SURGICAL TECHNIQUE GUIDE:

1st MTP ARTHRODESIS FOLLOWING FAILED SYNTHETIC CARTILAGE IMPLANT

Exclusively foot & ankle

Paragon 28®

AVITRAC™

PRESERVE™ BONE GRAFT SYSTEM

GORILLA® R3CON PLATING SYSTEM

PRODUCT DESCRIPTION

The AVITRAC™ bone graft was designed to provide structural rigidity to the 1st metatarsal following removal of a failed synthetic cartilage implant when converting to an MTP arthrodesis. The AVITRAC™ graft is made of dense cancellous allograft using aseptic processing and is part of the Paragon 28® PRESERVE™ line of biologic products. Both the AVITRAC™ grafts and reamers are sterile packaged. Use of this AVITRAC™ graft is shown with a Gorilla® MTP plate and Mini-Monster® crossing screw; however, alternative fixation can be considered.

AVITRAC™ GRAFT


Ø9 mm


Ø11 mm


Ø13 mm

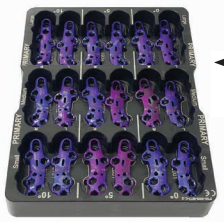
AVITRAC™ REAMERS


Ø9 mm


Ø11 mm


Ø13 mm

ASSOCIATED PARAGON 28® PRODUCTS



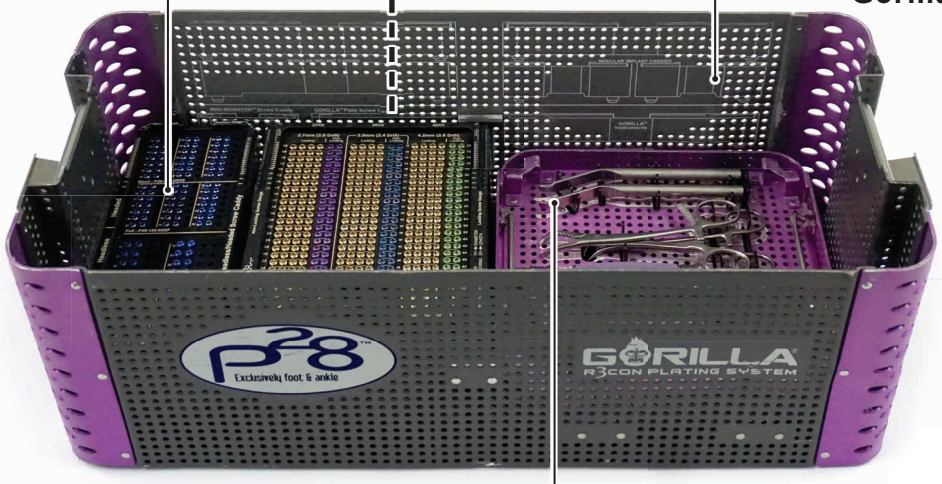

MTP Caddy

Gorilla® R3CON Instrument Caddy

Additional Gorilla® Caddies

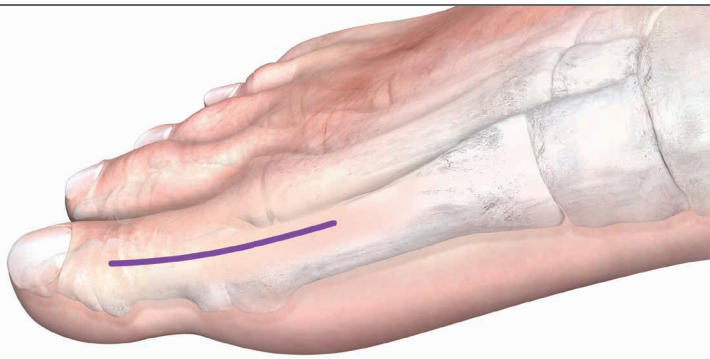
Mini-Monster® Screw Caddy

Gorilla® Case



Gorilla® R3CON Instruments

INCISION/EXPOSURE



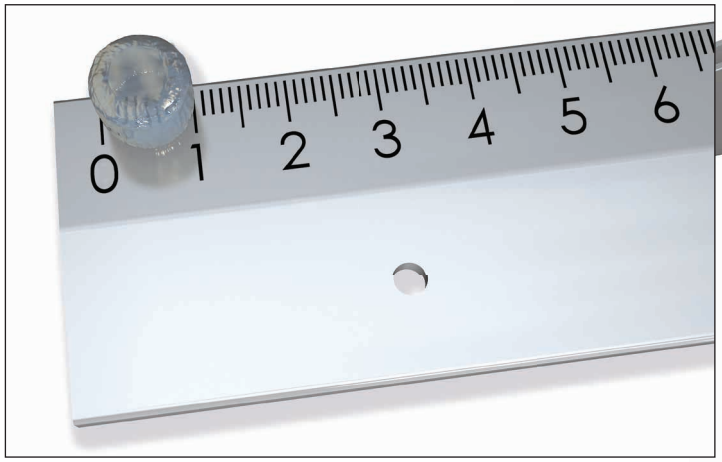
Supine patient positioning with fluoroscopy available is recommended for this procedure. A dorsomedial incision over the 1st metatarsophalangeal joint is made, following the previous surgical incision.

