Exclusively foot & ankle

Paragon 28®

SURGICAL TECHNIQUE GUIDE

EVANS CALCANEAL OSTEOTOMY

HEvans™ Plate

BOW & ARROW™ Evans Plate

GORILLA®

R3CON PLATING SYSTEM

GORILLA®
R3CON PLATING SYSTEM

Surgical Technique Guide

Evans Calcaneal Osteotomy

GORILLA PLATING OPTIONS: 2 Plate Styles

HEvans™ Plate

Right and Left

Small, Medium and Large Size Options
- Small: used with a 6 mm graft
- Medium: used with an 8 mm graft
- Large: used with a 10 or 12 mm graft

Located in the Universal Plate Caddy

Compatible with the 2.7 mm, 3.5 mm and 4.2 mm GORILLA® Screws in Locking or Non-locking Varieties

BOW & ARROW™ Evans Plate

Universal for Right and Left

Available in 4 Sizes: 6 mm, 8 mm, 10 mm, 12 mm

Sizes Correspond to PRESERVE™ Evans Lateral Column Lengthening Grafts

Located in the BOW & ARROW™ Plate Caddy

Compatible with the 2.7 mm, 3.5 mm and 4.2 mm GORILLA® Screws in Locking or Non-locking Varieties

DISCLAIMER

The purpose of the Evans Calcaneal Osteotomy Surgical Technique Guide is to demonstrate the use of the HEvans™ Plate and BOW & ARROW™ Evans Plates in the Gorilla® Recon Plating System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device.

This document is contained under the umbrella document "Gorilla® Recon Plating System Surgical Technique Guide". A more detailed description of implant features, options for compression, and alternative techniques for the products mentioned in this guide are presented in the umbrella document.

Refer to pages 13-14 of the Gorilla® Recon Plating System Surgical Technique Guide for Indications, Contraindications and Warnings for the Gorilla® Recon Plating System which encompasses the HEvans™ Plates and BOW & ARROW™ Evans Plates.

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GORILLA®
R3CON PLATING SYSTEM

Surgical Technique Guide

Evans Calcaneal Osteotomy

GORILLA PLATING OPTIONS: Plate Design Features

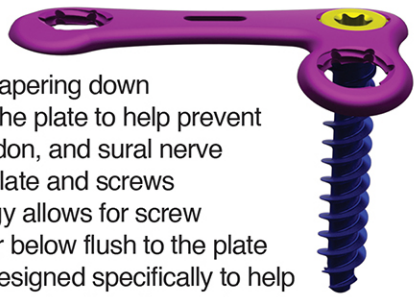
HEvans™ Plate

THREE SCREW FIXATION
- Supports graft
- Helps to prevent graft subsidence with subsequent loss of calcaneal length seen in the early post-operative period due to graft resorption

SINGLE PROXIMAL SCREW
- Helps prevent peroneal tendon irritation

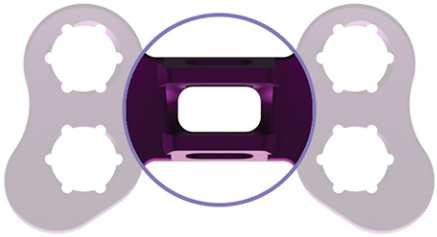
TWO DISTAL SCREWS
- Helps to avert subluxation of the calcaneocuboid joint with dorsal displacement of the distal calcaneal fragment
- Dual point fixation at the distal fragment mitigates the prospect of rotation of the distal fragment with the calcaneocuboid joint anatomy

LOW PROFILE
- 1.1 mm plate thickness tapering down to 0.5 mm at the end of the plate to help prevent soft tissue, peroneal tendon, and sural nerve irritation caused by the plate and screws
- Locking screw technology allows for screw heads that are flush to or below flush to the plate
- Ramped proximal arm designed specifically to help prevent peroneus brevis tendon irritation such that the tendon can glide over the plate



BOW & ARROW™ Evans Plate

FOUR SCREW FIXATION
- Helps to prevent subluxation of the calcaneocuboid joint with dorsal displacement of the distal calcaneal fragment
- Helps to prevent graft subsidence with subsequent loss of length of calcaneus seen in the early post-operative period due to graft resorption



TAPERED "BOW"
- Mimics the shape of the PRESERVE™ Evans Lateral Column Lengthening Grafts based on plate size
- Helps evenly distribute vertical pressure along the graft due to the anatomically matched taper
- Reduced plantar point loading decreases risk of tearing or attenuation of the lateral aspect of the long plantar ligament
- Arrow on "bow" latches onto the cortex to prevent lateral dislocation of plate once inserted

