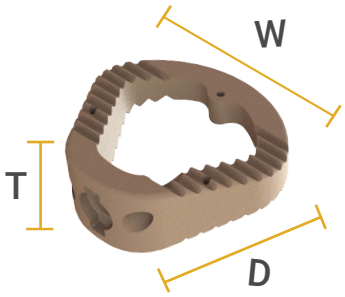
trigon®
CC WEDGE SYSTEM

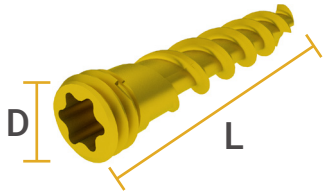
Surgical Technique Guide

NVision™
biomedical technologies

trigon®
CC WEDGE SYSTEM

Legend





Product Sizes Available

CC Wedge Footprint (WxD): 25mm x 25mm
CC Wedge Thickness: 8mm, 10mm, 12mm, 14mm

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 throughout the PEEK.

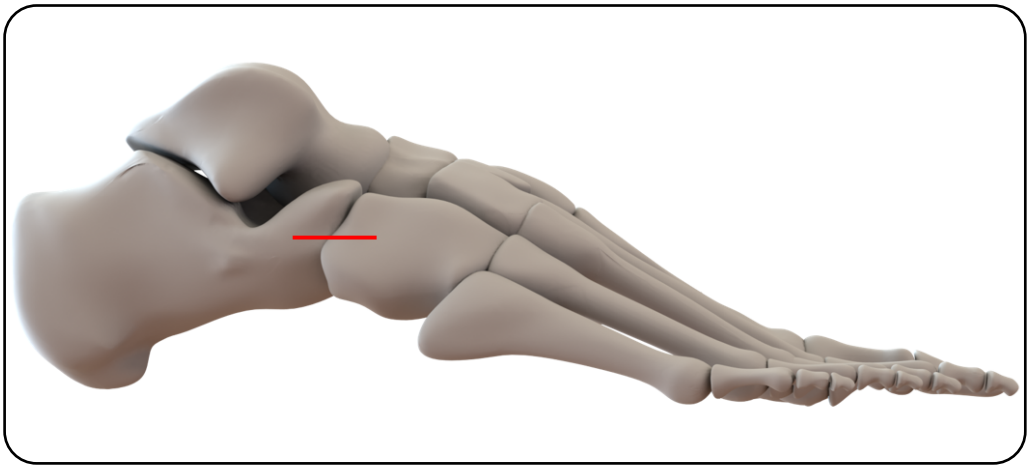
The Trigon® HA Stand-Alone Wedge is provided in a configuration for Calcaneocuboid Arthrodesis. This configuration is available in a variety of sizes, allowing for precise and reliable correction that accommodate a large patient population.

Ergonomic instrumentation allow for accurate wedge insertion and precise screw placement.

Calcaneocuboid Arthrodesis Surgical Technique

Step 1 - Site Preparation

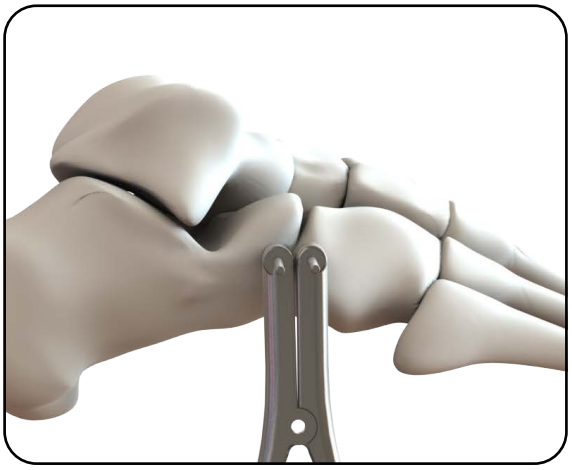
Make a 2-3cm longitudinal incision over the calcaneocuboid joint and retract soft tissue as necessary to expose the desired joint space.