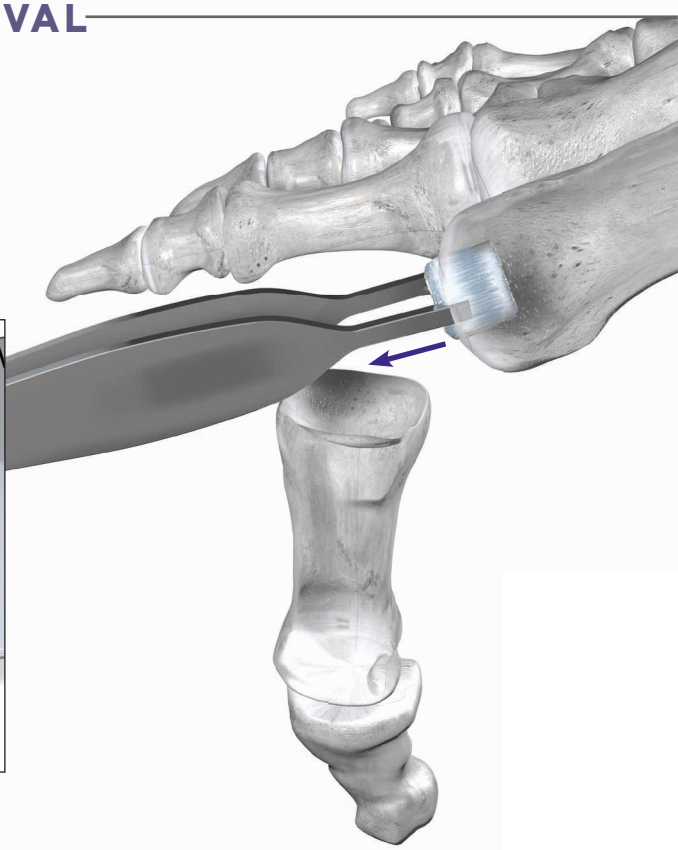
Soft tissue dissection is continued to expose the 1st metatarsophalangeal joint. Release the soft tissue to obtain exposure of the articular surfaces of the 1st metatarsal head and hallux proximal phalanx base.

SYNTHETIC CARTILAGE IMPLANT REMOVAL

Use a grasping-type instrument such as a forcep to remove the synthetic cartilage implant.

Thoroughly irrigate the area following removal of the implant. Measure the implant diameter using a ruler, if unknown. If a bone void is present that appears larger than the implant at the 1st metatarsal head, measure the diameter of the bone void.