LOW PROFILE
- Thickness of 1.15 mm tapering to 0.5 mm
- Ramped plantar aspect of plate minimizes risk of soft tissue irritation
- Locking screw technology allows for screw heads that are flush to or below flush to the plate

Exclusively foot & ankle Paragon 28®

Surgical Technique

Paragon 28 offers two plating options for the Evans Calcaneal Osteotomy: the HEvans Plate and the BOW & ARROW Plate. The surgical technique begins the same way regardless of which plate is being used. Following the osteotomy, joint distraction, and placement of graft, individual surgical techniques will be outlined for each plate, starting on page 6.

INCISION/EXPOSURE

This procedure may be done as a sole procedure or combined with various procedures to address Stage II Posterior Tibial Tendon Dysfunction or a pediatric flatfoot at the discretion of the surgeon. This technique will describe only the Evans Calcaneal Osteotomy (Lateral Column Lengthening) procedure for flatfoot correction.

Patient positioning in a lateral decubitus or supine position with fluoroscopy available is recommended for this procedure. A standard lateral incision is shown but can be varied according to surgeon preference. (A) Dissection is carried down to the lateral wall of the calcaneus without entering the capsule of the calcaneocuboid joint.

CALCANEAL OSTEOTOMY

An osteotomy is made in the calcaneus according to surgeon's desired method and technique, generally 1.0 cm - 1.5 cm proximal to and parallel to the calcaneocuboid joint. (B)

JOINT DISTRACTION

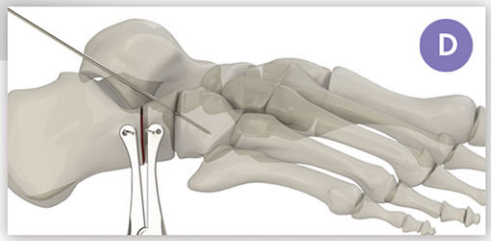
A K-wire can be placed across the calcaneocuboid joint at this time to prevent dorsal dislocation of the distal fragment of the calcaneus. (C)

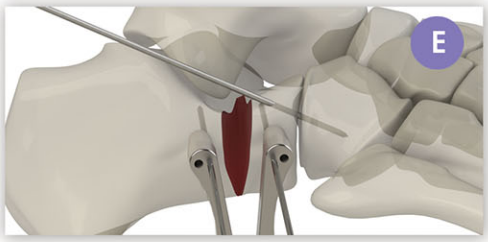
There are multiple options available in the Gorilla Plating System for distraction of the calcaneal osteotomy and for visualizing length to achieve desired correction. These options include curved and straight osteotomes, the Paragon 28 Caspar Device or a Hintermann distractor (shown). Other bone spreaders and distraction devices are available upon request.

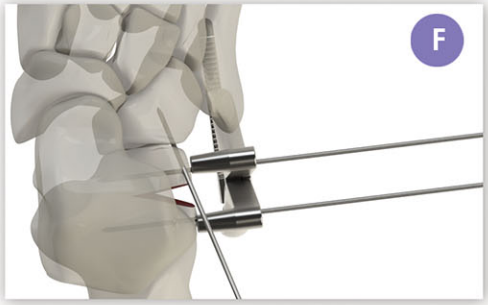
TIP: Although surgeons have their preference on distraction, it is recommended to use a device that is external to the osteotomy such as a Hintermann distractor or the Paragon 28 Caspar Device. These devices hold distraction once the appropriate length is achieved and do not prohibit insertion of the PRESERVE trials or graft wedges into the osteotomy.

The Hintermann distractor is secured to either side of the osteotomy using two K-wires. (D) The smaller, inside hole accepts up to a 1.6 mm K-wire (more suitable for bending wires out of the way) and the larger, outer hole accepts up to a 2.3 mm K-wire.

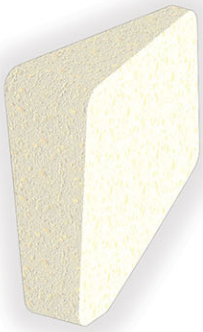
Distract the Hintermann distractor until adequate correction is achieved in desired planes. (E) (F) Confirm reduction of deformity using fluoroscopy, if desired.







GRAFT SELECTION



The Gorilla HEvans plate and BOW & ARROW plate are intended to be used with the PRESERVE Evans Lateral Column Lengthening Grafts, although a different source of bone graft can be used with either plate, per surgeon preference.

