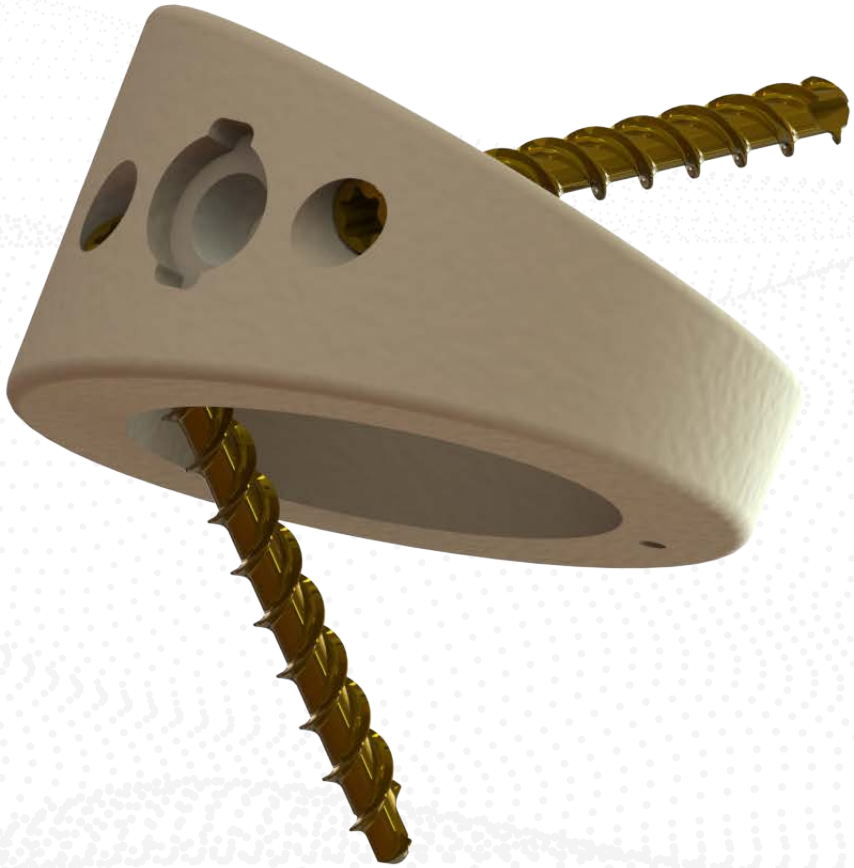
# trigon®

SUBTALAR WEDGE SYSTEM

## Surgical Technique Guide



NVision™

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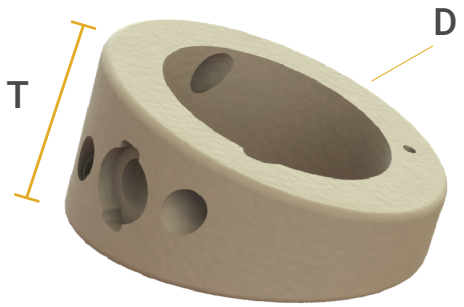
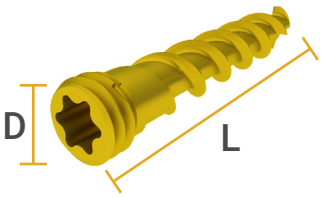
SUBTALAR WEDGE SYSTEM

**Legend**




**Product Sizes Available**

Diameter: 25mm

Thickness: 6mm (parallel), 8mm (parallel), 10mm, 12mm, 14mm, 16mm

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.

