



SURGICAL TECHNIQUE GUIDE

Lateral Column Arthrodesis

Gorilla[®] Lateral Column
Fusion Plating System



PRODUCT DESCRIPTION

Paragon 28® developed the Gorilla® Lateral Column Fusion (LCF) Plating System to allow a surgeon to provide fixation across the 4th/5th tarsometatarsal joint and the calcaneocuboid joint. If the cuboid is subluxed plantarly while the 4th and 5th metatarsals are subluxed dorsally, breakdown of the tissue plantar to the cuboid can result in ulceration. The Gorilla® Lateral Column Plating System helps to address this problem by using a plate with locking screws across the 4th and 5th metatarsals and cuboid to help prevent the metatarsals from shifting dorsally, while using a 5.5 mm screw integrated into the plate to keep the cuboid from subluxing plantarly. This system is intended to address the difficulty of placing beaming screws into the 4th or 5th metatarsals, while providing a rigid construct to maintain proper cuboid alignment.

IMPLANT OFFERING

LCF Plates:



Left (Standard)



Left (Large)



Right (Standard)



Right (Large)

LCF Screw Offering:



Gorilla® Type II Anodized 5.5 mm Partially Threaded Beaming Plate Screws

- Offered in 80 - 120 mm, 5 mm increments
- Solid core, non-locking
- Consistent shank length to provide maximum amount of threads in the calcaneus



Gorilla® Type II Anodized 5.5 mm Fully Threaded Beaming Plate Screws

- Offered in 80 - 120 mm, 5 mm increments
- Solid core, non-locking

INSTRUMENTATION

LCF Plates:



Left Template (Standard)



Left Template (Large)



Right Template (Standard)



Right Template (Large)

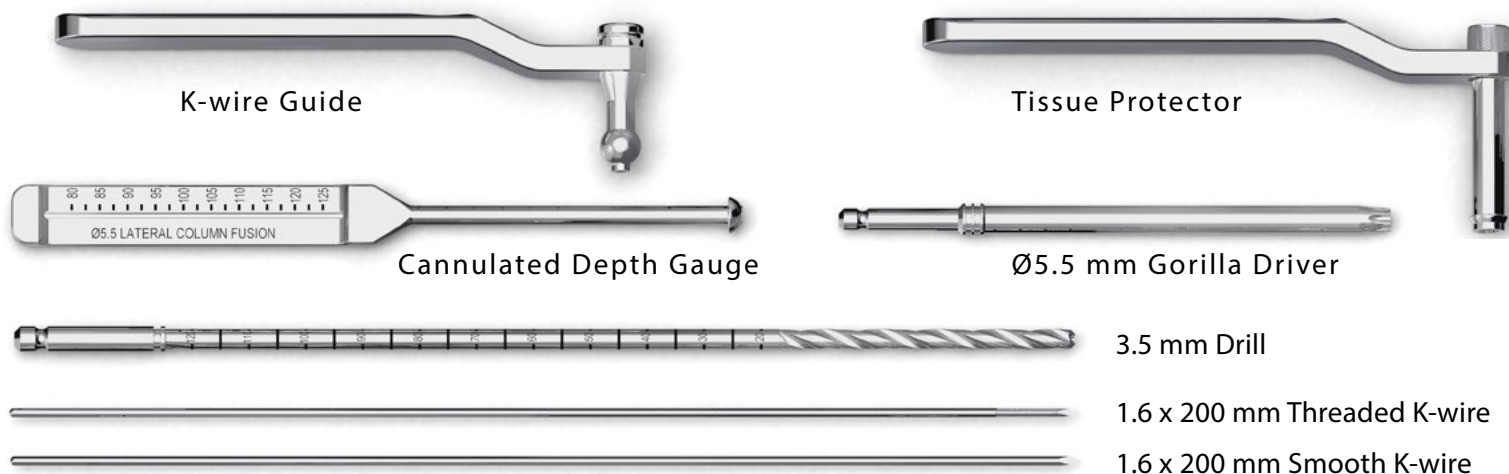


Joint Preparation Paddle



Reamer

INSTRUMENTATION



INCISION/EXPOSURE



Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference. An incision is made over the calcaneocuboid joint proximally extending past the 4th/5th metatarsal-cuboid joint distally. Continue soft tissue dissection until the aforementioned joints are accessible.

