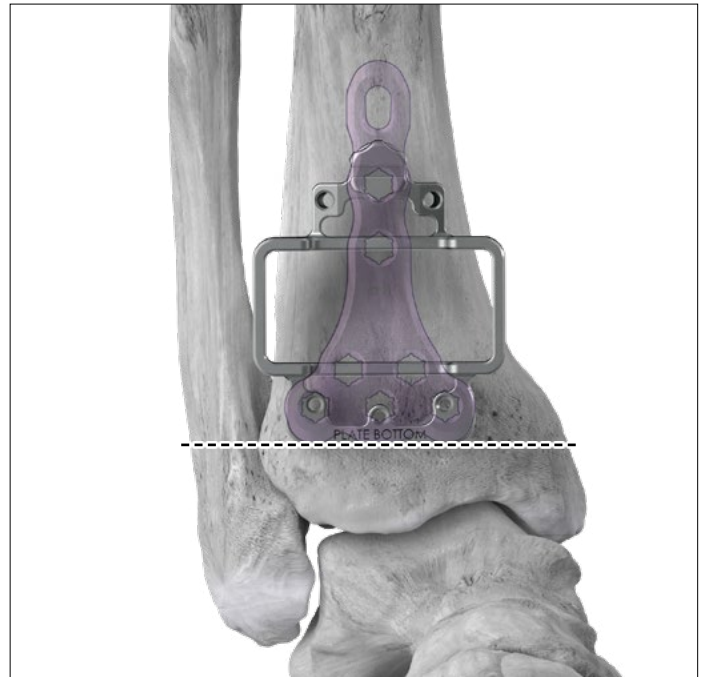
19 mm Straight Osteotome

INCISION/EXPOSURE

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



OSTEOTOMY AND DEFORMITY CORRECTION

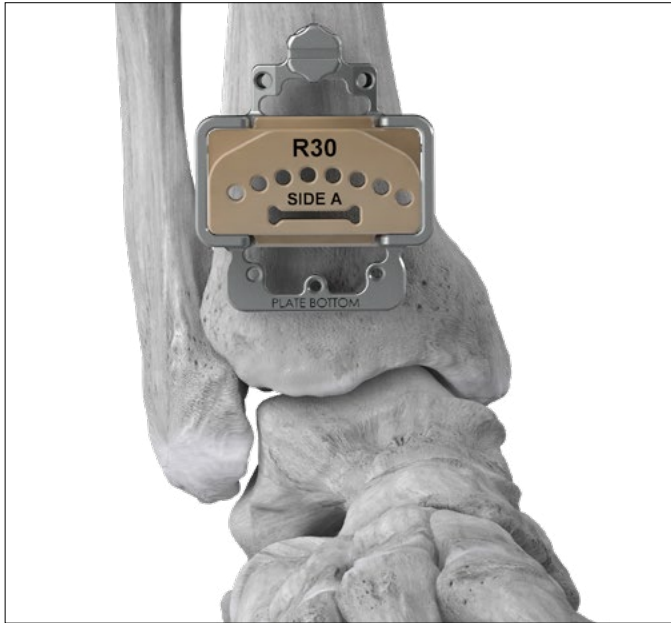


After exposing and preparing the distal tibia, position the Anterior Drill Guide Template on the tibia. Center the Anterior Drill Guide Insert housing of the Template over the planned osteotomy site, which should be located at the apex of the deformity.



Note: The distal bar on the Template corresponds to the location of the bottom of the plate, regardless of plate size.

OSTEOTOMY AND DEFORMITY CORRECTION

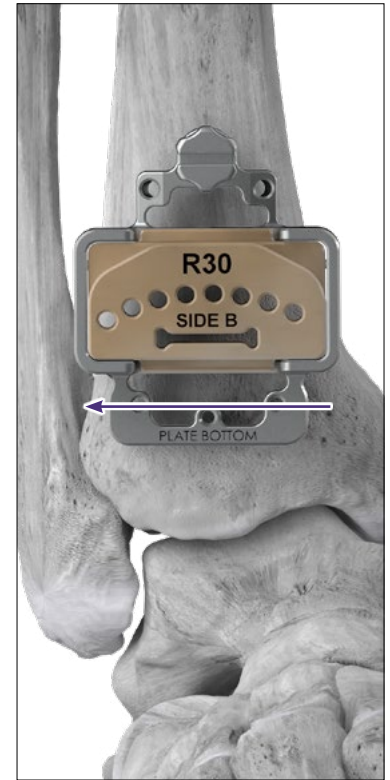
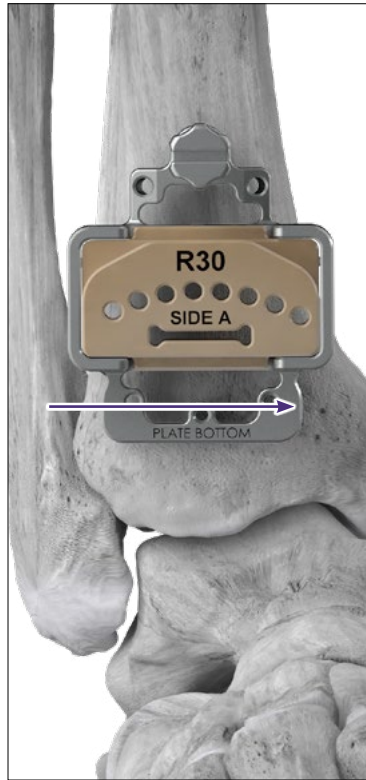


Choose the appropriate Anterior Drill Guide Insert based on the desired curvature for the osteotomy according to surgeon preference and place in the Template with side A visible (for a right leg). Confirm intended osteotomy curvature either visually or using fluoroscopy. Ensure that the dome exits medially on the tibial cortex and does not continue distal along the cortex to prevent an irregular medial osteotomy surface from forming.



Note: The number on the Anterior Drill Guide Insert corresponds to the radius of the osteotomy.

Once the desired position is achieved, provisionally secure the Template with Olive Wires in the distal holes per surgeon preference.



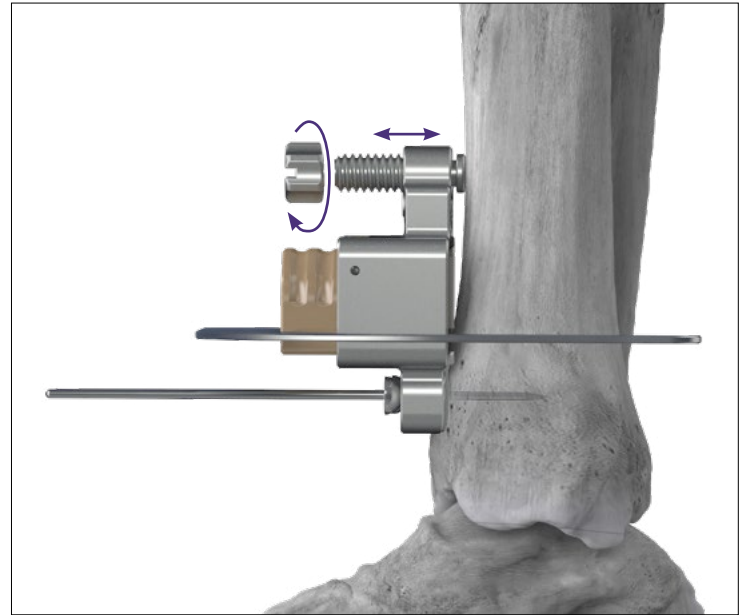
Note: The holes of the Anterior Drill Guide Insert are offset. For right limbs, side A biases medially and side B biases laterally. This is the opposite for left limbs, with side B biasing medially and side A biasing laterally.