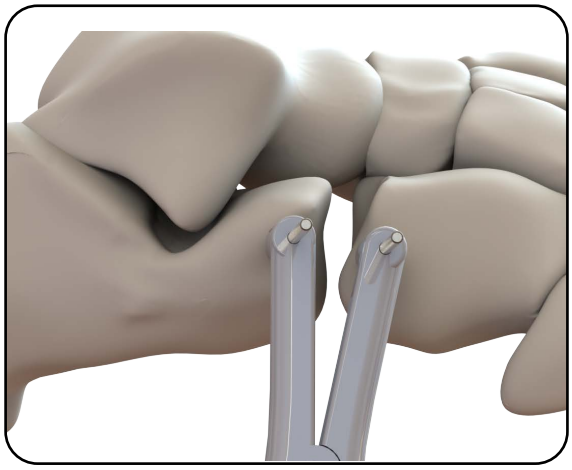


Step 2 - Distraction and Joint Preparation

A. Once the calcaneocuboid joint is exposed, place the pin distractor on either side of the joint and secure with pins.

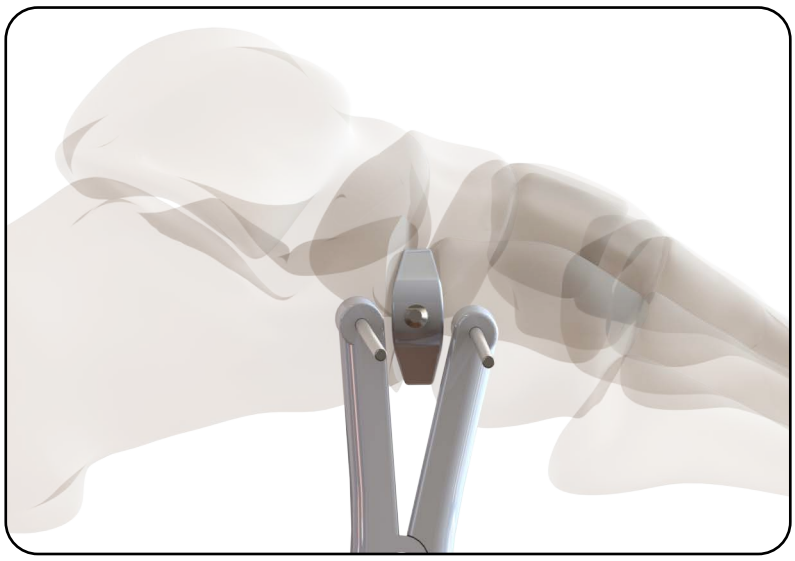
B. Distract the joint and perform cartilage resection on either side.





Step 3 - Trial/Implant Selection

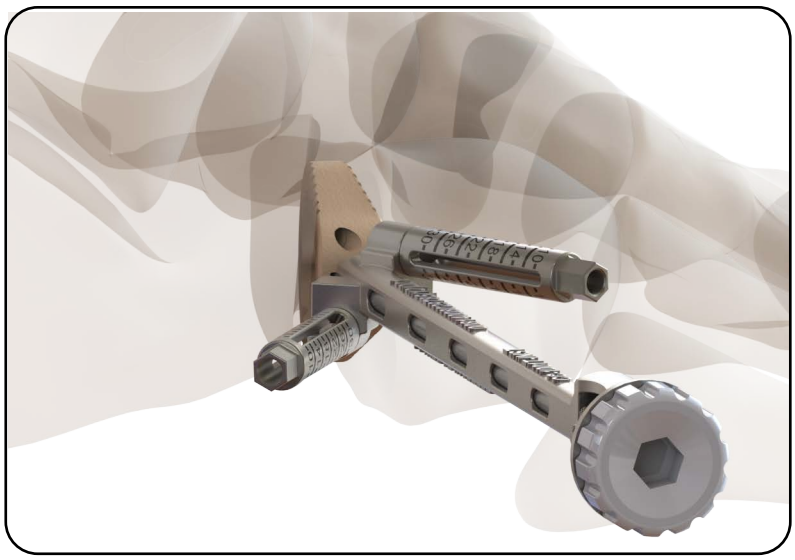
Use the trials provided to determine the appropriate size implant. Start with smaller trials and increase the thickness as needed to achieve the desired correction. Use fluoroscopy to confirm.



