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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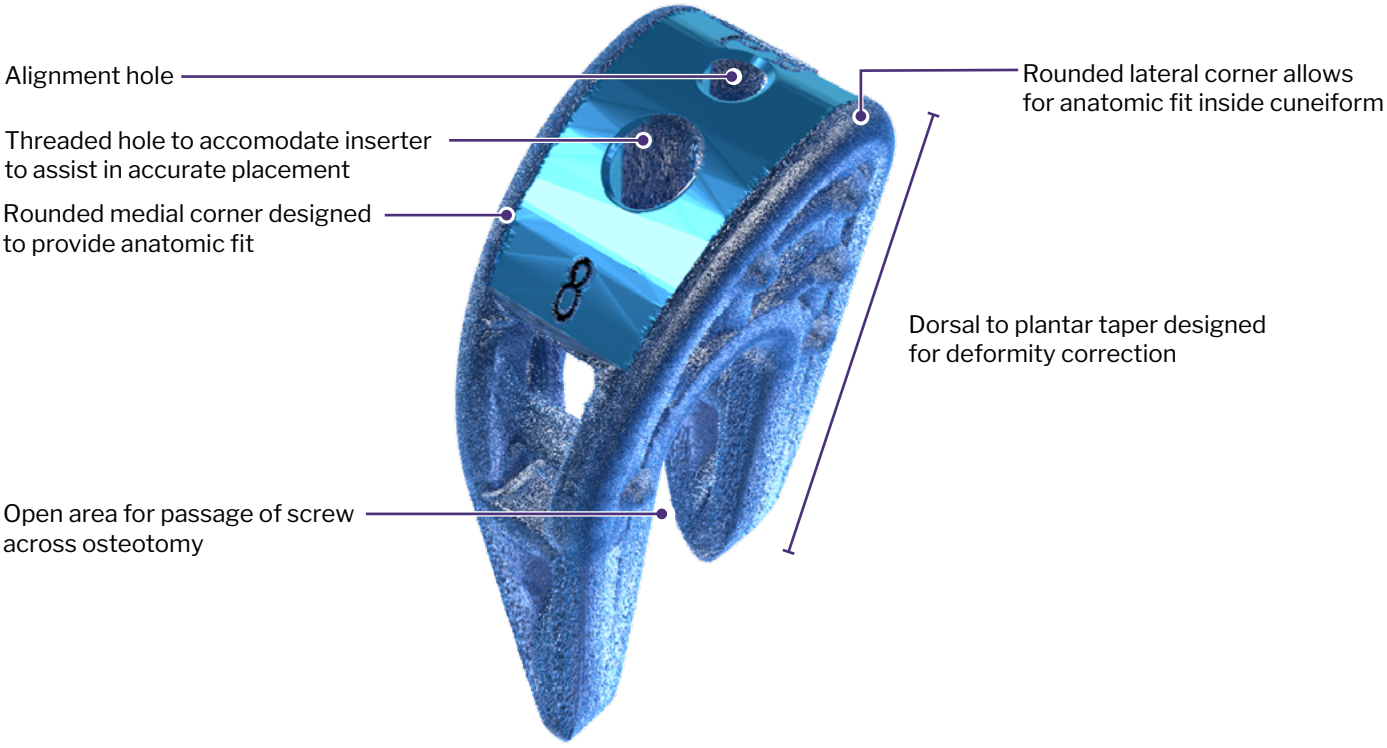
Titan 3-D Cotton wedge features

- 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

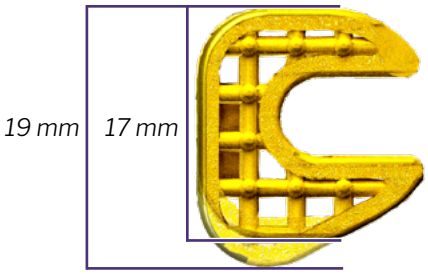


TITAN 3-D™ WEDGE FEATURES AND INSTRUMENTATION

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

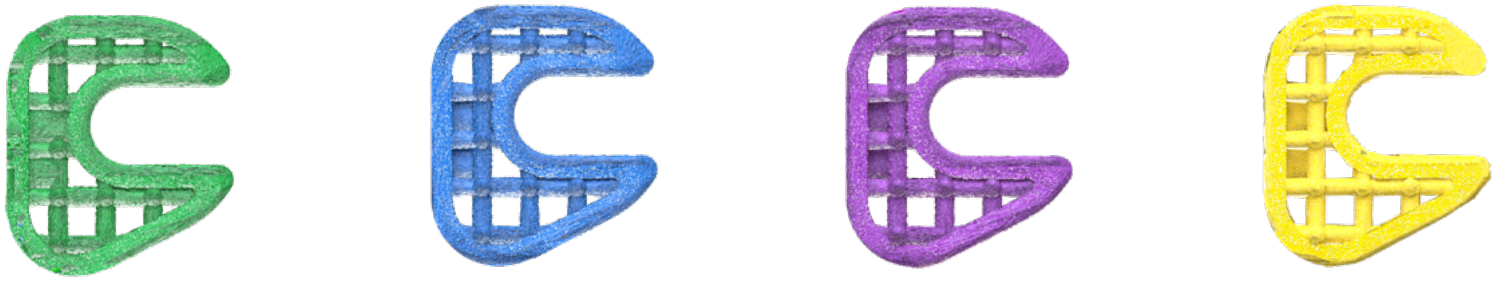
Evans Small Wedge overlay on Large Wedge



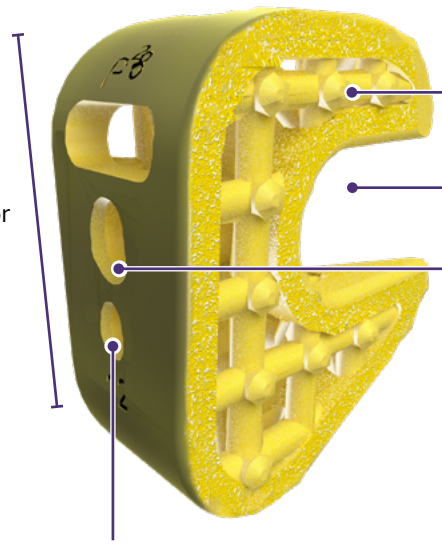
Evans Small Wedges

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

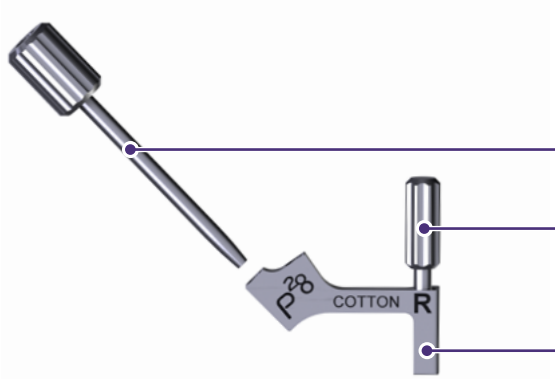
Threaded hole to accomodate inserter to assist in accurate placement