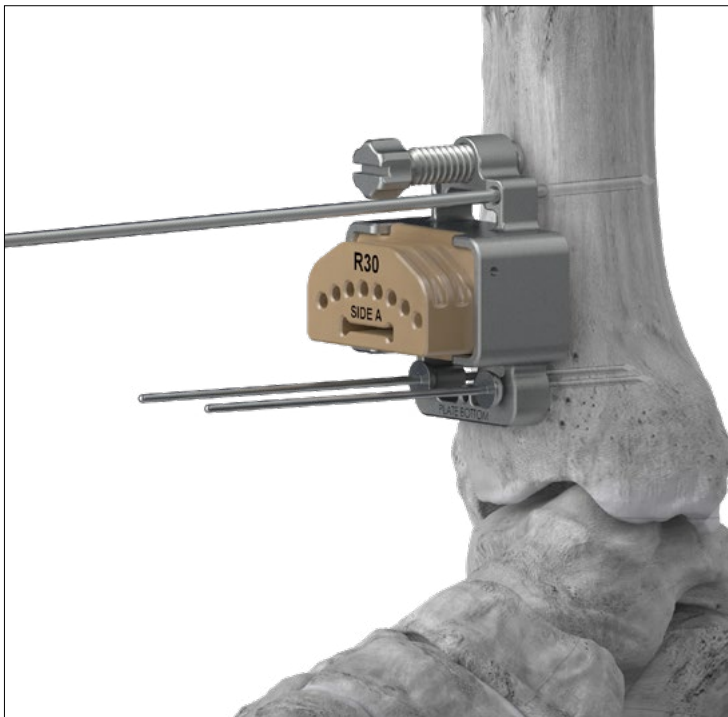
OSTEOTOMY AND DEFORMITY CORRECTION



To approximate sagittal alignment of the intended osteotomy, place the provided Angelwing in the slot of the Anterior Dome Insert. This will confirm that the osteotomy is perpendicular to the tibia to avoid secondary deformity and should be confirmed fluoroscopically.



To adjust the sagittal alignment of the intended osteotomy, rotate the proximal screw in the Template to increase or decrease the angle.

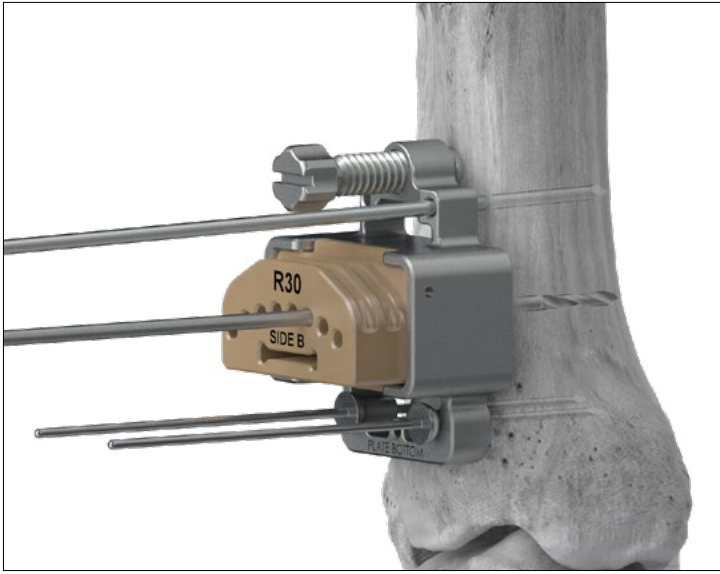


After confirming Template position, the intended radius of the osteotomy, and sagittal alignment. Place a K-wire in one of the proximal holes of the Template to secure position. An optional second wire can be placed per surgeon preference.



Use the Fluted K-Wire to drill bi-cortically through all holes of the Insert.

OSTEOTOMY AND DEFORMITY CORRECTION



Flip the Insert to the other side (side B for a right leg) and repeat the same bi-cortical drilling through all the holes. Remove the Insert and Template.



Complete the osteotomy with one of the provided straight osteotomes per surgeon preference. It is important to complete the osteotomy posteriorly with an osteotome and not to lever it open, which may produce an irregular posterior surface.



A fibular osteotomy should be planned for a deformity greater than 10 degrees and the shape of the osteotomy must be planned in order to avoid the fibula blocking the rotation of the tibia. Per surgeon preference, create an oblique fibular osteotomy that follows the arc of the tibial osteotomy. The fibular osteotomy should be performed through a separate lateral incision for the purposes of fixation. If correcting a varus deformity, a wedge should be taken from the fibula to reduce impingement.



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

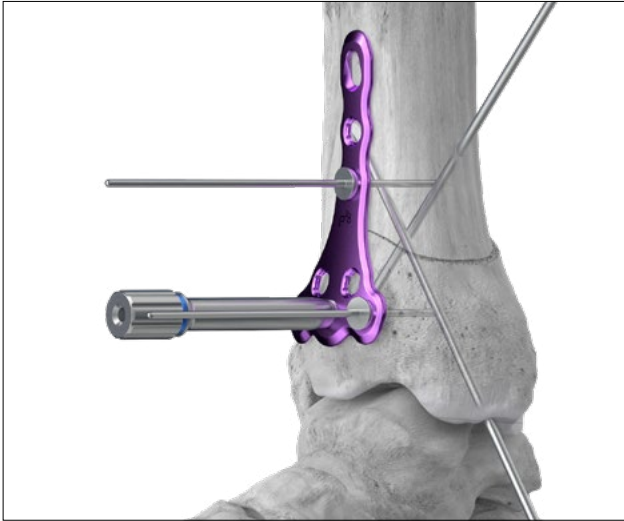


Note: Ø2.3 mm K-wires are available for provisional fixation of the osteotomy. If planning to place a crossing screw across the osteotomy, it is recommended to use the K-wire sized to be the guide wire for the desired crossing screw diameter for provisional fixation.

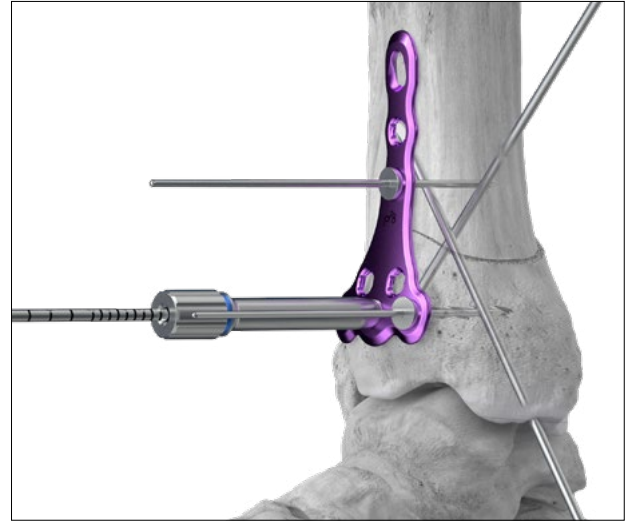
PLATE PLACEMENT AND PERMANENT FIXATION



Note: If placement of a crossing screw across the osteotomy first is preferred, a K-wire sized to be the guide wire for the desired crossing screw diameter is placed according to surgeon preference (see page 15).



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 fix it to the bone with 2 Olive Wires. Confirm plate position using fluoroscopy.



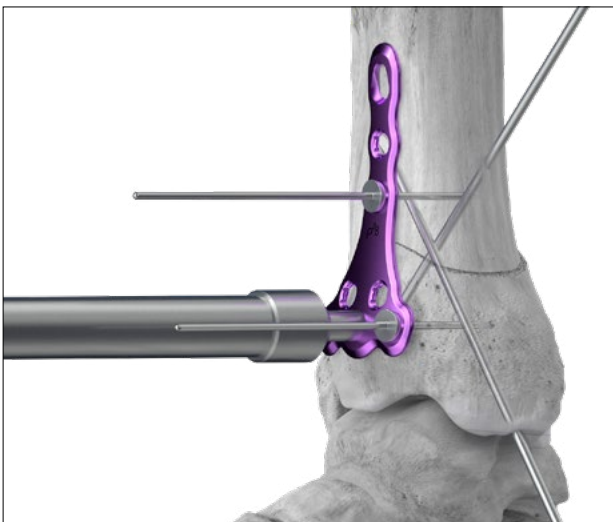
Drill through the drill guide with the appropriately sized drill for the desired screw diameter.