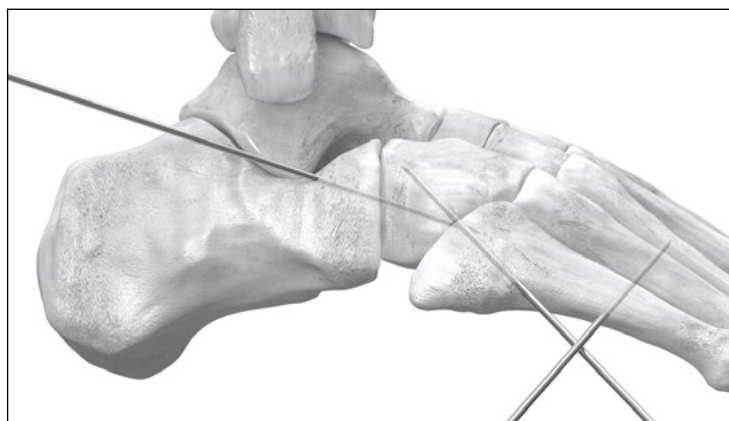
JOINT PREPARATION/ TEMPORARY FIXATION



Remove the cartilage from the 4th/5th metatarsal-cuboid joint as well as the calcaneocuboid joint using a preferred technique.

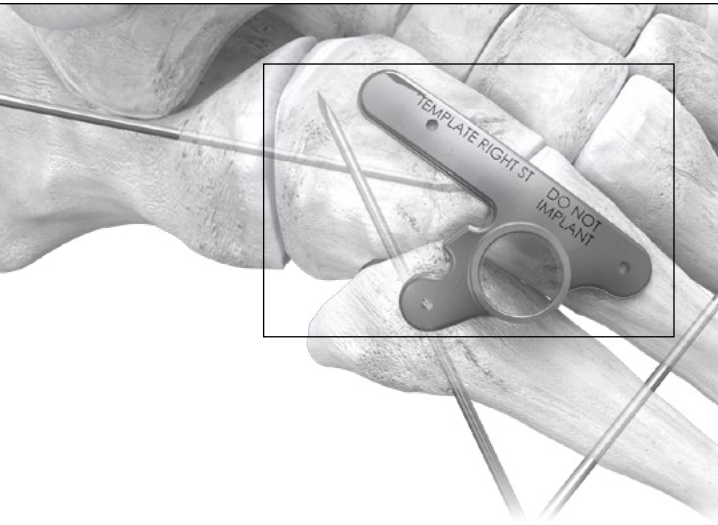
NOTE: An attempt should be made to preserve the capsular ligaments of the proximal 4th/5th intermetatarsal joint to maintain stability of the 5th metatarsal during reaming and internal fixation.

Manipulate the calcaneus, cuboid and 4th/5th metatarsals to properly align the lateral column.

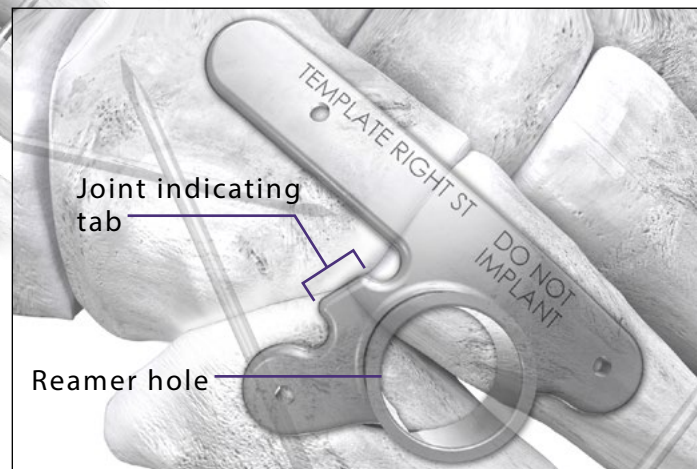


A first temporary fixation K-wire can be placed from the dorsal 5th metatarsal into the cuboid proximally. A second K-wire can be placed across the 5th, 4th and 3rd metatarsal. Temporary stabilization of the cuboid to the calcaneus is achieved by use of a 3rd K-wire. Variations in temporary fixation may exist due to bone quality and surgeon preference.