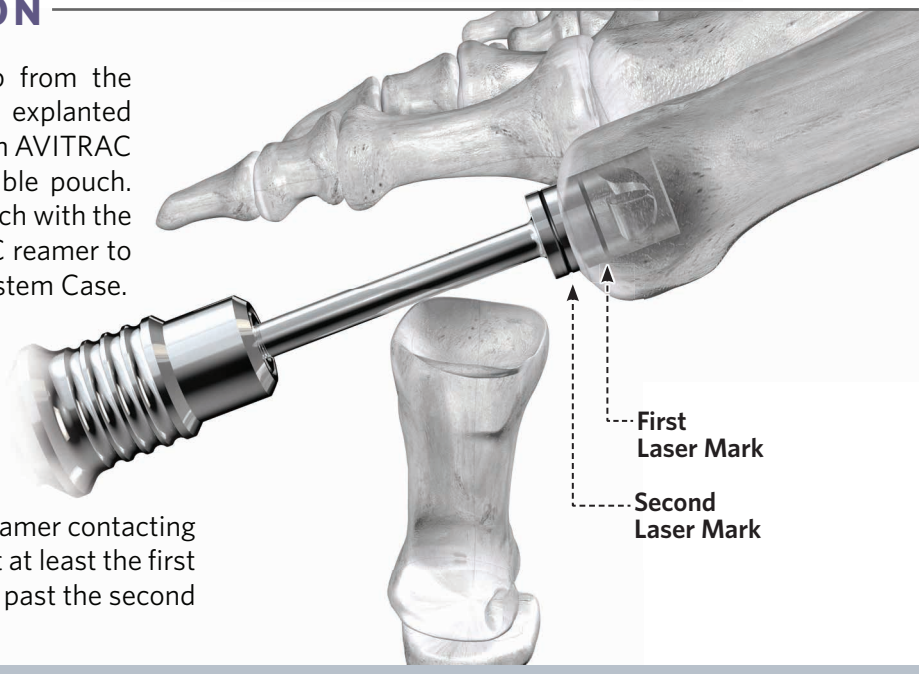


1st METATARSAL PREPARATION

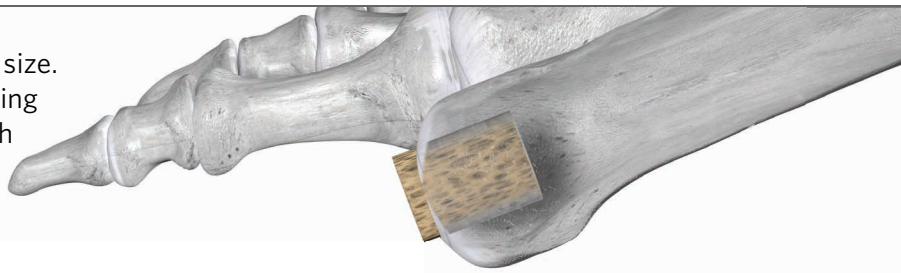
Retrieve the AVITRAC reamer that is one size up from the measured implant or bone void. For example, if the explanted implant measured about Ø10 mm, retrieve the Ø11 mm AVITRAC reamer. The AVITRAC reamer is packaged in a double pouch. Using standard aseptic technique, place the inner pouch with the instrument onto the sterile field. Attach the AVITRAC reamer to the AO connection handle from the Gorilla Plating System Case.

Insert the AVITRAC reamer into the void from the explanted synthetic cartilage implant.

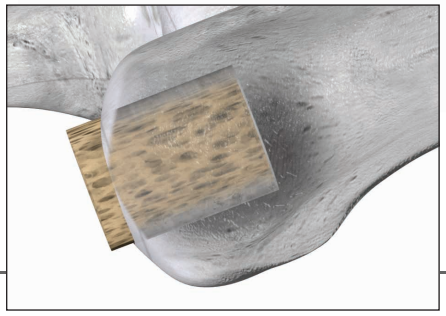
Hand ream until resistance is felt from the tip of the reamer contacting the metaphyseal bone of the metatarsal, ensuring that at least the first laser mark is buried in the 1st metatarsal. Do not ream past the second laser mark. Irrigate the area following reaming.



AVITRAC GRAFT PLACEMENT



Retrieve the AVITRAC graft size matching the reamer size. The AVITRAC graft is packaged in a double pouch. Using standard aseptic technique, place the inner pouch with the AVITRAC graft onto the sterile field. Hydrate the AVITRAC graft in normal sterile saline for a minimum of 5 minutes.



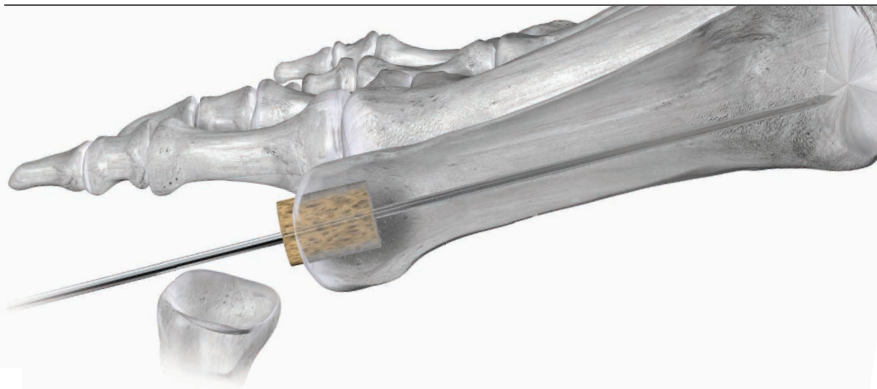
Using a grasping-type instrument, place the AVITRAC graft into the bone void in the 1st metatarsal. Advance the AVITRAC graft proximally until resistance is appreciated. Light tapping on the graft with a mallet may be performed to fully seat the graft.

NOTE: Some portion of the AVITRAC graft may remain proud distally. This portion will be removed with the female metatarsal reamer, or can be removed with a saw or rongeur, if preferred.

