Exclusively foot & ankle

Paragon 28®

SURGICAL TECHNIQUE GUIDE

COTTON OSTEOTOMY
EVANS CALCANEAL OSTEOTOMY

TITAN 3-D™ Wedge System

TITAN 3-D™ WEDGE SYSTEM

TITAN 3-D™ WEDGE SYSTEM

Surgical Technique Guide

Cotton Osteotomy
Evans Calcaneal Osteotomy

TITAN 3-D™ Cotton Procedure

Product Offering

5 mm 6 mm 7 mm 8 mm

Compatible with Cotton Trial Handles

TITAN 3-D™ Evans Procedure

Product Offering

6 mm Large 8 mm Large 10 mm Large 12 mm Large

Taller height to account for patients with larger anatomy

6 mm Small 8 mm Small 10 mm Small 12 mm Small

Shorter height to account for patients with smaller anatomy

Compatible with Evans Trial Handles

DISCLAIMER

The purpose of the TITAN 3-D™ Bone Wedge System Surgical Technique Guide is to demonstrate the optionality and functionality of the patent pending TITAN 3-D™ Wedge System implants and instrumentation. The technique and fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of the system. Variations in placement and sizing of the TITAN 3-D™ Bone Wedge System can be employed, appropriate for the size of the device, per surgeon preference. Indications, contraindications and warnings begin on page 13.

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PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

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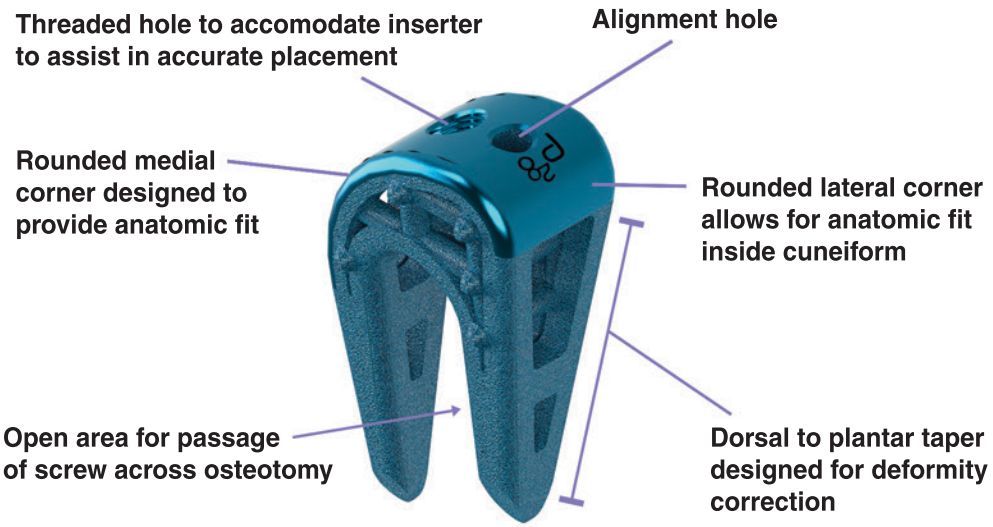
TITAN 3-D Cotton Wedge Features and Instrumentation

TITAN 3-D COTTON WEDGE FEATURES



- Sizes range from 5-8mm of correction
- Smooth back surface and corners to help prevent soft tissue irritation
- Open geometry allows for cross communication of blood, bone through growth and the incorporation of biologic products, if used
- Spikes on both sides to help prevent expulsion of implant from osteotomy site
- Tapered nose to aid in insertion

TITAN 3-D COTTON WEDGE INSTRUMENTATION

TITAN 3-D Cotton Inserter

TITAN 3-D Cotton Precision Guide

TITAN 3-D Cotton Resection Guides

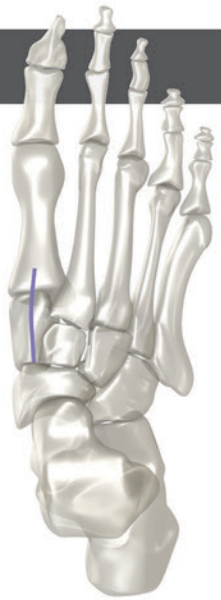
Cotton Osteotomy Surgical Technique

INCISION/EXPOSURE

This procedure may be performed as a sole procedure or combined with various procedures to address Stage II Posterior Tibial Tendon Dysfunction, a pediatric flatfoot or other deformity at the discretion of the surgeon. This technique will describe the Cotton Osteotomy procedure for flatfoot correction.

Patient positioning in a supine position with fluoroscopy available is recommended for this procedure. A dorsal longitudinal incision over the medial cuneiform and base of the first metatarsal is shown, but can be varied according to surgeon preference. (A) Dissection is carried down to the dorsal aspect of the medial cuneiform.