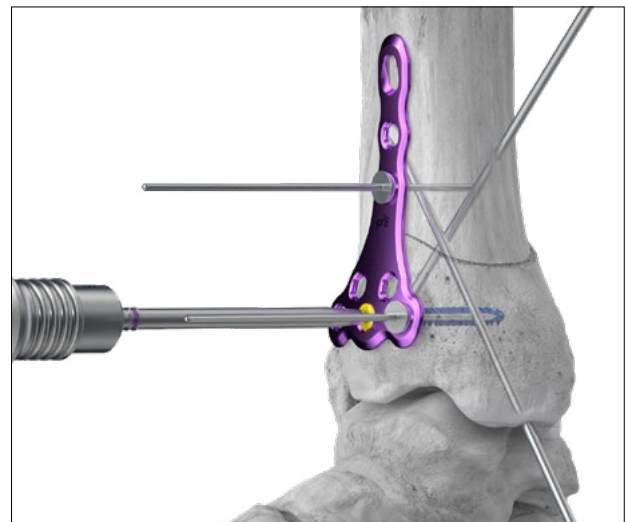
Note: For more information and instructions on the use of Paragon28's Gorilla® plates and screws, please refer to the Gorilla® R3CON Surgical Technique Guide: P51-STG-3001.



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.

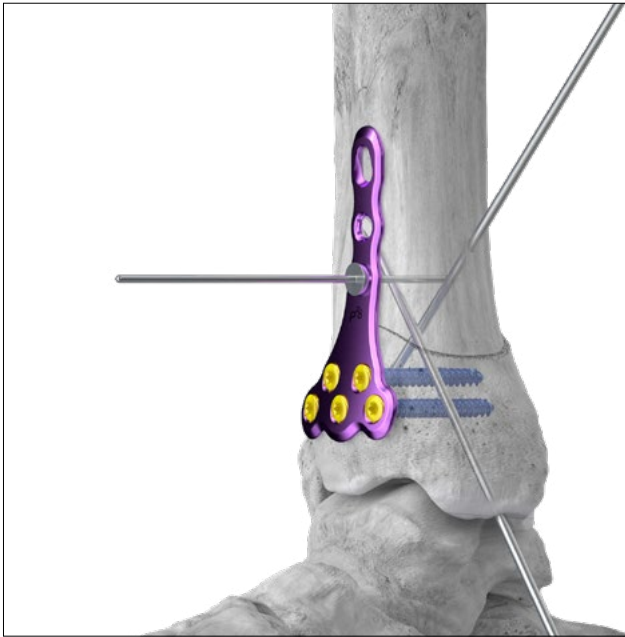


Measure screw length using the provided depth gauge.



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.

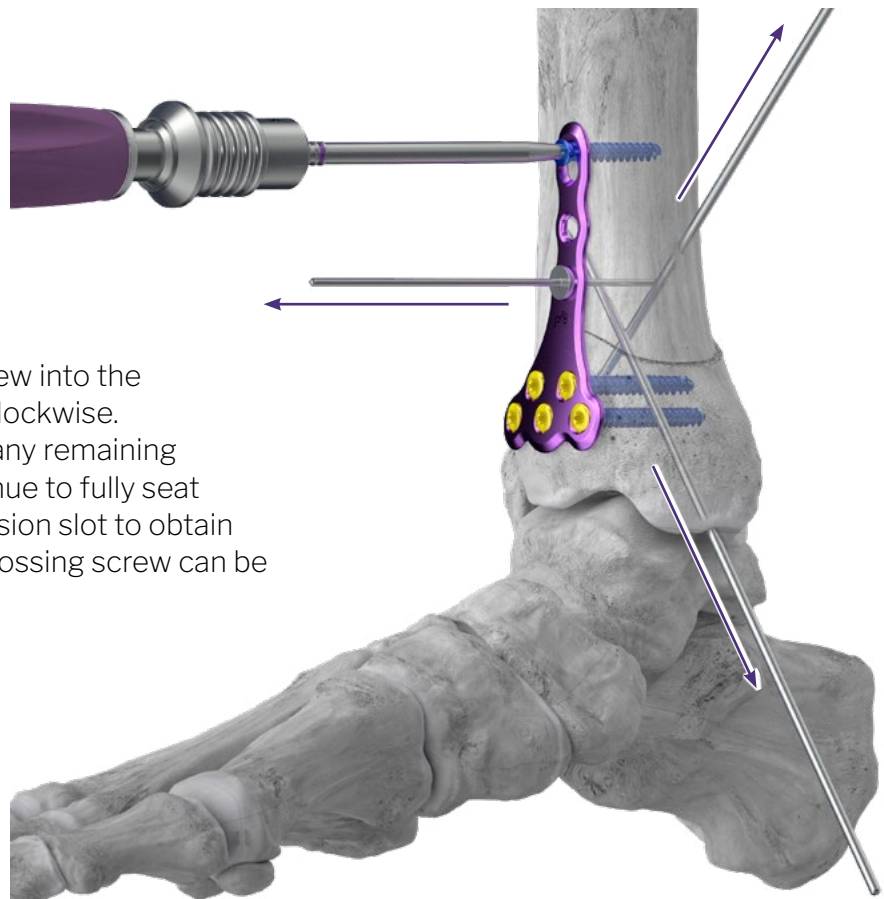
PLATE PLACEMENT AND PERMANENT FIXATION



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. Instead of using the compression slot to obtain compression, alternatively, an oblique crossing screw can be inserted (as shown on page 17).

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. Any bony prominence at the osteotomy site on the fibula should be leveled before fibular plating and the cortical shavings from this can be used to fill in any gaps remaining in the fibula.

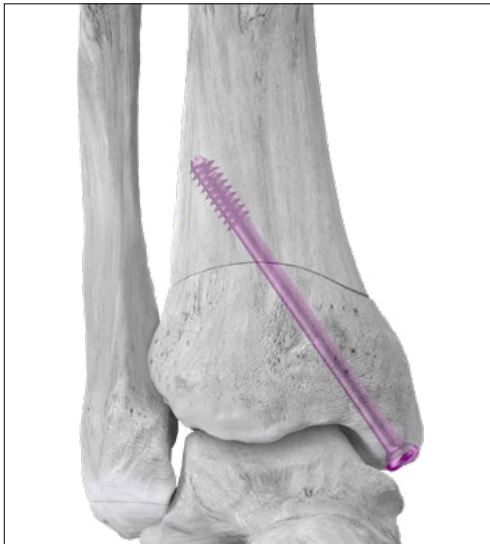
Proceed to incision closure or concomitant procedures at this time.



Note: For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-3008.



ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a partially or fully-threaded Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-3001).



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.



If placing a screw in the compression slot when 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.

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

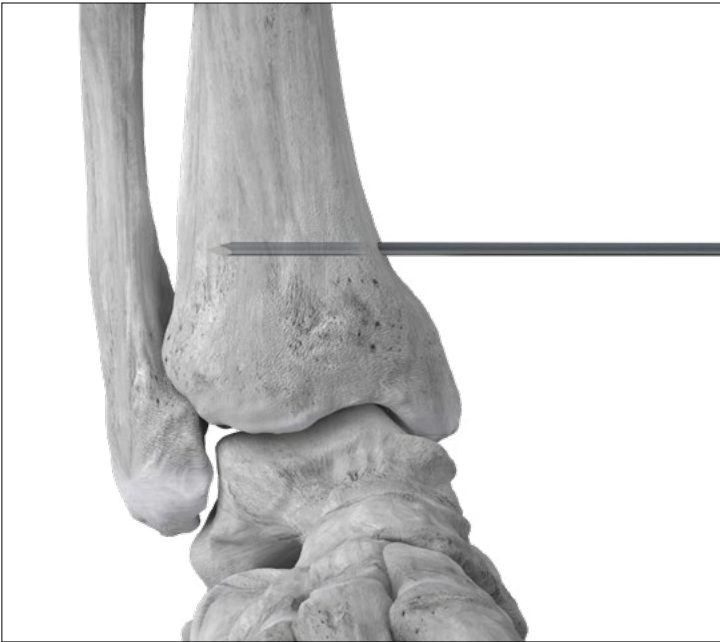
If a fibula osteotomy was performed, place a fibula plate as previously described. Confirm plate position and screw lengths using fluoroscopy.