PLATE TEMPLATES

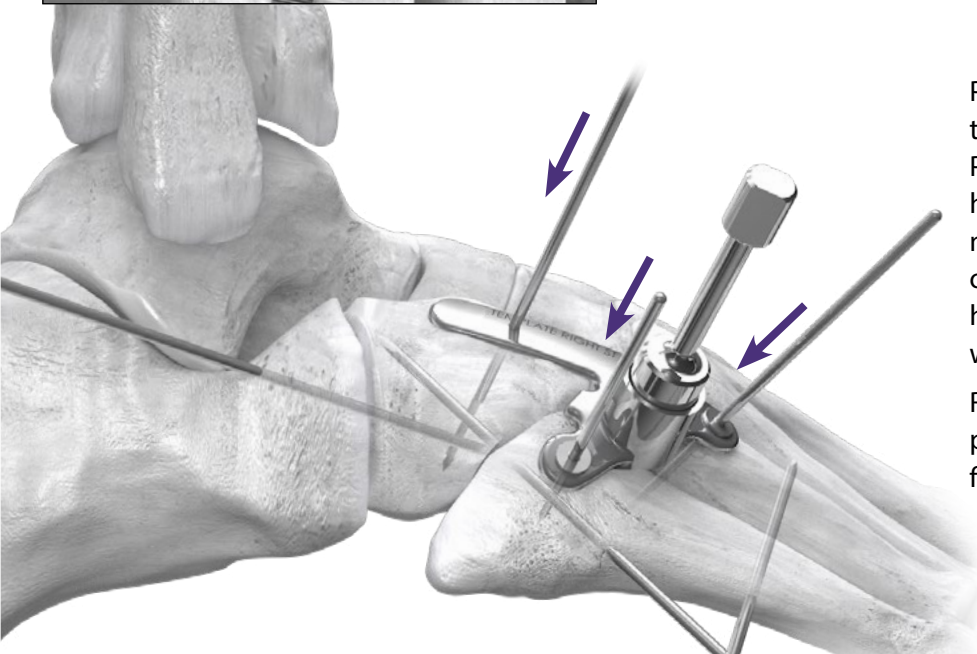


Position the Plate Template for the desired plate size over the cuboid and the 4th/5th metatarsals. Align the joint indicating tab (labeled below) of the Plate Template with the junction of the 4th/5th metatarsal-cuboid joint. Center the Plate Template over the 4th and 5th metatarsals as best as possible and confirm appropriate plate size.



Locate the 4th/5th metatarsal joint by placing the Joint Preparation Paddle in the reamer hole (labeled above) in the Plate Template. Allow the Joint Preparation Paddle to align parallel to the metatarsals until it is able to be pushed into the 4th/5th metatarsal joint to center the Plate Template. This allows for equal reaming of the 4th and 5th metatarsals to limit weakening of a single bone.

Use of the Plate Template and Joint Preparation Paddle allow for the starting point of the 5.5 mm screw to be positioned 1 cm from the 4th/5th metatarsal-cuboid joint and centered for reaming between the 4th and 5th metatarsals.



Place a threaded 1.6 mm K-wire into the cuboid through the proximal aspect of the Plate Template. Place two threaded olive wires into the distal holes of the Plate Template into the 4th and 5th metatarsals, respectively. Threaded K-wires and olive wires are provided and recommended to help prevent back-out of the Plate Template while reaming.

Remove the Joint Preparation Paddle. Confirm placement of the Plate Template under fluoroscopy.