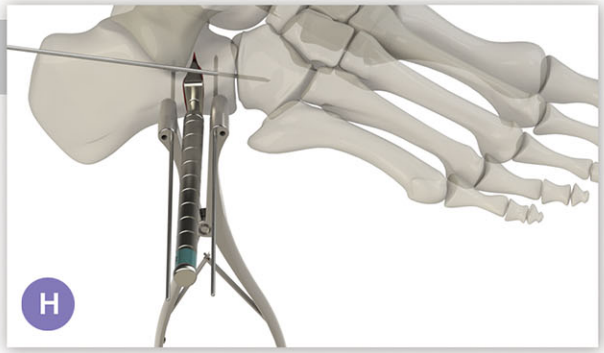
PRESERVE Evans Lateral Column Lengthening Grafts: 4 sizes – 6 mm, 8 mm, 10 mm, 12 mm

PRESERVE Trial Sizers:

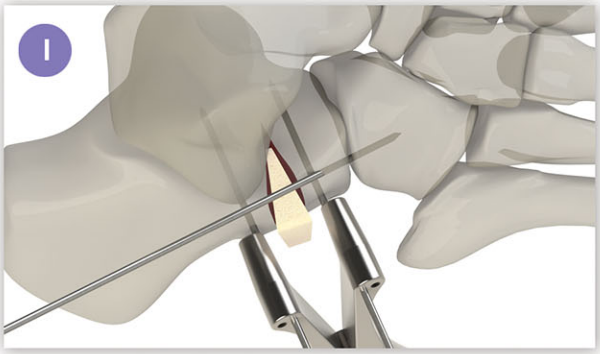
- Mimics the exact size and shape of the 4 available PRESERVE Evans Lateral Column Lengthening Grafts, helping to eliminate speculation of which graft size to use. (G)
- The joystick handle allows easy manipulation of the trials – limiting surgeon radiation exposure while determining correct size.
- Located in the Allograft Evans & Cotton Caddy

DETERMINING GRAFT SIZE

Select the trial sizer that appears closest to the osteotomy distraction width and introduce the trial sizer such that the graft sizing portion is wider dorsally. If more or less correction is desired, insert a larger or smaller trial sizer until the preferred amount of correction is achieved. (H) If the ideal amount of correction is between trial sizes, a smaller graft size can be selected and inserted with more depth to achieve the appropriate amount of correction.

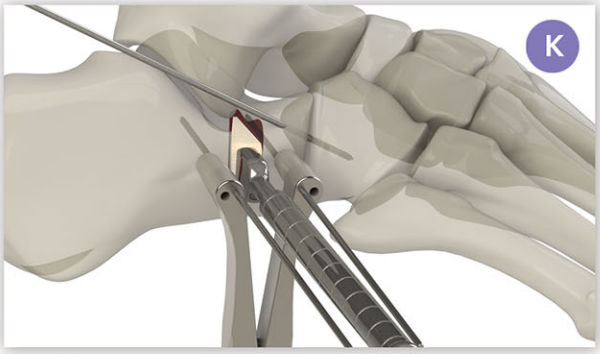


Remove the trial and pass from the operating field. The chosen bone wedge size is opened and should be hydrated on the back table in normal sterile saline for a minimum of 5 minutes. If blood, BMA or PRP is to be added to the graft, this should be done after hydration and prior to insertion of the graft.

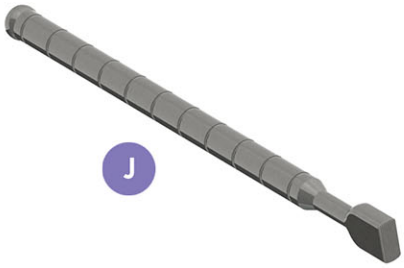


TIP: During this hydration time, plate selection can be performed, as the distractor will continue to maintain approximate graft size.

With the osteotomy maintained using a distractor, insert the hydrated PRESERVE graft into the osteotomy site. (I) A tamp is available in the Allograft Evans & Cotton Caddy to assist in insertion, if necessary. (J) (K) Once the graft position and size is confirmed using fluoroscopy, remove all instrument distractors.



The surgical technique guide for the Evans Calcaneal Osteotomy will continue on as two sections: first, the remainder of the procedure using the HEvans Plate on pages 6-7 and second, the remainder of the procedure using the BOW & ARROW Evans Plate on page 8-9.