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. It is important to protect the posterior tibial tendon when making the osteotomy cut, and the tendon sheath should be elevated and protected during this procedure.



OSTEOTOMY AND DEFORMITY CORRECTION



Place a smooth K-wire through the tibia from medial to lateral at the level of the intended osteotomy. The wire should be adjacent to (but not through) the lateral cortex to maintain the hinge.

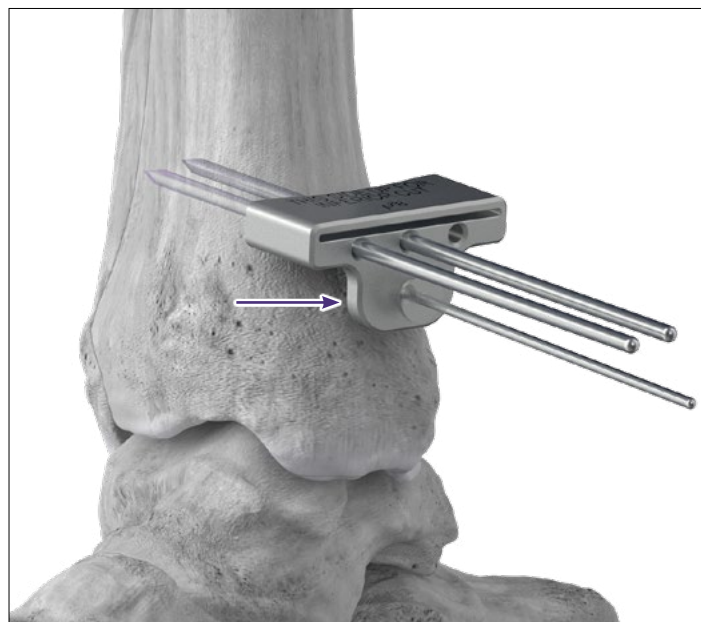


Slide the Medial Cut Guide over the wire and press on to the bone. The cutting slot should be superior to the distal wires. Confirm the position of the inferior and superior sagittal alignment of the Cut Guide either visually or using fluoroscopy.

OSTEOTOMY AND DEFORMITY CORRECTION



After confirming alignment, place a second wire in either of the remaining holes and to the same depth as the first wire. Secure the Cut Guide by placing an Olive Wire through the hole in the pad.



Note: The Cut Guide can either be held in position manually or can be secured by placing an Olive Wire through the hole in the distal pad.



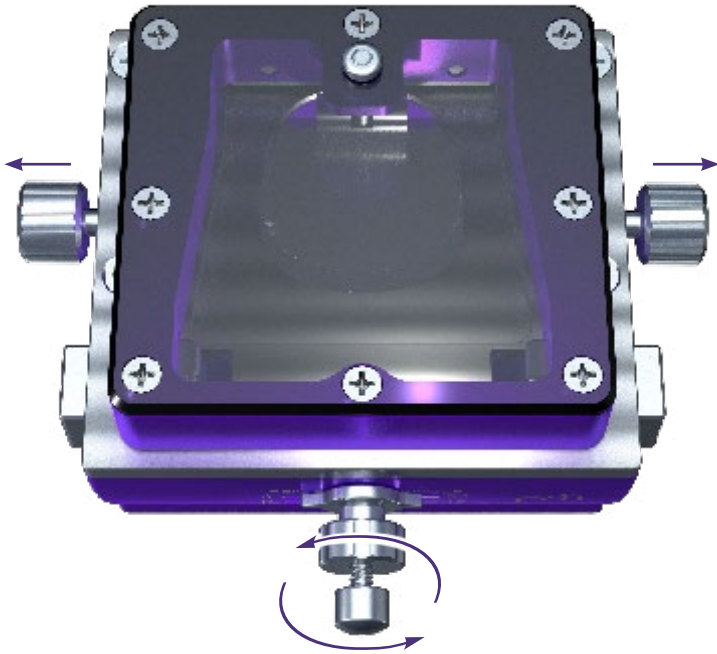
Place the saw in the Cut Guide. Trim wires as necessary to accommodate instrumentation using the provided Wire Cutter. Saw through the Cut Guide, taking care to avoid violating the lateral cortex of the tibia. The lateral tibial surface is narrower than the medial surface and one must be careful not to “overcut” laterally. If a plate has been placed anterolaterally, this will block excessive excursion of the saw.



For deformities greater than 10 degrees, a fibular osteotomy is performed, and should be made transversely or obliquely from proximal lateral to distal medial as illustrated. If the osteotomy is made in a different plane it will block movement of the fibula.

OSTEOTOMY AND DEFORMITY CORRECTION

The **SMO Allograft Wedge** consists entirely of dense cancellous bone. To prepare, soak the **SMO Allograft Wedge** in normal sterile saline or a biologic for at least 5 minutes.



If necessary, loosen the back screw and raise the stage to the top, if not there already. Tighten the screw to lock the position at the top. Loosen the left and right screws on the Allograft Cutting Jig.



Open the lid and place the SMO Allograft Wedge in the stage. The flat side of the wedge with the 90° angle should be placed down into the stage and the acute angle side should be face up. Press down on the wedge while tightening the left and right screws to lock the position of the wedge in the stage.



Loosen and adjust the back screw to the desired wedge height/angle. This measures the height of the most medial aspect of the wedge or the angle of the correction.



Once at the desired height/angle, tighten the back screw to lock the position.

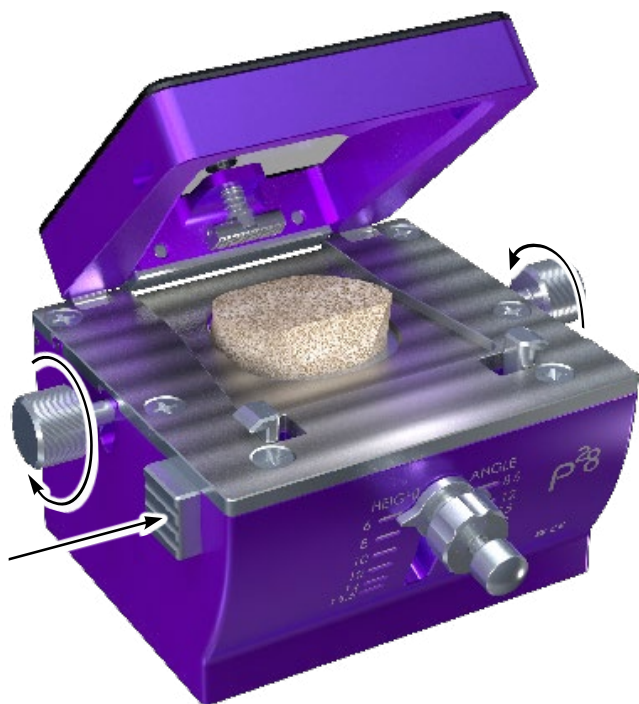
OSTEOTOMY AND DEFORMITY CORRECTION



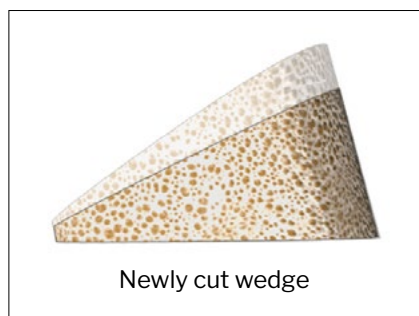
Close the lid and ensure it snaps into the lid lock features by pressing in the buttons on the side and then releasing when the lid is seated or firmly pressing down the lid until it clicks in.



Place the saw through the cut slot and cut the wedge to the appropriate size.



Press in the lid lock buttons on the sides, open the lid, and discard the loose (top) portion of the wedge. The wedge screwed into the stage is the one to be used.