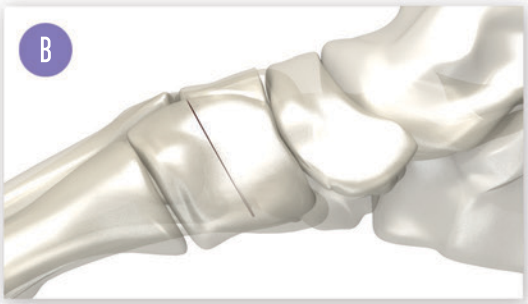
A



MEDIAL CUNEIFORM OSTEOTOMY

An osteotomy is made at the central aspect of the medial cuneiform down to, but not through, the plantar cortex. (B)

B

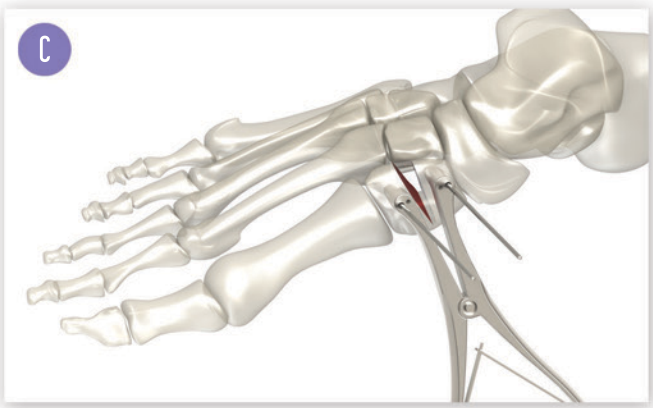


DEFORMITY CORRECTION

An external distractor, such as a pin distractor, is recommended to open the osteotomy and create plantarflexion of the first ray. (C)

Trial sizers are available to match the correction amount of the available TITAN 3-D Cotton Wedges—5 mm, 6 mm, 7 mm and 8 mm. (D)

C



D

Cotton Osteotomy Surgical Technique

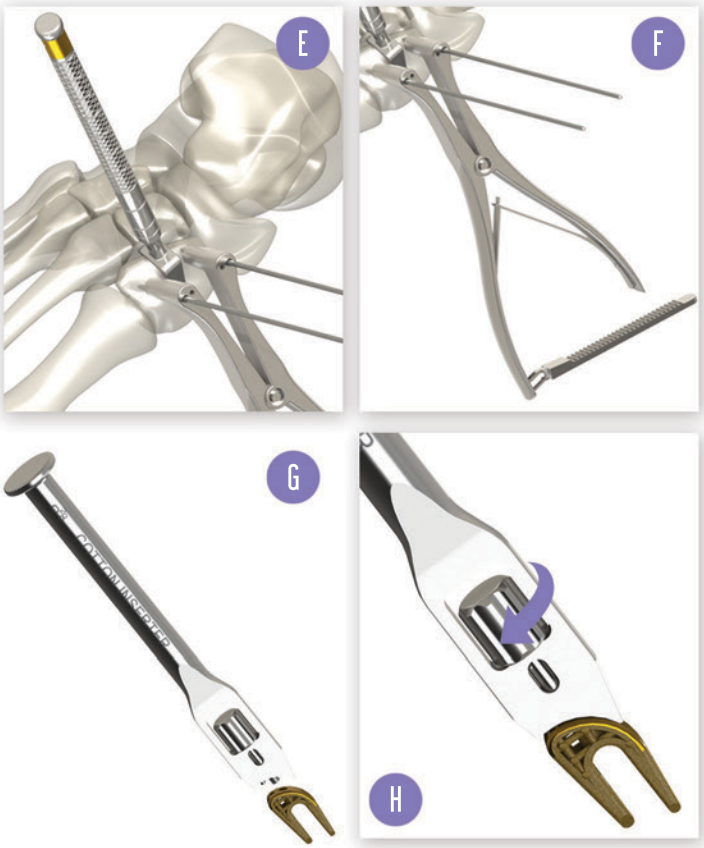
DEFORMITY CORRECTION

Select a trial sizer that best approximates intended correction and place into osteotomy site. (E) If more correction is necessary, go up a trial size. If less correction is desired, go down a trial size.

TIP: It is recommended to open up the hinge on the pin distractor while testing trial sizers to allow for adjustment of 1st ray plantarflexion between trial sizers. (F)

Once the appropriate amount of 1st ray plantarflexion is determined using the trial sizers, the TITAN 3-D Cotton Wedge is selected that corresponds to the trial sizer that provided desired correction. An unsterile team member should open the box to retrieve the double pouch containing the TITAN 3-D implant. The unsterile team member should open the outer pouch and present the sterile inner pouch to a sterile team member using aseptic technique. The TITAN 3-D Cotton Wedge is removed from the sterile inner package.