Step 4 - Implant Insertion/Fixation

A. Implant Insertion

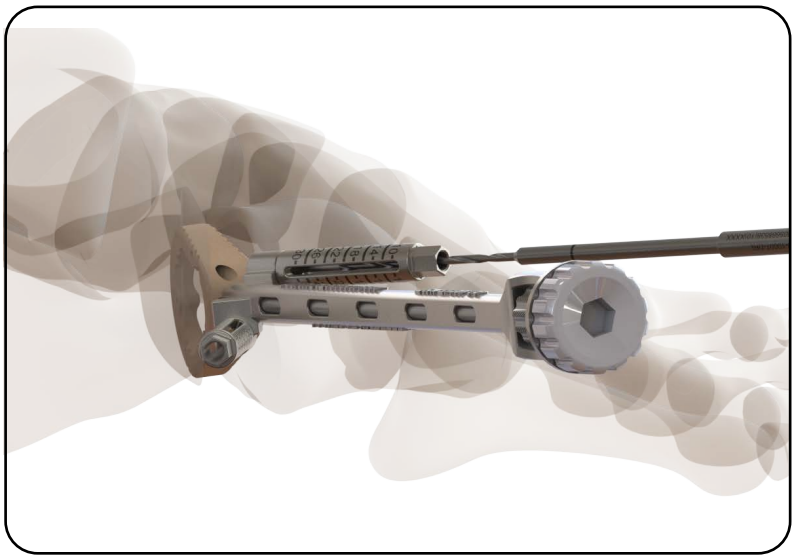
Use the CC Wedge Inserter to insert the selected implant in the joint space until the implant is subflush and/or the inserter reaches the stop. Fluoroscopy can be used to confirm desired correction of deformity is achieved once implant is in place.



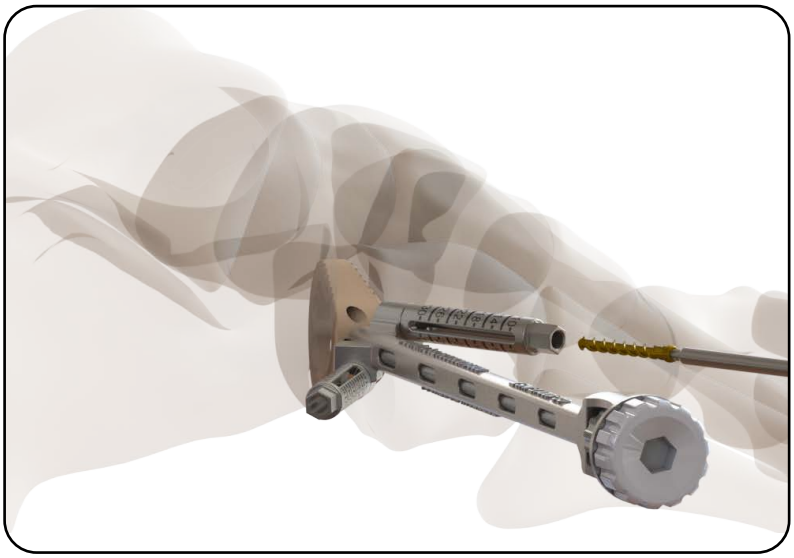
Note: A graft packing block and tamp are available to insert bone graft into the implant's graft window before insertion.

B. Fixation

Keeping the wedge in position, remove distraction then 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.



