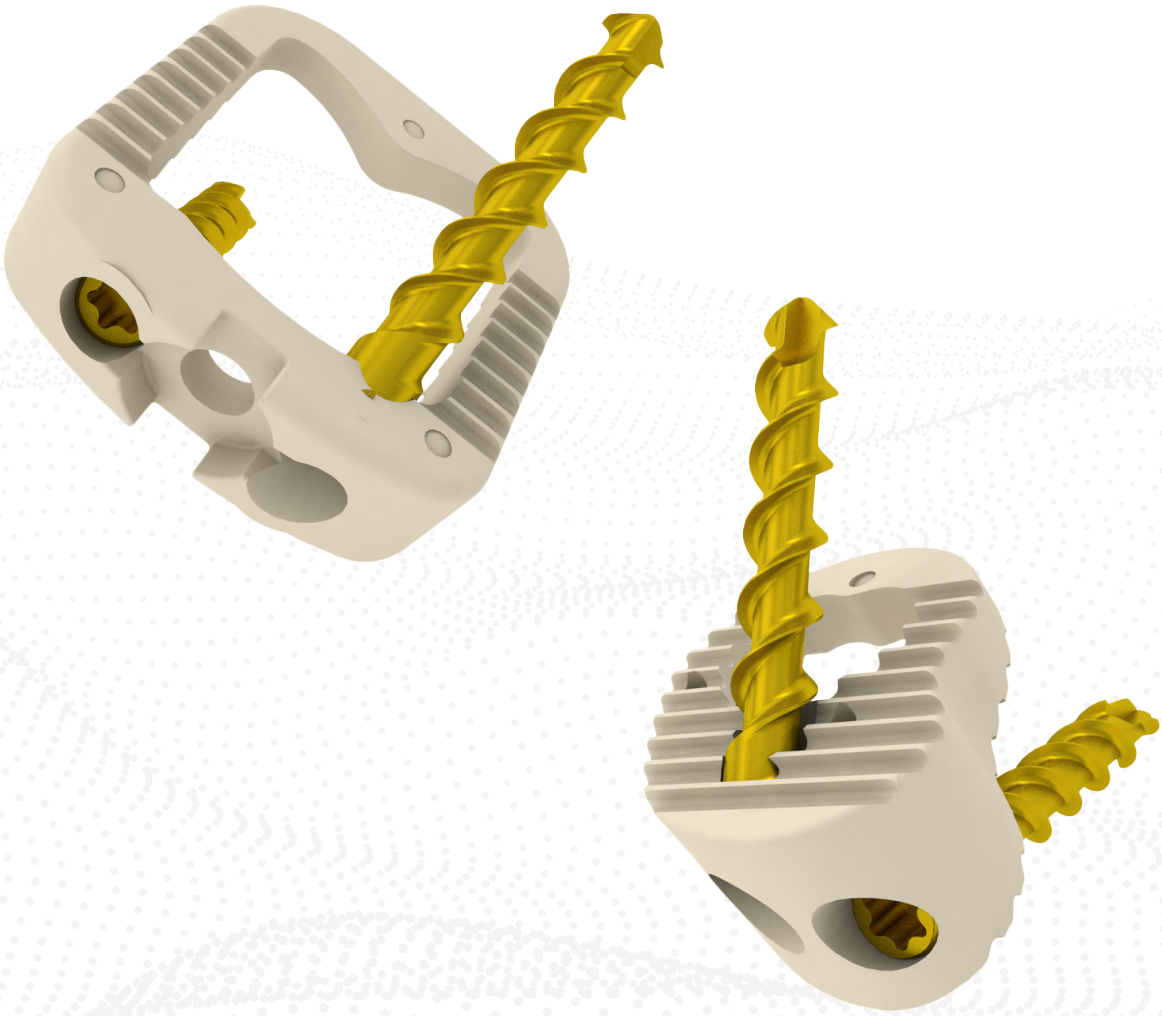
trigon®

OSTEOTOMY WEDGE SYSTEM

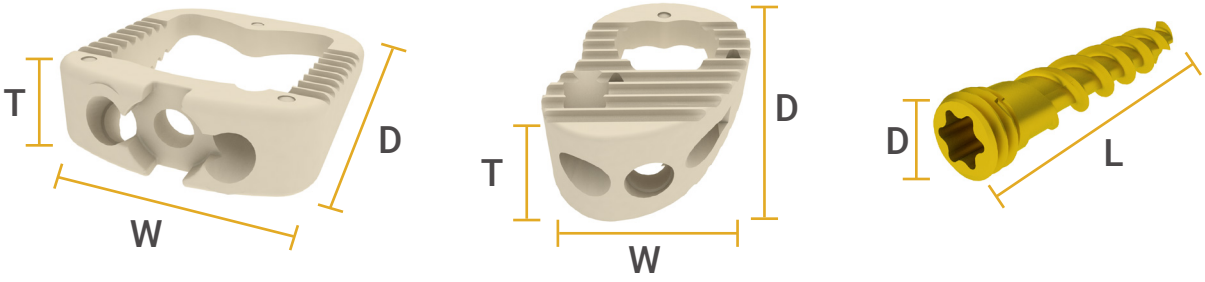
Surgical Technique Guide



NVision™
biomedical technologies

trigon®
OSTEOTOMY WEDGE SYSTEM

Legend



Product Sizes Available

Evans Footprints (WxD): 16x18, 18x20, 20x22
Evans Thickness: 6mm, 8mm, 10mm, 12mm