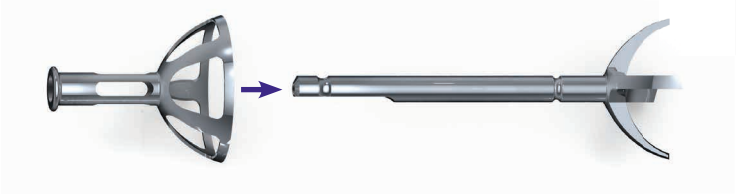
JOINT PREPARATION

Remove any osteophytes surrounding the joint using a saw or osteotome. The method of cartilage resection is according to surgeon preference. Use of the Paragon 28 MTP reamers and spin guards (located within the Gorilla MTP Caddy) is described below:

PREPARATION OF THE 1st METATARSAL HEAD:



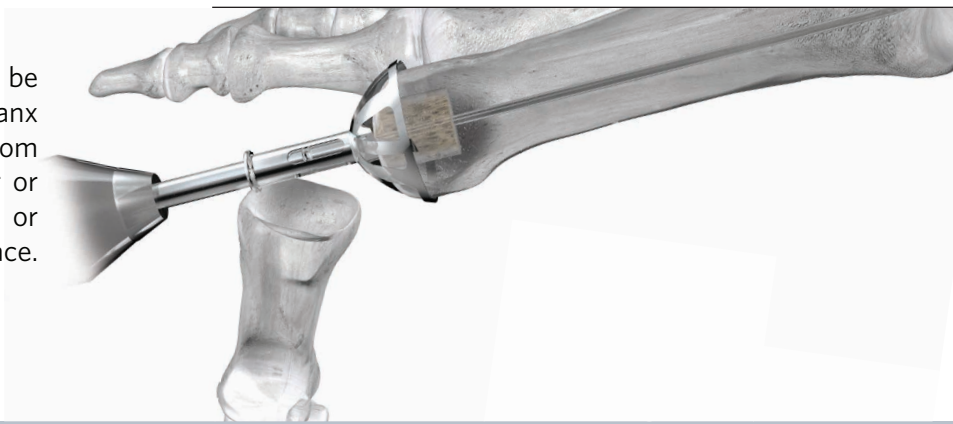
A Ø1.6 mm K-wire is inserted down the central shaft of the AVITRAC graft and metatarsal head, from distal to proximal. Ensure that the K-wire is advanced far enough to purchase bone more proximally in the metatarsal. Select the female reamer size based on the 1st metatarsal head size, with the reamer as wide or slightly wider than the diameter of the cartilage covering the 1st metatarsal head.



Connect the matching female spin guard to the end of the female reamer. Attach the construct to a powered driver and slide over the Ø1.6 mm K-wire. Begin motion of the reamer prior to making contact with the AVITRAC graft and 1st metatarsal head.

Use the female reamer to remove excess graft length, if necessary. Remove all of the cartilage on the 1st metatarsal head, using a pulsing motion of the reamer on a powered driver to facilitate cartilage removal, if necessary. If the outer cartilage remains, go up a reamer size. If the reamer is too large, go down a size. Remove cartilage until bleeding subchondral bone is observed and take care not to over-shorten the 1st metatarsal.

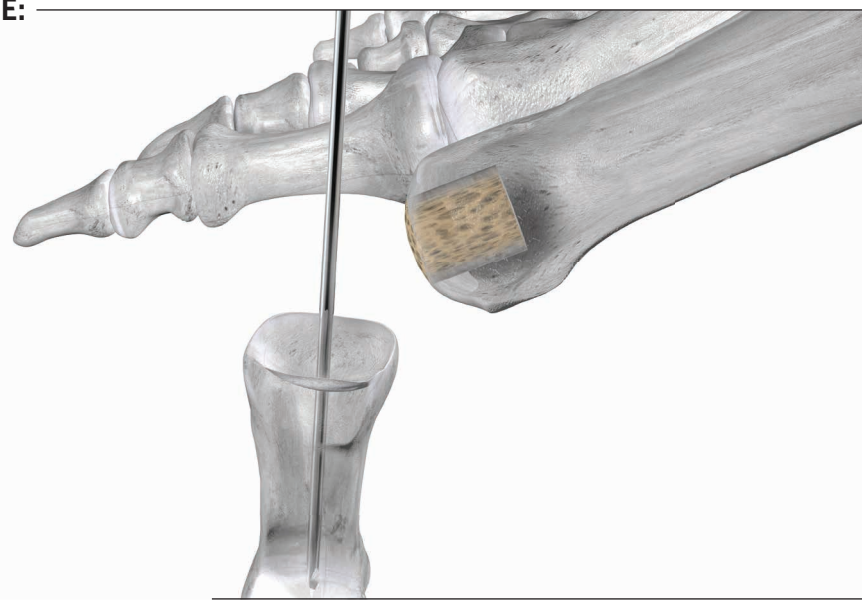
Take note of the last reamer size used, as this will be the size designated for reaming the proximal phalanx of the hallux. When finished, remove the K-wire from the central shaft of the 1st metatarsal. A rongeur or curette can be employed to resect any cartilage or rough edges from the 1st metatarsal head joint surface.