The TITAN 3-D Cotton Inserter is attached to the TITAN 3-D Cotton Wedge. The alignment pin on the inserter is mated to the alignment hole on the wedge. (G) The screw on the inserter is turned in a clockwise direction to fasten to the threaded hole on the TITAN 3-D Cotton Wedge until secure. (H)



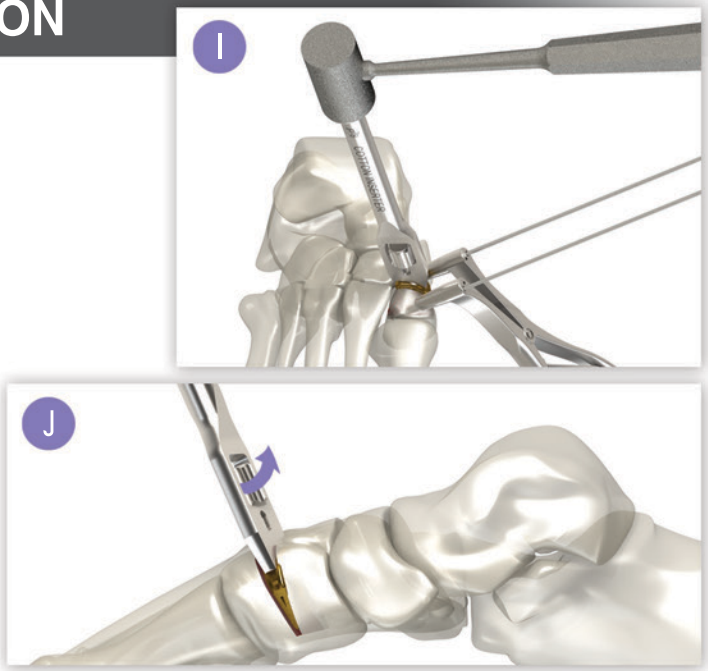
TITAN 3-D COTTON WEDGE INSERTION

The pin distractor is held open or preferred distraction is applied to open the osteotomy.

TIP: Opening up the pin distractor or preferred distraction device to a slightly larger width than the trial sizer may allow easier implant insertion. This will help provide clearance of the spikes on the TITAN 3-D Wedge.

The TITAN 3-D Cotton Wedge is placed into the medial cuneiform osteotomy site using the inserter. A mallet can be used on the back of the inserter to further advance the TITAN 3-D Cotton Wedge into the osteotomy. (I)

The TITAN 3-D Cotton Inserter is detached from the TITAN 3-D Cotton Wedge by rotating the screw in a counterclockwise direction. (J)



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Cotton Osteotomy Surgical Technique

ANCILLARY FIXATION

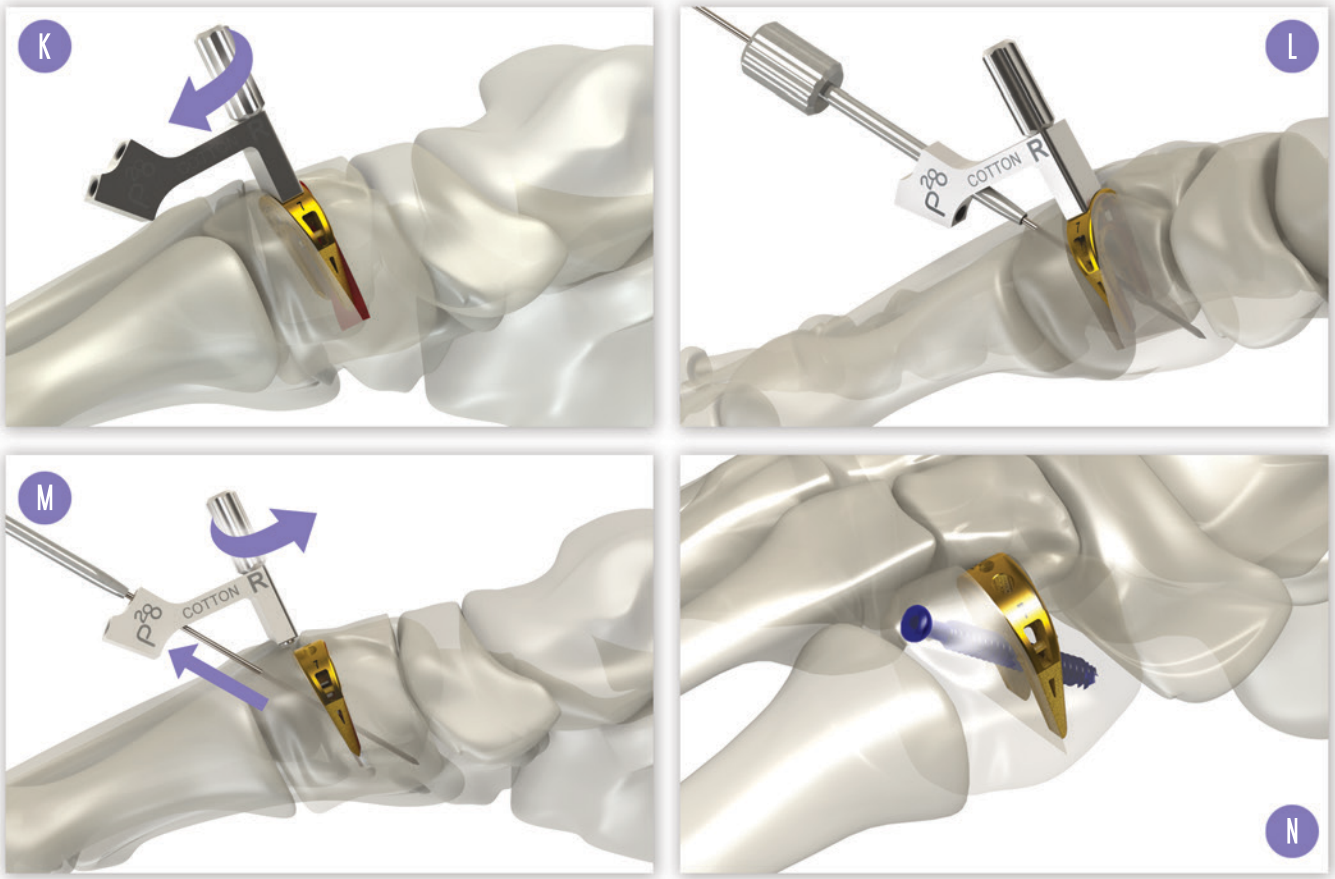
A TITAN 3-D Cotton Precision Guide is available to provide a trajectory for cannulated screw placement through the open area of the implant, such that the screw does not collide with the implant.