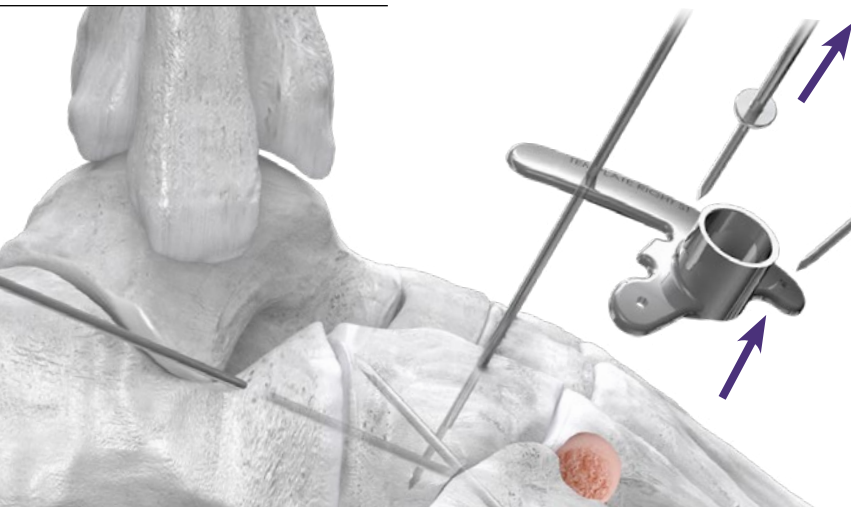
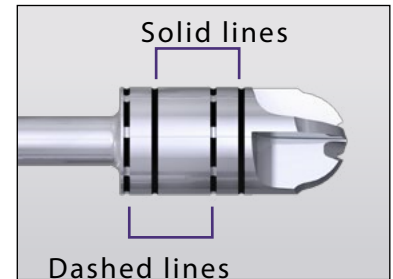
SURGICAL TECHNIQUE GUIDE:

LATERAL COLUMN ARTHRODESIS

PLATE TEMPLATE



Once the Plate Template is secured, attach the reamer to the handle. Insert the reamer into the reamer hole in the Plate Template until it contacts bone. Note which line (solid or dashed) is closest to the top of the reaming hole. Ream until the next solid or dashed line, respectively, to ensure adequate depth of the reamed hole.



Remove the two olive wires distally, but retain the 1.6 mm K-wire in the cuboid for plate alignment. Slide the Plate Template off of the 1.6 mm K-wire.

PLATE FIXATION



The selected plate is then slid over the proximal K-wire such that the recessed hole of the plate fits in the reamed area of the 4th and 5th metatarsals.

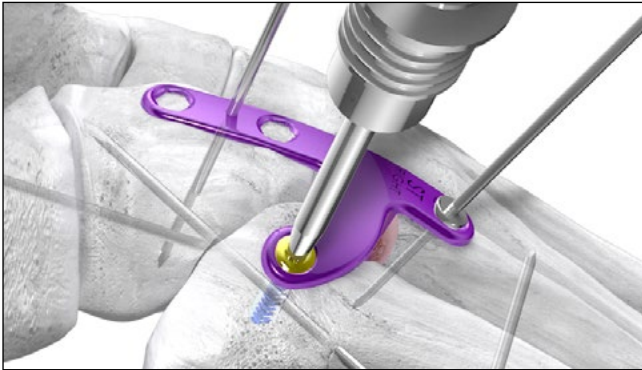
NOTE: If the decision to move up or down a plate size at this point is made, the K-wire and reaming hole will still align to a different size plate.

Additional reaming may be necessary to seat the plate properly in the joint.

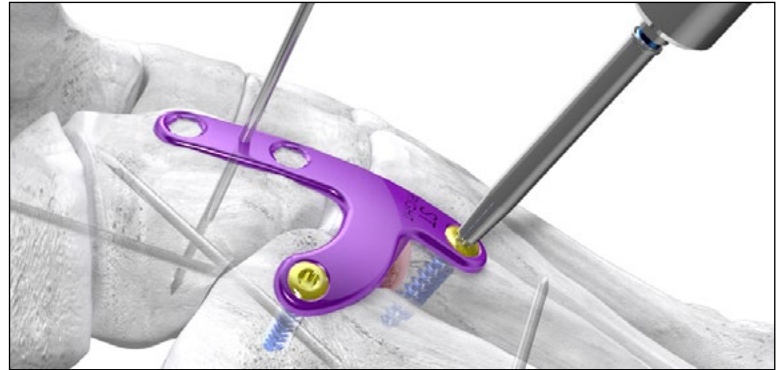


Place an olive wire in the 4th metatarsal plate hole. All plate holes (with the exception of the recessed hole) accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking Gorilla screws. Place a drill guide into the 5th metatarsal plate hole. Drill a hole using the drill corresponding to the desired screw diameter. Measure screw length using a depth gauge.