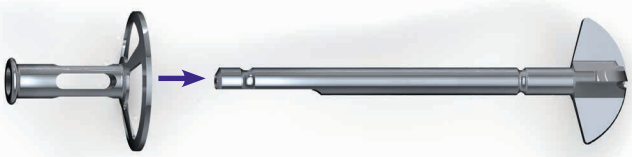


JOINT PREPARATION

PREPARATION OF THE PROXIMAL PHALANX BASE:

Insert the same Ø1.6 mm K-wire down the central shaft of the hallux proximal phalanx, from proximal to distal. The convex male reamer is selected to match the last size of reamer used on the 1st metatarsal head.





Attach the matching male spin guard to the end of the male reamer. The male reamer is placed over the K-wire and is secured to the powered driver. Begin motion of the reamer prior to contact with the proximal phalanx.

Remove all of the cartilage from the base of the hallux proximal phalanx until bleeding subchondral bone is observed. Remove the K-wire from the base of the hallux proximal phalanx. A rongeur or curette can be employed to resect any additional cartilage from the edges or joint surface. Subchondral bone preparation can be performed following reaming using the provided subchondral drill or surgeon's preferred technique.

TEMPORARY FIXATION

Place a K-wire across the arthrodesis site from proximal medial to distal lateral to serve as temporary fixation.

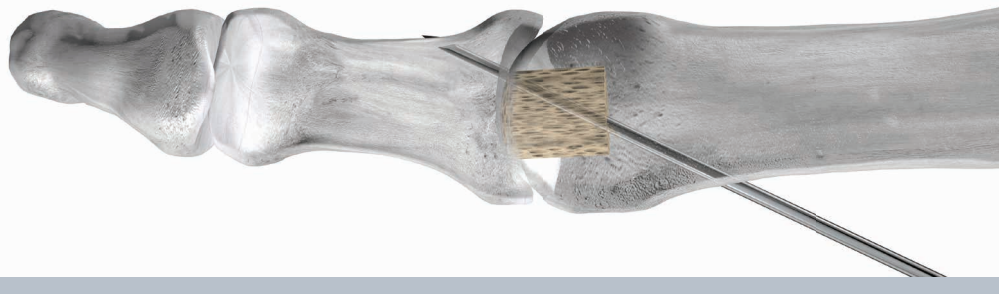
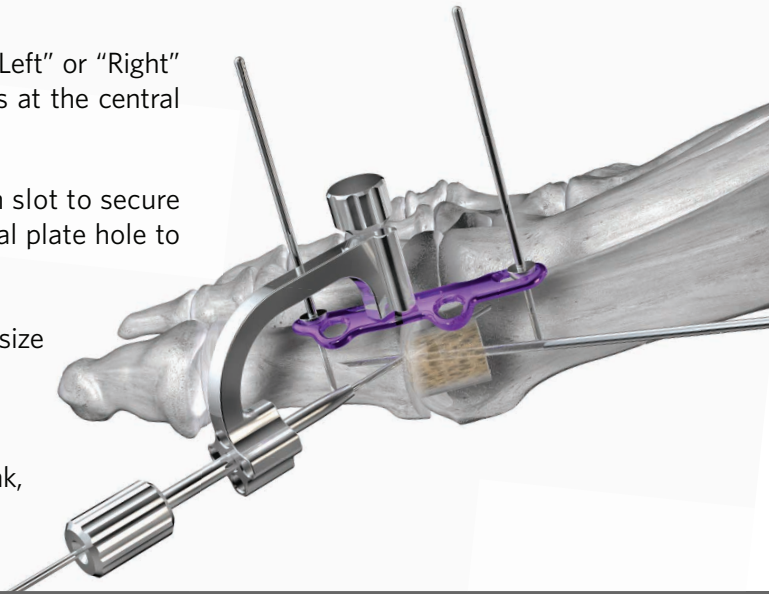


