Exclusively foot & ankle

Paragon 28®

TITAN 3-D®

WEDGE SYSTEM

SURGICAL TECHNIQUE GUIDE

PRODUCT DESCRIPTION

The TITAN 3-D™ Wedge System offers porous titanium wedges that provide an alternative to allograft/autograft bone for an Evans Calcaneal Osteotomy for lateral column lengthening and Cotton Osteotomy for plantar flexion of the medial cuneiform . The TITAN 3-D™ Wedge System builds on Paragon 28®'s portfolio of osteotomy wedges and uses the same patented shapes as the PRESERVE™ Evans and Cotton Wedges.

The TITAN 3-D™ Wedges have an open geometry with a three-dimensional scaffold that allows for blood entry, bone through growth, and the incorporation of biologics if used. Each wedge has a central opening which allows for passage of a 3.5- or 4.0-mm screw across the osteotomy to help increase stability of the construct. To ensure accurate and consistent placement of this crossing screw, both wedge families leverage the patented PRECISION GUIDE™ System. To increase the coefficient of friction and minimize the chance of implant expulsion, the TITAN 3-D™ wedges are built with spikes which interface with bony surfaces. To facilitate accurate implantation, the system includes product specific inserters which thread onto the back of each wedge and have a strike plate to aid in final seating. The system also includes resection guides which limit excessive bone removal if explanation is required. The TITAN 3-D™ Evans Wedges are available 6-, 8-, 10-, and 12-mm options with either small or large height. The TITAN 3-D™ Cotton Wedges are available in 5-, 6-, 7-, and 8-mm options.

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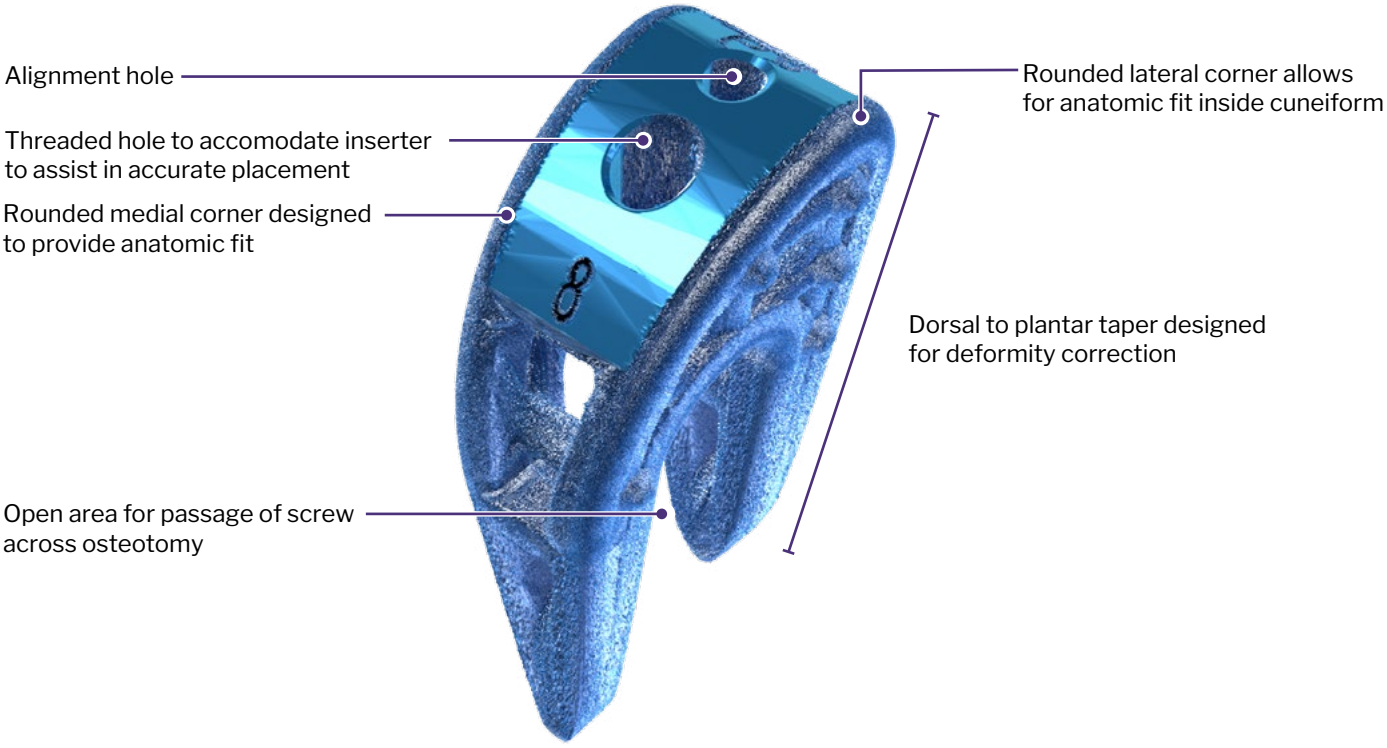
TITAN 3-D™ WEDGE FEATURES AND INSTRUMENTATION

Titan 3-D Cotton wedge features

- Sizes range from 5-8 mm 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 biological products, if used
- Spikes on both sides to help prevent expulsion of implant from osteotomy site
- Tapered nose to aid in insertion

Cotton Wedges

5 mm | 6 mm | 7 mm | 8 mm

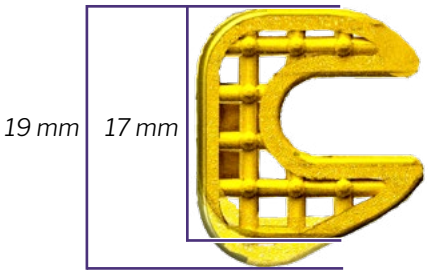


TITAN 3-D™ WEDGE FEATURES AND INSTRUMENTATION

Titan 3-D Evans Wedge Features

- Sizes range from 6-12 mm 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

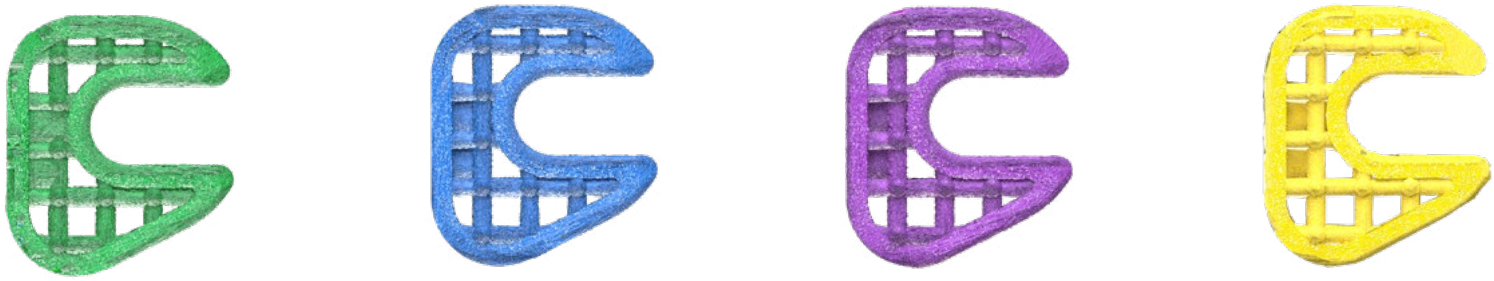
Evans Small Wedge overlay on Large Wedge



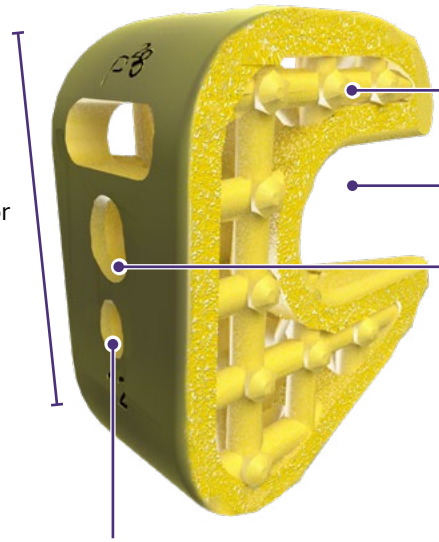
Evans Small Wedges

6 mm | 8 mm | 10 mm | 12 mm

Evans Large Wedges



6 mm | 8 mm | 10 mm | 12 mm



Dorsal to plantar taper designed for plantar ligament stress reduction

Spikes on both sides to help prevent expulsion of implant from osteotomy site

Open area for passage of screw across osteotomy

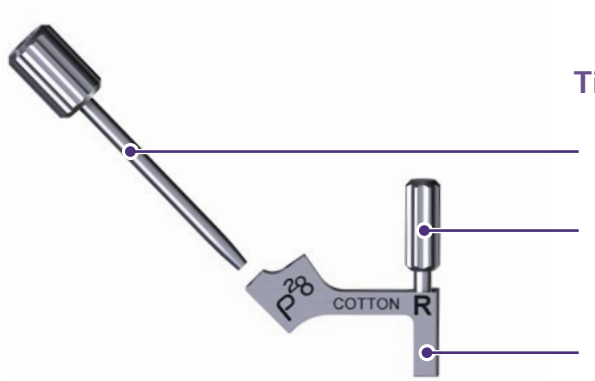
Threaded hole to accomodate inserter to assist in accurate placement