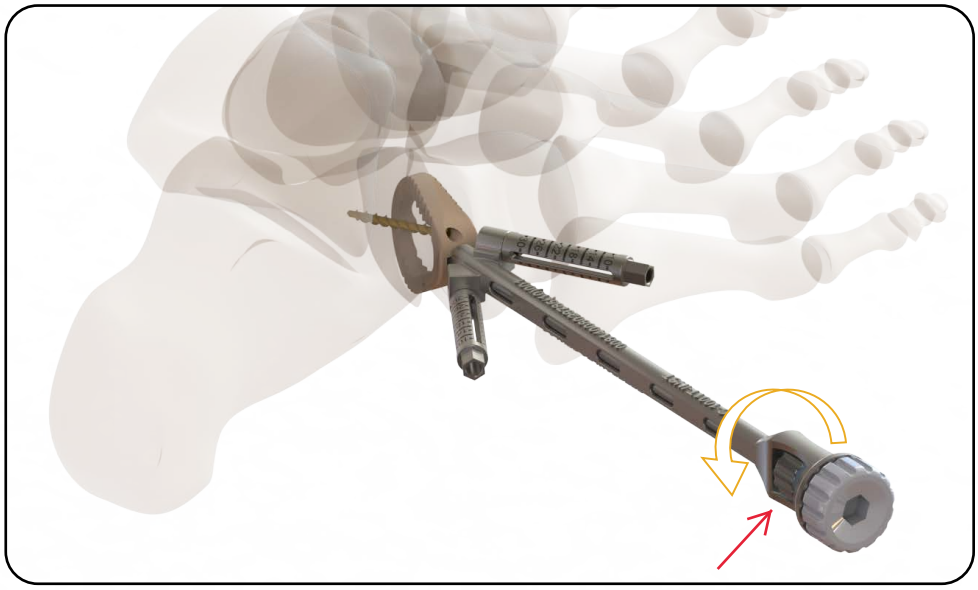
Note: Screws are not designed to be bicortical.

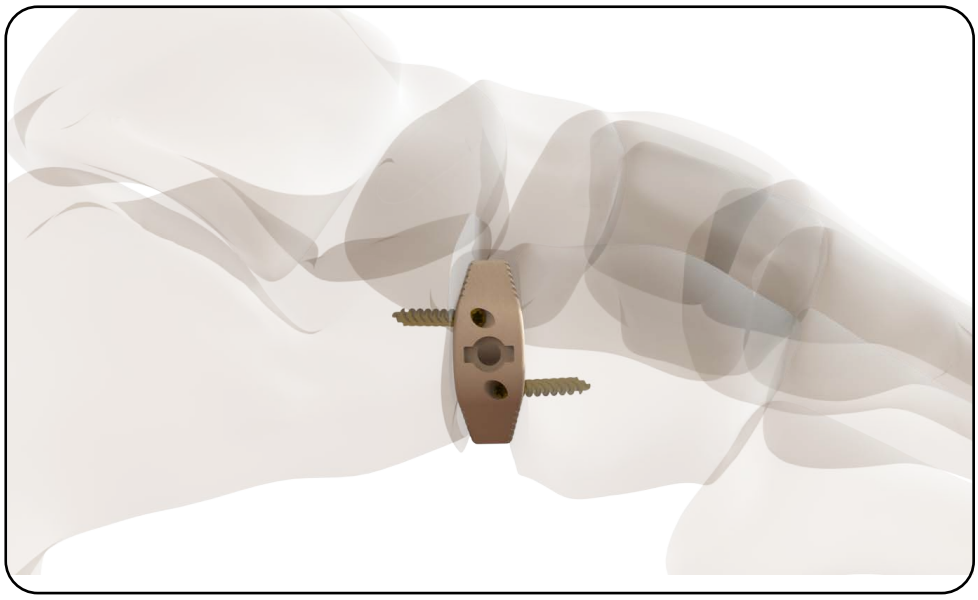


Note: In case of loss in screw engagement, the wedge inserter towers may be removed to finish screw insertion. Screws should be inserted until they are just subflush of the implant, over-insertion could cause loss of engagement between the screw and the wedge.

C. Inserter Disengagement

Turn the distal knob counterclockwise to disengage the inserter from the implant.