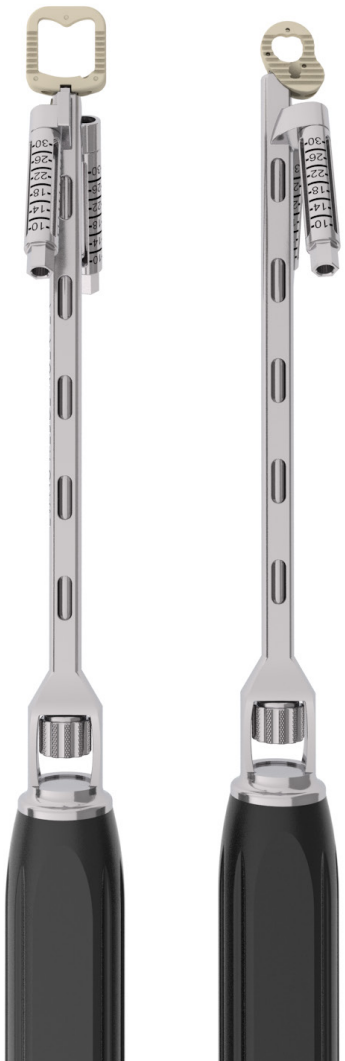
Cotton Footprints (WxD): 16x16, 18x20
Cotton Thickness: 6mm, 7mm, 8mm

2.5mm Diameter Screws: 10mm-30mm lengths in 2mm increments

The Trigon® HA Stand-Alone Wedge is made of PEEK-Optima® HA Enhanced, where the HA is fully integrated into the PEEK (not just coated) making it available on all surfaces of the implant.

The Trigon HA Stand-Alone Wedge is provided in two different configurations to be used for Evans and Cotton osteotomies in a variety of sizes to accommodate unpredictable anatomical circumstances providing a precise and reliable correction.

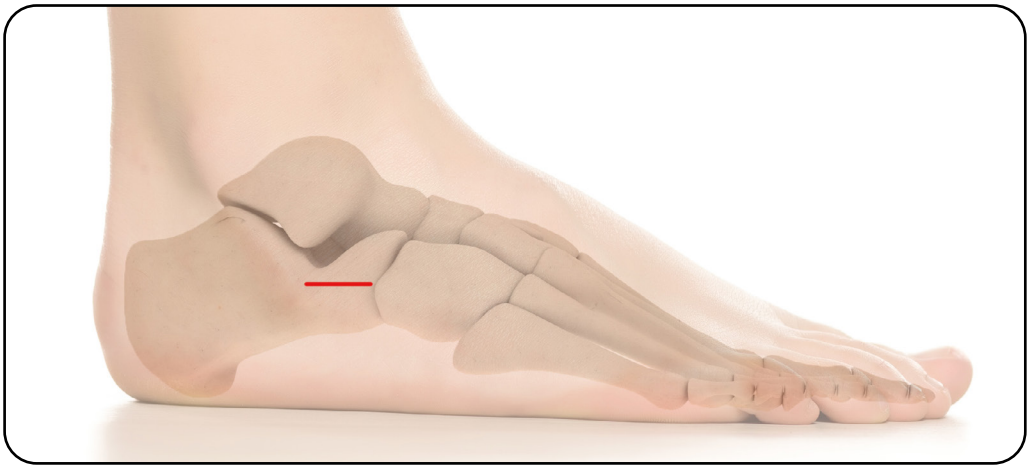
The Trigon HA Wedge is a stand-alone device, consisting of the wedge and screws, that does not require any additional fixation such as plating. Additionally, the Trigon HA Stand–Alone Wedge Fixation System offers ergonomic instrumentation that allows for accurate insertion and precise screw placement.



Evans Osteotomy Surgical Technique

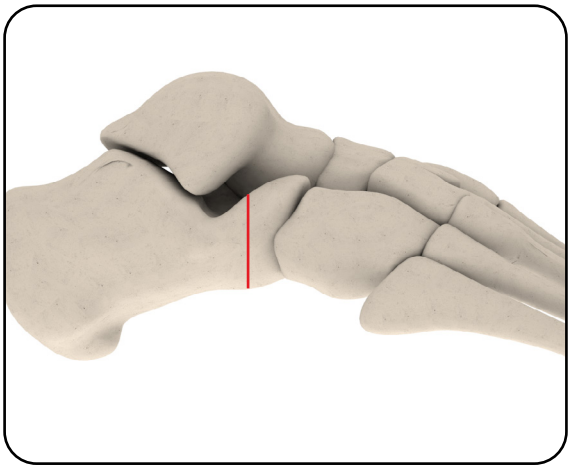
Step 1 - Site Preparation

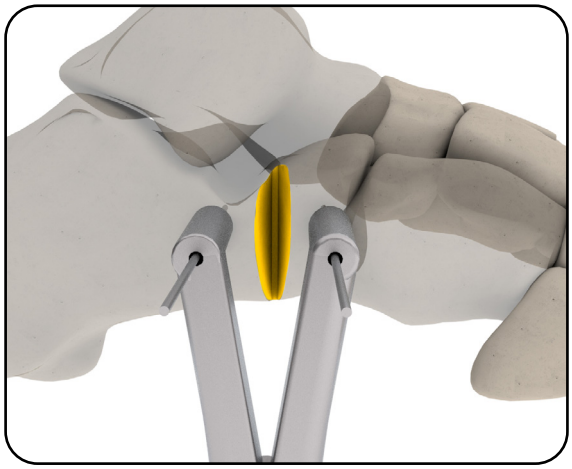
Make a 2-3cm longitudinal incision lateral to the calcaneocuboid joint and retract soft tissue as necessary to expose the desired osteotomy site.