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

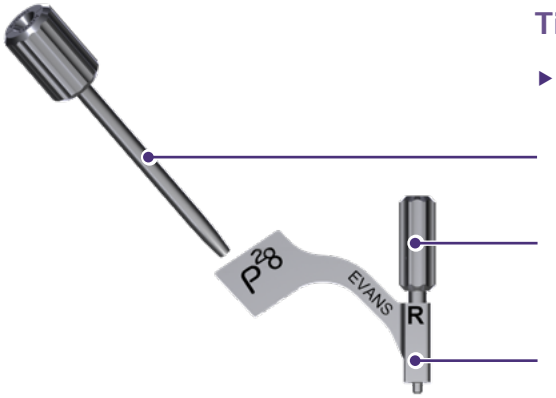
- Used to guide resection around the the wedge if removal or revision is necessary

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



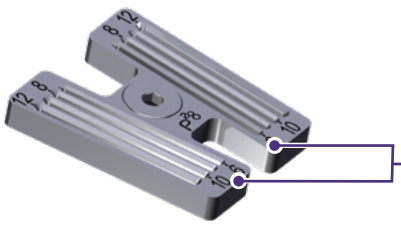
Titan 3-D Evans Precision Guide

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

K-Wire Guide

Set Screw

Precision Guide

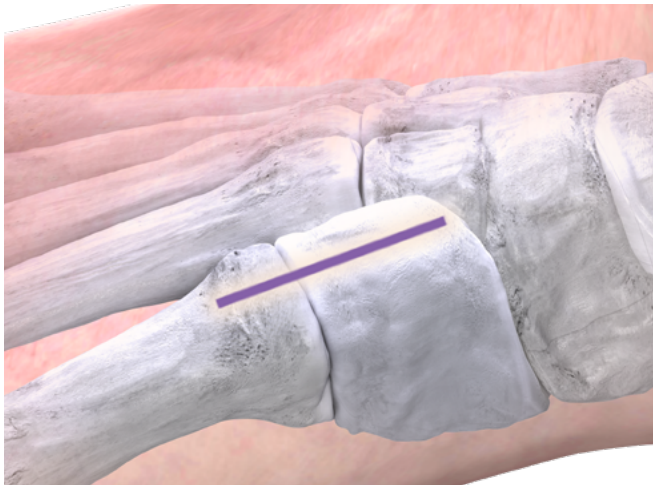


Titan 3-D Evans Resection Guide

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

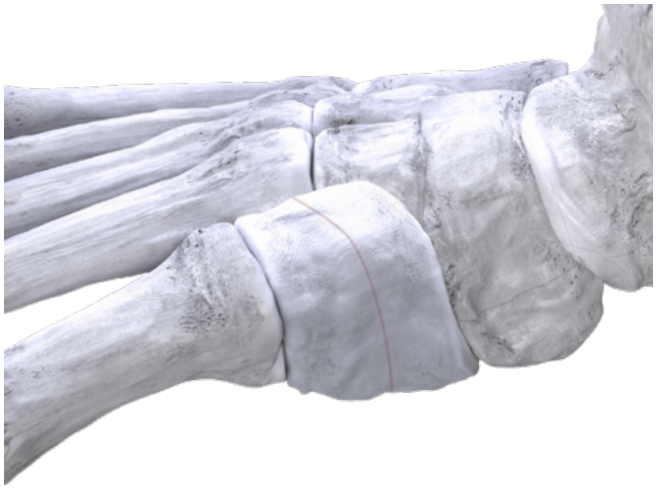
INCISION/EXPOSURE

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

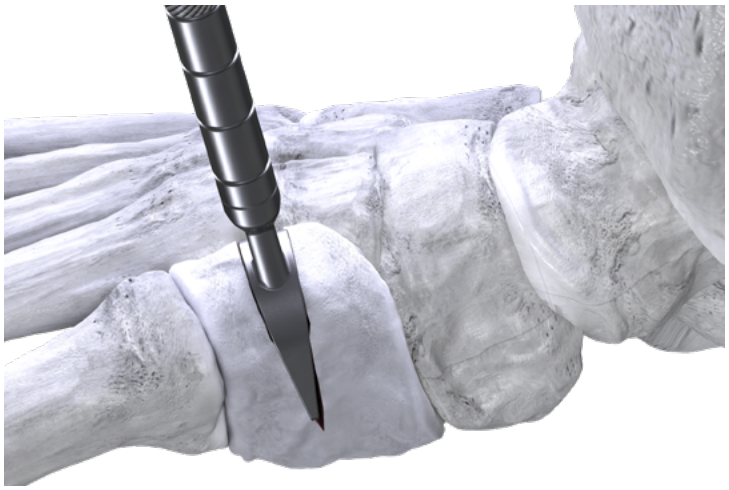
Perform an osteotomy at the central aspect of the medial cuneiform down to, but not through, the plantar cortex of the cuneiform.



DEFORMITY CORRECTION

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

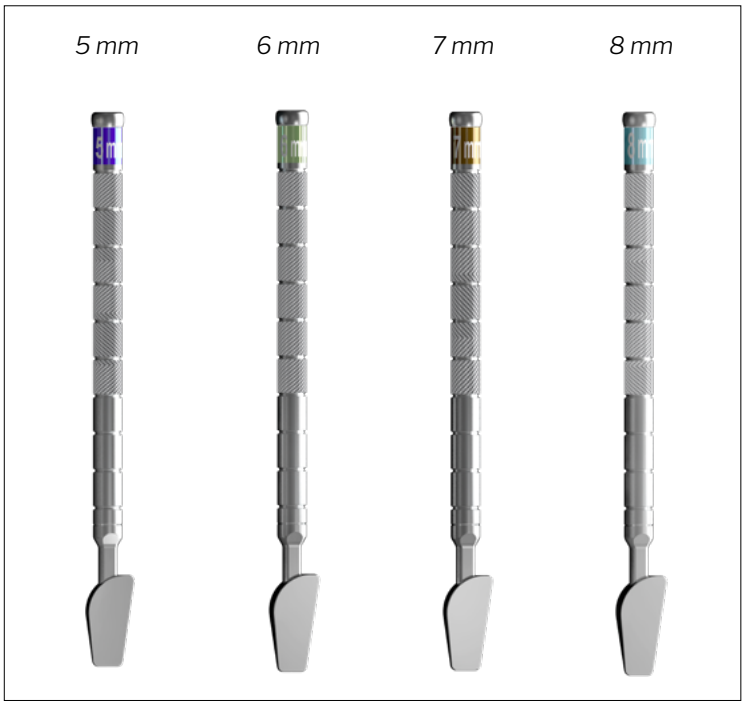
DEFORMITY CORRECTION



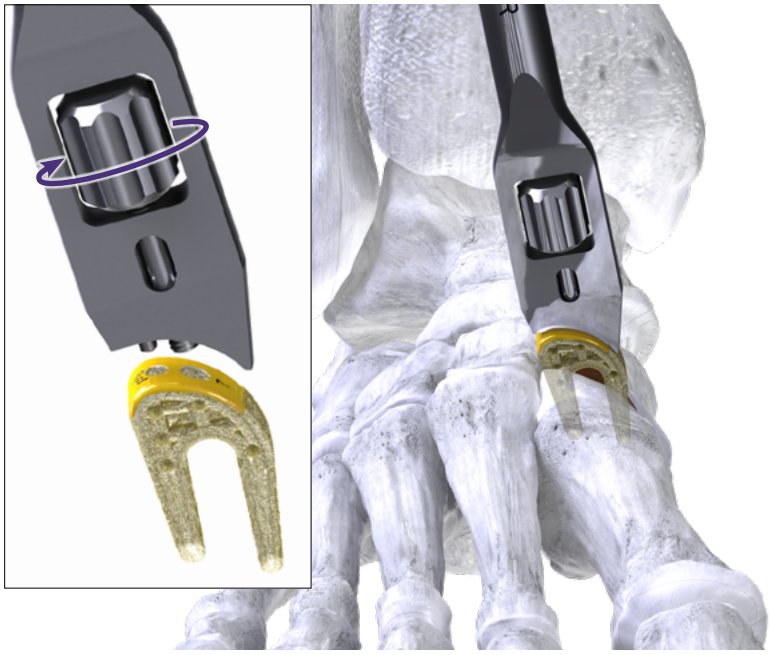
Use the provided trial sizers to determine the wedge size that best approximates the intended correction. Place the trial into the osteotomy site. If more correction is necessary, go up a trial size.
If less correction is desired, go down a trial size.