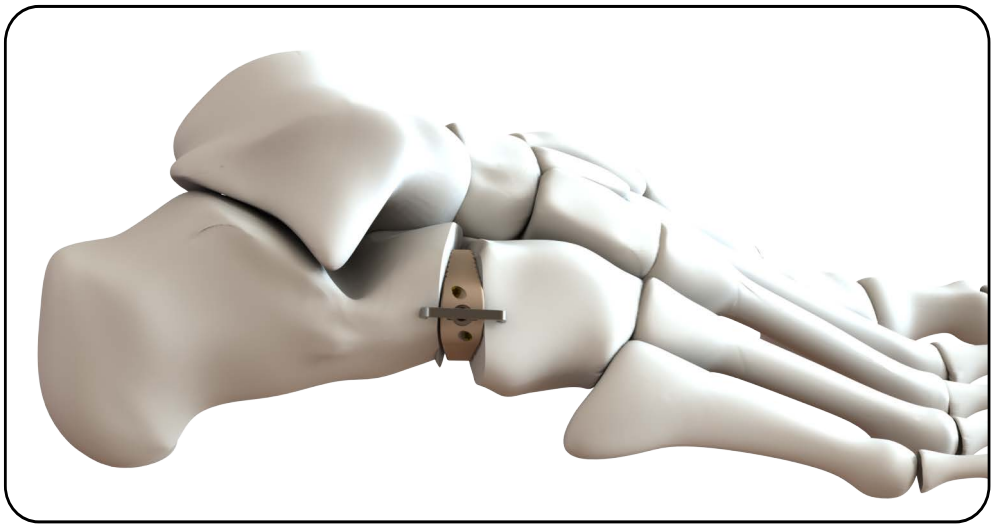




Step 5 - Additional Fixation

The Trigon HA Calcaneocuboid Wedge requires additional fixation. Additional fixation to be used is surgeon preference.

Image below shows an example of additional fixation: The Nvision Vertex System, 20mm staple can be inserted over the wedge's insertion feature without interfering with the Trigon screws.



Implant Removal

1. If additional fixation was initially used with the Calcaneocuboid Wedge, remove this with corresponding instrumentation.
2. Use Trigon Screw Inserter (T7) to remove both cancellous Trigon Screws.
3. Use Trigon Wedge Inserter to reattach and secure to wedge. Pull or slide wedge out of osteotomy.
    a. Use burr or sagittal saw to remove any bone growth on or through wedge.
    b. Use distractors to distract joint space if wedge is tightly positioned.

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
- First Metatarsal-Cuneiform Lengthening Arthrodesis
- Subtalar Fusion
- Calcaneocuboid Arthrodesis

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

Notes

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ORDERING INFORMATION

trigon® CC WEDGE SYSTEM

Calcaneocuboid Implants

Part Number	Description
CC-2525-08	PEEK HA CC Wedge 8mm
CC-2525-10	PEEK HA CC Wedge 10mm
CC-2525-12	PEEK HA CC Wedge 12mm
CC-2525-14	PEEK HA CC Wedge 14mm

Instruments

Part Number	Description
WD-1001T-CCI	CC Wedge Inserter
WD-1000T-SREW	Trigon Screw Inserter
WD-1000T-TRI2	Trigon Trial Inserter2
WD-1000T-DRL	Drill for 2.5mm Screw
CSRW-1000T-352	K-Wires (2.4mmx150mm)
CSRW-1000T-800	Pickups
HAN-1000T-AOSM	Small AO Handle
INST-1000T-HRTD	Heart Distractor
INST-1000T-HINT	Hintermann Pin Distractor
WD-1000T-CGPB	Trigon CC Graft Packing Block

Locking Screws

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

Trials

Part Number	Description
WD-2508T-CC	CC Wedge 8mm Trial
WD-2510T-CC	CC Wedge 10mm Trial
WD-2512T-CC	CC Wedge 12mm Trial
WD-2514T-CC	CC Wedge 14mm Trial

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