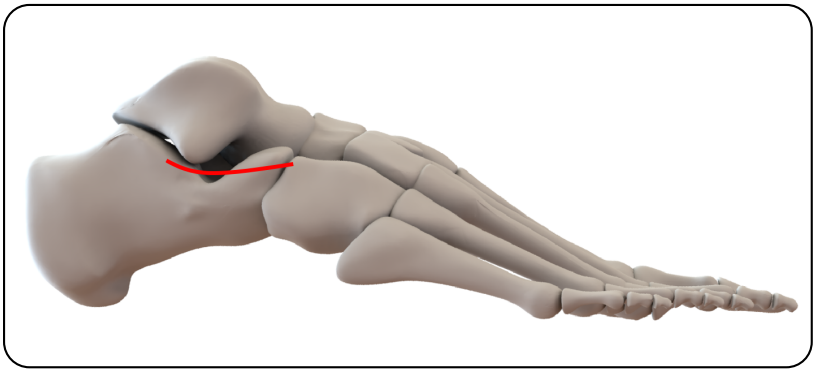
The Trigon® HA Stand-Alone Wedge is provided in a circular configuration for Subtalar Fusions. Multiple thicknesses are available, allowing for precise and reliable correction that accommodate a large patient population.

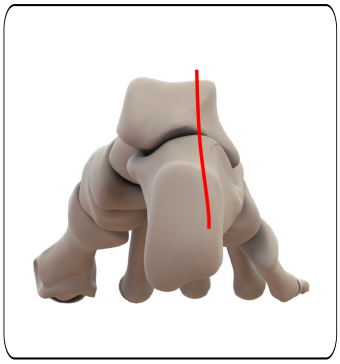
The Trigon® HA Stand-Alone Wedge System for Subtalar Fusions includes a targeting jig for the insertion of a compression screw through the wedge if desired. Additional ergonomic instrumentation allow for accurate wedge insertion and precise screw placement.

# Subtalar Fusion Surgical Technique

## Step 1 - Joint Preparation

A. Lateral or posterior incision placement is available for this procedure and is dependent on previous incisions or hardware removal considerations.



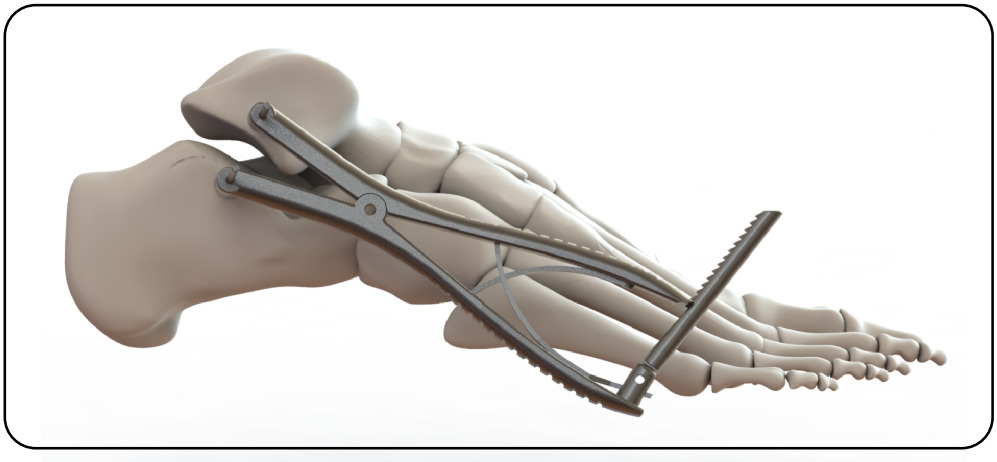


B. Ensure adequate visualization of the posterior facet has been achieved and release the calcaneofibular ligament and mobilize the peroneal tendons, sural nerve and flexor hallucis longus tendon to retract them away from the surgical site.

## Step 2 - Distraction and Joint Preparation

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

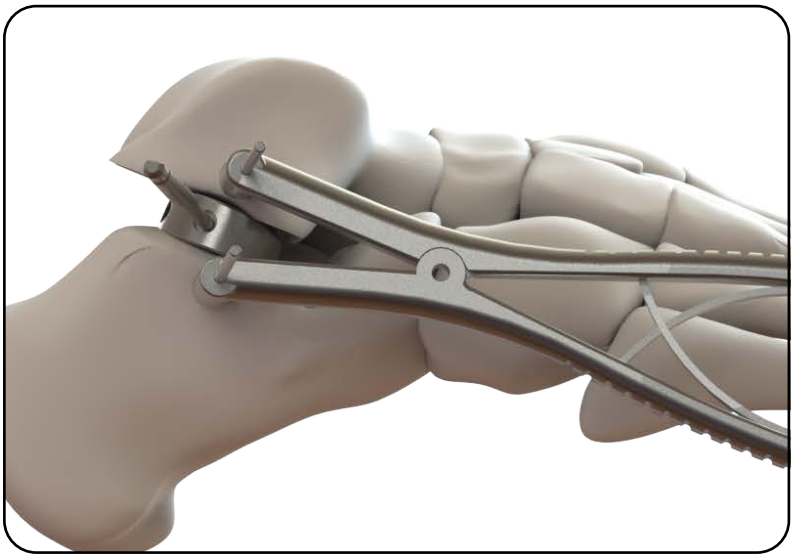
B. Distract the subtalar joint and perform cartilage resection on either side.