Alignment Hole

TITAN 3-D COTTON WEDGE FEATURED INSTRUMENTATION

Titan 3-D Cotton Inserter

- Threads into the wedge to assist in handling and accurate placement of the wedge in the osteotomy site



Titan 3-D Cotton Precision Guide

K-Wire Guide

Set Screw

Precision Guide

Titan 3-D Cotton Resection Guides

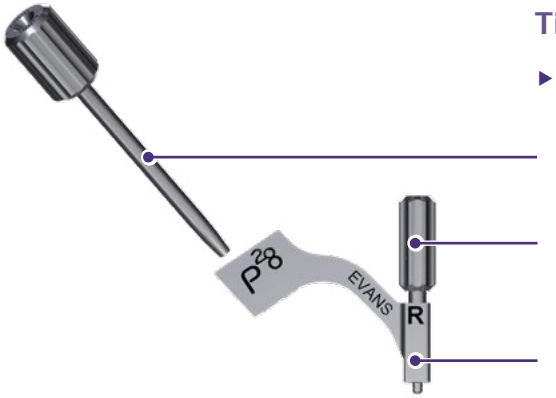
- Used to guide resection around the the wedge if removal or revision is necessary

Cut slots correspond to size 5 and 7 mm wedges

Cut slots correspond to size 6 and 8 mm wedges

TITAN 3-D EVANS WEDGE FEATURED INSTRUMENTATION

Titan 3-D Evans Inserter



Titan 3-D Evans Precision Guide

- Guides placement of screw through the wedge and across the osteotomy without interfering with the wedge

K-Wire Guide

Set Screw

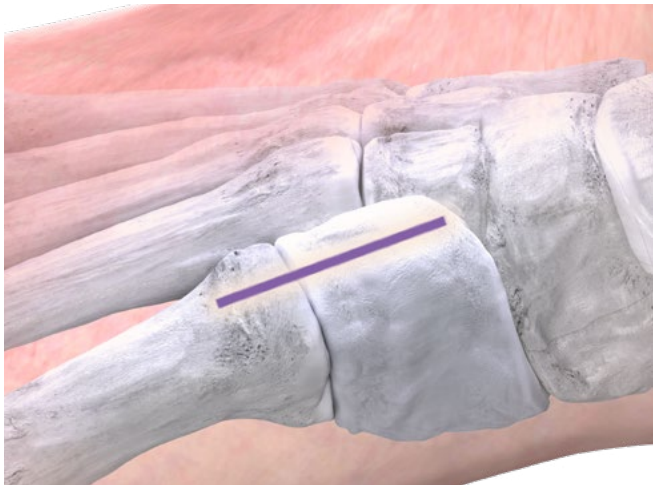
Precision Guide

Titan 3-D Evans Resection Guide

Cut slots correspond to 6 mm, 8 mm, 10 mm, and 12 mm size wedges

INCISION/EXPOSURE

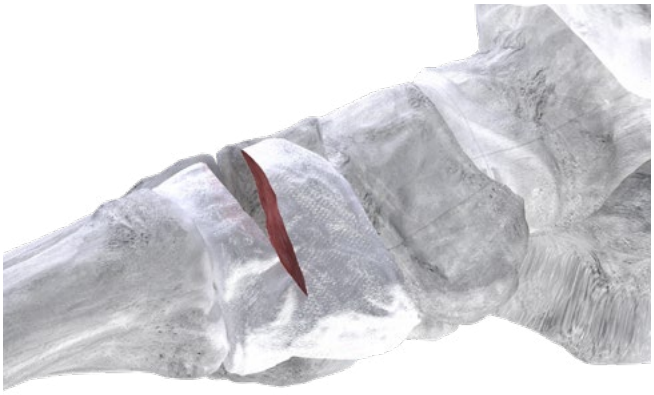
Make a dorsal longitudinal incision over the medial cuneiform and base of the first metatarsal. This can be varied according to surgeon preference. Dissection is carried down to the dorsal aspect of the medial cuneiform.



MEDIAL CUNEIFORM OSTEOTOMY

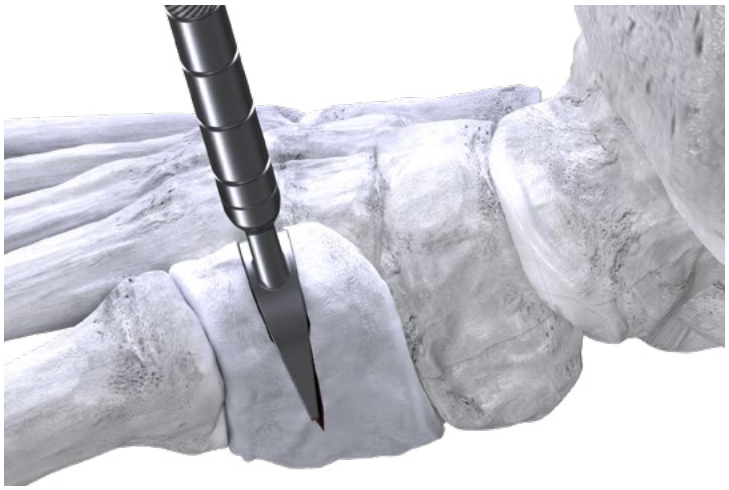
Perform an osteotomy at the central aspect of the medial cuneiform down to, but not through, the plantar cortex of the cuneiform.

DEFORMITY CORRECTION



Distract the osteotomy per surgeon preference. It is recommended to open the osteotomy and create plantarflexion of the first ray.