PLATE FIXATION

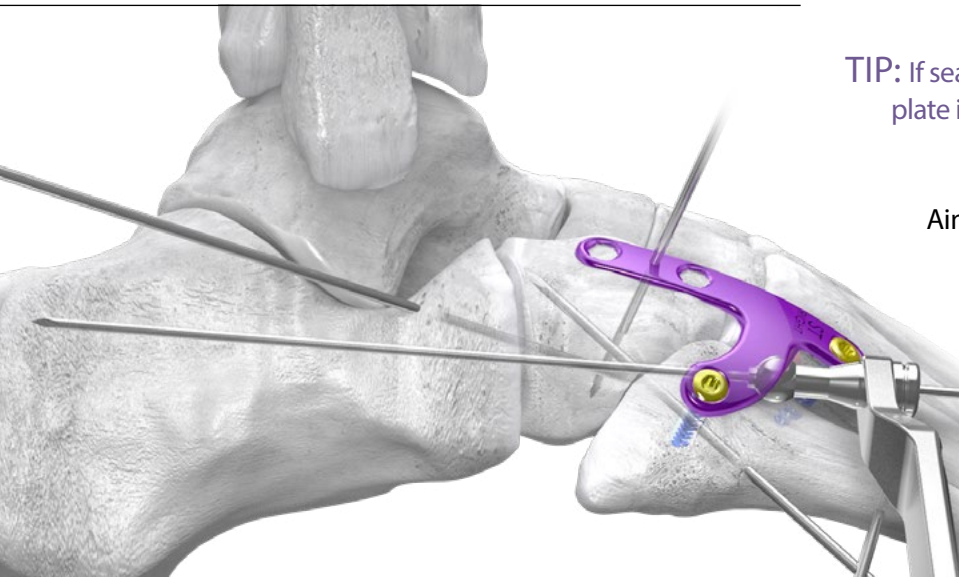


Insert the selected screw into the hole of the plate.
Remove the olive wire from the 4th metatarsal.



Using the technique described above for inserting plate screws,
insert a plate screw into the 4th metatarsal plate hole.

CROSSING SCREW PLACEMENT



Mate the K-wire Guide in the recessed hole.

TIP: If seating of the K-wire Guide into the recessed hole of the plate is difficult, use a rongeur to remove a small amount of bone or soft tissue just distal to the recessed hole to make room for the K-wire Guide.

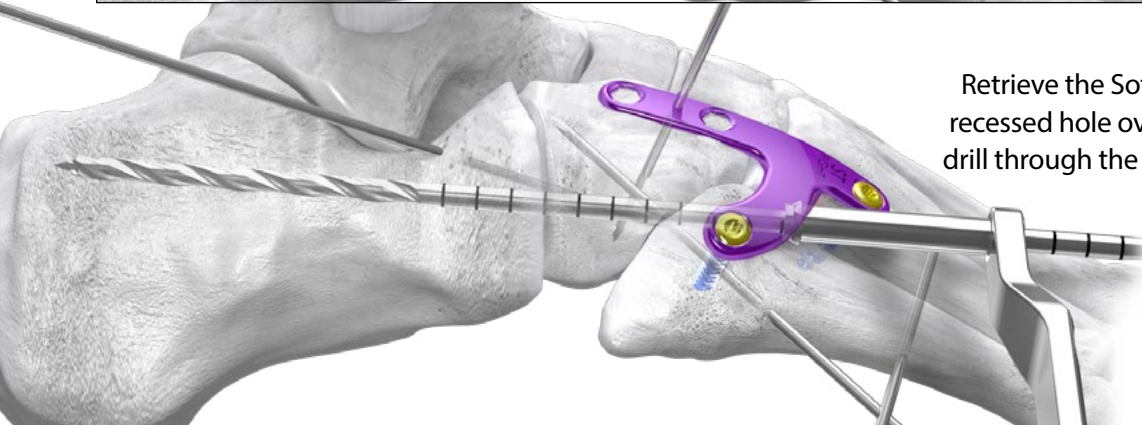
Aiming for the central body of the calcaneus, insert the 1.6 mm K-wire through the K-wire Guide.