Loosen the left and right screws and remove the shaped SMO Allograft wedge that is ready for use.

PLATE PLACEMENT AND PERMANENT FIXATION



Distract the tibial osteotomy according to surgeon preference and insert the appropriately sized autograft or allograft wedge. If the bone graft protrudes slightly medially, it should be trimmed with a saw prior to applying the plate.



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 fix the plate with 2 Olive Wires. Confirm the plate position using fluoroscopy.



Note: If placement of a crossing screw across the osteotomy first is preferred, a K-wire sized to be the guide wire for the desired crossing screw diameter is placed according to surgeon preference (see page 20).

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.

Measure the screw length using the provided depth gauge.



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.



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-3001.

PLATE PLACEMENT AND PERMANENT FIXATION



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.



Refer to page 14 for instruction for drilling and placing a screw in the compression slot.

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. Any bony prominence at the osteotomy site on the fibula should be leveled before fibular plating and the cortical shavings from this can be used to fill in any gaps remaining in the fibula.

Proceed to incision closure or concomitant procedures at this time.



Note: For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-3008.

ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a partially or fully-threaded Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-3001).



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.



If preferred and there is not a risk of a secondary translational deformity, the anterolateral cortex of tibia can be preemptively secured with a plate at the level of the planned osteotomy to help keep the lateral cortex of the tibia intact while performing the opening wedge osteotomy.

If placing a screw in the compression slot when 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.

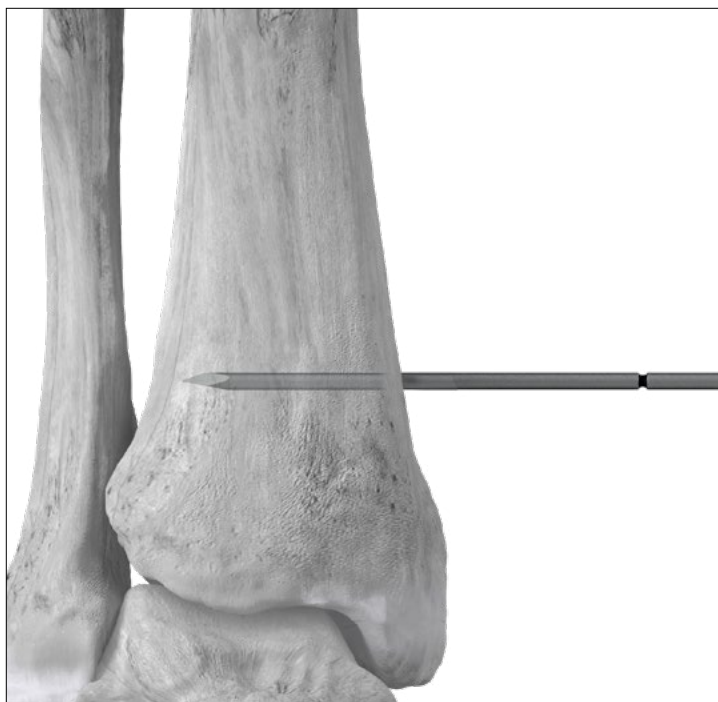
REMOVAL: Use provided drivers to remove all plate screws and any crossing screws. Remove the plate and confirm removal of all plates and screws under fluoroscopy.

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. It is important to protect the posterior tibial tendon when making the osteotomy cut, and the tendon sheath should be elevated and protected during this procedure.



OSTEOTOMY AND DEFORMITY CORRECTION



After exposing the tibia, place a notched K-wire through the tibia from medial to lateral at the level of the intended distal cut of the osteotomy. Be sure that the notched portion of the K-wire is still accessible and avoid violating the lateral cortex of the tibia.

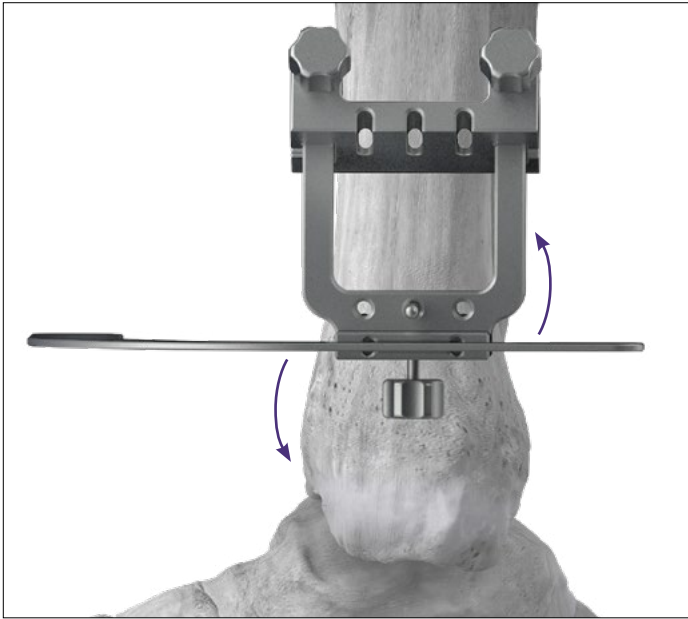


Ensure the set screw of the distal portion of the Medial Sextant Jig is loose and slide the middle hole of the Jig over the notched K-wire. The Jig should engage with the notch on the K-wire.



Note: If the surgeon is concerned with osteotomy gapping laterally, prematurely plate the anterolateral tibial cortex through the same incision used for the fibular osteotomy, as shown on page 16

OSTEOTOMY AND DEFORMITY CORRECTION



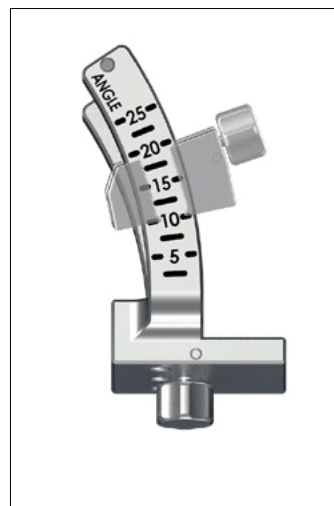
To assess planned osteotomy sagittal alignment, place the Angelwing in the Angelwing slot and assess alignment either visually or using fluoroscopy. Rotate the Jig to desired alignment.



Confirm position of the Medial Sextant Jig and lock position by tightening the screw. Place a second smooth K-wire in either the anterior or posterior hole in the guide. A third wire can be placed in the last hole per surgeon preference.



Slide the proximal portion of the Medial Sextant Jig along the arms to the desired height/angle for the intended wedge to be removed. Tighten the screws to lock the position at the intended height/angle.



ANGLE READING



HEIGHT READING



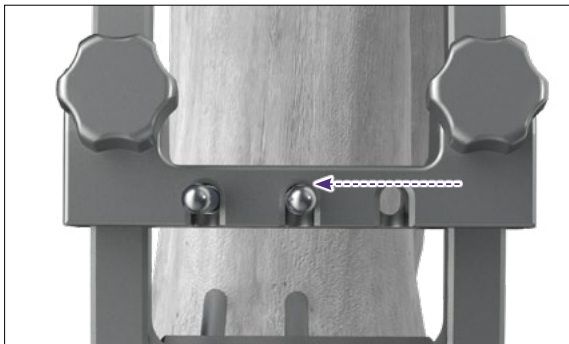
Note: The Medial Sextant has two sides with readings. One side has angle readings while the other side has height readings for the intended wedge to be removed.

OSTEOTOMY AND DEFORMITY CORRECTION

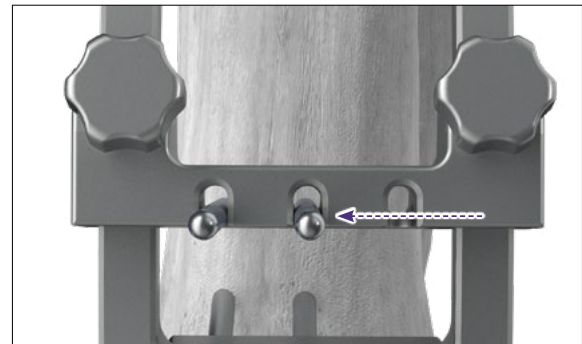


Place a pair of smooth K-wires through any 2 of the possible 3 holes in the proximal portion of the guide.