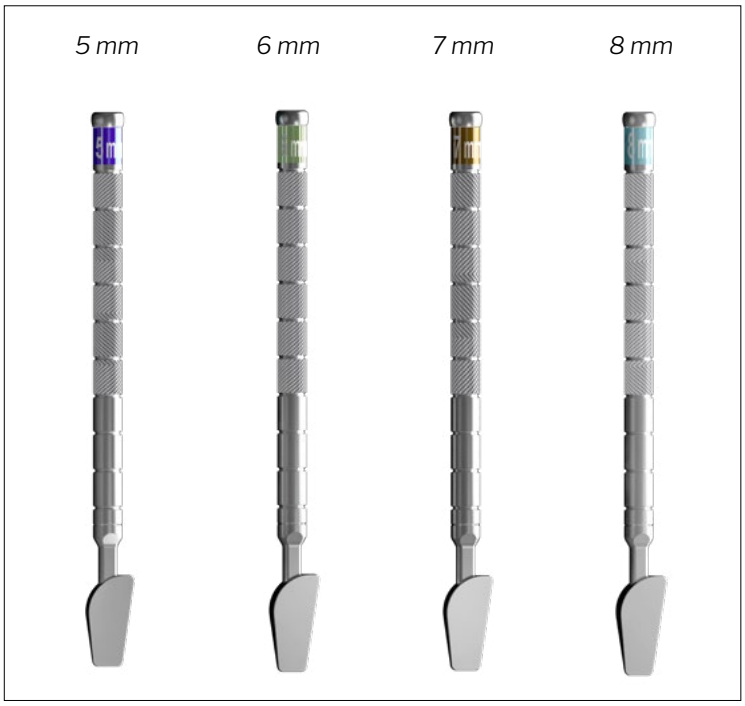
DEFORMITY CORRECTION



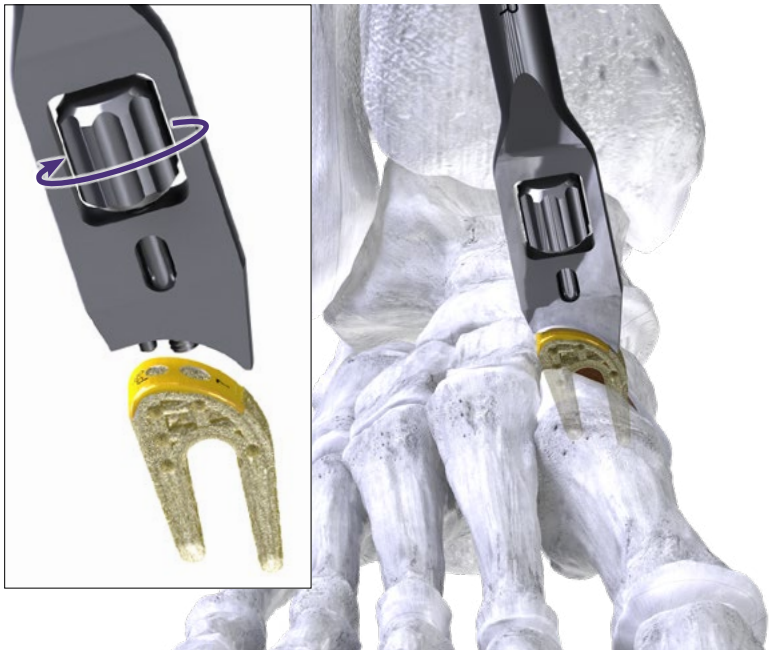
Use the provided trial sizers to determine the wedge size that best approximates the intended correction. Place the trial into the osteotomy site. If more correction is necessary, go up a trial size.
If less correction is desired, go down a trial size.

TIP: *If using a pin distractor, it is recommended to open the hinge on the distractor while testing trial sizers to allow for adjustment of 1st ray plantarflexion between trial sizers.*

NOTE: 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.

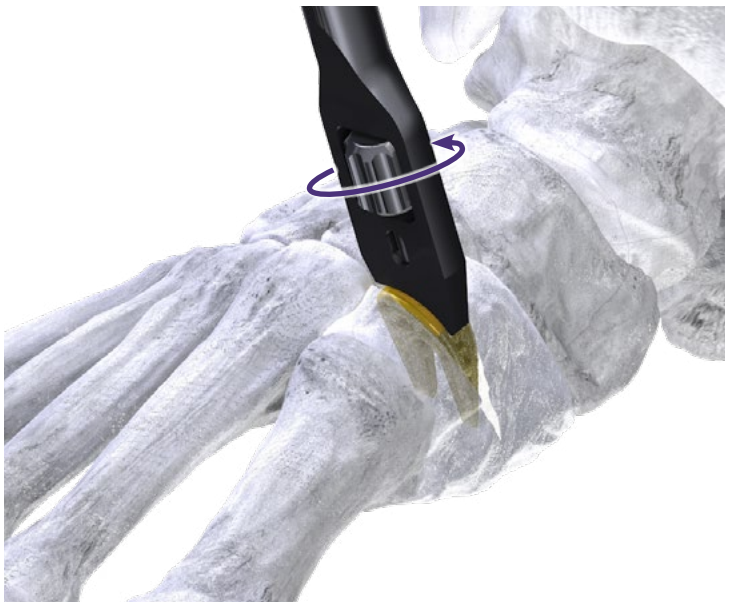


Once the appropriate amount of 1st ray plantarflexion is determined using the trial sizers, select the TITAN 3-D Cotton Wedge that corresponds to the trial sizer that provided the desired amount of correction. Retrieve the appropriate sterile packed TITAN 3-D Cotton Wedge. Attach the TITAN 3-D Cotton Inserter to the TITAN 3-D Cotton Wedge by mating the alignment pin on the inserter to the alignment hole on the wedge. Turn the screw on the inserter clockwise into the threaded hole on the TITAN 3-D Cotton Wedge until secure.



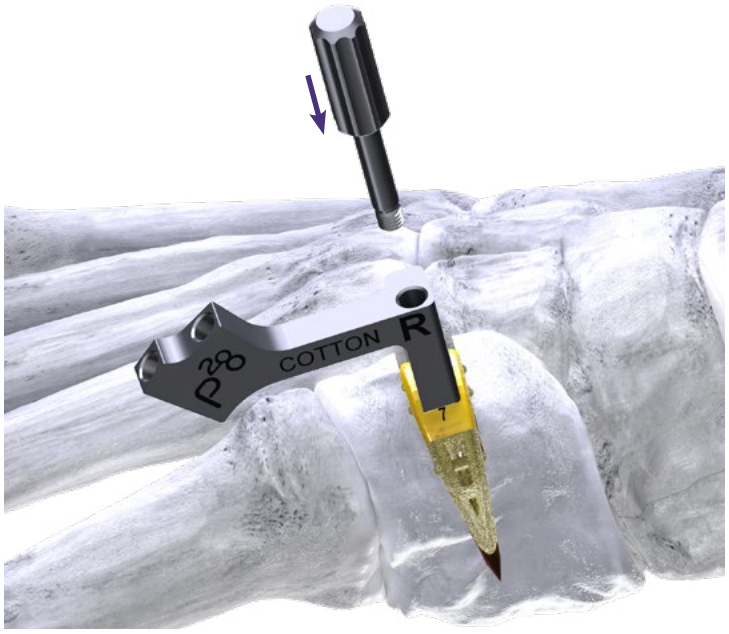
Distract the osteotomy according to surgeon preference and place the TITAN 3-D Cotton wedge in the osteotomy site using the inserter. The back of the inserter can be tapped with a mallet to further advance the TITAN 3-D Cotton Wedge into the osteotomy.

TITAN 3-D COTTON WEDGE INSERTION

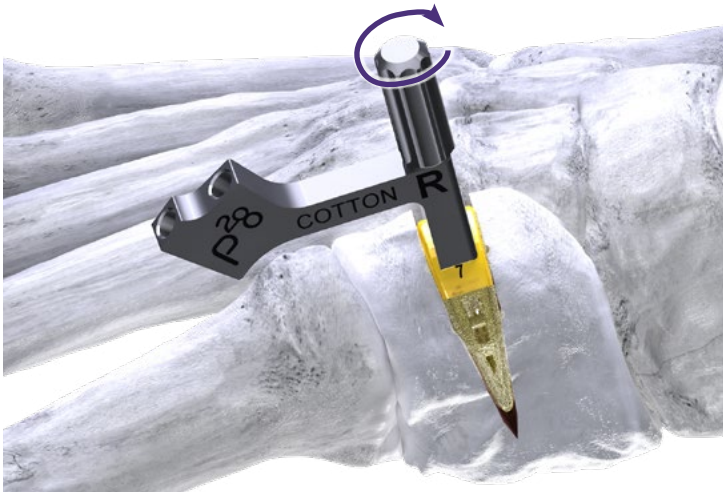


After placing the wedge in proper position, detach the TITAN 3-D Cotton Wedge from the Inserter by rotating the screw in a counterclockwise direction and removing the inserter.

ANCILLARY FIXATION



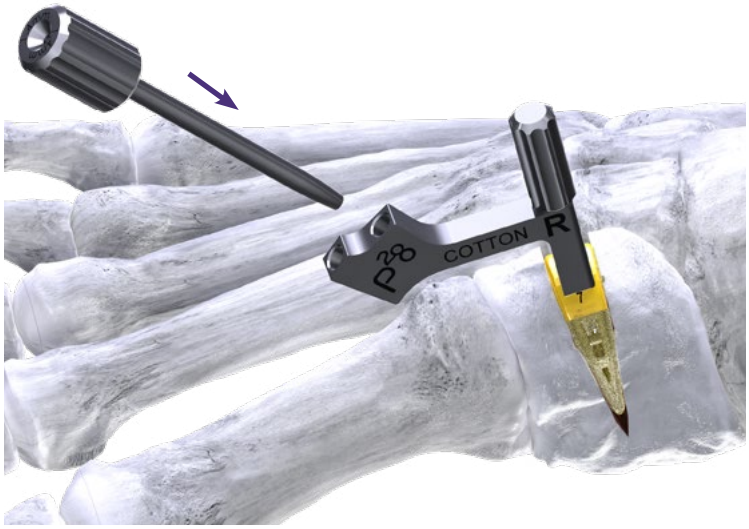
After the TITAN 3-D Cotton Wedge implant is placed, secure the Precision Guide to the implant by placing the peg of the Precision Guide into the alignment hole on the wedge.



Thread the Set Screw from the Precision Guide to mate with the threaded hole on the TITAN 3-D Cotton Wedge until secure.