NOTE: The K-wire Guide has the ability to place the K-wire for the 5.5 mm screw 15° off-axis in any direction. Directing the screw greater than 15° off-axis may result in a screw head that is not seated in the plate.

Remove the K-wire Guide from the recessed hole.
Confirm K-wire position under fluoroscopy.



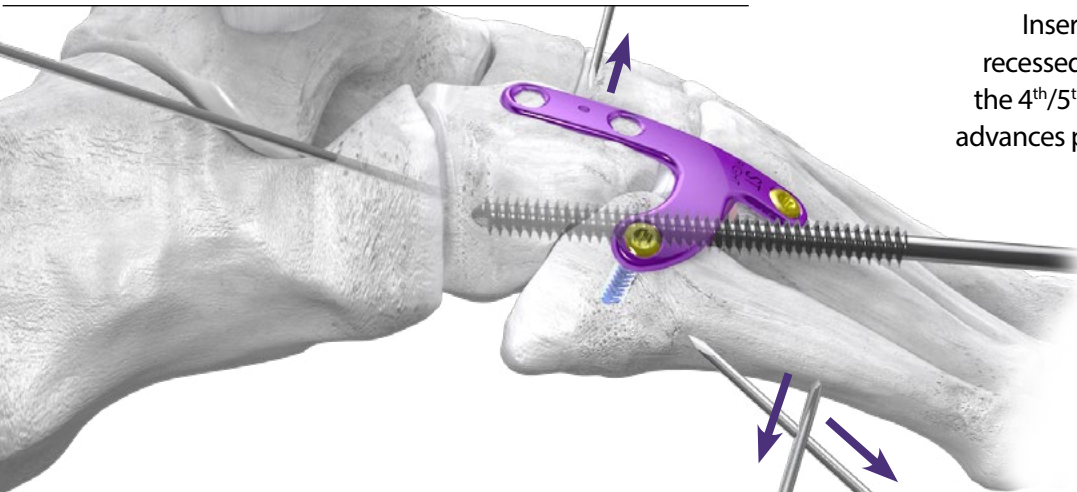
Measure K-wire length using the
cannulated depth gauge.



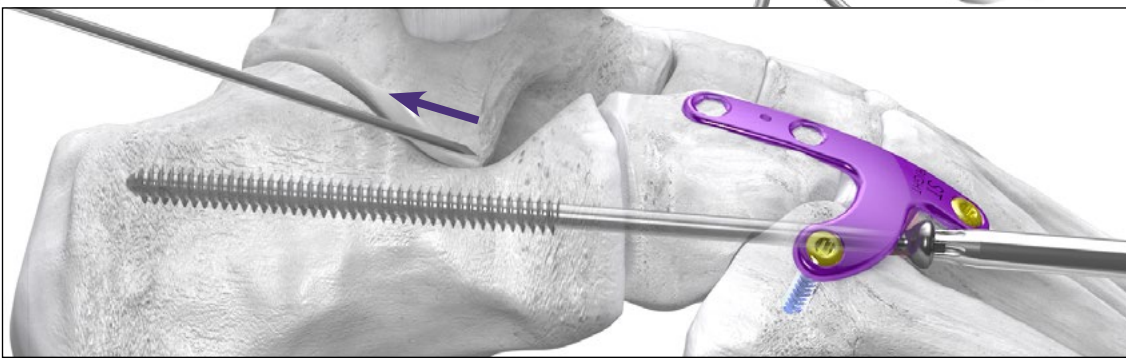
Retrieve the Soft Tissue Protector and mate with the recessed hole over the K-wire. Using the 3.5 mm Drill, drill through the Soft Tissue Protector over the K-wire.

Remove the Soft Tissue Protector
and K-wire to allow 5.5 mm
screw insertion.