After the TITAN 3-D Cotton Wedge implant is placed, the TITAN 3-D Cotton Precision Guide is secured to the implant in a similar manner as the inserter. A peg on the undersurface of the Precision Guide is inserted into the alignment hole on the wedge. The screw that extends through the Precision Guide is rotated in a clockwise direction to mate with the threaded hole on the TITAN 3-D Cotton Wedge until secure. (K)

The K-wire Guide is inserted into the receiving hole on the Precision Guide. A guide wire for the cannulated screw size selected is inserted through the K-wire guide into the Precision Guide. (L)

TIP: The opening width on the TITAN 3-D Cotton Wedge between the two legs is sized to receive a 3.5 mm or 4.0 mm cannulated Mini-Monster® Screw. A fully threaded screw is recommended in order to help maintain length of the osteotomy.*

Once the guide wire is placed, the Precision Guide can be removed from the implant by turning the screw in a counterclockwise direction and sliding the Precision Guide off of the guide wire. (M) Following drilling, countersinking and measuring, a cannulated screw is placed over the guide wire and the guide wire is removed. (N)



* Alternatively, other Paragon 28 products made of the same material can be used as ancillary fixation per surgeon preference.

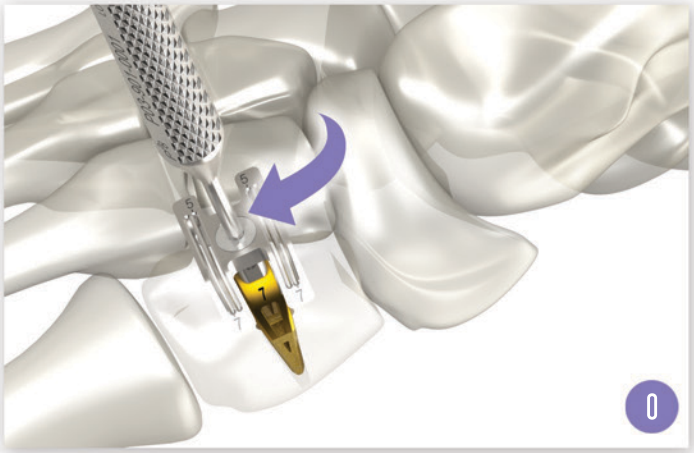
REVISION/REMOVAL OF A TITAN 3-D COTTON WEDGE IMPLANT

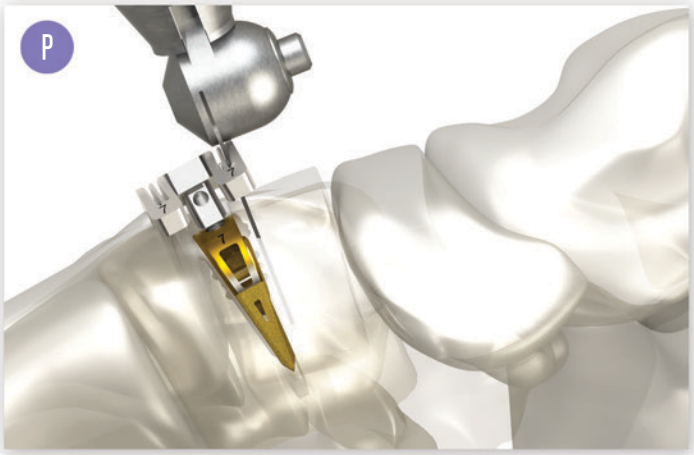
If removal or revision of a TITAN 3-D Cotton Wedge is necessary, a TITAN 3-D Cotton Resection Guide is available to assist in removal as freehand removal can be difficult due to the implant spikes and/or bone growth throughout the implant. This technique allows for removal of the implant while minimizing bone loss.

Select the TITAN 3-D Cotton Resection Guide that has the size corresponding to the implant. There are two Cotton Resection Guides—one for the 6 mm and 8 mm implant and one for the 5 mm and 7 mm implant. A dental pick or a K-wire can be used to clear the alignment hole and threaded hole in the TITAN 3-D Cotton Wedge implant. The resection guide attaches as described for the inserter and Precision Guide, with an alignment tab inserting into an alignment hole. The screw on the resection guide is then threaded into the TITAN 3-D Cotton Wedge implant by rotating the driver in a clockwise direction. (O)

The resection guide has slots that are labeled for each implant size. The implant size can be determined by the color of the implant. Insert a sagittal saw corresponding to the implant size and create a cut along the implant. Repeat this process for the slot on the opposite side of the guide/implant. (P) Upon completion of cutting, remove the resection guide and the implant together, or detach the resection guide from the implant, insert the insertion guide, and use a mallet on the handle to tap out the implant.