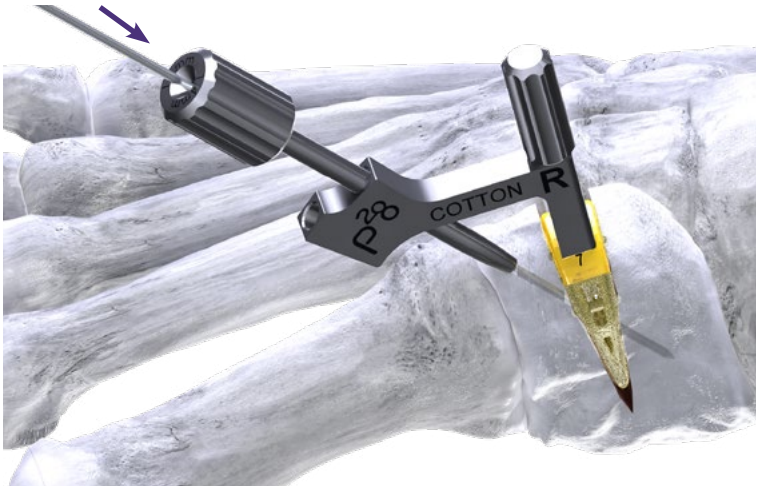
ANCILLARY FIXATION

The TITAN 3-D Cotton Precision Guide can be used to guide the trajectory of a cannulated screw such that the screw does not collide with the implant.

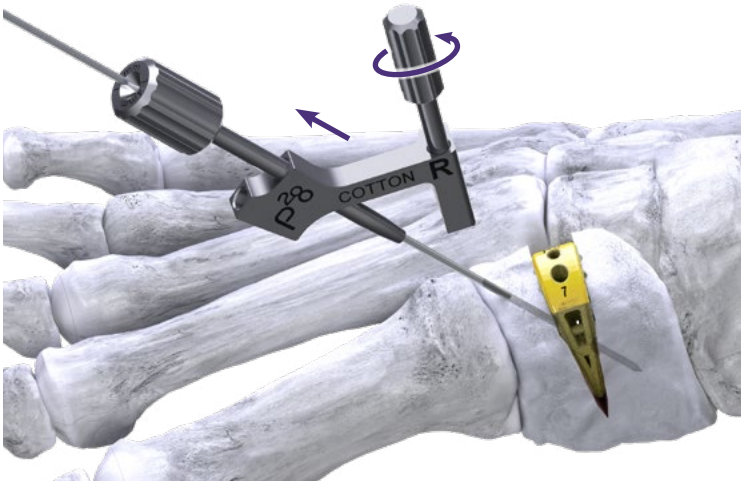


Place the K-wire Guide in either hole in the Precision Guide, depending on the desired start point and position of the screw.

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



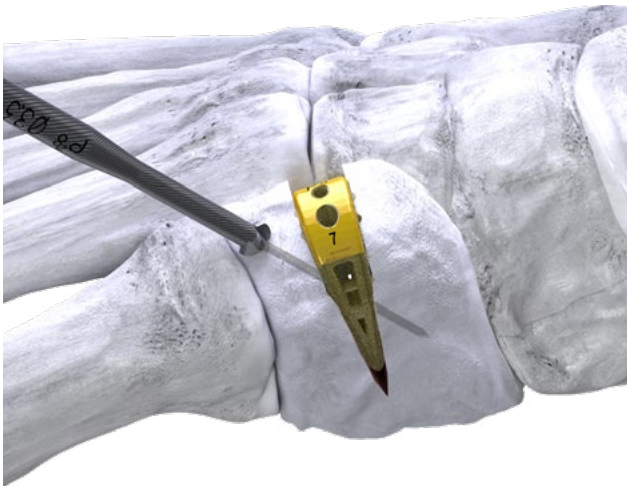
Place a guide wire sized for the cannulated screw to be used through the guide and into the bone. Confirm wire placement and insertion depth using fluoroscopy.

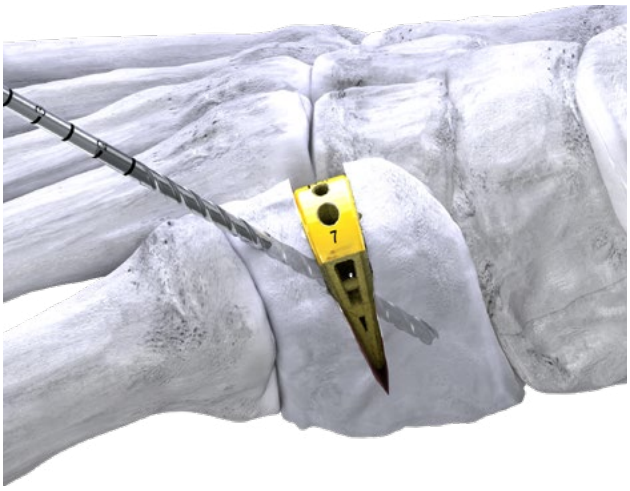


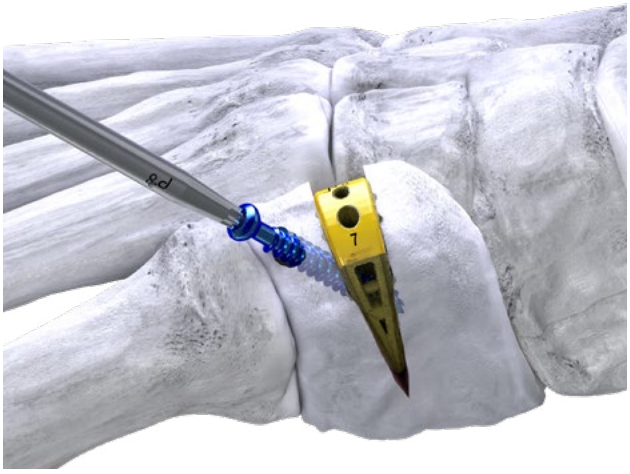
Once the guide wire position is confirmed, remove the Precision Guide from the implant by turning the Set Screw counterclockwise and sliding the Precision Guide off of the guide wire.

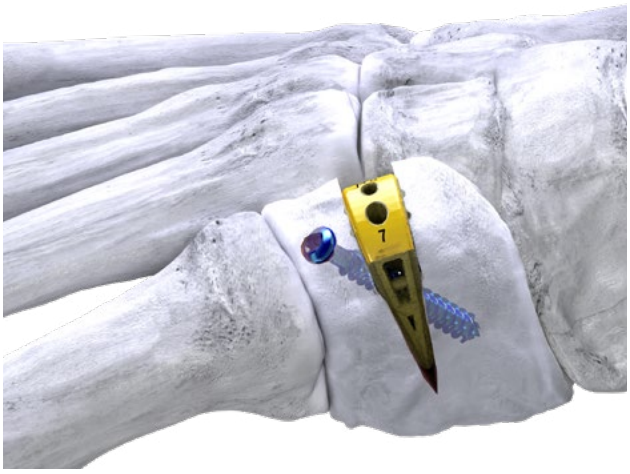
PLATE SELECTION AND FIXATION

Countersink, measure, drill, and insert the appropriately sized cannulated screw over the guide wire, according to surgeon preference.

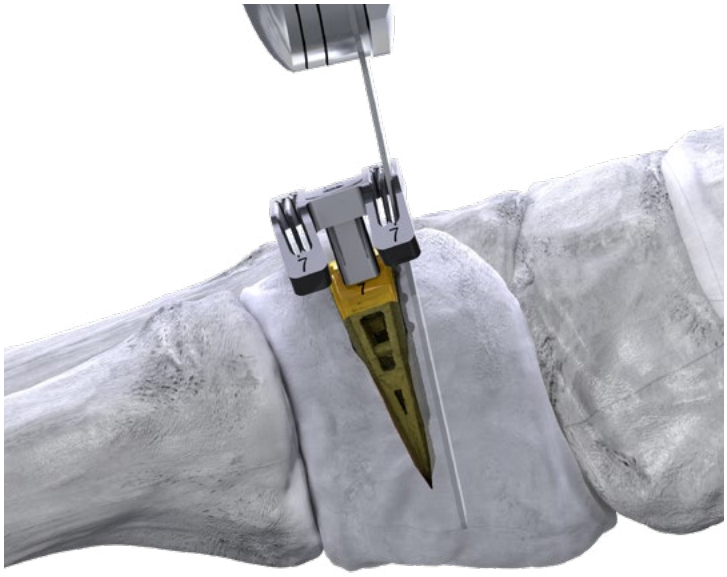








REVISION/REMOVAL OF A TITAN 3-D COTTON WEDGE IMPLANT



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 of the implant while minimizing bone loss.