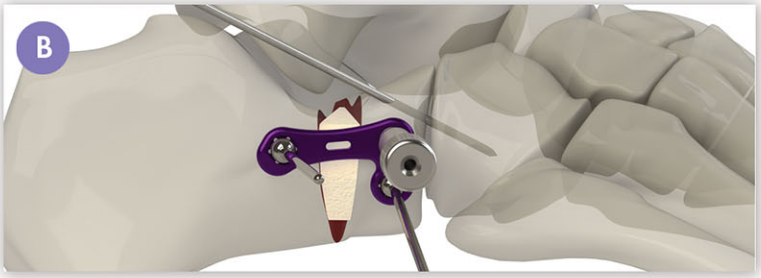


Surgical Technique Guide

HEvans™ Plate

TEMPORARY FIXATION OF PLATE

The locking drill guide is screwed into the dorsal distal hole on the HEvans plate and can be used as a lever for plate insertion. (A) One olive wire can be placed on either side of the osteotomy, if desired. (B) The position of the HEvans plate should be more dorsal than plantar on the lateral wall of the calcaneus to avoid the peroneal tendons. Confirm the plate position using fluoroscopy, if desired.



TIP: It is advised to use a drill guide with both locking and non-locking screws to avoid screw head prominence by off-axis drilling due to the thinness of the HEvans™ plate.

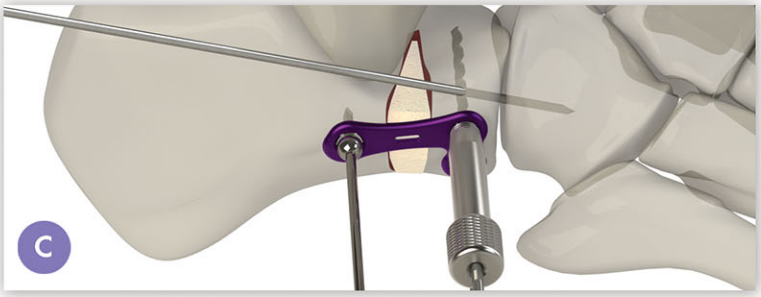
PERMANENT FIXATION OF PLATE

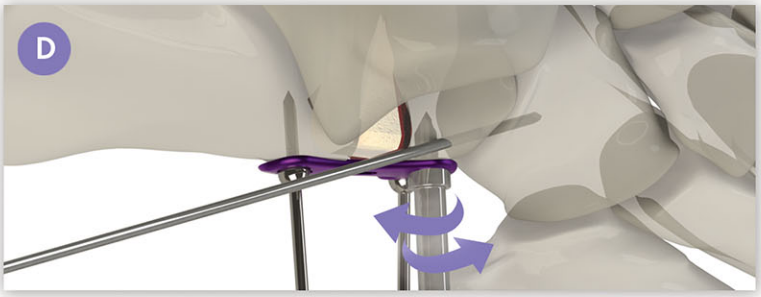
Using the 2.0 mm drill, drill a hole through the locking guide. (C)

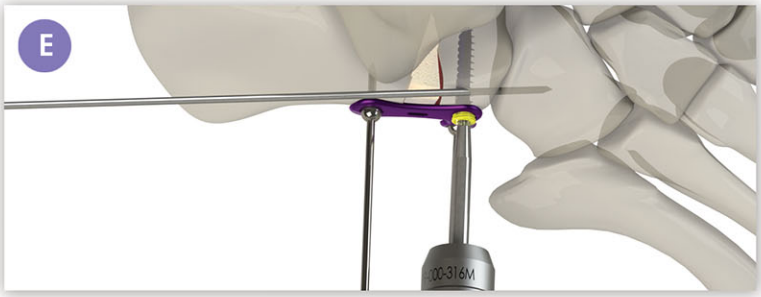
TIP: Locking screws are recommended for use with the HEvans plate due to the cancellous nature of bone in this area as well as unicortical fixation. The plate and screw construct is designed to provide better protection against loss of correction during graft resorption and subsequent remodeling.