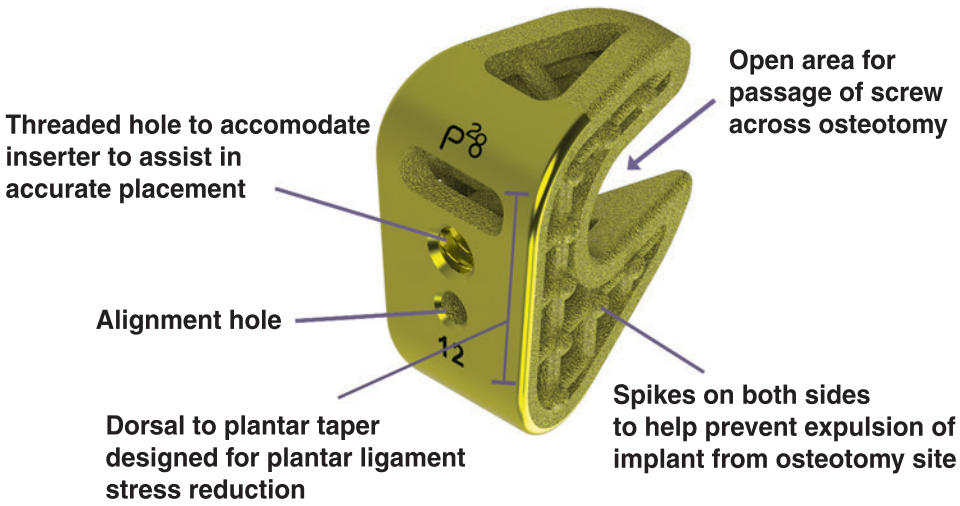
The void remaining in the bone following resection guide use will usually be 2 mm larger than the previous TITAN 3-D Cotton Wedge implant that was placed. For instance, if a 6 mm implant was used initially, an 8 mm implant would be required to fill the bone void while achieving the same amount of correction that was initially attained.





TITAN 3-D Evans Wedge Features and Instrumentation

TITAN 3-D EVANS WEDGE FEATURES

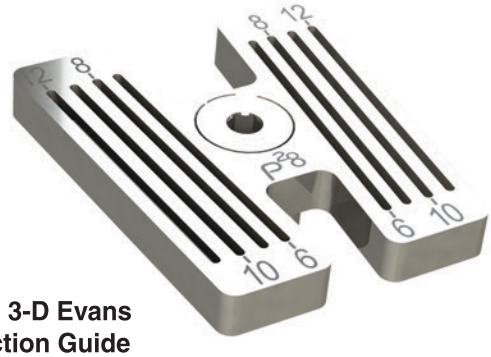


- Sizes range from 6-12mm of correction with a lateral to medial taper for lateral column lengthening
- Open geometry allows for cross communication of blood, bone through growth and the incorporation of biologic products, if used
- Smooth back surface and corners to help prevent soft tissue irritation
- Tapered nose to aid in insertion

TITAN 3-D EVANS WEDGE INSTRUMENTATION

TITAN 3-D Evans Inserter

TITAN 3-D Evans Precision Guide



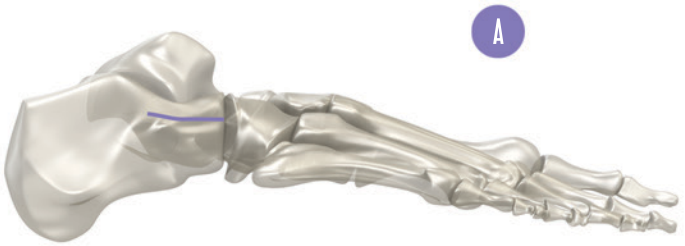
TITAN 3-D Evans Resection Guide

Evans Calcaneal Osteotomy Surgical Technique

INCISION/EXPOSURE

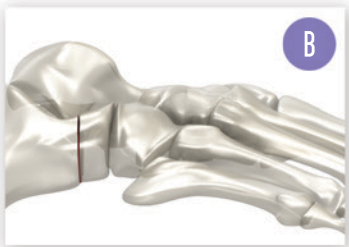
This procedure may be performed as a sole procedure or combined with various procedures to address Stage II Posterior Tibial Tendon Dysfunction, a pediatric flatfoot or other deformity at the discretion of the surgeon. This technique will describe the Evans Calcaneal Osteotomy procedure for flatfoot correction.