Use the TITAN 3-D Cotton Resection Guide that is appropriately sized for the implant to be removed. If necessary, clear the alignment and threaded hole in the TITAN 3-D Cotton Wedge implant with a K-wire or dental pick. Attach the Resection Guide to the implant by placing the alignment tab of the guide into the hole on the implant and turning the screw on the Resection Guide clockwise until it threads into the TITAN 3-D Cotton Wedge implant.

Use the cut slots that match the implant size and cut through the slots on both sides of the implant using a sagittal saw.

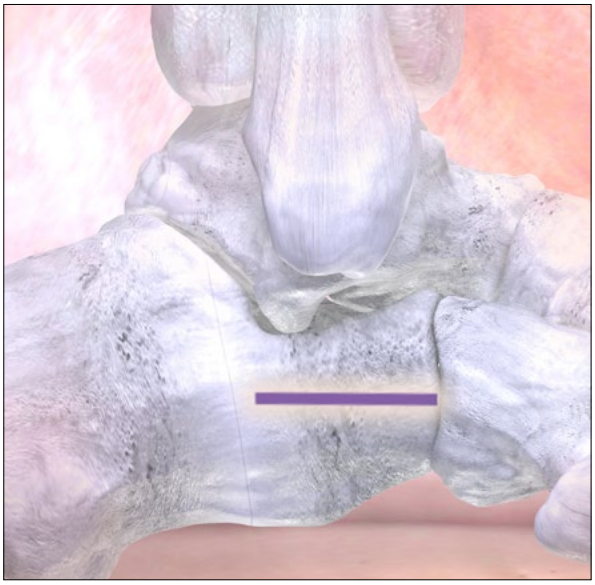
TIP: *One resection guide is used for 6 mm and 8 mm implants and one is used for 5 mm and 7 mm implants.*

After completing the cuts, remove the resection guide and implant together or detach the resection guide from the implant and use the inserter and a mallet to tap the implant out.

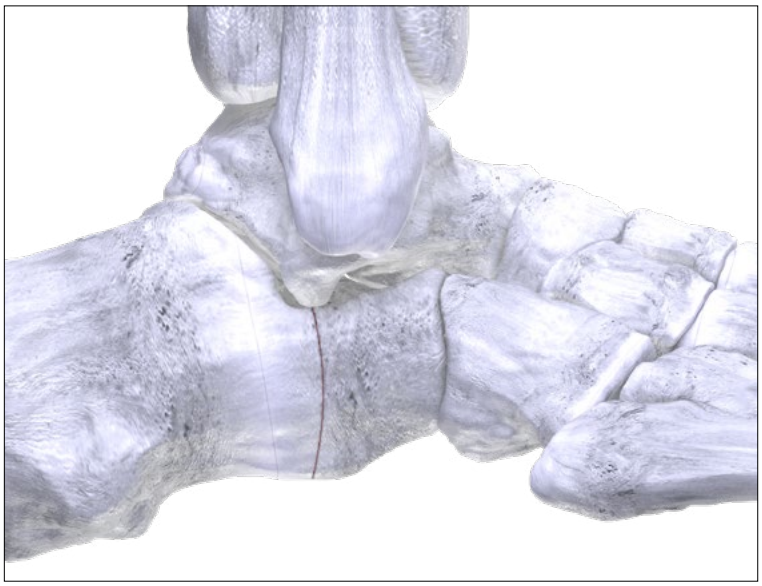
NOTE: The bone void remaining following resection is typically 2 mm larger than the size of the implant placed.

INCISION/EXPOSURE

Make an incision over the calcaneus according to surgeon preference. Dissection is carried down to the lateral wall of the calcaneus without entering the capsule of the calcaneocuboid joint.



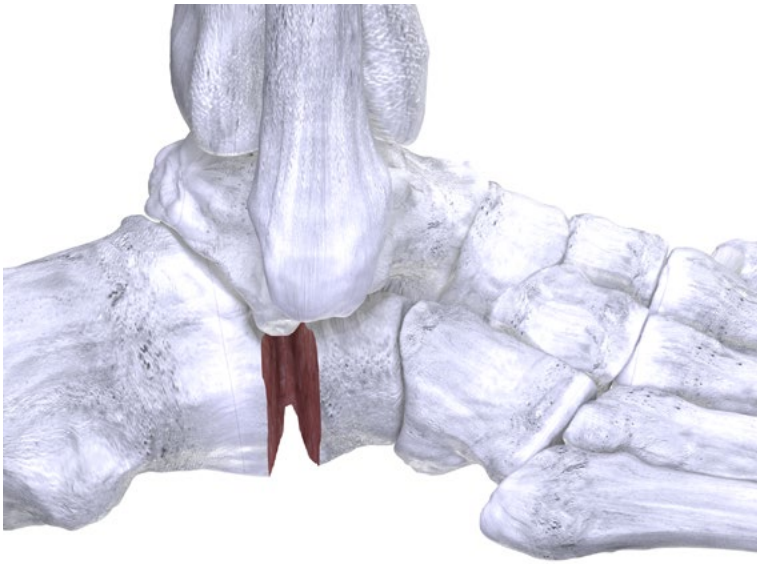
CALCANEAL OSTEOTOMY



Create an osteotomy in the calcaneus according to surgeon preference, generally 1 – 1.5 cm proximal to and parallel to the calcaneocuboid joint.

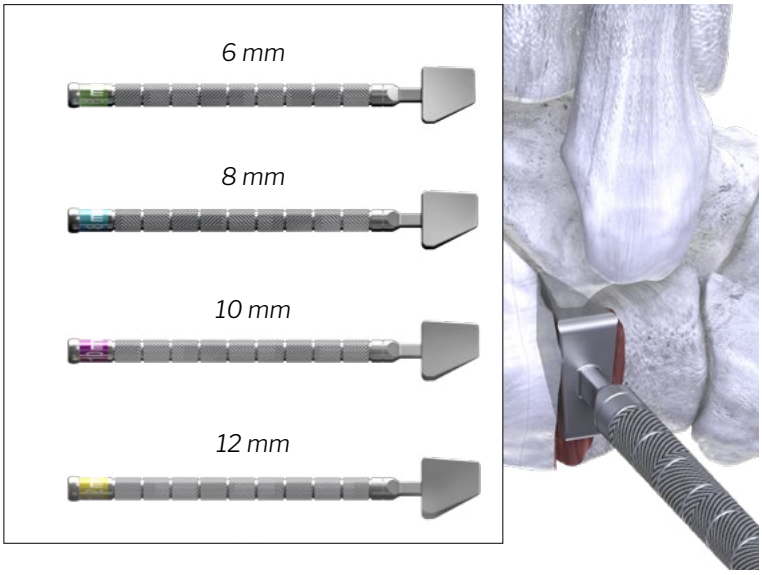
Optional: A K-wire can be placed across the calcaneocuboid joint to reduce dorsal dislocation of the distal fragment of the calcaneus during osteotomy distraction.

DEFORMITY CORRECTION



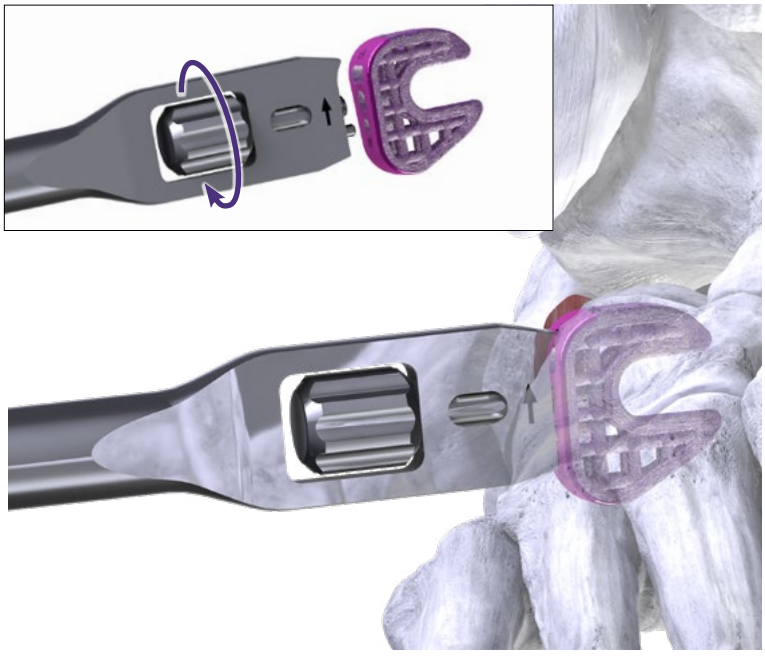
Distract the osteotomy according to surgeon preference. It is recommended to open the osteotomy and visualize lengthening of the lateral column.