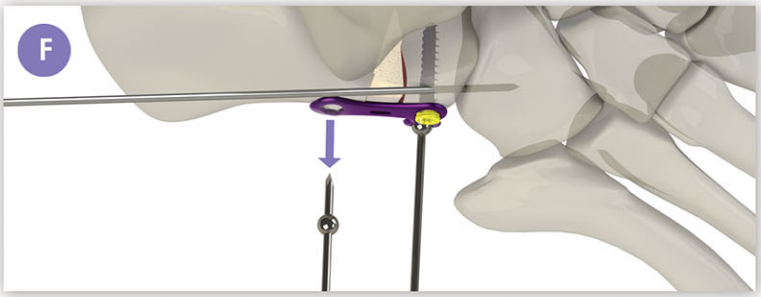
Remove the locking guide. Measure the screw length using the depth gauge. Alternatively, the surgeon may read the screw length from the numerical markings on the drill off the drill guide, if desired. While the screw is being selected on the back table, use the punch to widen the near cortex to accept the wider neck of the TUFFNEK™ Screw and allow proper seating of the screw into the screw hole. (D)

Insert the selected locking screw using the provided screw driver but do not fully seat the screw. (E) Remove the proximal olive wire from the HEvans plate. (F)

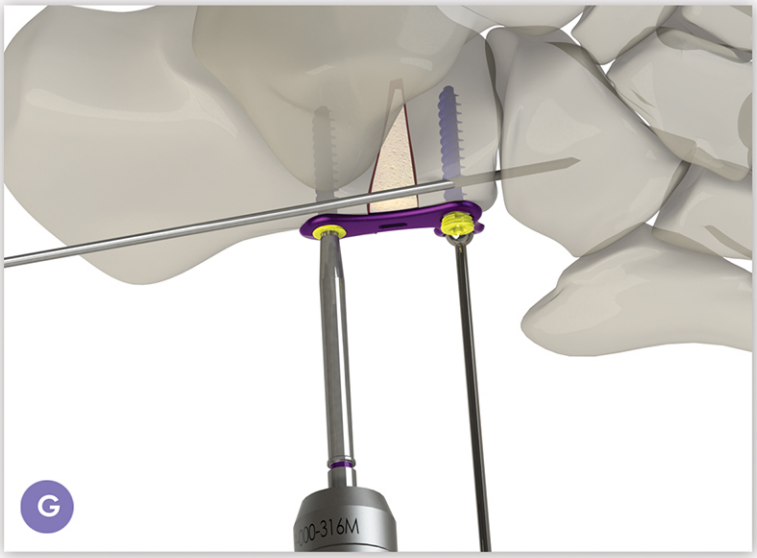




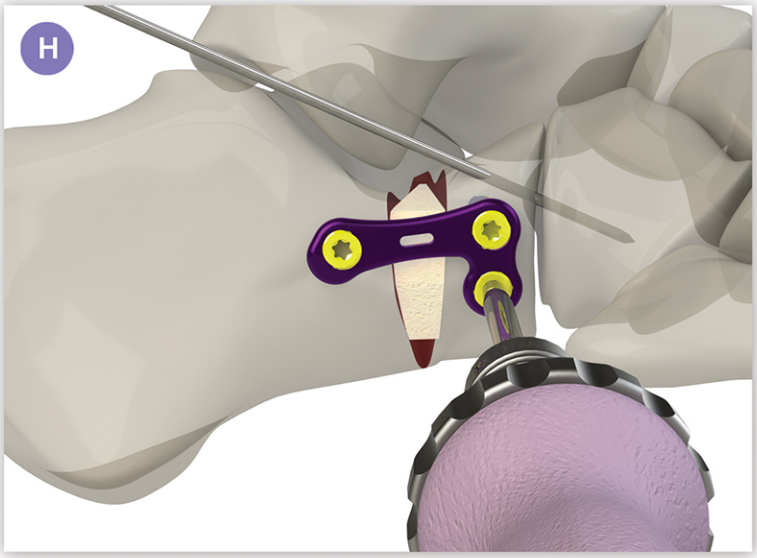


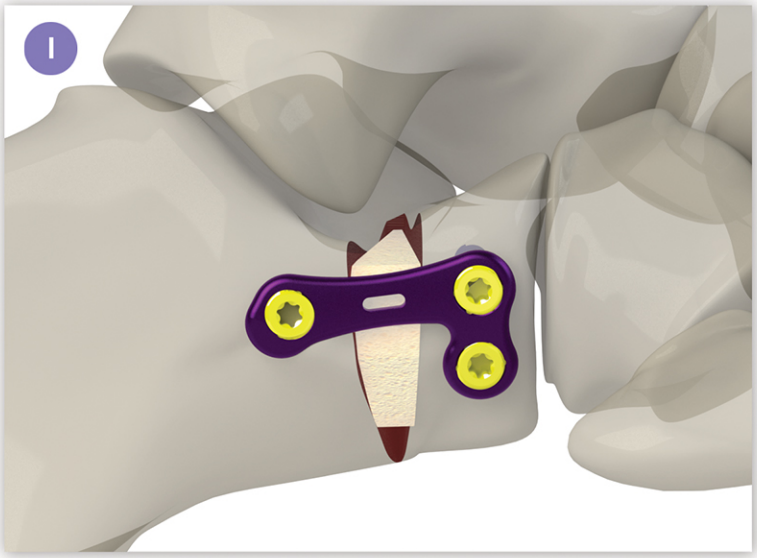


PERMANENT FIXATION OF PLATE



Using the technique described above, insert the proximal screw. It is recommended to complete final tightening of the proximal screw at this time. (G) Remove the remaining olive wire. Insert the final distal screw using the same