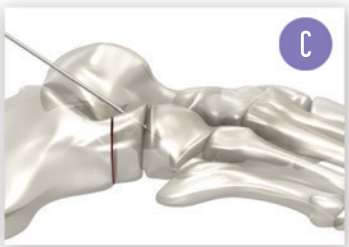
Patient positioning in a lateral decubitus or supine position with fluoroscopy available is recommended for this procedure. A standard lateral incision is shown but can be varied according to surgeon preference. (A) Dissection is carried down to the lateral wall of the calcaneus without entering the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



CALCANEAL OSTEOTOMY

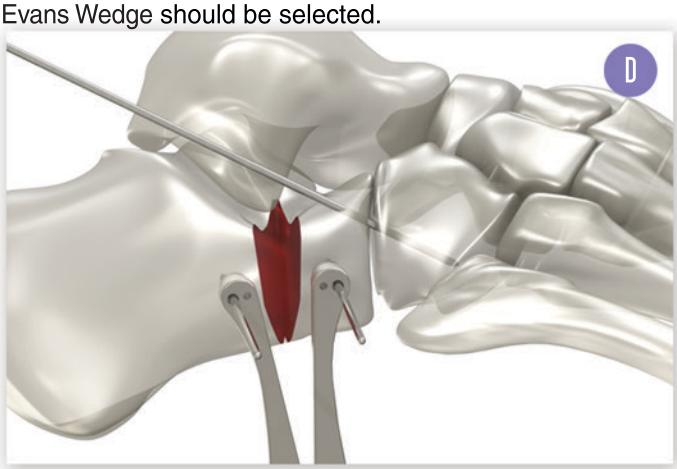
An osteotomy is made in the calcaneus, generally 1.0 cm – 1.5 cm proximal to and parallel to the calcaneocuboid joint. (B) A K-wire can be placed across the calcaneocuboid joint at this time to prevent dorsal dislocation of the distal fragment of the calcaneus. (C)

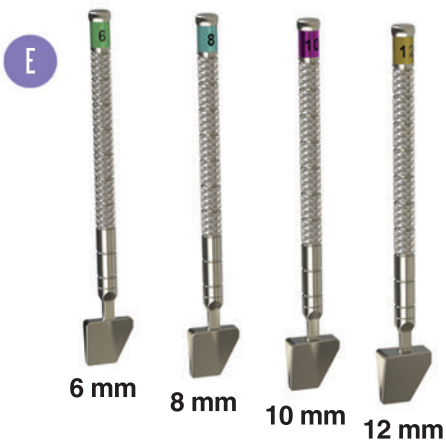




DEFORMITY CORRECTION

An external distractor, such as a pin distractor, is recommended to open the osteotomy and visualize lengthening of the lateral column. (D)
Trial sizers are available to match the correction amount of the available TITAN 3-D Evans Wedges—6 mm, 8 mm, 10 mm and 12 mm. (E)
TIP: The height of the trial sizer is matched to the Large TITAN 3-D Evans Wedge height. If the trial extends beyond the bone, a Small TITAN 3-D Evans Wedge should be selected.





Evans Calcaneal Osteotomy Surgical Technique

DEFORMITY CORRECTION

Select a trial sizer that best approximates intended correction and place into osteotomy site. In this instance, a Large TITAN 3-D Evans Wedge is selected, as the trial height is appropriate for this patient and does not project beyond the bone. (F) If more correction is necessary, go up a trial size. If less correction is desired, go down a trial size.

TIP: It is recommended to open up the hinge on the pin distractor while testing trial sizers to allow for adjustment of lateral column lengthening and to visualize planar correction. (G)

Once the appropriate amount of lateral column lengthening is determined using the trial sizers, the TITAN 3-D Evans Wedge is selected that corresponds to the trial sizer that provided desired correction. An unsterile team member should open the box to retrieve the double pouch containing the TITAN 3-D implant. The unsterile team member should open the outer pouch and present the sterile inner pouch to a sterile team member using aseptic technique. The TITAN 3-D Evans Wedge is removed from the sterile inner package.

The TITAN 3-D Evans Inserter is attached to the TITAN 3-D Evans Wedge. The alignment pin on the inserter is mated to the alignment hole on the wedge. (H) The screw on the inserter is turned in a clockwise direction to fasten to the threaded hole on the TITAN 3-D Evans Wedge until secure. (I)

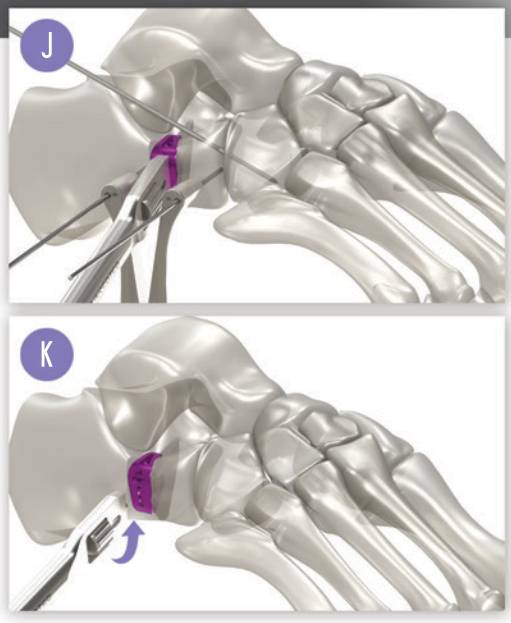
TITAN 3-D EVANS WEDGE INSERTION

The pin distractor is held open or preferred distraction is applied to open the osteotomy.

TIP: Opening up the pin distractor or preferred distraction device to a slightly larger width than the trial sizer may allow easier implant insertion. This will help provide clearance of the spikes on the TITAN 3-D Wedge.