TIP: *If using a pin distractor, it is recommended to open the hinge on the distractor while testing trial sizers to allow for adjustment of lateral column lengthening and to visualize plantar correction.*



Select a trial sizer that best approximates the intended correction and place into osteotomy site. If more correction is necessary, use a larger trial size. If less correction is desired, use a smaller trial size. If the trial projects beyond the bone, use small size implants.

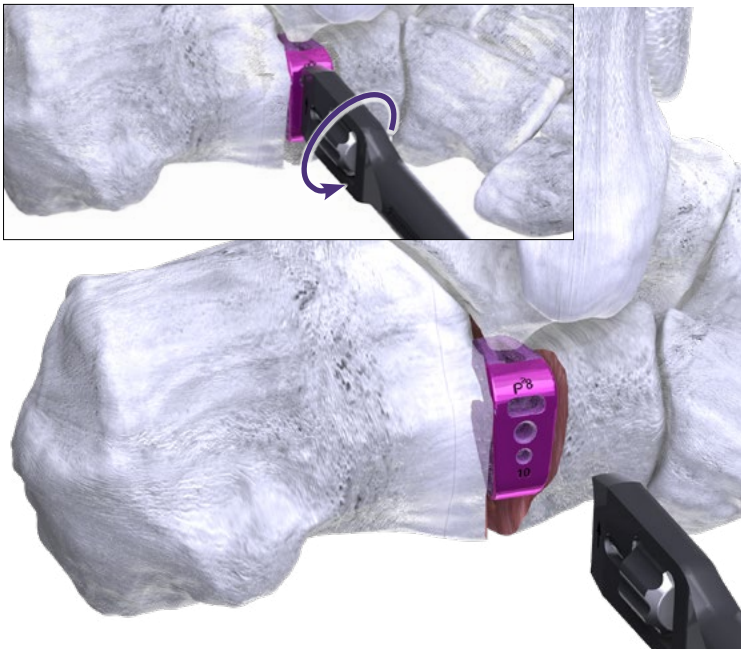
NOTE: Trial sizers are available to match the correction amount of the available TITAN 3-D Evans Wedges: 6 mm, 8 mm, 10 mm, and 12 mm.



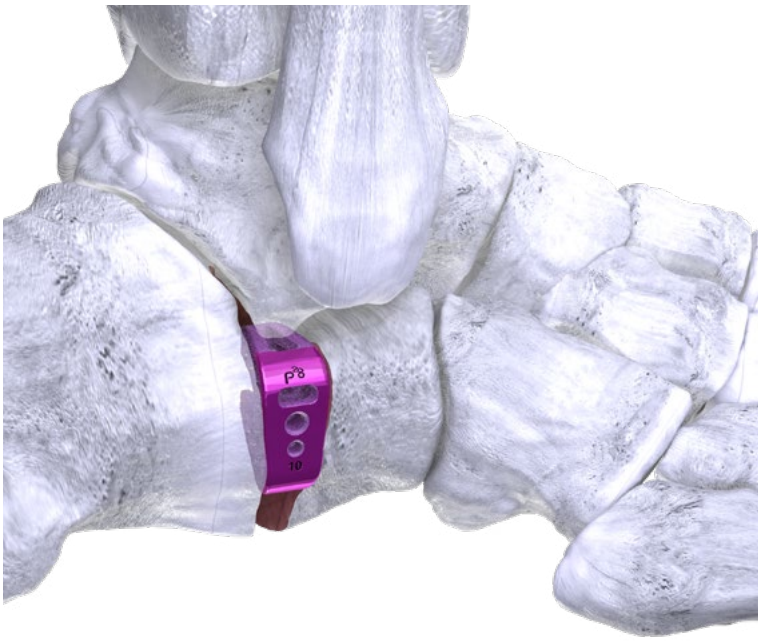
Once the appropriate amount of lateral column lengthening is determined using the trial sizers, select the TITAN 3-D Evans Wedge that corresponds to the trial sizer that provided the desired amount of correction. Retrieve the appropriate sterile packed TITAN 3-D Evans Wedge. Attach the TITAN 3-D Evans inserter to the TITAN 3-D Evans wedge by mating the alignment pin on the inserter to the alignment hole on the wedge. Turn the screw on the inserter clockwise into the threaded hole on the TITAN 3-D Evans Wedge until secure.

Distract the osteotomy according to surgeon preference and place the TITAN 3-D Evans Wedge in the osteotomy site using the inserter. The back of the inserter can be tapped with a mallet to further advance the TITAN 3-D Evans Wedge into the osteotomy.

TITAN 3-D EVANS WEDGE INSERTION

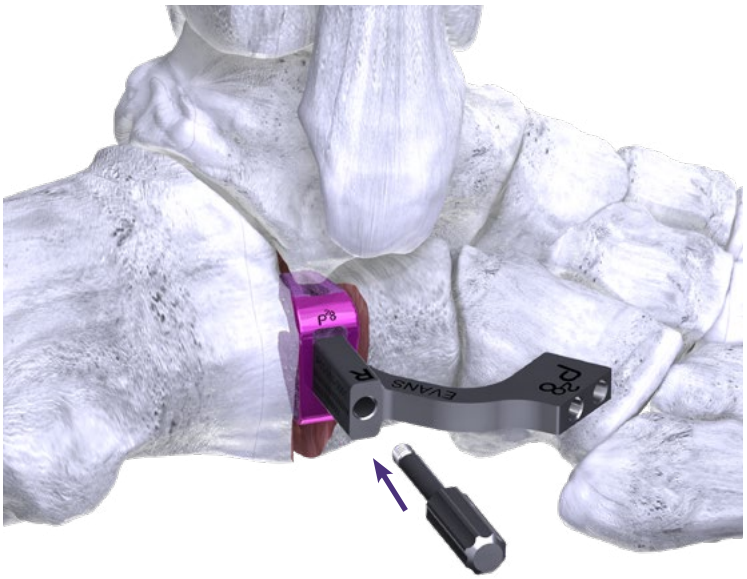


After placing the wedge in proper position, detach the TITAN 3-D Evans Wedge from the inserter by rotating the screw counterclockwise and removing the inserter.



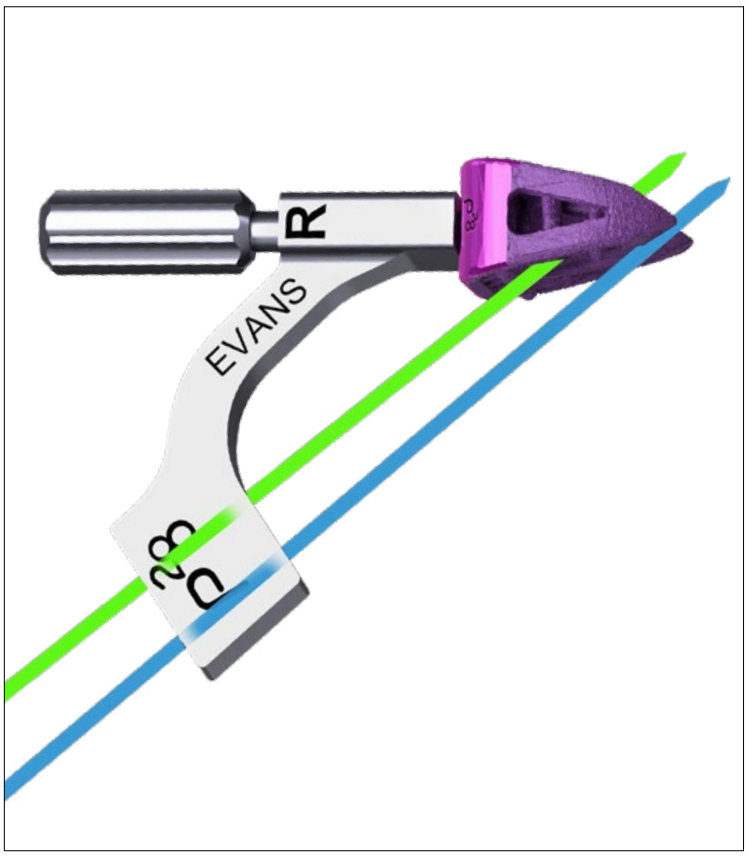
Confirm appropriate correction was achieved with the wedge that was placed.