CROSSING SCREW PLACEMENT



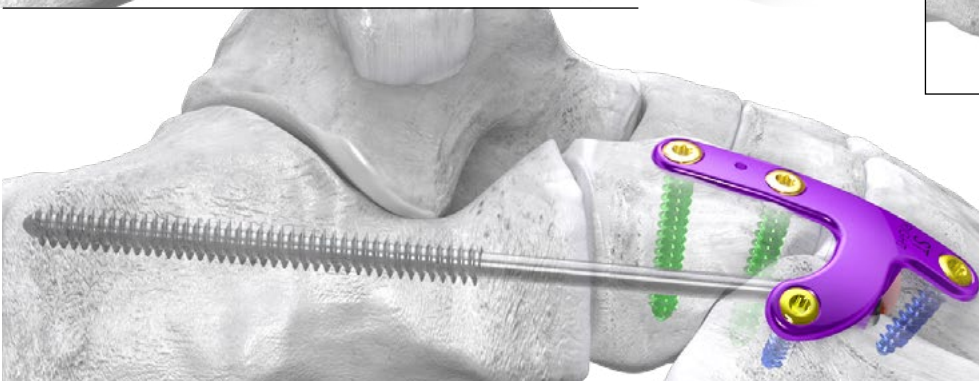
Insert the selected 5.5 mm screw through the recessed hole. Remove temporary fixation across the 4th/5th metatarsal-cuboid joint as the screw tip advances past this joint if using a partially threaded screw to allow for compression. Remove the threaded K-wire in the cuboid from the plate.



Continue screw insertion. Remove temporary fixation across the calcaneocuboid joint before screw is fully seated in plate hole.



Using the technique described for inserting plate screws, insert the final plate screws into the plate holes in the cuboid.



Confirm screw length and position using fluoroscopy. Additional fixation for the calcaneocuboid joint should be considered at the surgeon's discretion.

CLOSURE

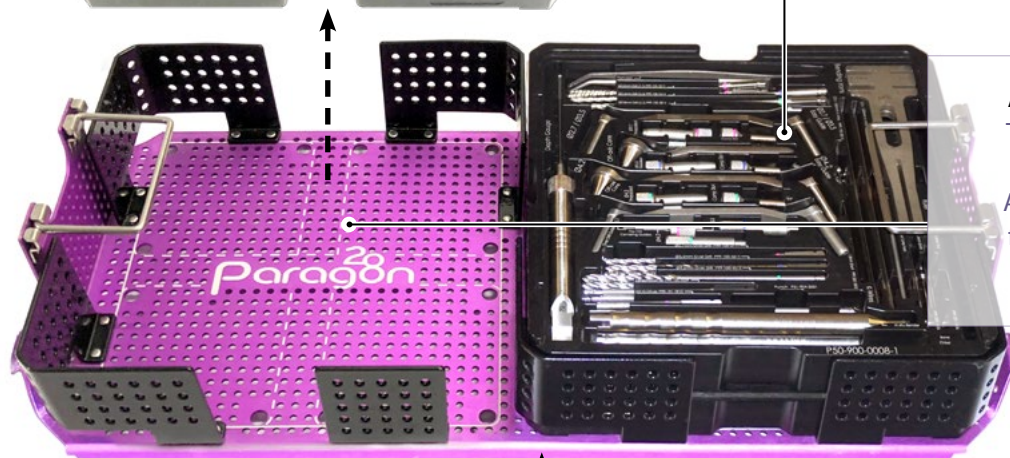
Proceed to incision closure or concomitant procedures at this time.

Lateral Column Fusion Plating System Caddy

The Gorilla® Lateral Column Fusion Plating System Caddy contains the Standard and Large Lateral Column Fusion Plates and Type II Anodized 5.5 mm Beaming Plate Screws. All instrumentation specific to the Lateral Column Fusion Plating System is located in the caddy including the Plate Templates, Joint Preparation Paddle, Reamer, K-wire Guide, Tissue Protector, Depth Gauge, 3.5 mm Drill, the Ø5.5 mm Gorilla Driver and the 1.6 mm K-wires.



Gorilla® R3CON Instrument Caddy
Drills, drill guides, centering guides, olive wires, plate benders, drivers, K-wires and a depth gauge are located in the Gorilla® R3CON Instrument Caddy.



Additional Gorilla® Caddies
The Gorilla® Case has room for additional Gorilla® Plate Caddies or PRESERVE™ Allograft caddies that may be needed for additional procedures performed in addition to a lateral column arthrodesis.