CORRECT: ✓

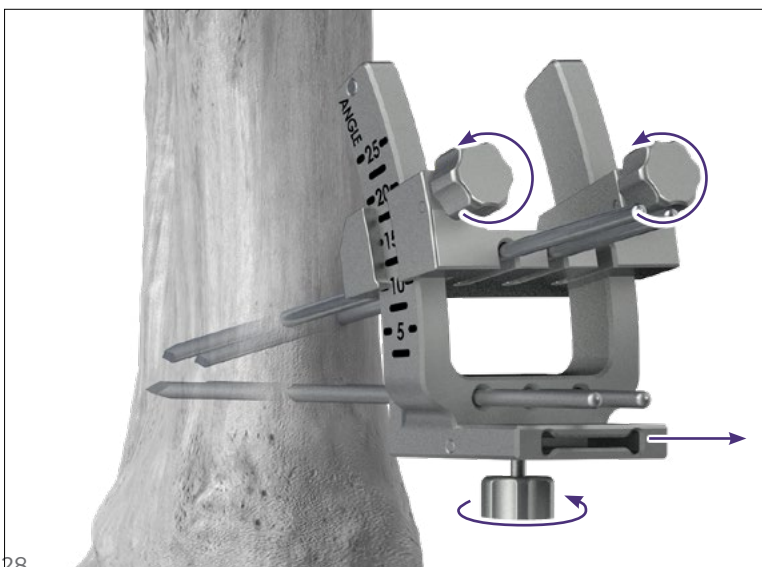


INCORRECT: ✗



Be sure to have the wires are pressing up against the proximal portion of the wire slots when placing to ensure accurate placement.

Confirm convergence of the proximal and distal wires using fluoroscopy.



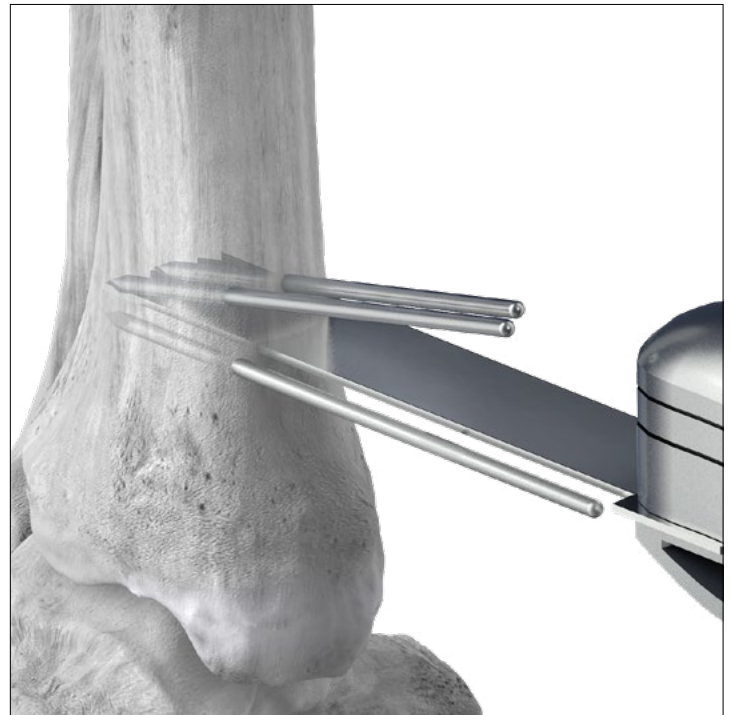
Loosen all screws on the Medial Sextant Jig and slide the whole Jig off the wires.

OSTEOTOMY AND DEFORMITY CORRECTION

Slide the Medial Cut Guide over the distal wires and push it against the bone. The cutting slot should be superior to the distal wires. Secure the Cut Guide to the bone by placing an Olive Wire through the hole in the pad. Trim wires as necessary to accommodate instrumentation using the provided Wire Cutter.



Place the saw in the Cut Guide. Saw through the Cut Guide, taking care to avoid violating the lateral cortex of the tibia.



Note: If preferred, the cut can be started using the saw and Cut Guide. The Cut Guide can then be removed and sawing can be finished according to surgeon preference.

OSTEOTOMY AND DEFORMITY CORRECTION

Place the Cut Guide over the proximal wires such that the cut guide is inferior to the proximal wires. Repeat securing Cut Guide, trimming wires, and sawing through Cut Guide. Take care to avoid violating the lateral cortex.



If necessary, finish the osteotomy with a provided osteotome. Remove the resected wedge. Additionally, create an oblique fibular osteotomy depending on the deformity being corrected and according to surgeon preference.



Manually correct the deformity and trim any bony prominence with a saw.

PLATE PLACEMENT AND PERMANENT FIXATION

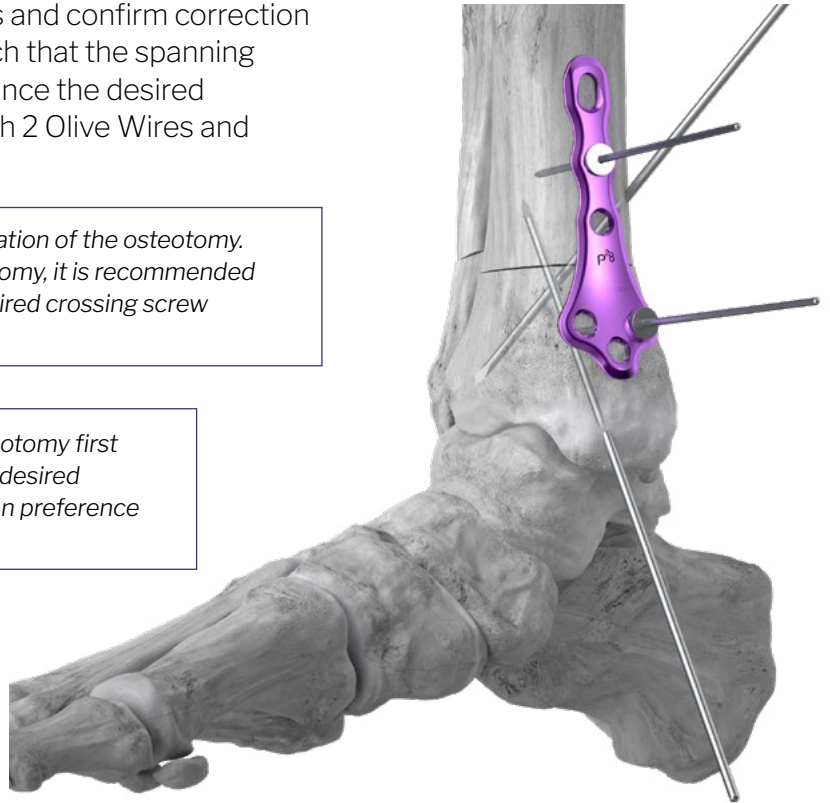
Provisionally fix the osteotomy with crossing K-wires and confirm correction using fluoroscopy. Position the plate on the bone such that the spanning region of the plate is centered over the osteotomy. Once the desired position is achieved, temporarily secure the plate with 2 Olive Wires and confirm the 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 placement of a crossing screw across the osteotomy first is preferred, a K-wire sized to be the guide wire for the desired crossing screw diameter is placed according to surgeon preference (see page 28).



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. Measure screw length using the provided depth gauge.



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.



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-3001.



PLATE PLACEMENT AND PERMANENT FIXATION



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 Olive Wires serving as temporary fixation in the distal portion to allow for screw placement.

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. Any bony prominence at the osteotomy site on the fibula should be leveled before fibular plating and the cortical shavings from this can be used to fill in any gaps remaining in the fibula.

Proceed to incision closure or concomitant procedures at this time.