Step 2 - Osteotomy/Distraction

Use a sagittal saw to perform an Evans osteotomy approximately 1-1.5cm proximal to the calcaneocuboid joint. Avoid compromising the medial calcaneal cortex. Use lamina spreaders or hintermann distractors to distract the osteotomy site.

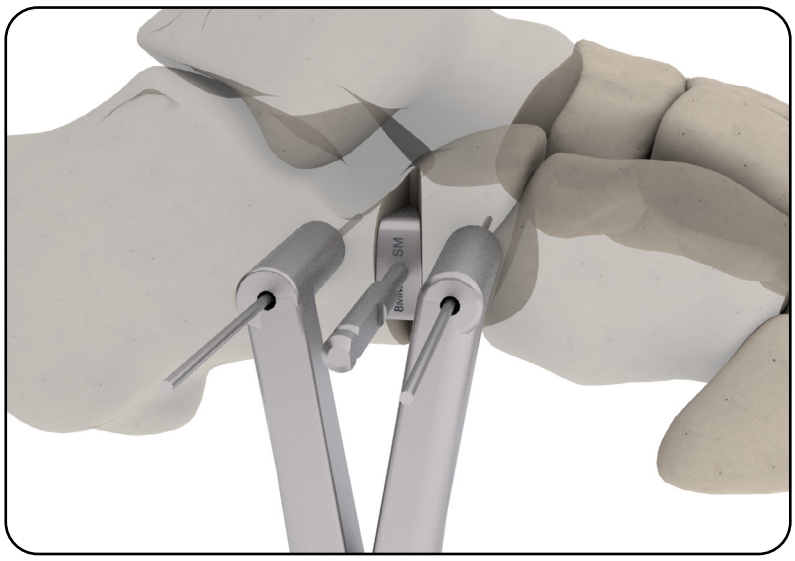




*If needed, use a k-wire to fixate calcaneocuboid joint to prevent subluxation during distraction

Step 3 - Trial/Implant Selection

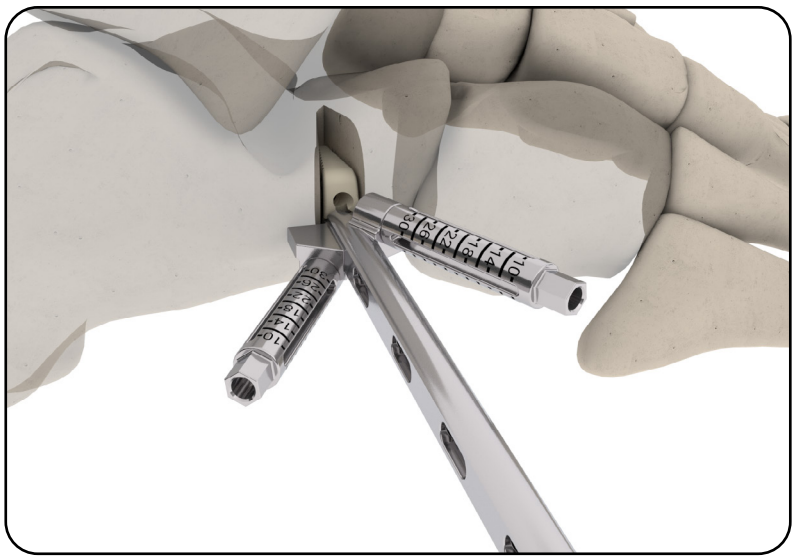
Use the trials provided to determine the appropriate size implant. Start with smaller trials and increase the trial footprint and thickness as needed to achieve the desired correction. Use fluoroscopy to confirm.



Step 4 - Implant Insertion/Fixation

A. Implant Insertion

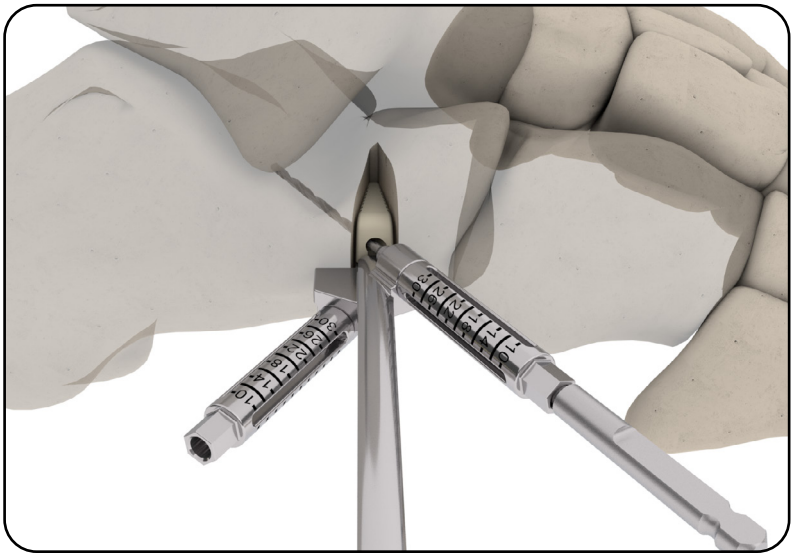
Use the Evans Wedge Inserter to insert the selected implant in the osteotomy site until the implant is subflush and/or the inserter reaches the stop. Fluoroscopy can be used to confirm desired correction of deformity is achieved once implant is in place.