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.

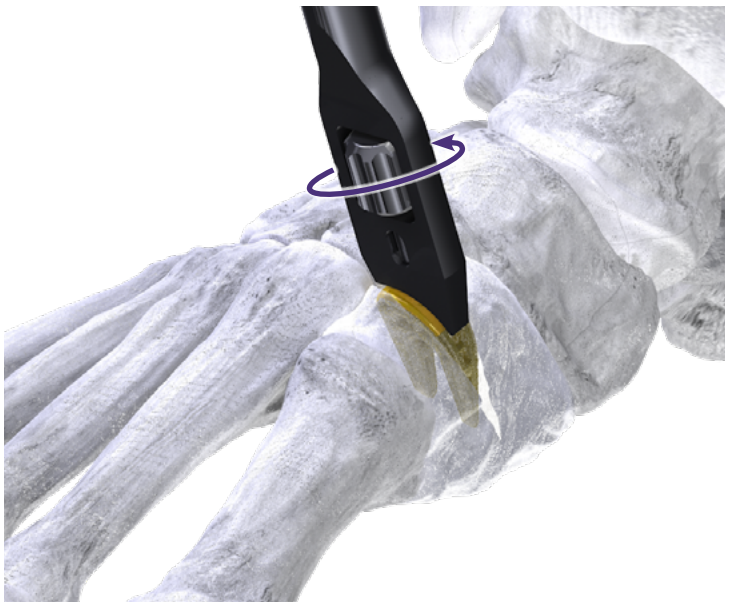


Once the appropriate amount of 1st ray plantarflexion is determined using the trial sizers, select the TITAN 3-D Cotton Wedge that corresponds to the trial sizer that provided the desired amount of correction. Retrieve the appropriate sterile packed TITAN 3-D Cotton Wedge. Attach the TITAN 3-D Cotton 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.



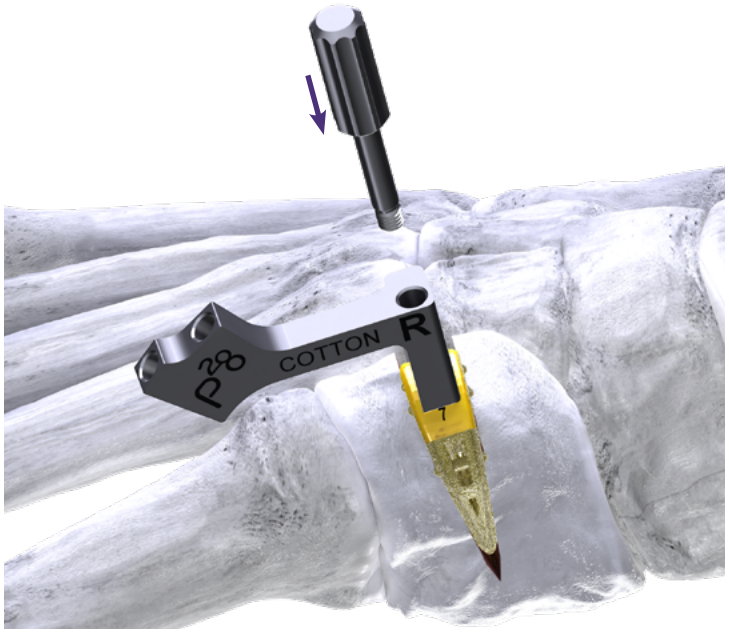
Distract the osteotomy according to surgeon preference and place the TITAN 3-D Cotton wedge in the osteotomy site using the inserter. The back of the inserter can be tapped with a mallet to further advance the TITAN 3-D Cotton Wedge into the osteotomy.

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

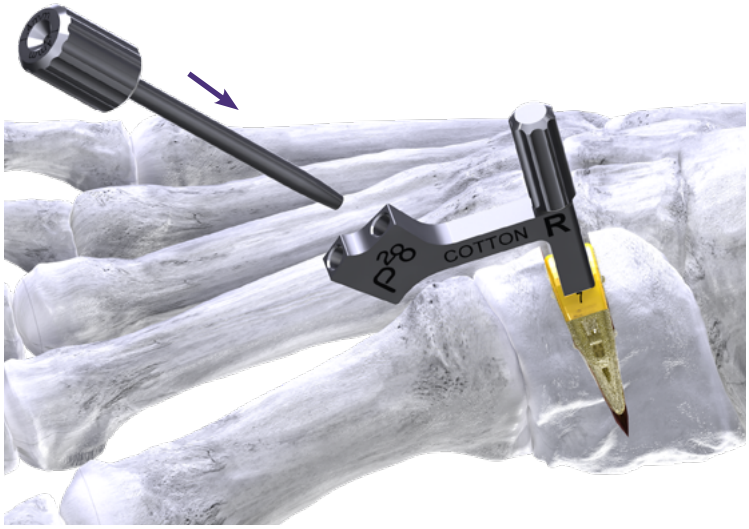


After the TITAN 3-D Cotton Wedge implant is placed, secure the Precision Guide to the implant by placing the peg of the Precision Guide into the alignment hole on the wedge.

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

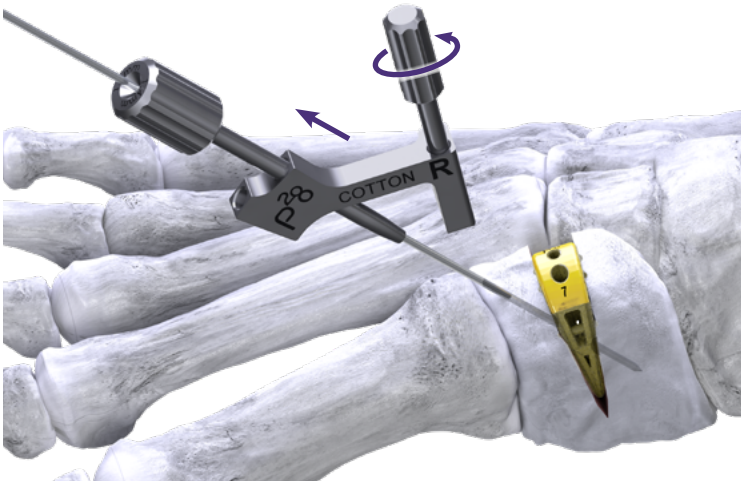
The TITAN 3-D Cotton Precision Guide can be used to guide the trajectory of a cannulated screw such that the screw does not collide with the implant.