PLATE SELECTION

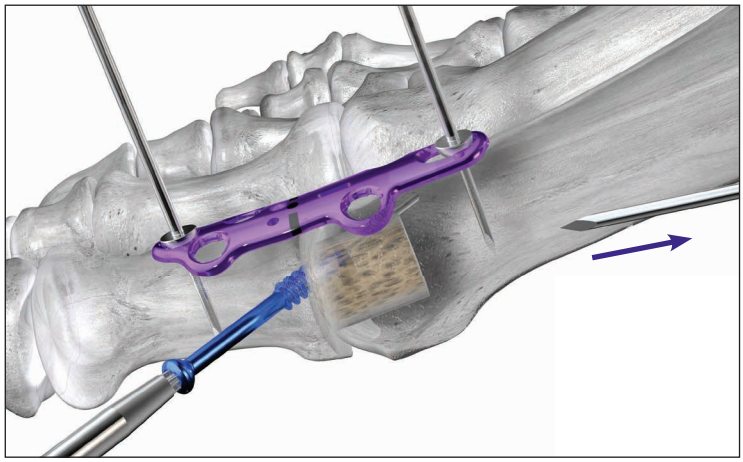
Attach the Precision® Guide to the plate. An appropriately sized "Left" or "Right" MTP arthrodesis plate is selected at this time. The laser markings at the central aspect of the plate should align with the joint.

Place an olive wire into the proximal aspect of the compression slot to secure the plate to the 1st metatarsal. Place a second olive wire in a distal plate hole to secure the plate to the proximal phalanx.

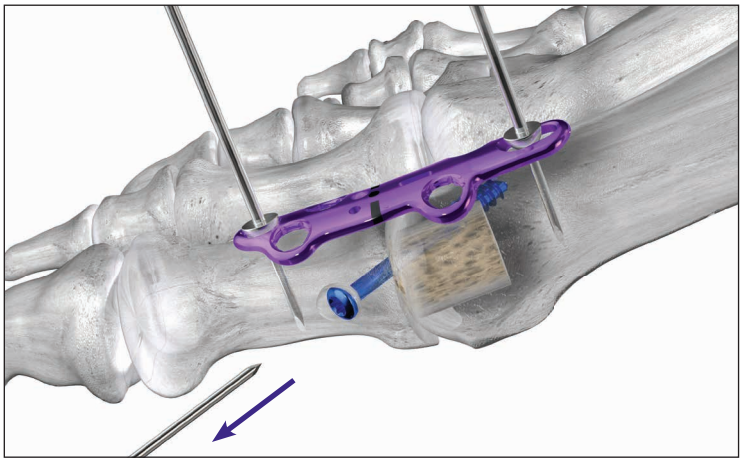
Insert the guide wire for the selected Mini-Monster crossing screw size into the guide wire sleeve such that it crosses the arthrodesis site and AVITRAC graft at a desired location. When the position and length of the guide wire is correct as confirmed by fluoroscopy, remove the guide wire sleeve and Precision® Guide arm. Countersink, measure and drill for the selected crossing screw diameter.



PERMANENT FIXATION

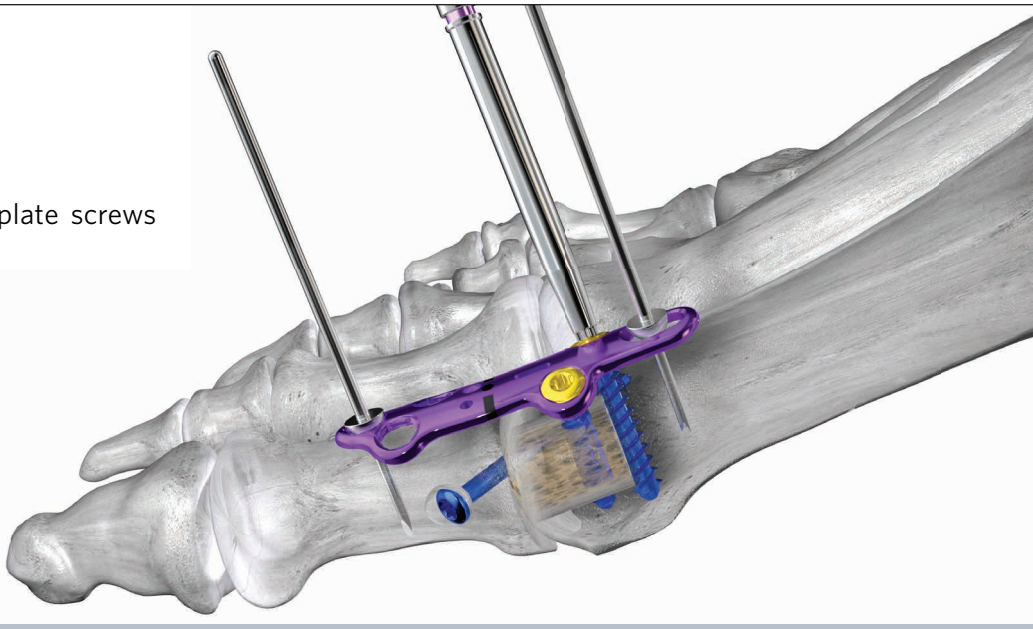


The selected crossing screw is inserted over the guide wire across the arthrodesis site. Remove the K-wire serving as temporary fixation prior to seating the head of the crossing screw.