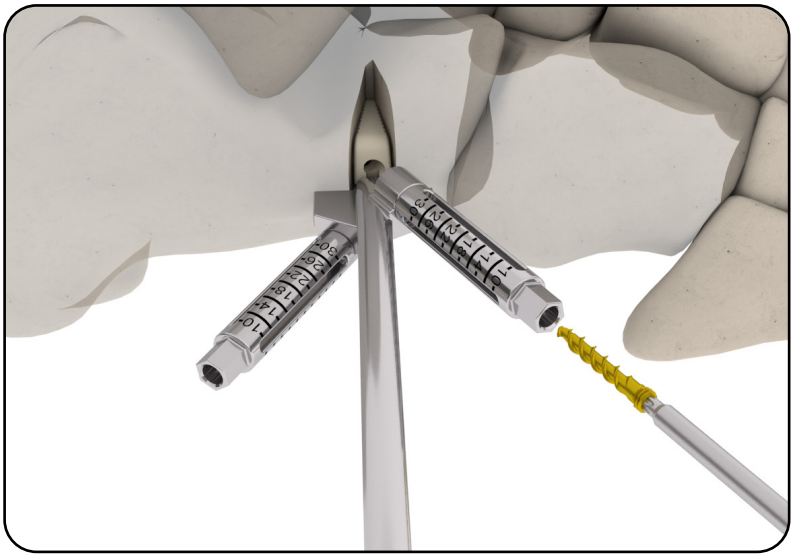


Note: A graft packing block and tamp are available to insert bone graft into the implant's graft window before insertion

B. Drill/Screw

Keeping the wedge in position, drill through the wedge inserter tower and refer to the depth indicator lines to determine screw length. Then advance the appropriate size screw until the screw inserter reaches the stop on the wedge tower to ensure screws are positioned subflush of the implant. Repeat the same step for the remaining screw.