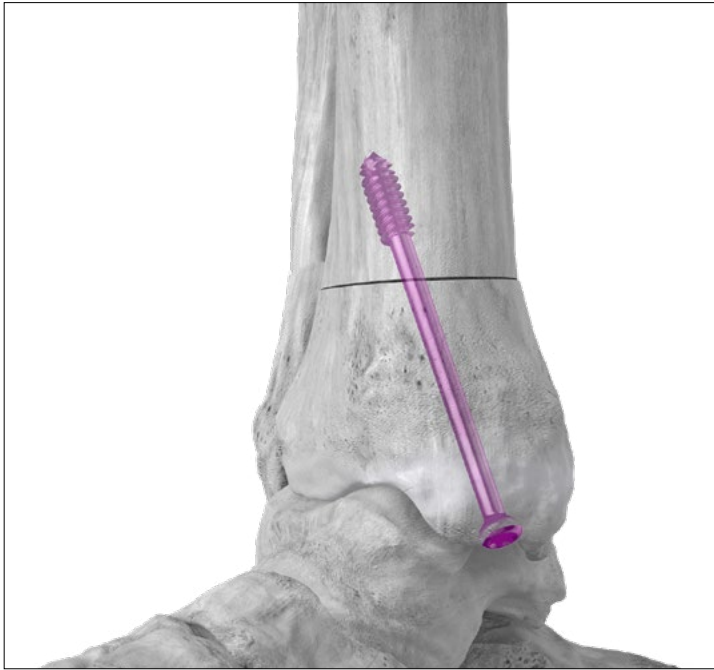


Refer to page 14 for instruction for drilling and placing a screw in the compression slot.



Note: For more information and instructions on plating the fibula, please refer to the Gorilla® Ankle Fracture 360 Surgical Technique Guide: P51-STG-3008.

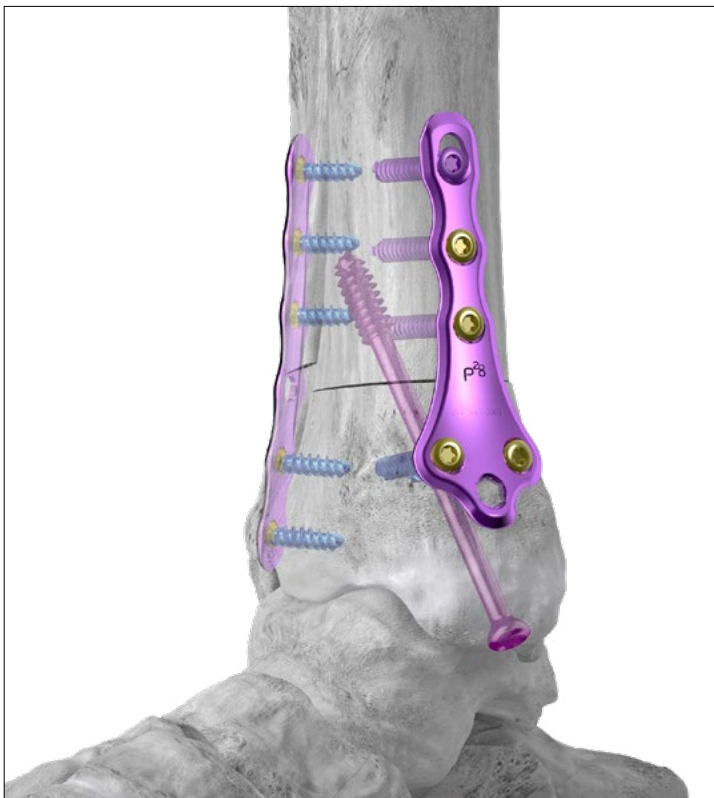
ALTERNATIVE PLATING METHODS



If crossing screw placement across the osteotomy is preferred prior to plating, place a partially or fully-threaded Monster® crossing screw across the osteotomy according to the Monster® Surgical Technique Guide (P20-STG-3001).



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.



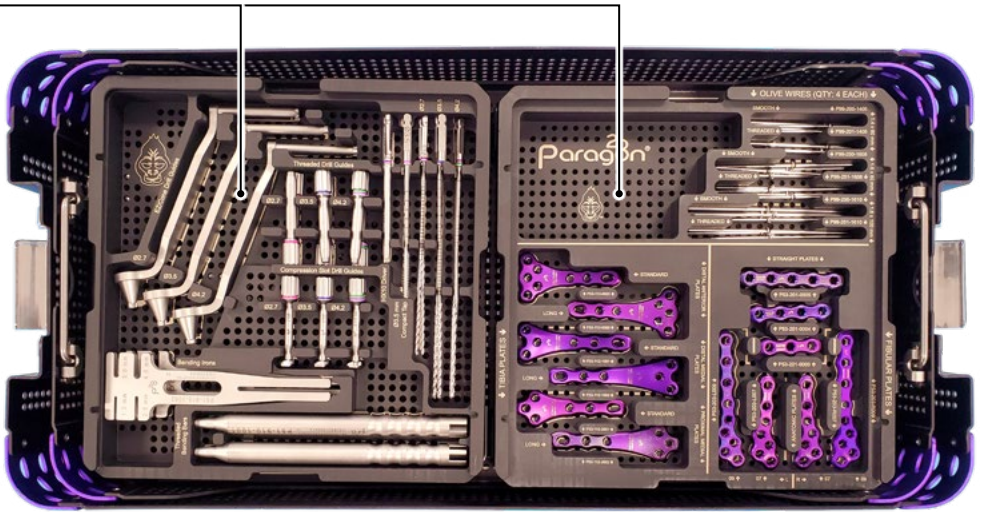
If placing a screw in the compression slot when a crossing screw across the osteotomy is already placed, position the compression slot drill guide such that the arrow faces away from the osteotomy to allow for distal screw placement in the slot. If a fibular osteotomy was performed, place a fibula plate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

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

GORILLA® CADDY AND CASE SYSTEM

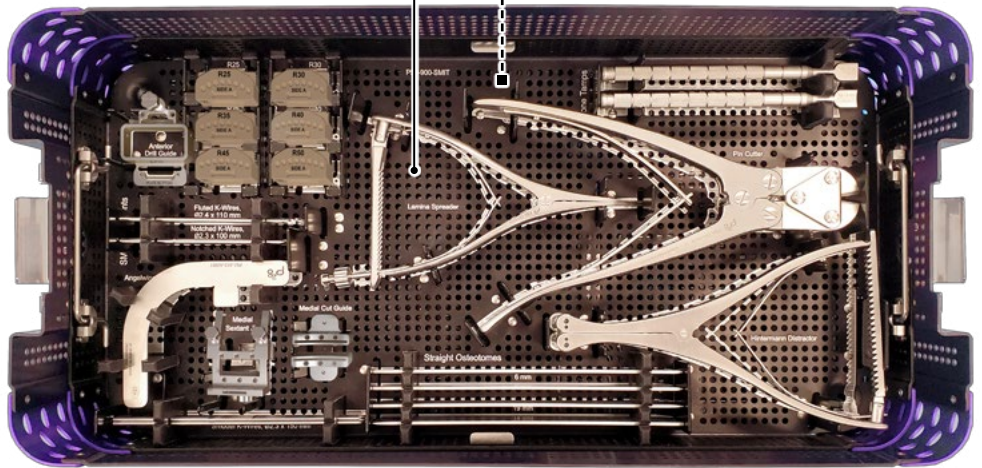
GORILLA® SUPRAMALLEOLAR OSTEOTOMY CADDIES

Drill guides, Drills, Bending Irons, Threaded Bending Bars, the standard and long Anterior Tibia, Distal Medial Tibia, and Proximal Medial Tibia Plate, Gorilla® Ankle Fracture 3, 4, or 5 hole Straight Fibular Plates, Ankle Fracture 7 or 9 hole left and right Anatomic Fibular Plates, and Smooth and Threaded Olive Wires are located in The Gorilla® Supramalleolar Osteotomy Caddies..