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.*

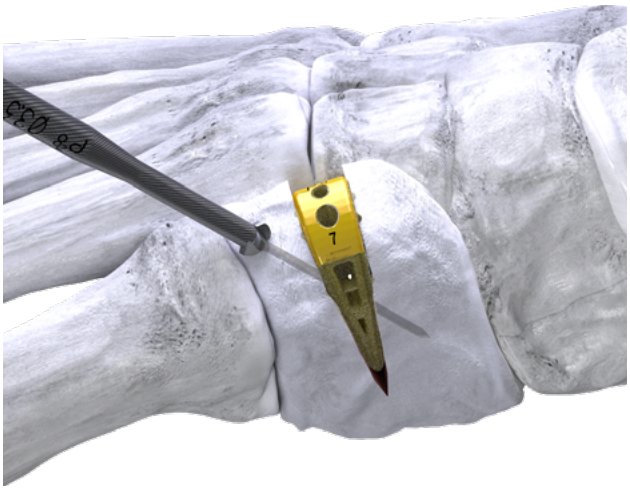
Place a guide wire sized for the cannulated screw to be used through the guide and into the bone. Confirm wire placement and insertion depth using fluoroscopy.

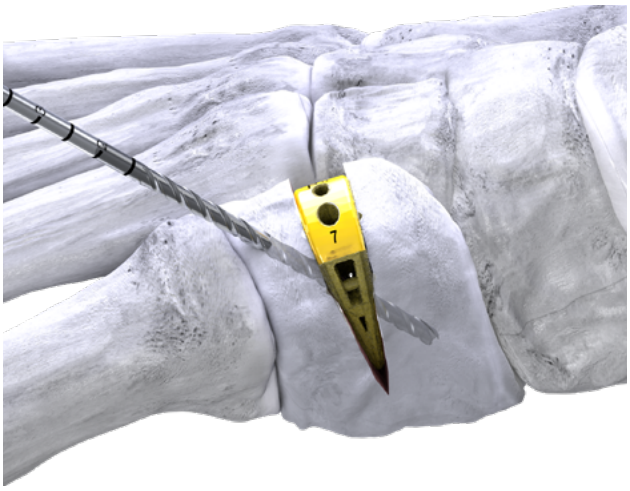


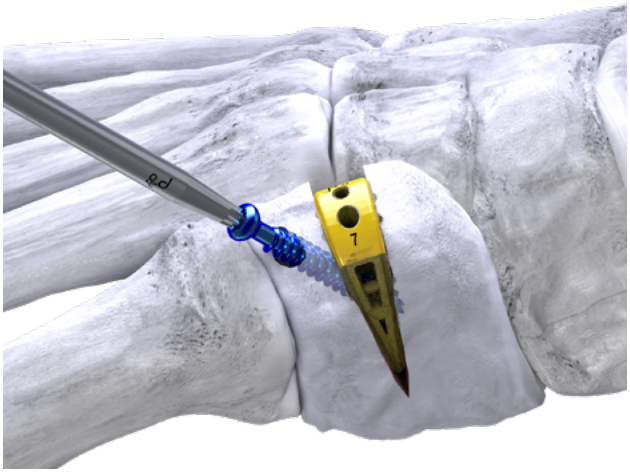
Once the guide wire position is confirmed, remove the Precision Guide from the implant by turning the Set Screw counterclockwise and sliding the Precision Guide off of the guide wire.

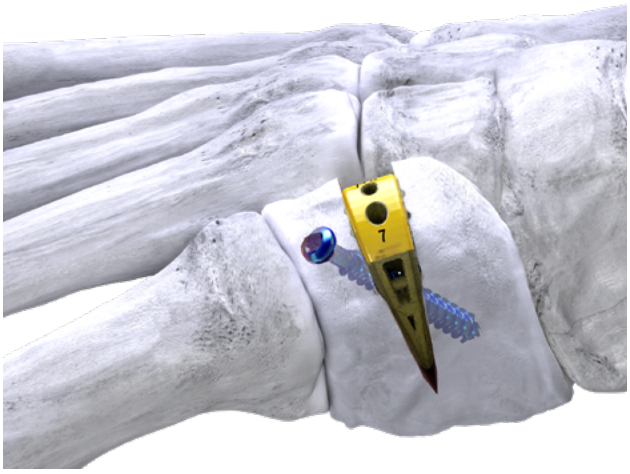
PLATE SELECTION AND FIXATION

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

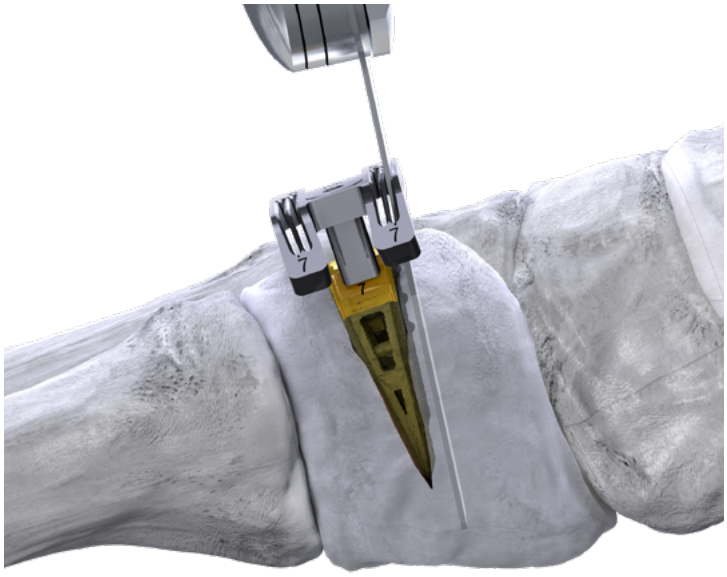








REVISION/REMOVAL OF A TITAN 3-D COTTON WEDGE IMPLANT



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.

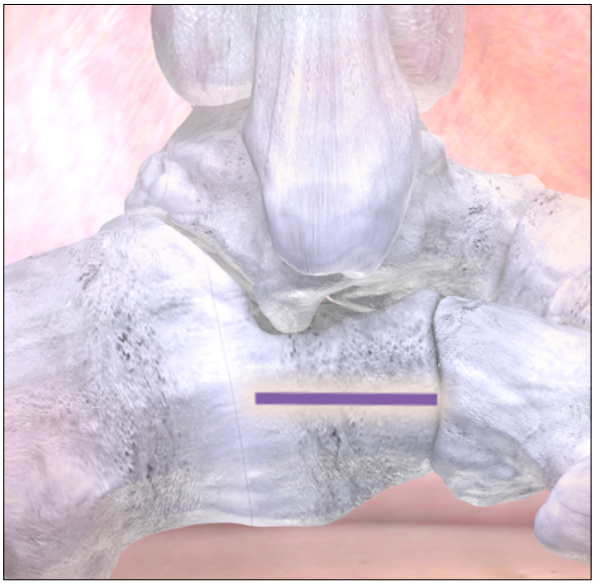
TIP: *One resection guide is used for 6 mm and 8 mm implants and one is used for 5 mm and 7 mm implants.*

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.