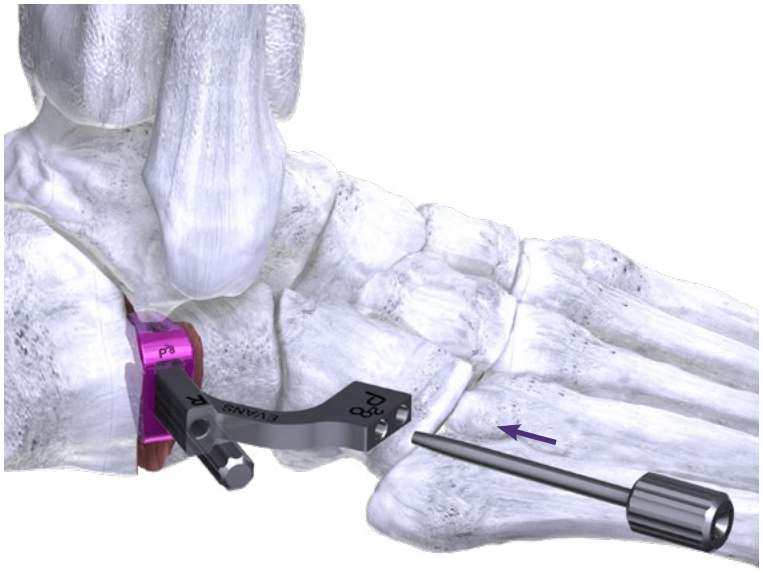
ANCILLARY FIXATION



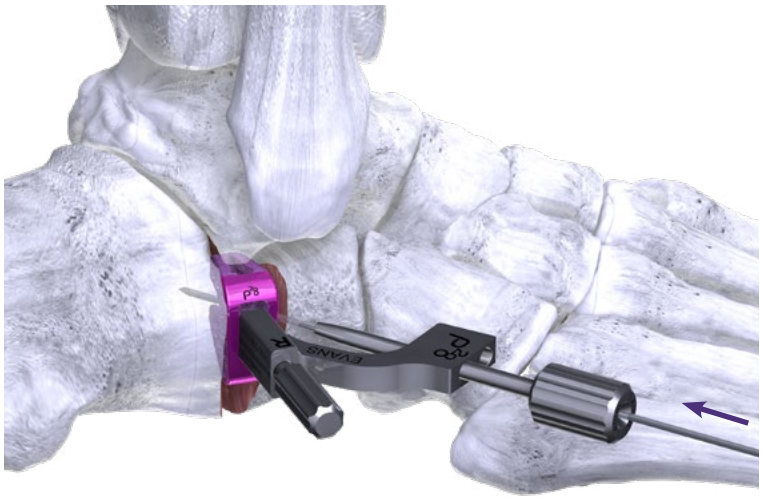
The TITAN 3-D Evans Precision Guide can be used to guide the trajectory of a cannulated screw placement such that the screw does not collide with the implant.
After the TITAN 3-D Evans Wedge implant is placed, secure the Precision Guide to the implant by placing the peg of the Precision Guide into the alignment hole on the wedge. Thread the Set Screw from the Precision Guide to mate with the threaded hole on the TITAN 3-D Evans Wedge until secure.

ANCILLARY FIXATION





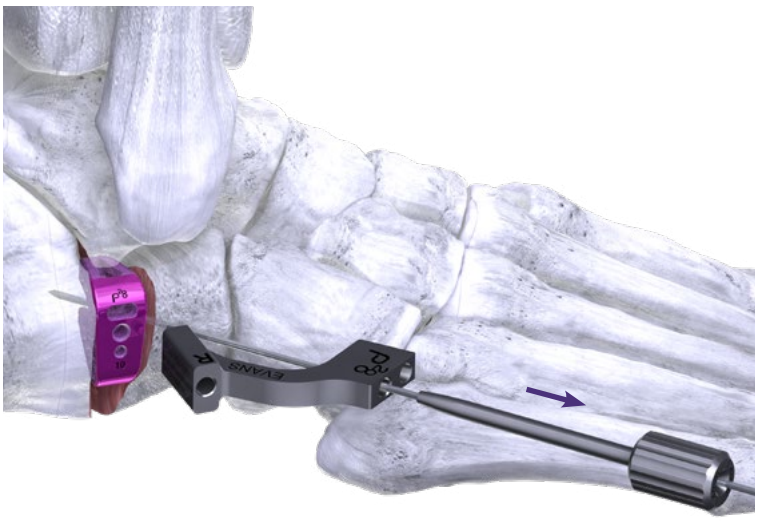
Place the K-wire Guide in either hole in the Precision Guide depending on the desired start point and position of screw.



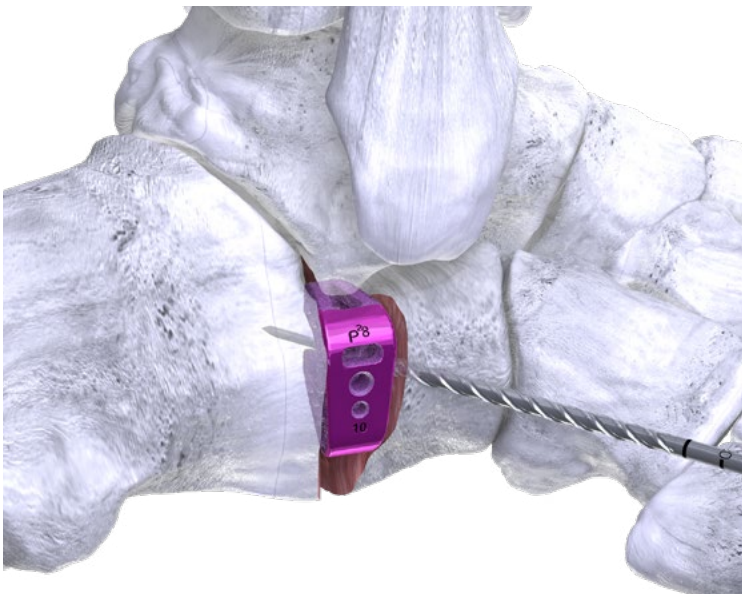
Place a guide wire sized for the cannulated screw to be used through the guide and into the bone. Confirm wire length and position using fluoroscopy.

TIP: *The opening width on the TITAN 3-D Evans Wedge between the two legs is sized to accommodate 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.*

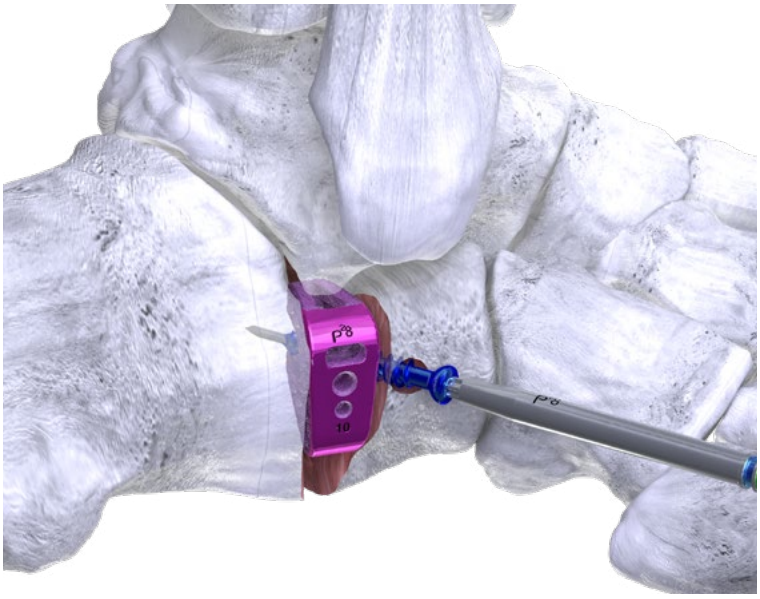
ANCILLARY FIXATION



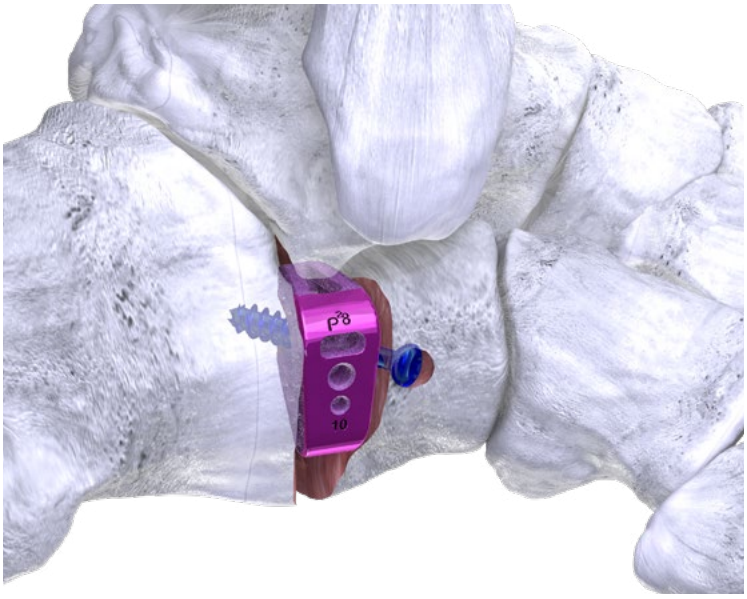
Once the wire is placed, remove the Precision Guide from the implant by loosening the screw and sliding the Precision Guide off of the guide wire.