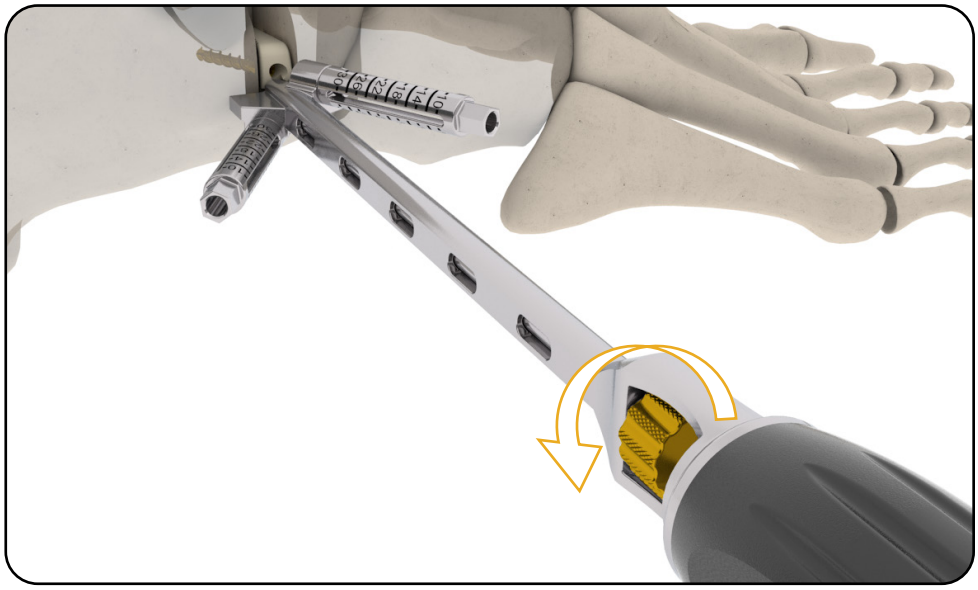


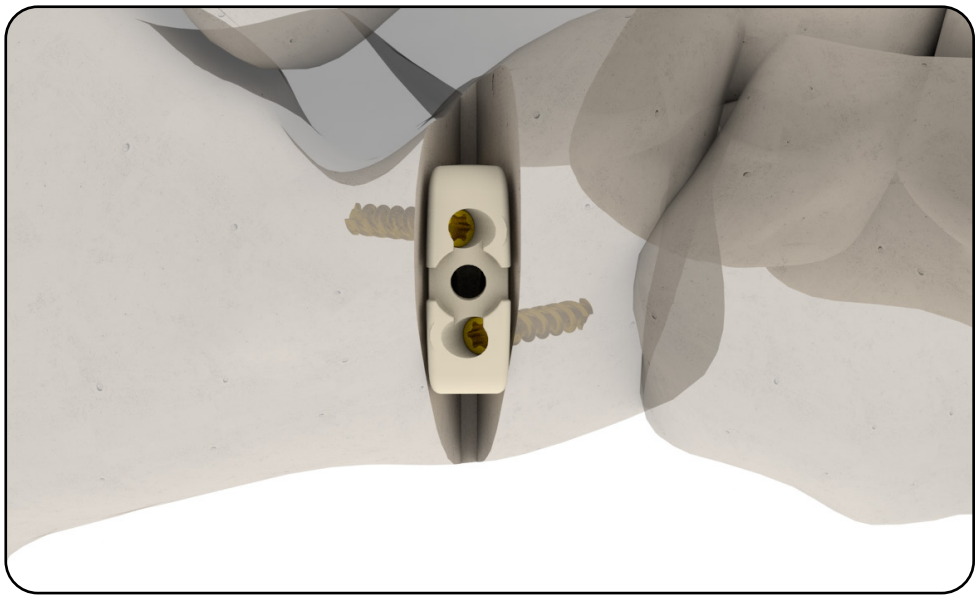


Note: In case of loss in screw engagement, the wedge inserter towers may be removed to finish screw insertion. Screws should be inserted until they are just subflush of the implant, over-insertion could cause loss of engagement between the screw and the wedge.

C. Inserter Disengagement

Turn the distal knob counterclockwise to disengage the inserter from the implant. If needed, further drive the screws until they are subflush with the implant.

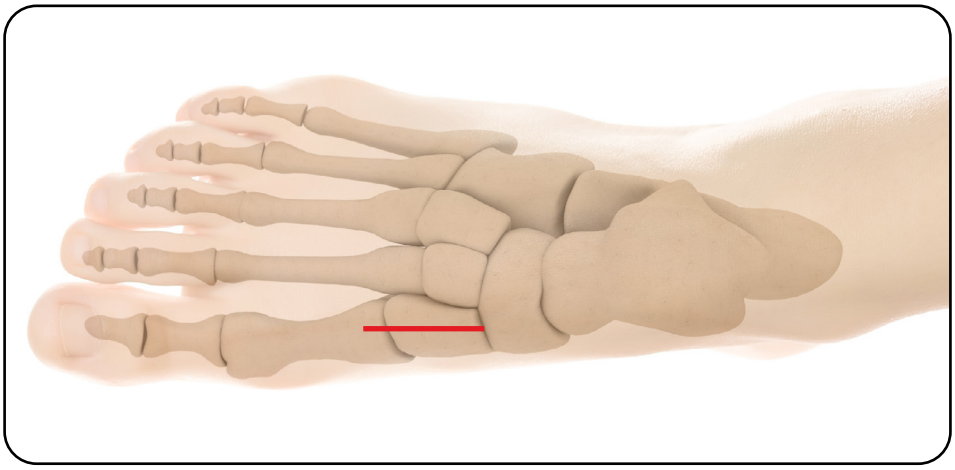




Cotton Osteotomy Surgical Technique

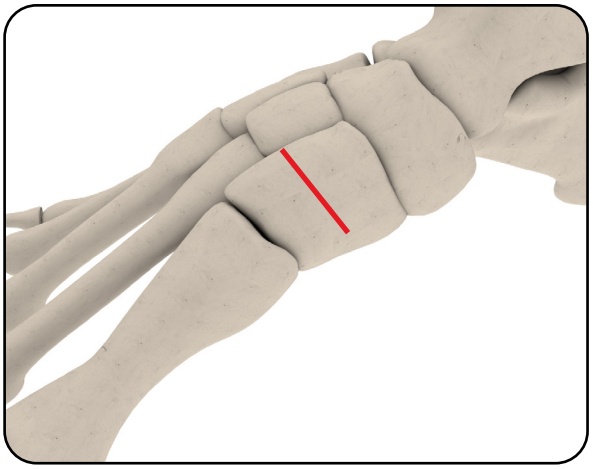
Step 1 - Site Preparation

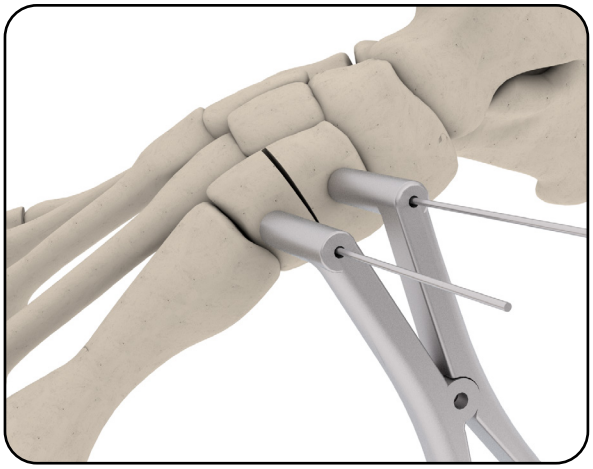
Make a dorsal, longitudinal incision over the medial cuneiform and base of first metatarsal and retract soft tissue as necessary to expose the medial cuneiform.