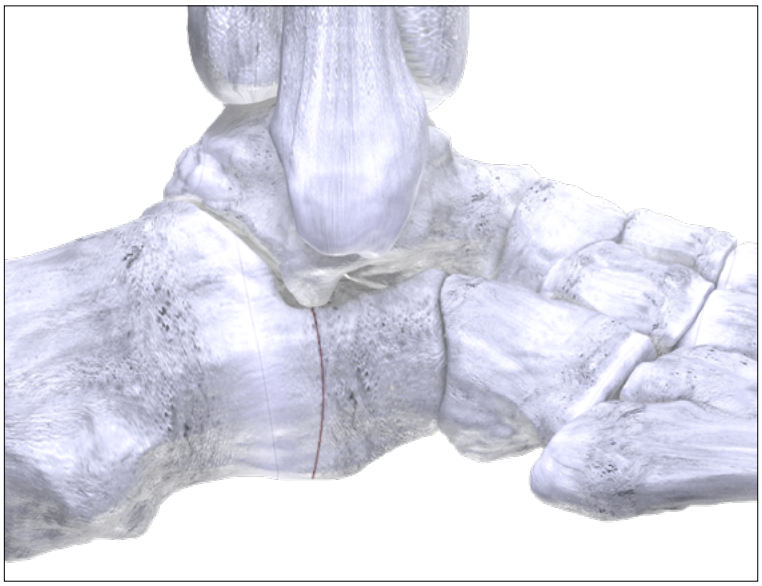
NOTE: The bone void remaining following resection is typically 2 mm larger than the size of the implant placed.

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.



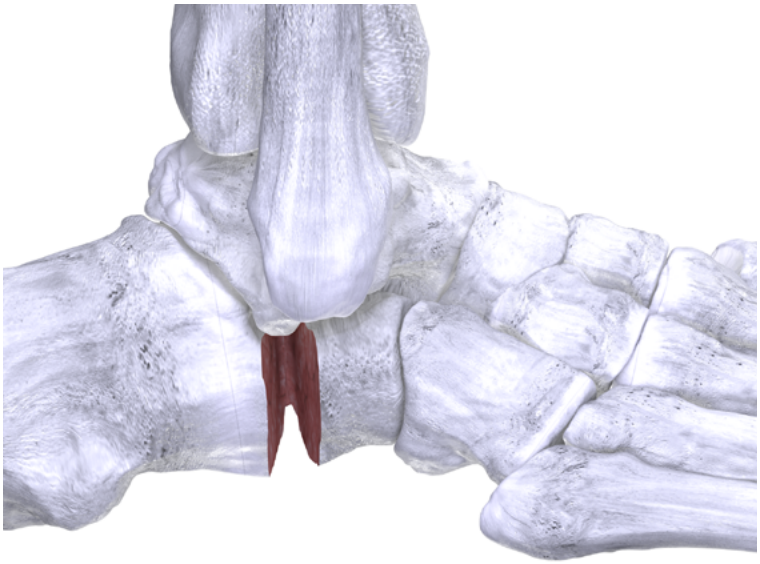
CALCANEAL OSTEOTOMY



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

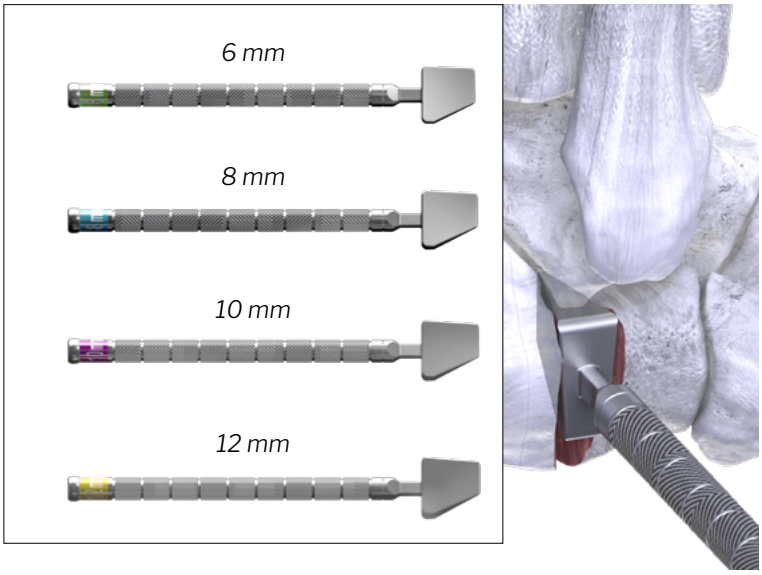
Optional: A K-wire can be placed across the calcaneocuboid joint to reduce dorsal dislocation of the distal fragment of the calcaneus during osteotomy distraction.

DEFORMITY CORRECTION



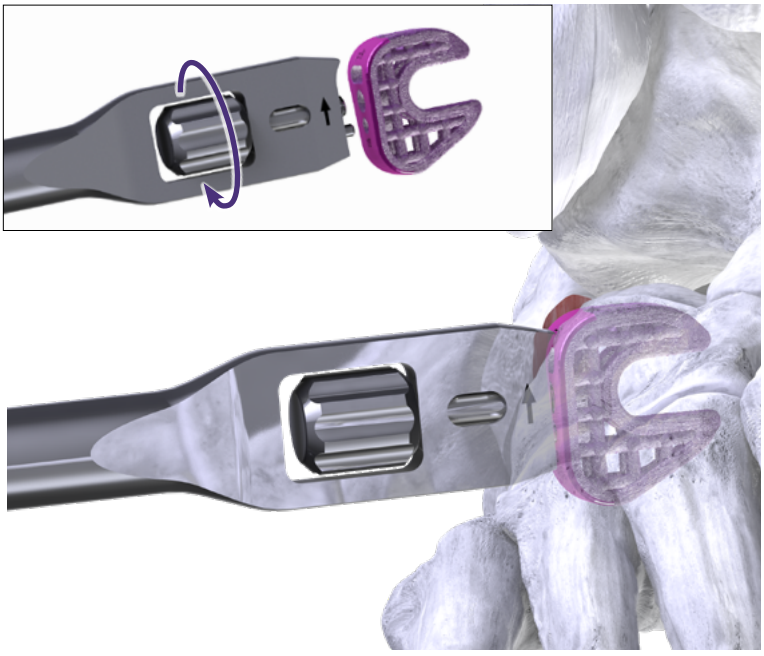
Distract the osteotomy according to surgeon preference. It is recommended to open the osteotomy and visualize lengthening of the lateral column.

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.