technique. (H) Complete final tightening of the two distal screws using a two finger tightening technique and remove the k-wire crossing the calcaneocuboid joint. (I) Confirm plate placement and screw length using fluoroscopy, if desired.



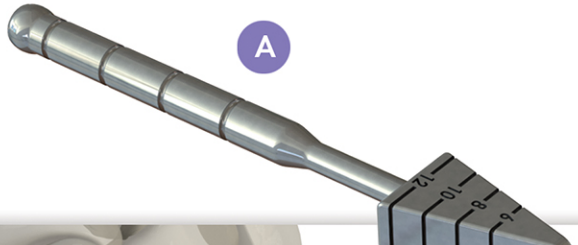


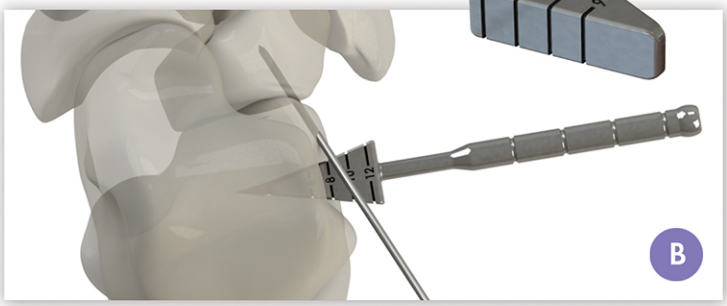
CLOSURE

Proceed to incision closure or concomitant procedures at this point.

Surgical Technique Guide

BOW & ARROW™ Evans Plate



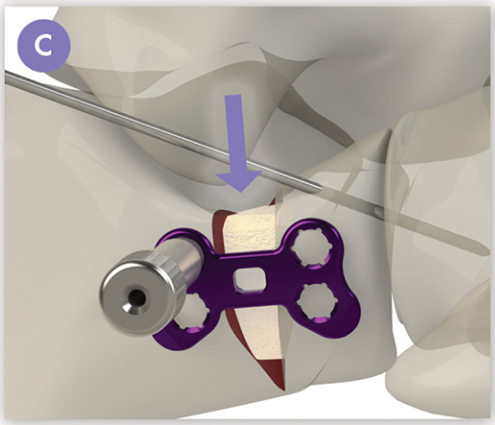


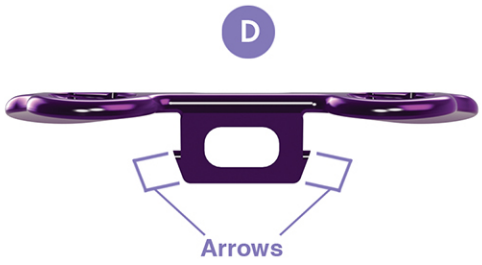
A sizing tool is located in the BOW & ARROW caddy for the Evans Calcaneal Osteotomy, which can be used if autograft or an alternate graft besides the PRESERVE bone wedges is used. (A)

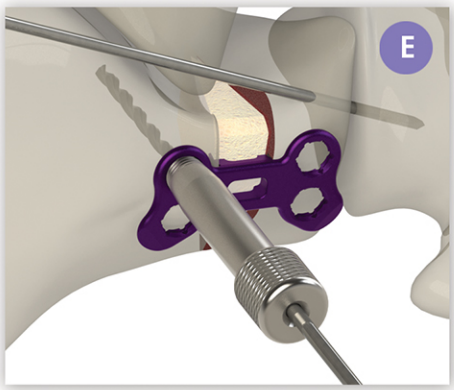
The sizing tool determines what size BOW & ARROW Evans plate should be used. In this example, a Size 8 plate should be used. (B) The PRESERVE trial sizers can likewise be used to determine graft and/or BOW & ARROW plate size.