Step 2 - Osteotomy/Distraction

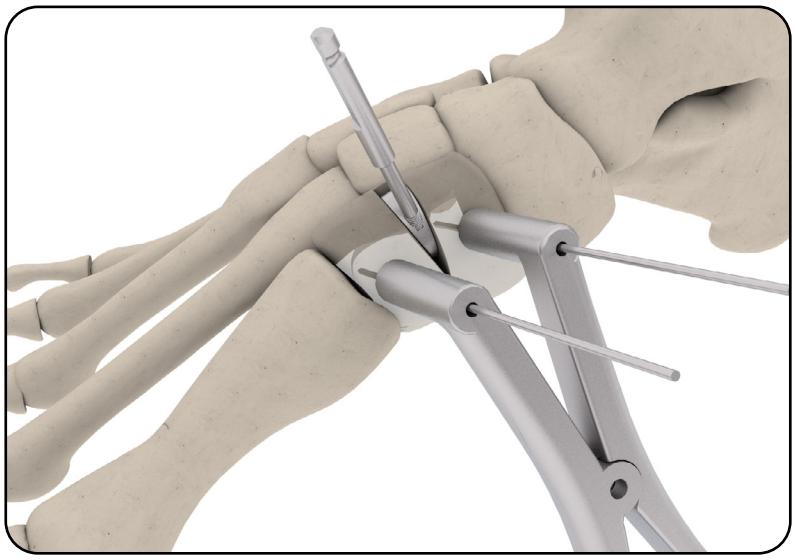
Use a sagittal saw to perform a Cotton osteotomy in the central aspect of the medial cuneiform. Avoid compromising the plantar cortex. Use lamina spreaders or hintermann distractors to distract the osteotomy site.





Step 3 - Implant Insertion

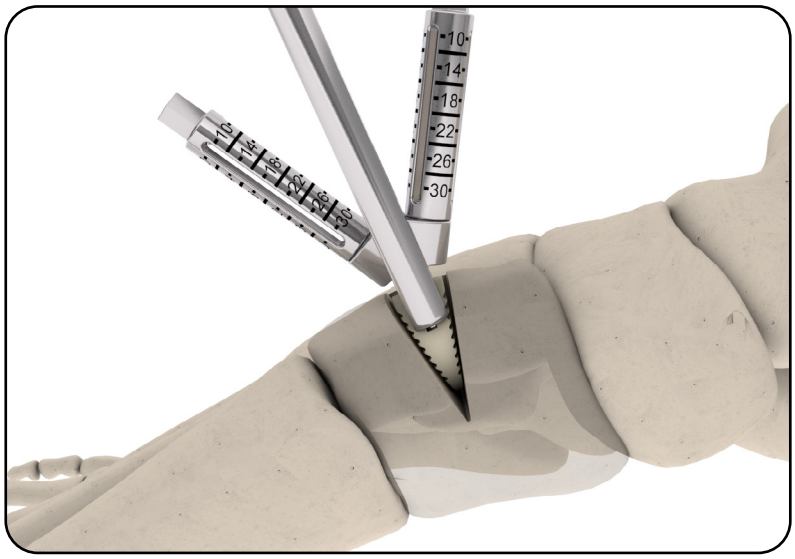
Use the trials provided to determine the appropriate size implant. Start with smaller trials and increase the trial footprint and thickness as needed to achieve the desired correction. Use fluoroscopy to confirm.



Step 4 - Implant Insertion/Fixation

A. Implant Insertion

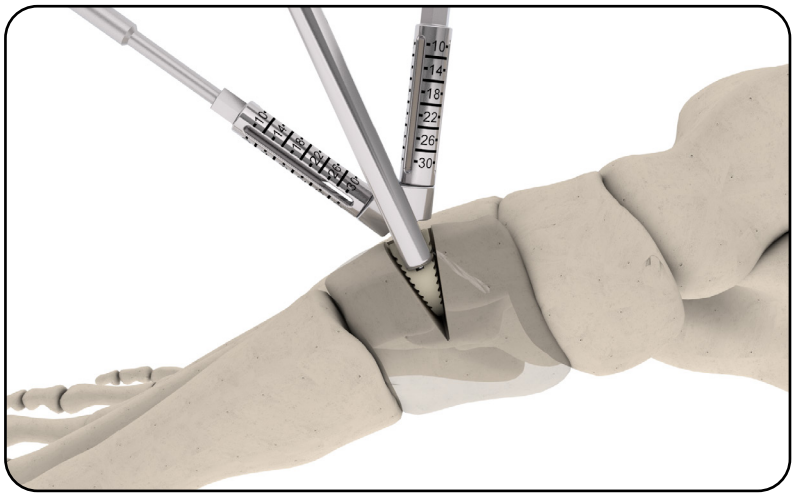
Use the Cotton Wedge Inserter to insert the selected implant in the osteotomy site until the implant is subflush. Fluoroscopy can be used to confirm desired correction of deformity is achieved once implant is in place.