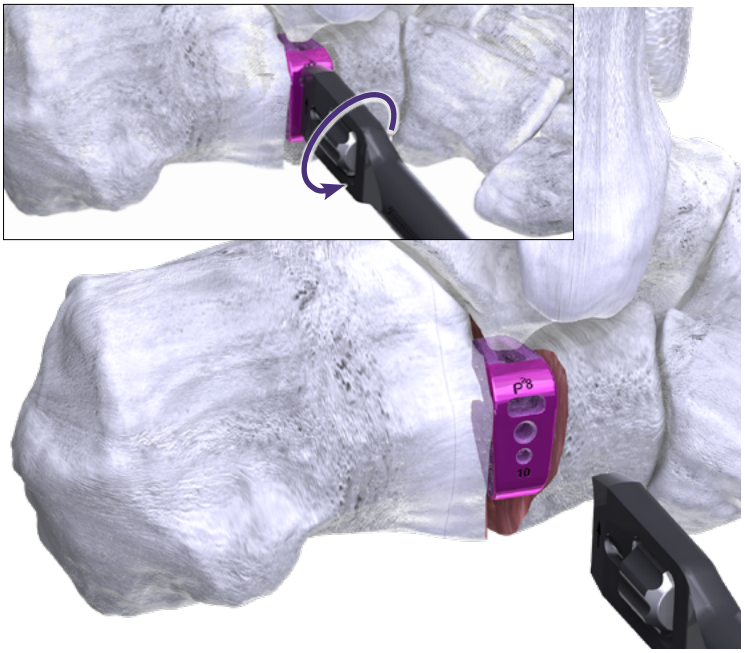
NOTE: Trial sizers are available to match the correction amount of the available TITAN 3-D Evans Wedges: 6 mm, 8 mm, 10 mm, and 12 mm.



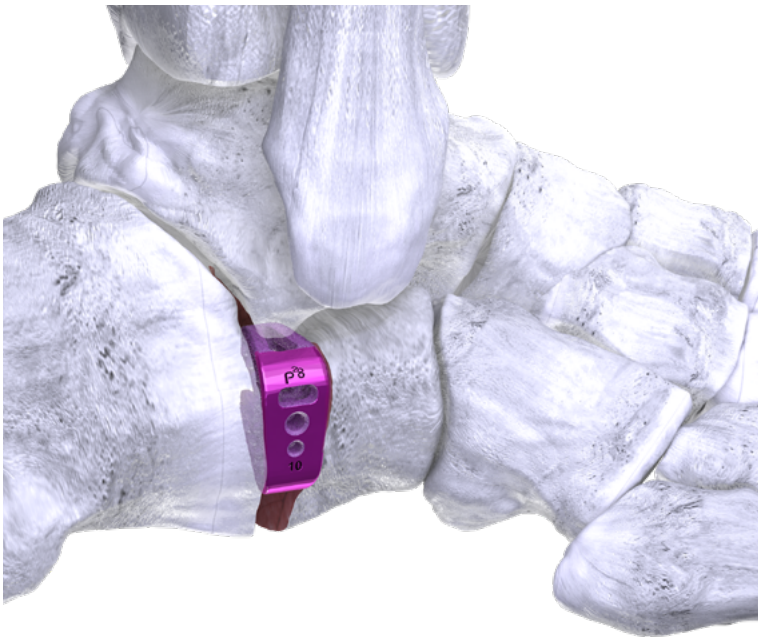
Once the appropriate amount of lateral column lengthening is determined using the trial sizers, select the TITAN 3-D Evans Wedge that corresponds to the trial sizer that provided the desired amount of correction. Retrieve the appropriate sterile packed TITAN 3-D Evans Wedge. Attach the TITAN 3-D Evans 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

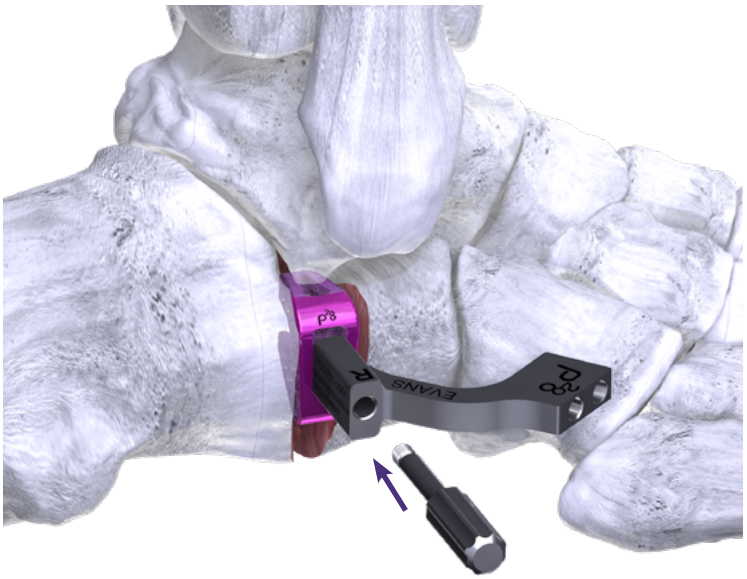


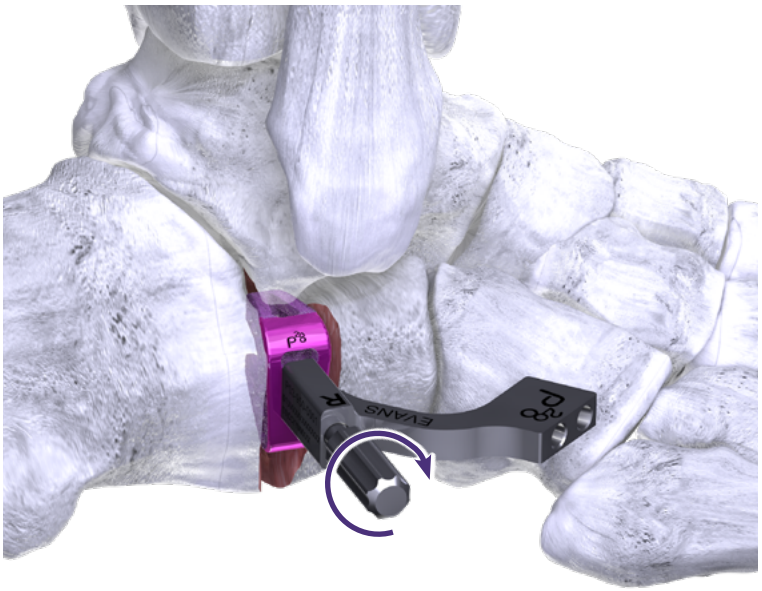
After placing the wedge in proper position, detach the TITAN 3-D Evans Wedge from the inserter by rotating the screw counterclockwise and removing the inserter.