PERMANENT FIXATION OF PLATE

If used with the BOW & ARROW plate, the PRESERVE graft is traditionally seated a few millimeters deep to the cortex to allow room for the plate. The locking drill guide is screwed into one of proximal locking holes on the BOW & ARROW plate and can be used as a lever for plate insertion. It is recommended to insert the plate from a more dorsal lateral approach, allowing the plate to be slid down the osteotomy and sit in the position where the "BOW" of the plate matches the contour of the PRESERVE graft. (C)



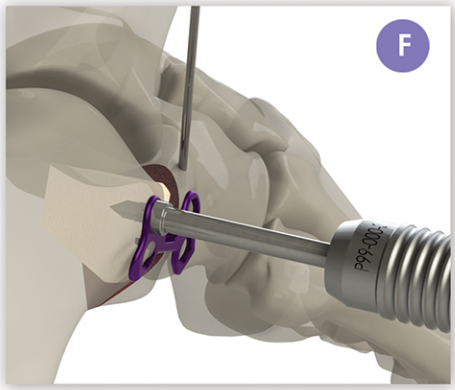




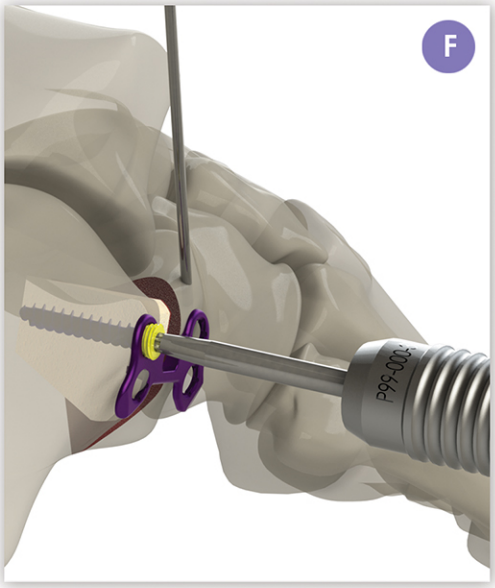
Because the "arrows" on the "bow" of the plate latch onto the inside of the cortex to help and prevent lateral displacement of the plate, temporary fixation using olive wires can be performed but is not necessary. (D)

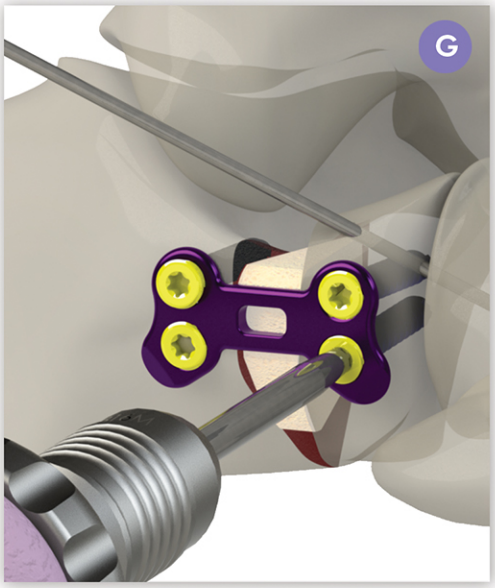
Confirm the plate position using fluoroscopy, if desired.

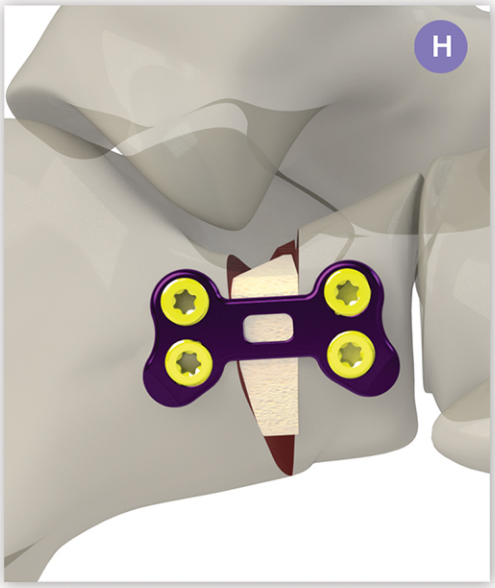
Drill a hole through the locking guide using the 2.0 mm drill. (E) Measure screw length using a depth gauge or measure off of the drill using the drill guide. Use the punch to prepare the near cortex. (F)