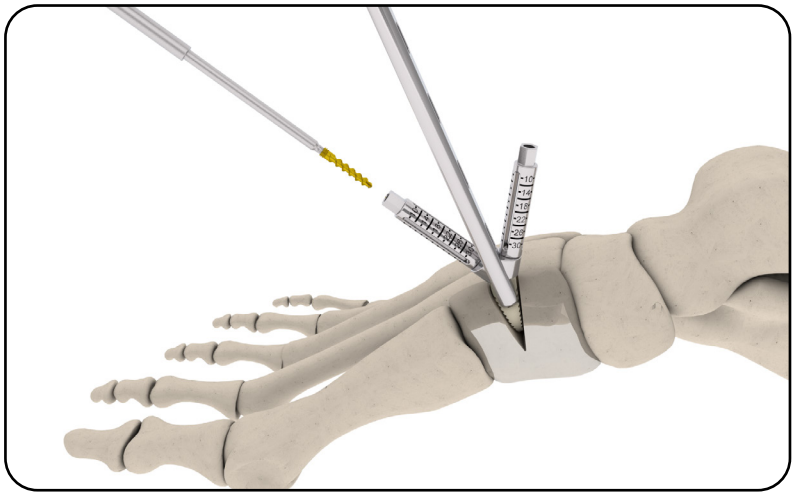


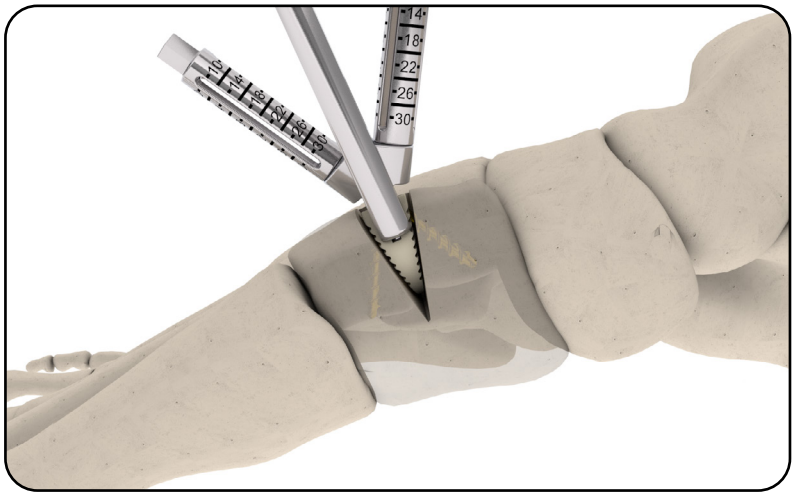
Note: A graft packing block and tamp are available to insert bone graft into the implant's graft window before insertion

B. Drill/Screw

Keeping the wedge in position, drill through the wedge inserter tower and refer to the depth indicator lines to determine screw length. Then advance the appropriate size screw until the screw inserter reaches the stop on the wedge tower. Repeat the same step for the remaining screw.







Note: In case of loss in screw engagement, the wedge inserter towers may be removed to finish screw insertion. Screws should be inserted until they are just subflush of the implant, over-insertion could cause loss of engagement between the screw and the wedge.

C. Inserter Disengagement

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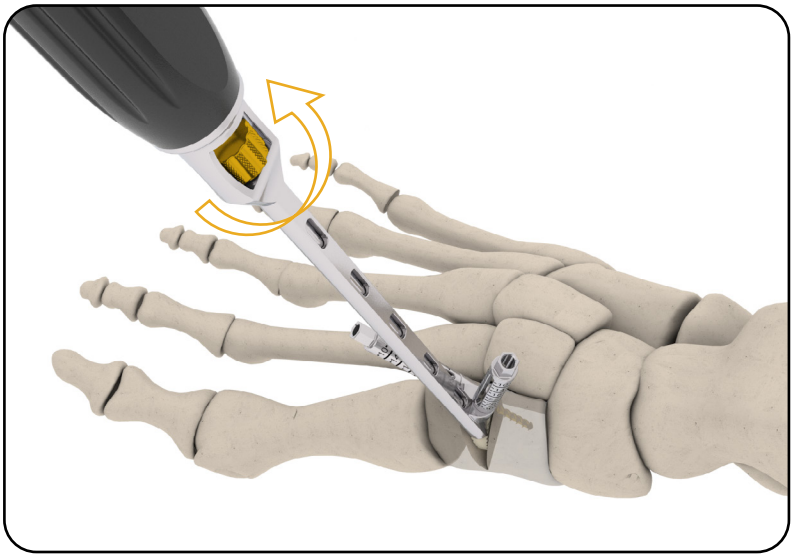

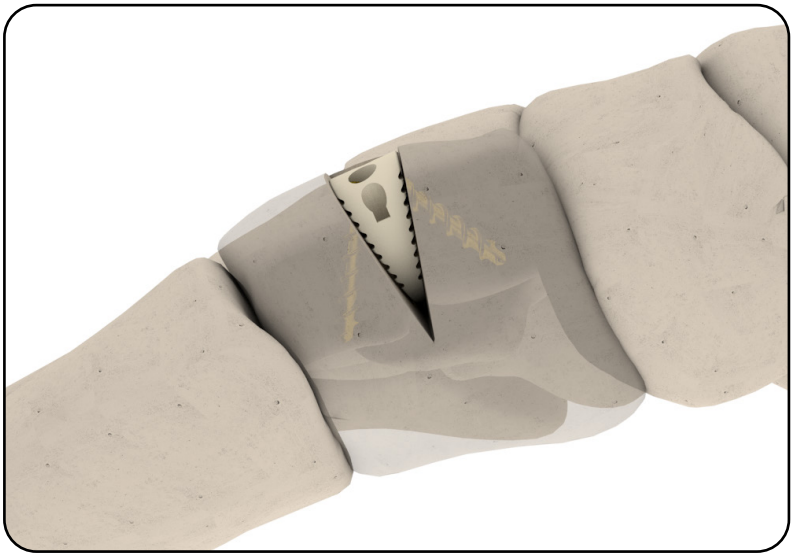

Indications for Use

The Trigon HA Stand-Alone Wedge Fixation System is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Trigon HA wedges are intended for use with ancillary fixation.