Countersink, measure, drill, and insert the appropriately sized cannulated screw to be placed over the guide wire, according to surgeon preference.



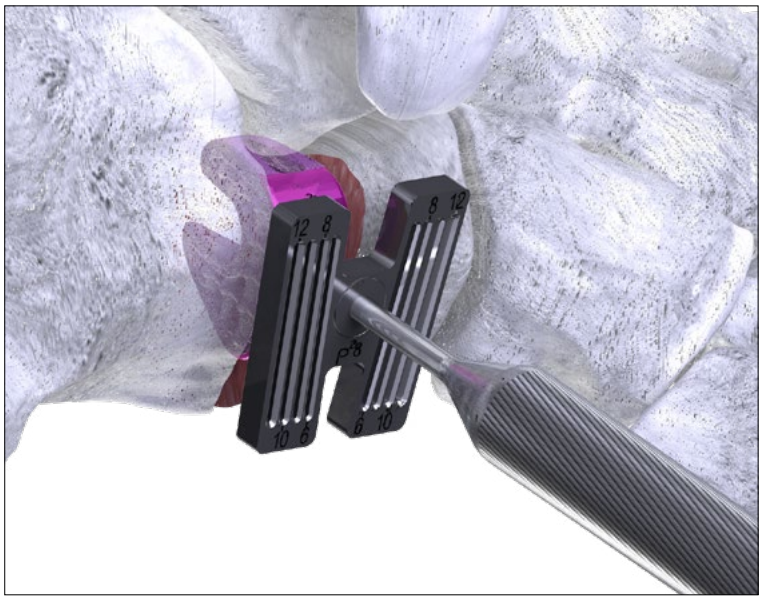
Place the appropriately sized cannulated screw over the guide wire.



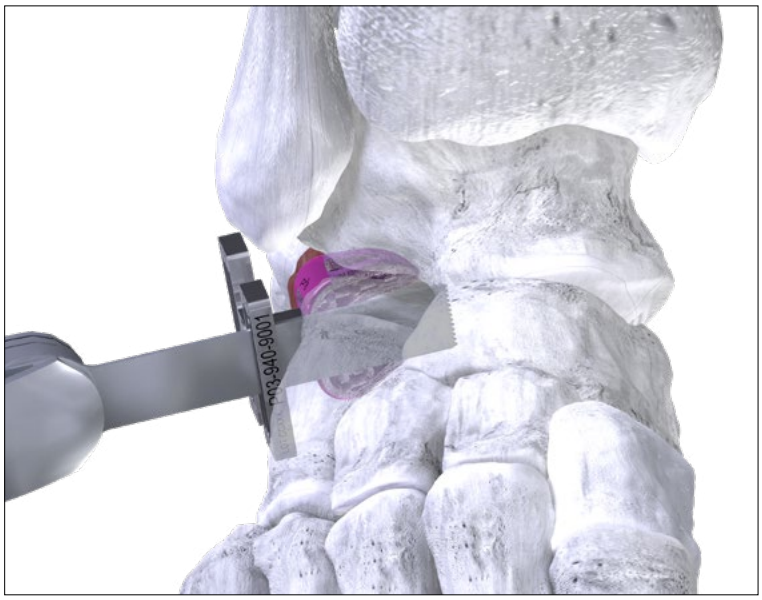
Confirm appropriate placement of the ancillary fixation.

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 of the implant while minimizing bone loss.



Use the TITAN 3-D Evans Resection Guide that is appropriately sized for the implant to be removed. If necessary, clear the alignment and threaded hole in the TITAN 3-D Evans Wedge implant with a K-wire or dental pick. Attach the Resection Guide to the implant by placing the alignment tab of the guide into the hole on the implant and turning the screw on the Resection Guide clockwise until it threads into the TITAN 3-D Evans Wedge implant.



Use the cut slots that match the implant size and cut through the slots on both sides of the implant using a sagittal saw.

NOTE: The bone void remaining following resection is typically 2 mm larger than the size of the implant placed.

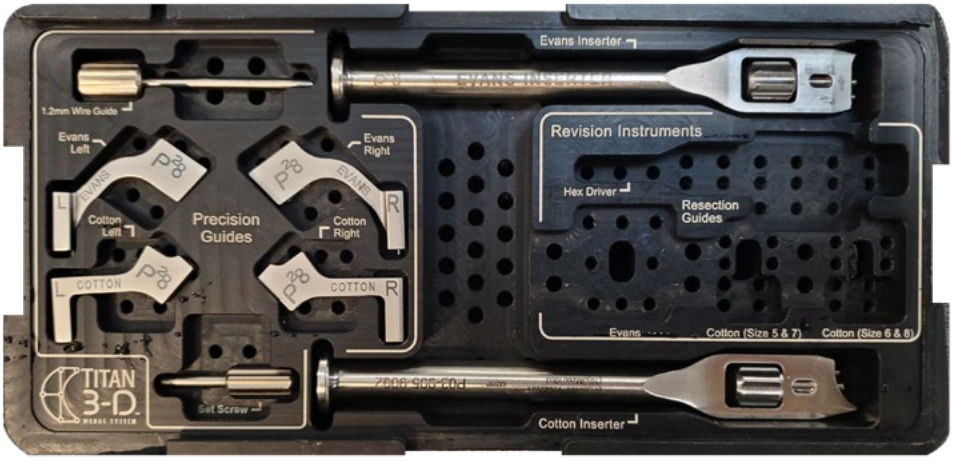
After completing the cuts, remove the resection guide and implant together or detach the resection guide from the implant and use the inserter and a mallet to tap the implant out.

Part #	Description	Use
P03-COT-100X-S	Cotton Wedges	Single-Use
P03-EVN-X0XX-S	Evan Wedges	Single-Use
P03-905-900X	Inserter	Re-usable
P03-950-000X	Precision Guide	Re-usable
P51-950-0002	Precision Guide Set Screw, Long	Re-usable
P51-950-0012	K-wire Guide, 1.2mm	Re-usable
P03-901-0001	2mm Hex Driver	Re-usable
P03-940-900X	Resection Guides	Re-usable
PET-09XX	Evans Trial Handle	Re-usable
PCT-00X	Cotton Trial Handle	Re-usable
P00-192-2315	2.3 x 150 mm K-wire	Single-Use

TITAN 3-D™ CADDY

TITAN 3-D™ INSTRUMENT CADDY

Evans Inserter, Cotton Inserter, and Precision Guides



TITAN 3-D™ TRIAL CADDY

Evans Wedge Trials (6, 8, 10, 12 mm), and Cotton Wedge Trials (5, 6, 7, 8 mm)

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

INDICATIONS FOR USE (TITAN 3-D®)

The TITAN 3-D® Wedge System implants are indicated 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 indicated for use in the spine.

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
- 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 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.
- 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 TITAN 3-D® Wedge System.
- Do not resterilize the TITAN 3-D® Wedge System implants.

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

MRI Safety Information

A person with the TITAN 3-D® Wedge 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	TITAN 3-D® Wedge System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3T
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
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 of 26mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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

- The presence of tumors
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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
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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.

TITAN 3-D® WEDGE SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P03-STG-0001 Rev G [2024-07-03]

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DISCLAIMER

The purpose of the TITAN 3-D® Wedge System Surgical Technique Guide is to demonstrate use of the TITAN 3-D Wedge in the TITAN 3-D Wedge 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. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.