The TITAN 3-D Evans Wedge is placed into the calcaneal osteotomy site using the inserter. (J) A mallet can be used on the back of the inserter to further advance the TITAN 3-D Evans Wedge into the osteotomy.

The TITAN 3-D Evans Inserter is detached from the TITAN 3-D Evans Wedge by rotating the screw in a counterclockwise direction. (K) The K-wire serving as temporary fixation across the calcaneocuboid joint is removed.



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Evans Calcaneal Osteotomy Surgical Technique

ANCILLARY FIXATION

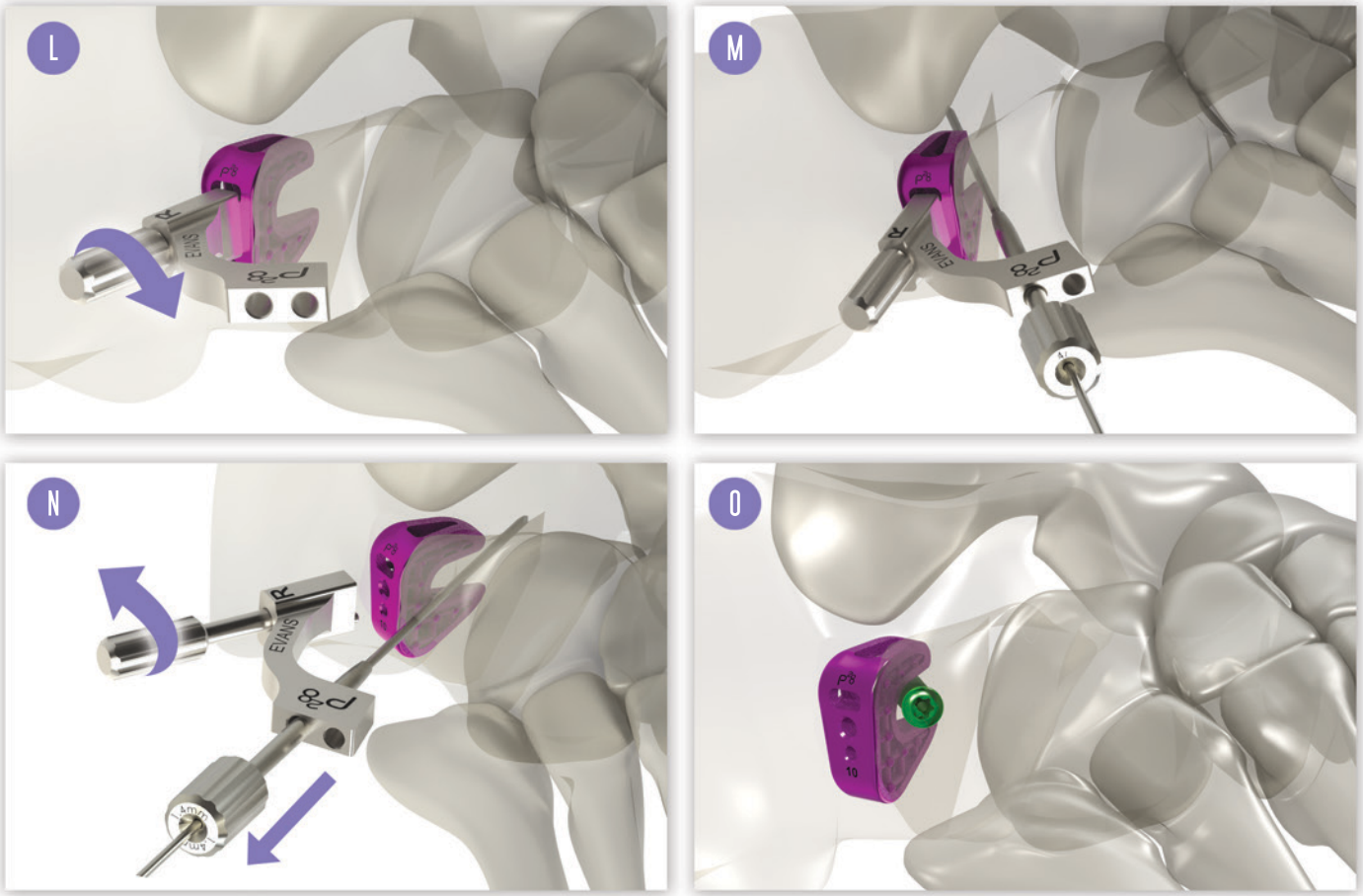
A TITAN 3-D Evans Precision Guide is available to provide a trajectory for cannulated screw placement through the open area of the implant, such that the screw does not collide with the implant.