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

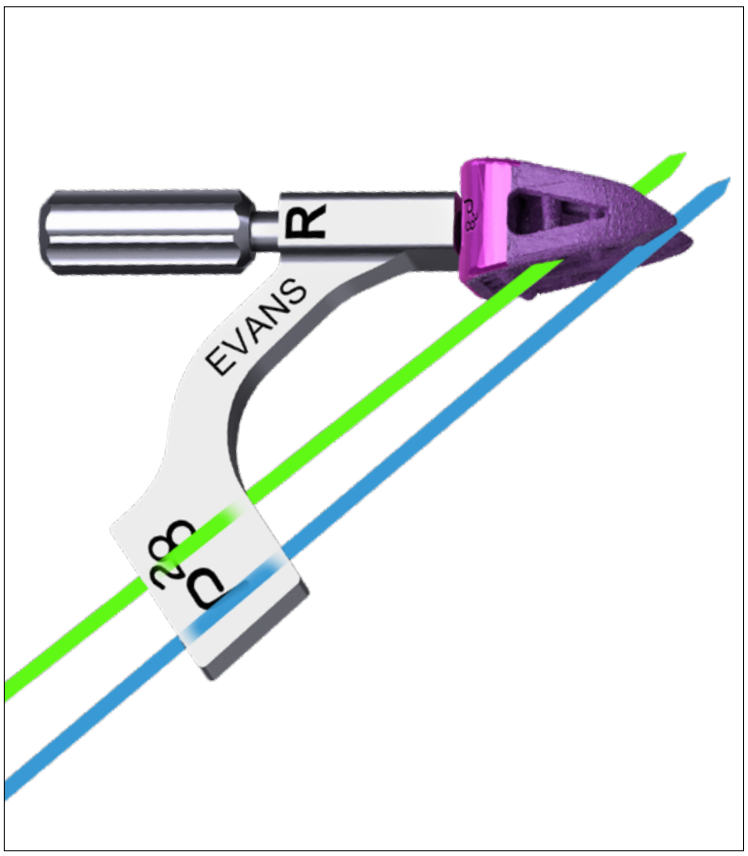
ANCILLARY FIXATION



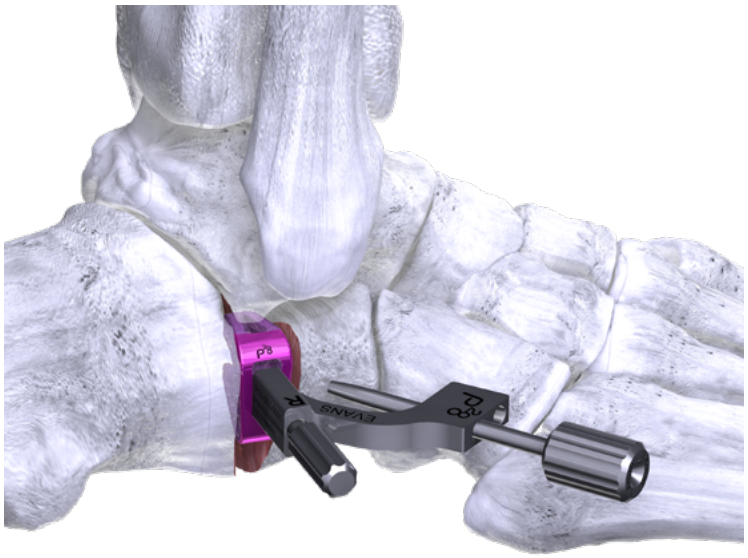


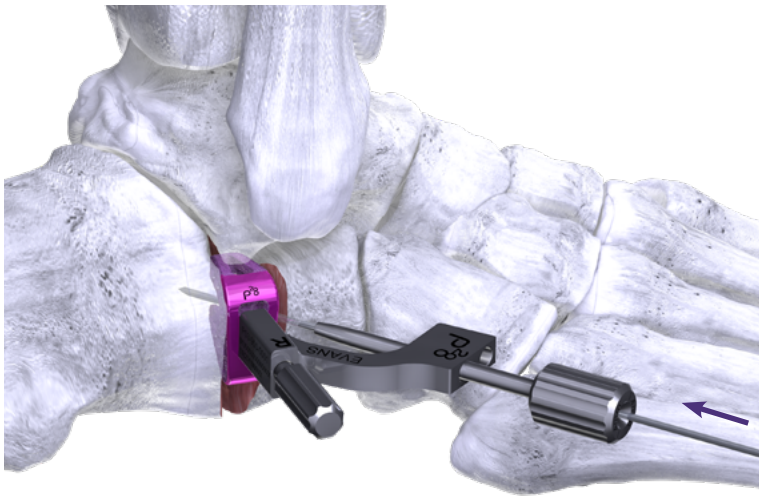
The TITAN 3-D Evans Precision Guide can be used to guide the trajectory of a cannulated screw placement such that the screw does not collide with the implant.
After the TITAN 3-D Evans Wedge implant is placed, secure the Precision Guide to the implant by placing the peg of the Precision Guide into the 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.



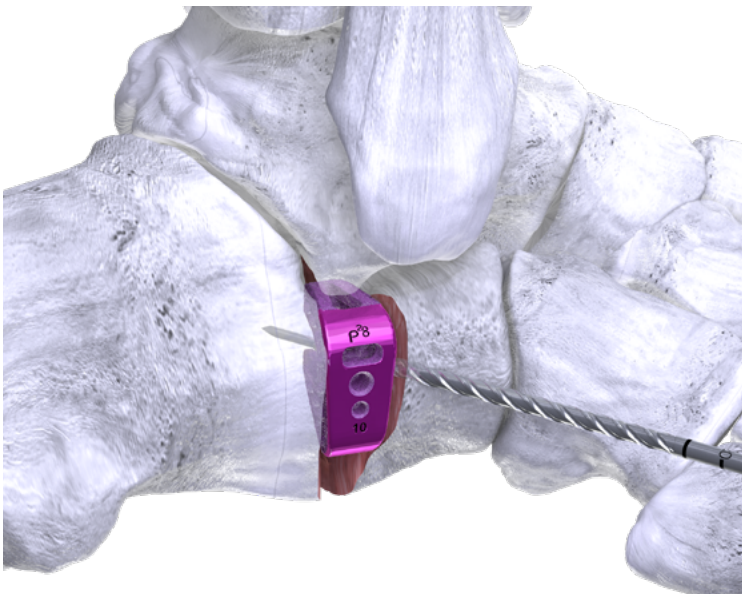


Place a guide wire sized for the cannulated screw to be used through the guide and into the bone. Confirm wire length and position using fluoroscopy.

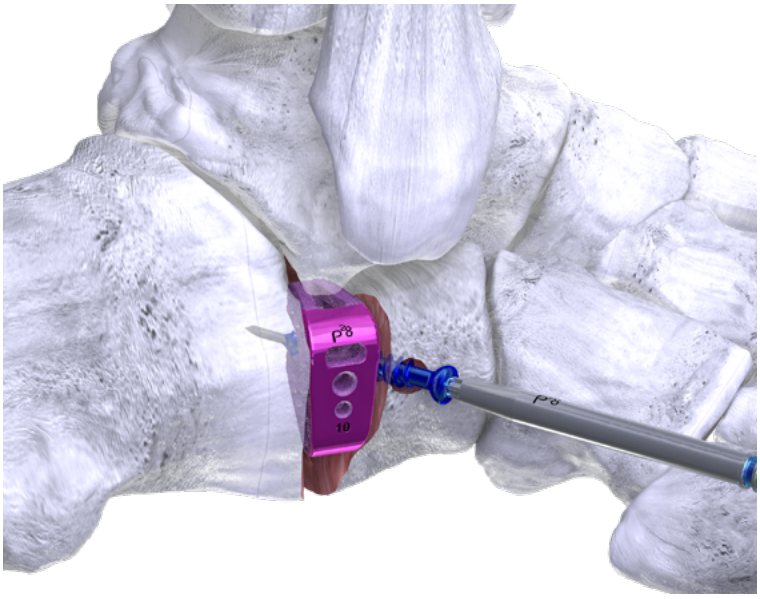
TIP: *The opening width on the TITAN 3-D Evans Wedge between the two legs is sized to accommodate a 3.5 mm or 4.0 mm cannulated Mini-Monster® Screw. A fully threaded screw is recommended in order to help maintain length of the osteotomy.*