## Step 3 - Trial/Implant Selection

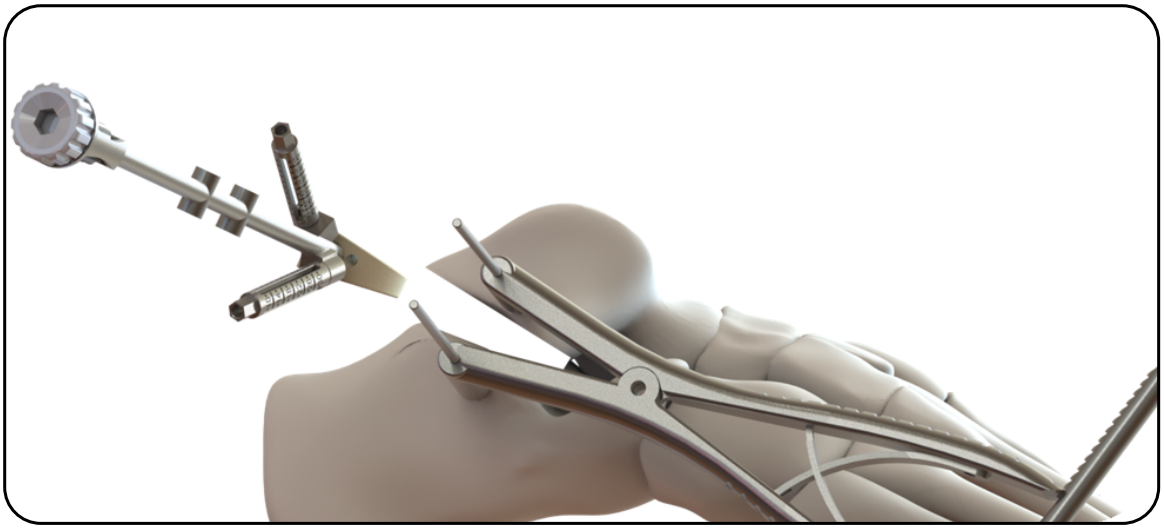
A. Set the pin distractor to the desired height for the subtalar joint correction. Select a trial size that appropriately fits in the open joint space.

B. Thread trial inserter into trial and insert trial into joint space (trial inserter can also be placed on a handle). Start with smaller trials and increase the trial thickness as needed to achieve the desired correction. Use fluoroscopy to confirm.