After the TITAN 3-D Evans Wedge implant is placed, the TITAN 3-D Evans Precision Guide is secured to the implant in a similar manner as the inserter. A peg on the undersurface of the Precision Guide is inserted into the alignment hole on the wedge. The screw that extends through the Precision Guide is rotated in a clockwise direction to mate with the threaded hole on the TITAN 3-D Evans Wedge until secure. (L)

The K-wire Guide is inserted into the top or bottom receiving hole on the Precision Guide, depending on fit. A guide wire for the cannulated screw size selected is inserted through the K-wire guide into the Precision Guide. (M)

TIP: The opening width on the TITAN 3-D Evans Wedge between the two legs is sized to receive a 3.5 mm or a 4.0 mm cannulated Mini-Monster Screw. A fully threaded screw is recommended in order to help maintain length of the osteotomy.*

Once the guide wire is placed, the Precision Guide can be removed from the implant by turning the screw in a counterclockwise direction and sliding the Precision Guide off of the guide wire. (N) Following drilling, countersinking and measuring, a cannulated screw is placed over the guide wire and the guide wire is removed. (O)



* Alternatively, other Paragon 28 products made of the same material can be used as ancillary fixation per surgeon preference.

Evans Calcaneal Osteotomy Surgical Technique

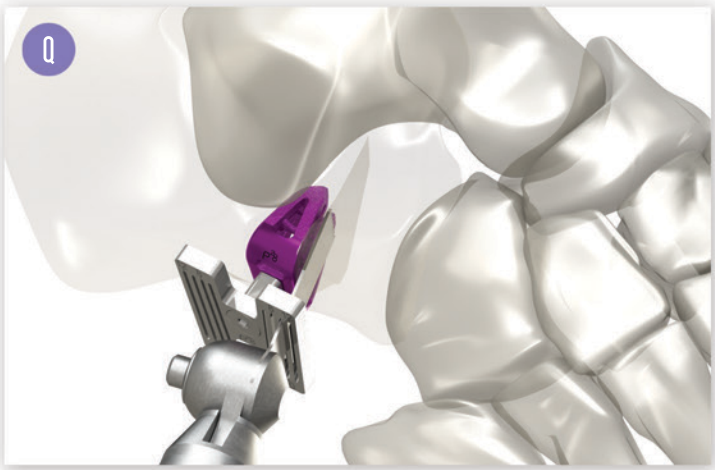
REVISION/REMOVAL OF A TITAN 3-D EVANS WEDGE IMPLANT

If removal or revision of a TITAN 3-D Evans Wedge is necessary, a TITAN 3-D Evans Resection Guide is available to assist in removal, as freehand removal can be difficult due to the implant spikes and/or bone growth throughout the implant. This technique allows for removal of the implant while minimizing bone loss.

The TITAN 3-D Evans Resection Guide is retrieved from the removal set. A dental pick or a K-wire can be used to clear the alignment hole and threaded hole in the TITAN 3-D Evans Wedge implant. The resection guide attaches as described for the inserter and Precision Guide, with an alignment tab inserting into an alignment hole. The screw on the resection guide is then threaded into the TITAN 3-D Evans Wedge implant by rotating the driver in a clockwise direction. (P)

The resection guide has slots that are labeled for each implant size. The implant size can be determined by the color of the implant. Insert a sagittal saw corresponding to the implant size and create a cut along the implant. Repeat this process for the slot on the opposite side of the guide/implant. (Q) Upon completion of cutting, remove the resection guide and the implant together, or detach the resection guide from the implant, insert the insertion guide, and use a mallet on the handle to tap out the implant.

The void remaining in the bone following resection guide use will usually be 2 mm larger than the previous TITAN 3-D Evans Wedge implant that was placed. For instance, if an 8 mm implant was used initially, a 10 mm implant would be required to fill the bone void while achieving the same amount of correction that was initially attained.



Indications, Contraindications, and Warnings:

Indications:

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Indications For Use: The TITAN 3-D Wedge System implants are intended to be used for internal bone fixation for bone fractures, fusions or osteotomies in the foot and ankle. The TITAN 3-D Wedge System implants are intended for use with ancillary fixation. The TITAN 3-D Wedge System implants are not intended for use in the spine.

Contraindications:

Contraindications: Use of the TITAN 3-D Wedge 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

Indications, Contraindications, and Warnings:

- 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 in the event that 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 non-compliant patient behavior.

Warnings:

Warnings and Precaution:

- 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.
- The implants and guide wires are intended for single use only
- Instruments, guide wires and screws are to be treated as sharps.
- The TITAN 3-D™ Wedge System has been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the TITAN 3-D™ Wedge System in the MR environment is unknown. **Scanning a patient who has this device may result in patient injury.**
- **Do not use other manufacturer's instruments or implants in conjunction with the TITAN 3-D™ Wedge System**
- **Do not resterilize the TITAN 3-D™ Wedge System implants**

MR (MAGNETIC RESONANCE) SAFETY INFORMATION:

Non-clinical testing has demonstrated the TITAN 3-D™ Wedge implants are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions

- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the TITAN 3-D Wedge is expected to produce a maximum temperature rise of less than 2.8°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 26 mm from the TITAN 3-D Wedge when imaged with a gradient echo pulse sequence and a 3 T MR system.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the device.
- The surgeon must exercise reasonable judgement when deciding to use the device.
- The TITAN 3-D Wedge System are not intended to endure excessive abnormal functional stresses.
- Failure to use dedicated, unique TITAN 3-D Wedge System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use and inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28 Inc. recommends the use of Paragon 28 Inc. products in a sterile environment.

Please contact company for product inquiries, cleaning instructions or to report any adverse event.

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 (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.

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.**

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.