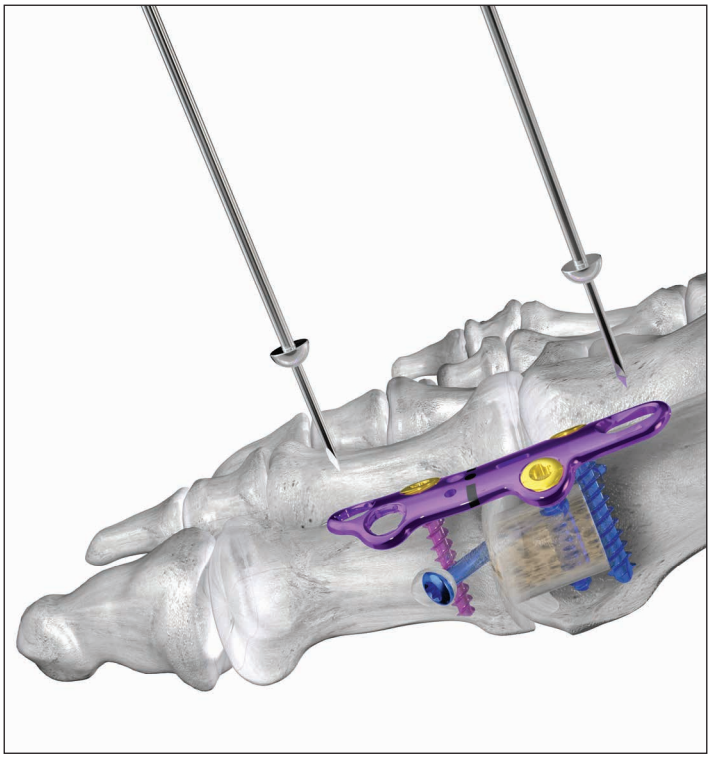


Confirm the screw position and length using fluoroscopy. Remove the guide wire from the crossing screw.

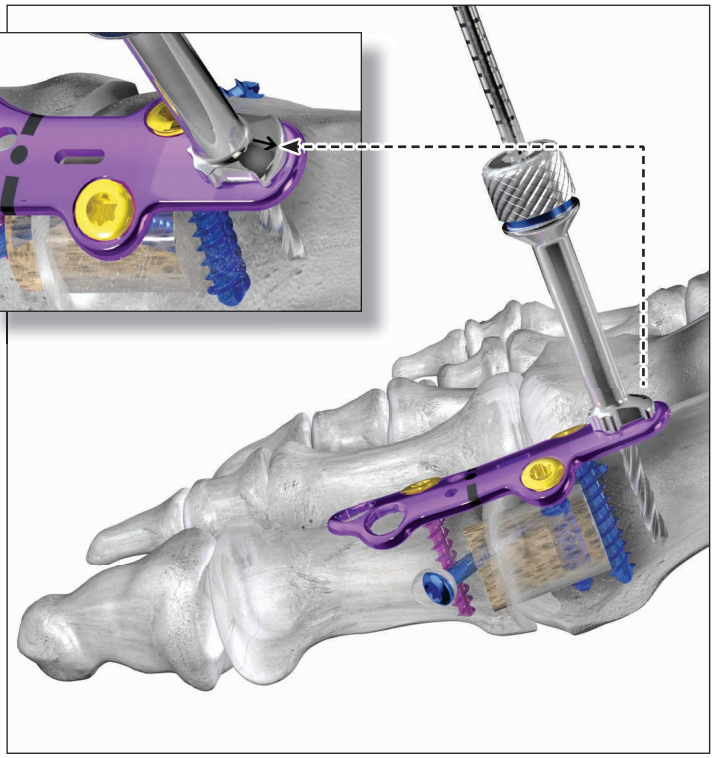
Place two Gorilla locking or non-locking plate screws into the two proximal plate holes.