The Trigon HA Stand-Alone Wedge Fixation System is not intended for use in the spine.

Contraindications

Use of the Trigon HA Stand-Alone Wedge Fixation System is contraindicated in the following instances:

- Active or suspected infection
- Patients who are physiologically or psychologically inadequate
- Patients with insufficient quantity or quality of skin, bone or neurovascular status to permit stabilization of the bony segments
- Irreparable tendon system
- Where there is a possibility for conservative treatment.
- Growing patients with open epiphyses
- Patients with high levels of activity
- Malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless additional supplemental fixation or stabilization methods are utilized.
- Foreign body sensitivity

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 implant 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 are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- Do not use other manufacturers' instruments or implants in conjunction with the Trigon HA Stand-Alone Wedge Fixation System.

Potential Adverse Effects

In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery but are important considerations particular to metallic internal stabilization devices.

- Infection
- Loosening, deformation, migration or fracture of the implant
- Fractures resulting from unilateral joint loading
- 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

Disclaimers

This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime.

All possible complications listed are not typical of Nvision Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with 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 Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

Additional Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons. As the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, TX 78249

ORDERING INFORMATION

trigon® OSTEOTOMY WEDGE SYSTEM

Evans Implants

Part Number	Description
EVP-16-18-06	PEEK Small Evans Wedge 6mm
EVP-16-18-08	PEEK Small Evans Wedge 8mm
EVP-16-18-10	PEEK Small Evans Wedge 10mm
EVP-16-18-12	PEEK Small Evans Wedge 12mm
EVP-18-20-06	PEEK Medium Evans Wedge 6mm
EVP-18-20-08	PEEK Medium Evans Wedge 8mm
EVP-18-20-10	PEEK Medium Evans Wedge 10mm
EVP-18-20-12	PEEK Medium Evans Wedge 12mm
EVP-20-22-06	PEEK Large Evans Wedge 6mm
EVP-20-22-08	PEEK Large Evans Wedge 8mm
EVP-20-22-10	PEEK Large Evans Wedge 10mm
EVP-20-22-12	PEEK Large Evans Wedge 12mm

Cotton Implants

Part Number	Description
COP-16-16-06	PEEK Small Cotton Wedge 6mm
COP-16-16-07	PEEK Small Cotton Wedge 7mm
COP-16-16-08	PEEK Small Cotton Wedge 8mm
COP-18-20-06	PEEK Large Cotton Wedge 6mm
COP-18-20-07	PEEK Large Cotton Wedge 7mm
COP-18-20-08	PEEK Large Cotton Wedge 8mm

Screws

Part Number	Description
WSC-25-10	2.50mm dia. 10mm long locking screw
WSC-25-12	2.50mm dia. 12mm long locking screw
WSC-25-14	2.50mm dia. 14mm long locking screw
WSC-25-16	2.50mm dia. 16mm long locking screw
WSC-25-18	2.50mm dia. 18mm long locking screw
WSC-25-20	2.50mm dia. 20mm long locking screw
WSC-25-22	2.50mm dia. 22mm long locking screw
WSC-25-24	2.50mm dia. 24mm long locking screw
WSC-25-26	2.50mm dia. 26mm long locking screw
WSC-25-28	2.50mm dia. 28mm long locking screw
WSC-25-30	2.50mm dia. 30mm long locking screw

Instruments

Part Number	Description
WD-1001T-EVI	Evans Wedge Inserter
WD-1001T-COI	Cotton Wedge Inserter
WD-1000T-SREW	Trigon Screw Inserter
WD-1000T-TRI	Trigon Trial Inserter
WD-1000T-DRL	Trigon 1.5mm Drill
CSRW-1000T-350	K-Wires (2.4mmx230mm)
CSRW-1000T-800	Pickups
CSRW-1000T-501	Small AO Handle
INST-1000T-SPR	Lamina Spreaders
INST-1000T-HINT	Hintermann Pin Distractor
WD-1000T-GRFB	Trigon Graft Packing Block
WD-1000T-GRFT	Trigon Graft Packing Tamp

Trials

Part Number	Description
WD-161806T-EV	Small Evans 6mm Trial
WD-161808T-EV	Small Evans 8mm Trial
WD-161810T-EV	Small Evans 10mm Trial
WD-161812T-EV	Small Evans 12mm Trial
WD-182006T-EV	Medium Evans 6mm Trial
WD-182008T-EV	Medium Evans 8mm Trial
WD-182010T-EV	Medium Evans 10mm Trial
WD-182012T-EV	Medium Evans 12mm Trial
WD-202206T-EV	Large Evans 6mm Trial
WD-202208T-EV	Large Evans 8mm Trial
WD-202210T-EV	Large Evans 10mm Trial
WD-202212T-EV	Large Evans 12mm Trial
WD-161606T-CO	Small Cotton 6mm Trial
WD-161607T-CO	Small Cotton 7mm Trial
WD-161608T-CO	Small Cotton 8mm Trial
WD-182006T-CO	Large Cotton 6mm Trial
WD-182007T-CO	Large Cotton 7mm Trial
WD-182008T-CO	Large Cotton 8mm Trial

NVISION™ biomedical technologies

Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, TX 78249
210-545-3713 ext. 112
orders@nvisionbiomed.com
www.nvisionbiomed.com

Scan to visit our website.

View Evans in augmented reality.

View Cotton in augmented reality.

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