ANCILLARY FIXATION

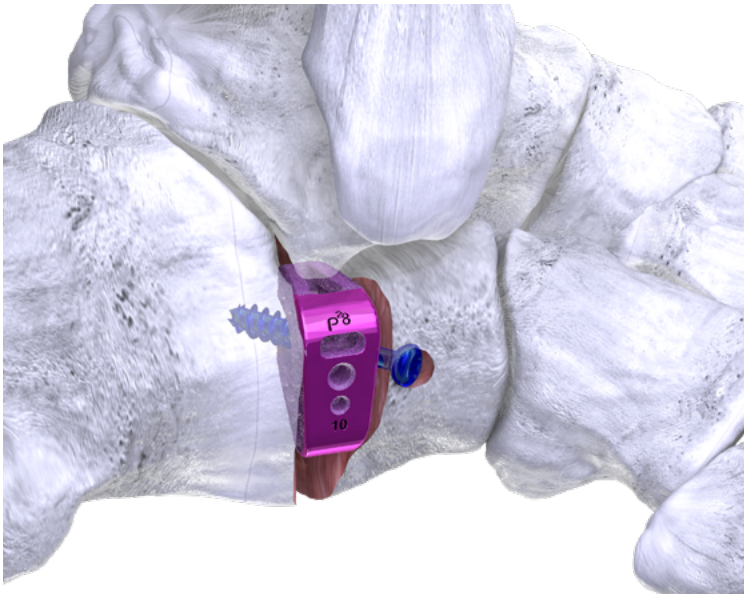
Once the wire is placed, remove the Precision Guide from the implant by loosening the screw and sliding the Precision Guide off of the guide wire.



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



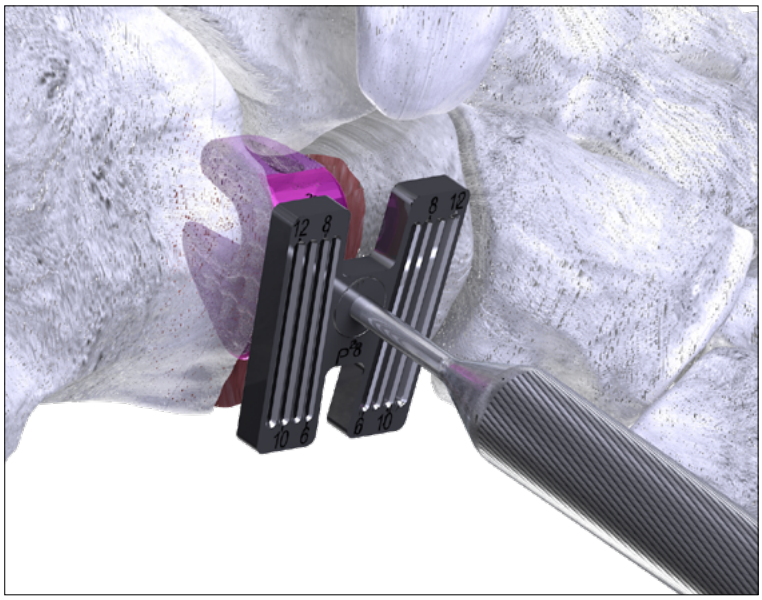
Place the appropriately sized cannulated screw over the guide wire.



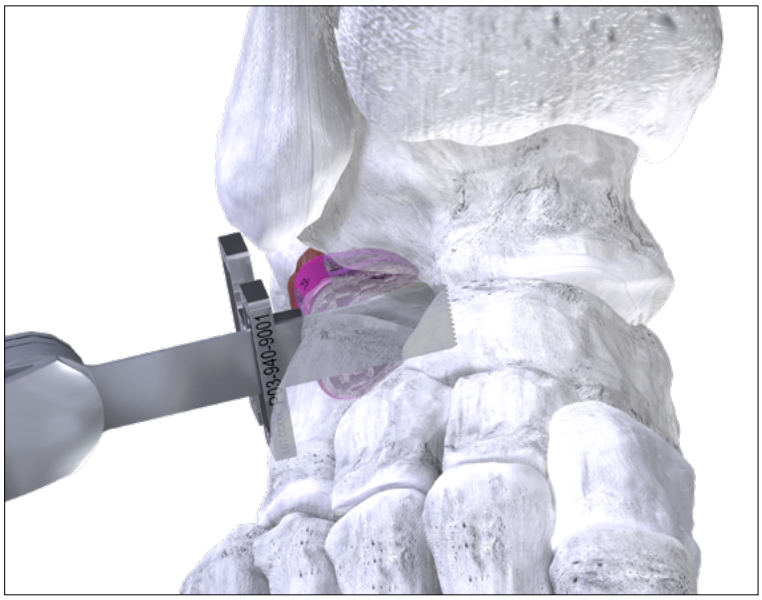
Confirm appropriate placement of the ancillary fixation.

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.

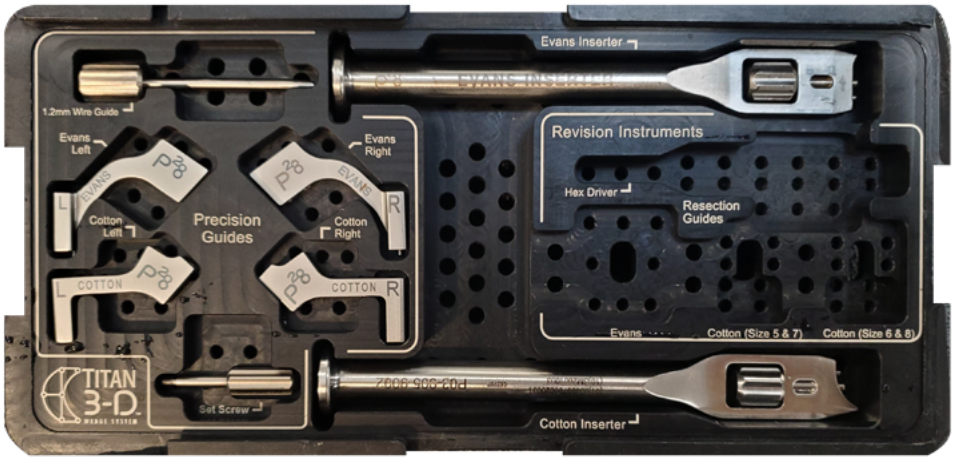
After completing the cuts, remove the resection guide and implant together or detach the resection guide from the implant and use the inserter and a mallet to tap the implant out.

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)

INSTRUCTIONS FOR USE: TITAN 3D™ WEDGE SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the TITAN 3-D™ Wedge system are contained in the Instructions for Use document of the TITAN 3D™ Wedge system P03-IFU-1001.

MR 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.

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

INSTRUCTIONS FOR USE: MONSTER® SCREW SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the TITAN 3D™ Wedge system are contained in the Instructions for Use document of the Monster® Screw system P20-IFU-1001.

MRI SAFETY INFORMATION

A person with the Paragon 28® Monster® Screw System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28® Monster® Screw System
Static Magnetic Field Strength [B0]	1.5 T or 3.0 T
Maximum Spatial Field Gradient	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	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 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 20 mm from the implant.

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

TITAN 3-D® WEDGE SYSTEM

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Exclusively foot & ankle Paragon 28®

P03-STG-1001 Rev F [2025-10-09]

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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.