Gorilla® Case



Gorilla® Screw Optionality

The Gorilla® screw length options for both locking and non-locking screws are as follows:

2.7 mm	1 mm increments, 8-20 mm	
2.7 mm	2 mm increments, 22-40 mm	
3.5 mm	2 mm increments, 10-50 mm	
4.2 mm	2 mm increments, 10-50 mm	
4.2 mm	5 mm increments, 55-70 mm	

Gorilla® R3CON Instruments

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

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - LATERAL COLUMN FUSION CADDY

Part #	Description	Use
P53-111-L001	Gorilla, Plate, LCF (Lateral Column Fusion), Left, Standard, TiA	Single-use
P53-111-L002	Gorilla, Plate, LCF (Lateral Column Fusion), Left, Large, TiA	Single-use
P53-111-R001	Gorilla, Plate, LCF (Lateral Column Fusion), Right, Standard, TiA	Single-use
P53-111-R002	Gorilla, Plate, LCF (Lateral Column Fusion), Right, Large, TiA	Single-use
P50-455-080F	Gorilla, Screw, LCF, Ø5.5 x 80mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-085F	Gorilla, Screw, LCF, Ø5.5 x 85mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-090F	Gorilla, Screw, LCF, Ø5.5 x 90mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-095F	Gorilla, Screw, LCF, Ø5.5 x 95mm, Non-Locking Fully Threaded, TiA	Single-use
P50-455-100F	Gorilla, Screw, LCF, Ø5.5 x 100mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-105F	Gorilla, Screw, LCF, Ø5.5 x 105mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-110F	Gorilla, Screw, LCF, Ø5.5 x 110mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-115F	Gorilla, Screw, LCF, Ø5.5 x 115mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-120F	Gorilla, Screw, LCF, Ø5.5 x 120mm, Non-Locking, Fully Threaded, TiA	Single-use
P50-455-080L	Gorilla, Screw, LCF, Ø5.5 x 80mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-085L	Gorilla, Screw, LCF, Ø5.5 x 85mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-090L	Gorilla, Screw, LCF, Ø5.5 x 90mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-095L	Gorilla, Screw, LCF, Ø5.5 x 95mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-100L	Gorilla, Screw, LCF, Ø5.5 x 100mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-105L	Gorilla, Screw, LCF, Ø5.5 x 105mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-110L	Gorilla, Screw, LCF, Ø5.5 x 110mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-115L	Gorilla, Screw, LCF, Ø5.5 x 115mm, Non-Locking, Partially Threaded, TiA	Single-use
P50-455-120L	Gorilla, Screw, LCF, Ø5.5 x 120mm, Non-Locking, Partially Threaded, TiA	Single-use
P51-111-L001	Gorilla, LCF, Plate Template Left, Standard, SS	Reusable
P51-111-L002	Gorilla, LCF, Plate Template Left, Large, SS	Reusable
P51-111-R001	Gorilla, LCF, Plate Template Right, Standard, SS	Reusable
P51-111-R002	Gorilla, LCF, Plate Template Right, Large, SS	Reusable
P51-924-0002	Gorilla, LCF, K-wire Guide, SS	Reusable
P51-924-0003	Gorilla, LCF, Joint Preparation Paddle, SS	Reusable
P51-924-0004	Gorilla, LCF, Reamer, SS	Reusable
P51-924-0005	Gorilla, LCF, Tissue protector, SS	Reusable
P51-924-0006	Gorilla, LCF, Depth Gauge, SS	Reusable
P99-110-3517	P28, Drill, Ø3.5mm x 16cm, SS	Reusable
P99-191-LC25	P28, Driver, Solid, TX 25, AO, SS	Reusable
P99-192-1620	P28, K-wire, Single Ended Trocar Tip, SMOOTH, 1.6 x 200 mm, SS	Single-use
P99-193-1620	P28, K-wire, Single Ended Trocar Tip, THREADED, 1.6 x 200 mm, SS	Single-use

*See the complete Gorilla Plating Surgical Technique Guide (P51-STG-0001) for general instrument information

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

INSTRUCTIONS for use: Baby Gorilla®/Gorilla® Plating System

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

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

NOTES:

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.



Gorilla® Lateral Column Fusion Plating System

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