PERMANENT FIXATION OF PLATE







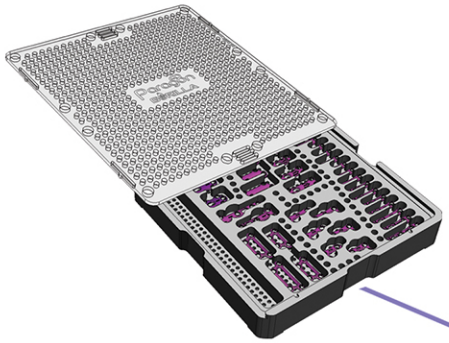
Insert the selected screw size using the screw driver but do not completely tighten. (F)

Insert the final three screws using the technique just described. Tighten all of the screws using a two finger tightening technique, returning to the first screw for tightening. (G) Remove the K-wire across the calcaneocuboid joint and confirm plate placement and screw length using fluoroscopy, if desired. (H)

CLOSURE

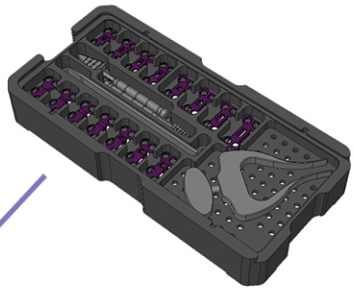
Proceed to incision closure or concomitant procedures at this point.

Gorilla® Recon Plating System Set



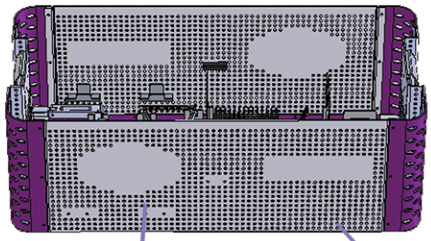
Gorilla® Universal Plate Caddy

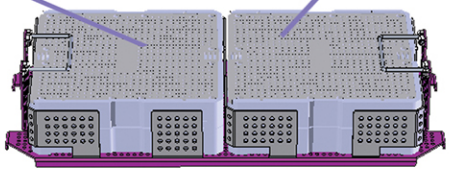
The Gorilla® Universal Plate Caddy contains many of the Paragon 28® Gorilla® plates, including the HEvans™ plate discussed in this surgical technique guide. The Allograft Evans & Cotton Caddy can also be available for use with the HEvans Plate.

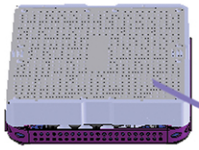


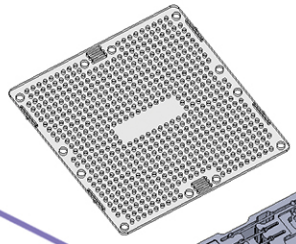
Gorilla® BOW & ARROW™ Plate Caddy

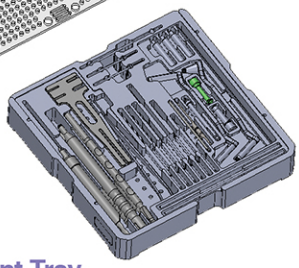
This Gorilla® Plate Caddy contains the BOW & ARROW™ Base Wedge, Cotton, and Evans plates. Additionally, instrumentation is included that is complementary to these plates comprising the tear drop spreader, osteotomes, and the BOW & ARROW™ sizing tool. The Allograft Evans & Cotton Caddy can also be available for use with the BOW & ARROW™ Evans Plate.





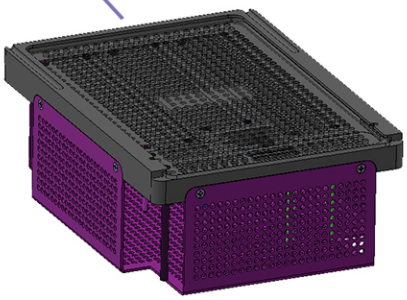






Mini-Monster™ Screw Caddy

The Gorilla® Case can accommodate one Mini-Monster™ Screw Caddy if another procedure is being performed that would require a headed or headless 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm screw.



Gorilla® Plate Screw Caddy

The Gorilla® Plate Screw Caddy contains the 2.7 mm, 3.5 mm, and 4.2 mm locking and non-locking screws for use with the Gorilla® Plating System.

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® Instrument Tray

Drills, drill guides, centering guides, olive wires, plate benders, and a depth gauge are located in the Gorilla® Instrument Tray.

Gorilla® Instruments

The Caspar Compression Device, osteotomes, Bennets, bone reduction clamps, periosteal elevator, Honey Badger cartilage removal device, Hintermann retractor, and handles are located at the bottom of the Gorilla® Case.

SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

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

INDICATIONS FOR USE (GORILLA®)

The 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, talus, and calcaneus. 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.
- Do not implant the instruments.

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 the Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.