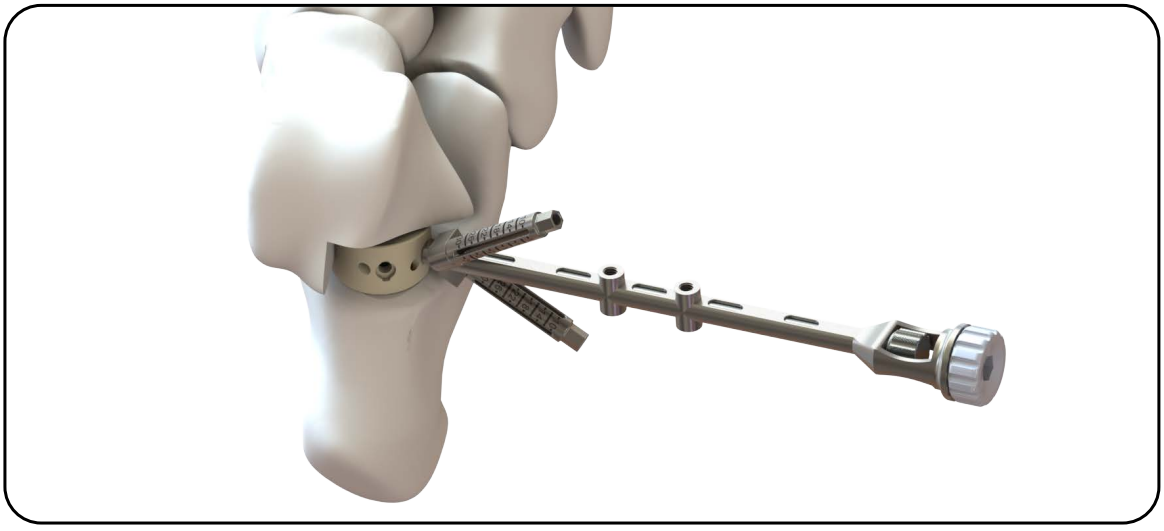


## Step 4 - Implant Insertion/Fixation

A. Use the wedge inserter to insert the selected implant in the joint space until the implant is subflush to the cortices. Fluoroscopy can be used to confirm desired correction of deformity is achieved once implant is in place.

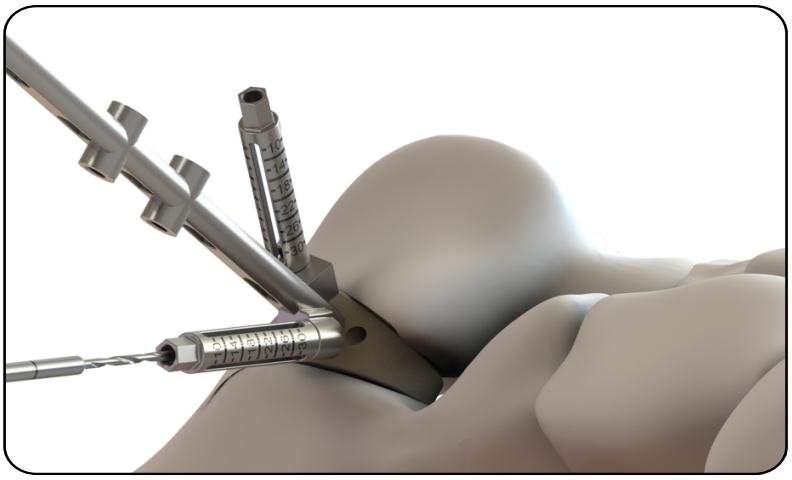


B. Remove pin distractor to begin implant fixation.

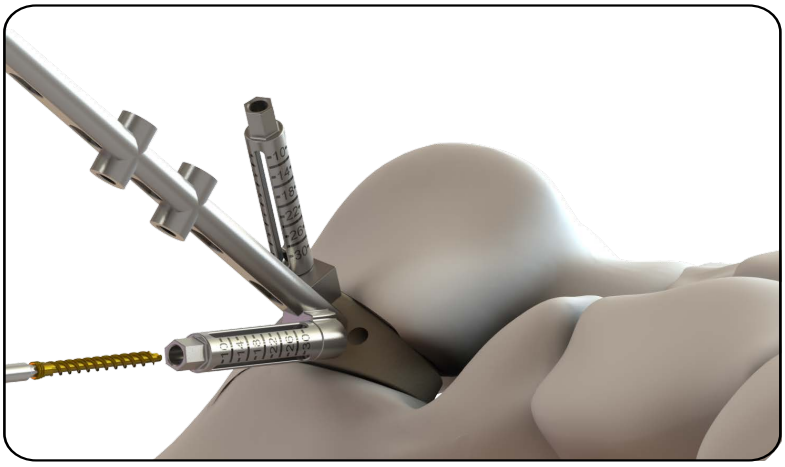


**Note:** A graft packing block and tamp are available to insert bone graft into the implant's graft window before insertion