GORILLA® SUPRAMALLEOLAR OSTEOTOMY INSTRUMENT CASE

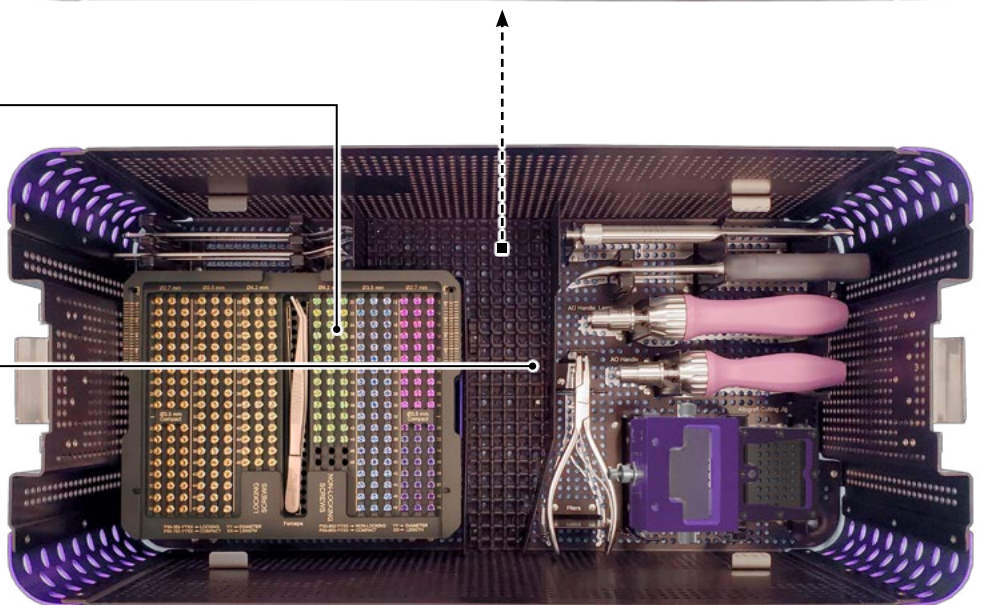
Anterior Drill Guide Template, Anterior Drill Guide Inserts, 2.4 mm Fluted K-wires, Notched 2.3 mm K-wires, Angelwing, Medial Sextant Jig, Medial Cut Guides, Smooth 2.3 mm K-wires, Lamina spreader, 6 & 19 mm Straight Osteotomes, Tamps, Pin cutters, and a HINTERMAN Distractor are located in the Gorilla® Supramalleolar Osteotomy Instrument Tray.



GORILLA® SUPRAMALLEOLAR OSTEOTOMY SCREW CADDY

GORILLA® SUPRAMALLEOLAR OSTEOTOMY CASE

The Hohmann retractors, Plate bending pliers, Periosteal elevator, Standard & Large AO handle and SMO Allograft Cutting Jig are located at the bottom of the Gorilla® Supramalleolar Osteotomy Case.



GORILLA, SUPRAMALLEOLAR OSTEOTOMY SYSTEM CASE

Part #	Description	Use
P01-954-0001	Preserve, SMO Allograft, Cutting Jig	Reusable
P51-910-1003	Pliers	Reusable
P99-000-AOLG	Mini-AO, Ratchet Handle, Purple Large	Reusable
P99-000-AOMN	Mini-AO, Ratchet Handle, Purple	Reusable
P99-150-0014	P28, Depth Gauge Plate Screw, 70 mm	Reusable
P99-150-0051	8mm Hohmanns	Reusable
P99-150-0052	16mm Hohmanns	Reusable
P51-912-2310	K-Wires, 2.3, 100mm, 67.5mm Notched	Single-use
P51-912-24DR	Fluted K-wire, 2.4, 160mm	Single-use
P51-912-AND1	SMO, Anterior Drill Guide, Template	Reusable
P51-912-AND[3-8]	SMO Insert	Reusable
P51-912-AW01	SMO Angelwing	Reusable
P51-912-ML01	SMO, Medial Sextant Jig	Reusable
P51-912-MLC1	SMO, Medial Cut Guide	Reusable
P99-150-0002	Flat Bone Tamp	Reusable
P99-150-0003	Radius Bone Tamp	Reusable
P99-150-0010	Large, Hintermann Distractor	Reusable
P99-150-0016	Pin Cutter	Reusable
P99-150-0040	6mm Osteotome	Reusable
P99-150-0042	19mm Osteotome	Reusable
P99-150-0114	Lamina Spreader	Reusable
P99-192-2315	2.3 x 150mm K-wire	Single-use

GORILLA, SUPRAMALLEOLAR OSTEOTOMY SYSTEM PLATING CADDY

Part #	Description	Use
P53-112-000[1/2]	Anterior Tibia Plate	Single-use
P53-112-100[1/2]	Distal Medial Tibia Plate	Single-use
P53-112-200[1/2]	Proximal Medial Tibia Plate	Single-use
P53-201-000[3-5]	Ankle Fracture, Straight Fibular Plate	Single-use
P53-203-L00[7/9]	Ankle Fracture, Anatomic Fibular Plate, Left	Single-use
P53-203-R00[7/9]	Ankle Fracture, Anatomic Fibular Plate, Right	Single-use
P99-20[0/1]-1406	1.4 x 6 cm Olive Wire	Single-use
P99-25[0/1]-1608	1.6 x 8 cm Olive Wire	Single-use
P99-25[0/1]-1610	1.6 x 10 cm Olive Wire	Single-use

GORILLA, SUPRAMALLEOLAR OSTEOTOMY SYSTEM INSTRUMENT CADDY

Part #	Description	Use
P51-900-100[4-6]	Threaded Locking Drill Guide	Reusable
P51-901-5027	2.7mm EZ Cone Drill Guide	Reusable
P51-901-5035	3.5mm EZ Cone Drill Guide	Reusable
P51-901-5042	4.2mm EZ Cone Drill Guide	Reusable
P51-903-300[4-6]	Compression Slot Drill Guide	Reusable
P51-910-1001	Plate Threaded Bending Bars	Reusable
P51-910-1002	Plate Bending Irons	Reusable
P51-911-3501	3.5mm Compact Thread Tap	Reusable
P99-100-2013	2.0 x 13 cm Solid Drill	Reusable
P99-100-2416	2.4 x 16 cm Solid Drill	Reusable
P99-100-2816	2.8 x 16 cm Solid Drill	Reusable
P99-191-AF10	Gorilla R3CON long, solid, driver	Reusable

GORILLA, SUPRAMALLEOLAR OSTEOTOMY SYSTEM SCREW CADDY

Part #	Description	Use
P99-150-0001	Screw Forceps	Reusable
P50-353-27[12-30]	2.7 mm Locking Screw	Single-use
P50-353-35[12-48]	3.5 mm Locking Screw	Single-use
P50-353-42[20-48]	4.2 mm Locking Screw	Single-use
P50-543-27[12-30]	2.7 mm Non-Locking Screw	Single-use
P50-453-35[12-48]	3.5 mm Non-Locking Screw	Single-use
P50-453-42[20-48]	4.2 mm Non-Locking Screw	Single-use
P50-753-35[20-34]	3.5 mm Locking Compact Thread Screw	Single-use
P50-853-35[20-34]	3.5 mm Non-Locking Compact Thread Screw	Single-use

GORILLA, SUPRAMALLEOLAR OSTEOTOMY SYSTEM BLACK BOX

Part #	Description	Use
P99-151-P51S-S	30 x 13 x 0.6 Small Stryker Saw Blade	Single-use
P99-151-P51L-S	70 x 11.5 x 0.8 Large Stryker Saw Blade	Single-use
PSMOST-025E	Modifiable SMO Allograft	Single-use

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

In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, appropriate for the size of the device.

CONTRAINDICATIONS

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

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

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

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

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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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

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

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

WARNINGS AND PRECAUTIONS

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

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

MRI SAFETY INFORMATION

A person with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Name/Identification of Device	Paragon 28® Baby Gorilla®/Gorilla® Plating System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

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

WARNINGS AND PRECAUTIONS

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

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

MRI SAFETY INFORMATION



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

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

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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