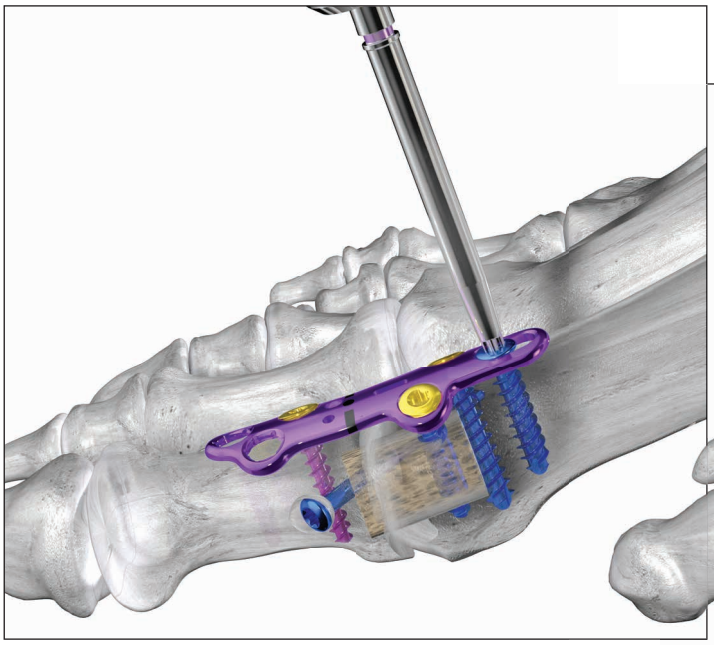
PERMANENT FIXATION



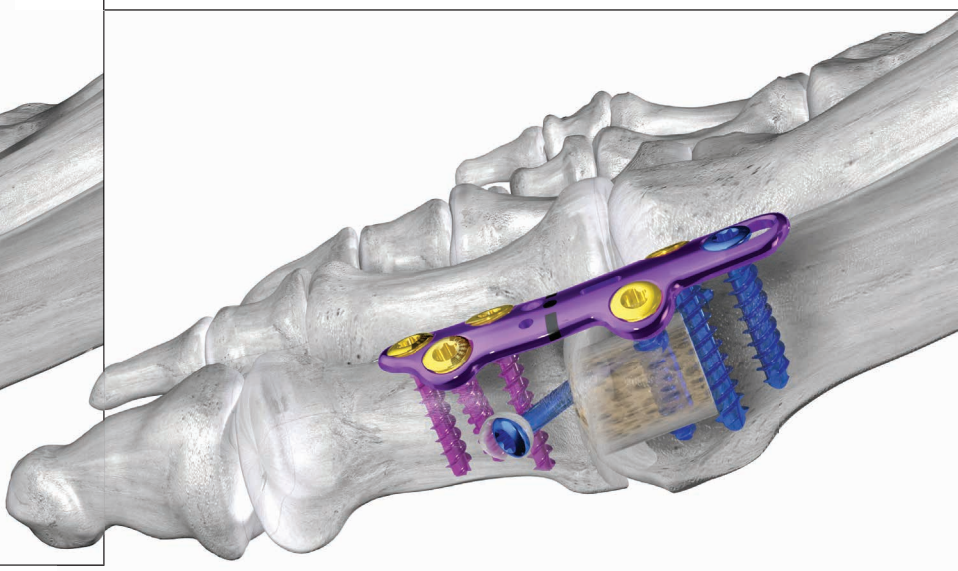
Place a locking or non-locking plate screw into the proximal phalanx and remove olive wires serving as temporary fixation.



When placing a non-locking screw in the compression slot, place the drill guide such that the arrow points away from the joint.



Insert a non-locking Gorilla screw into the compression slot using the provided driver.



Fill the remaining plate screws in the proximal phalanx with locking or non-locking screws, per surgeon preference.

Confirm plate and screw position using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

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

INDICATIONS FOR USE (GORILLA®)

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

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

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

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

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

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

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

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

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

CONTRAINDICATIONS

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

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

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

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

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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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

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

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

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION

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

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INDICATIONS FOR USE (MONSTER®)

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

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

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

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

Fusion resulting from neuropathic osteoarthopathy (Charcot) such as:
- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

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.

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- All concomitant pathologies that could affect the function of the implant
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- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR SAFETY INFORMATION

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

AVITRAC™

GORILLA® R3CON PLATING SYSTEM

PRESERVE™ BONE GRAFT SYSTEM

MONSTER™ SCREW SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle

Paragon 28®

www.paragon28.com

The AVITRAC™ Graft is a human cell, tissue, and cellular and tissue-based product (HCT/P) that is regulated under 21 CFR 1271.3(d)(1) and Section 361 of the Public Health Service Act and is intended for homologous use only.

P01-STG-0003 RevC

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DISCLAIMER

The purpose of the AVITRAC™ Surgical Technique Guide is to demonstrate use of the AVITRAC™ graft and instrumentation in conjunction with the Paragon 28® Gorilla® Plating System and Monster® Screw System. Please refer to the system surgical technique guide (P20-STG-0001 Monster® Screw System Surgical Technique Guide, P51-STG-0001 Gorilla® Plating System Surgical Technique Guide) for more detailed implant use instructions. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.