C. 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.



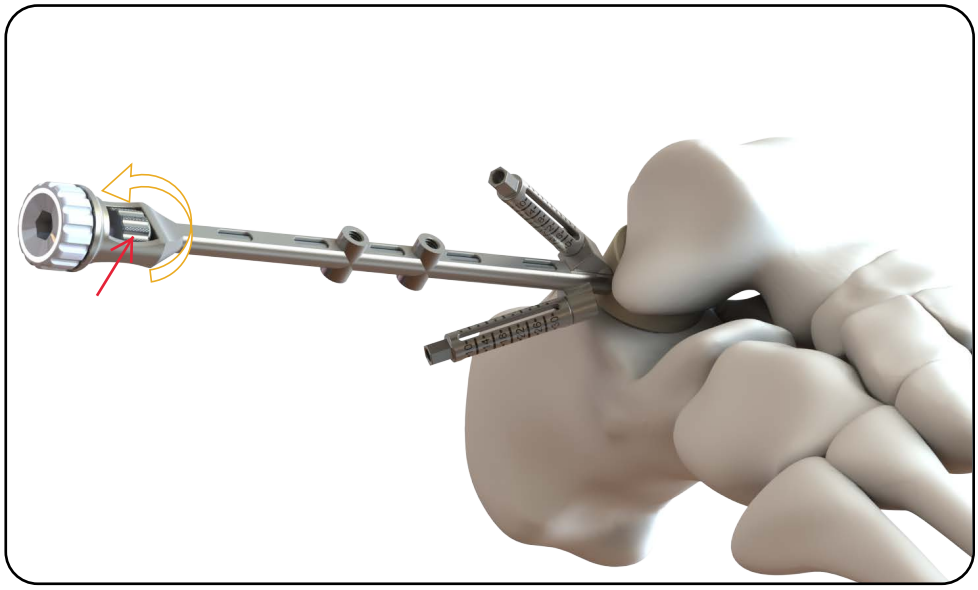
**Note:** Screws are not designed to be bicortical.

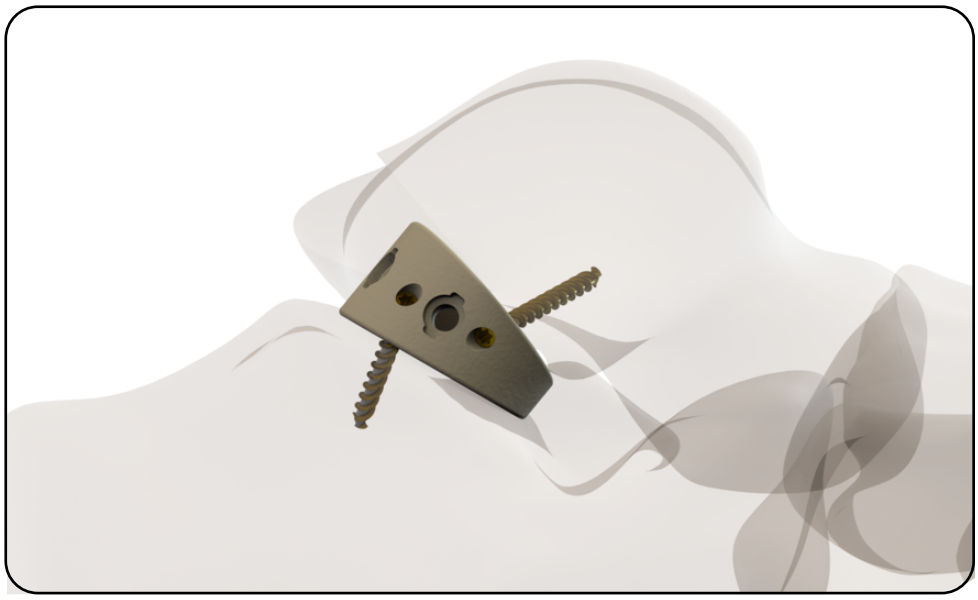


**Note:** In case of loss in screw engagement, the wedge inserter towers may be removed to finish screw insertion. Screws should be inserted until they are just subflush of the implant, over-insertion could cause loss of engagement between the screw and the wedge.

C. Inserter Disengagement

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



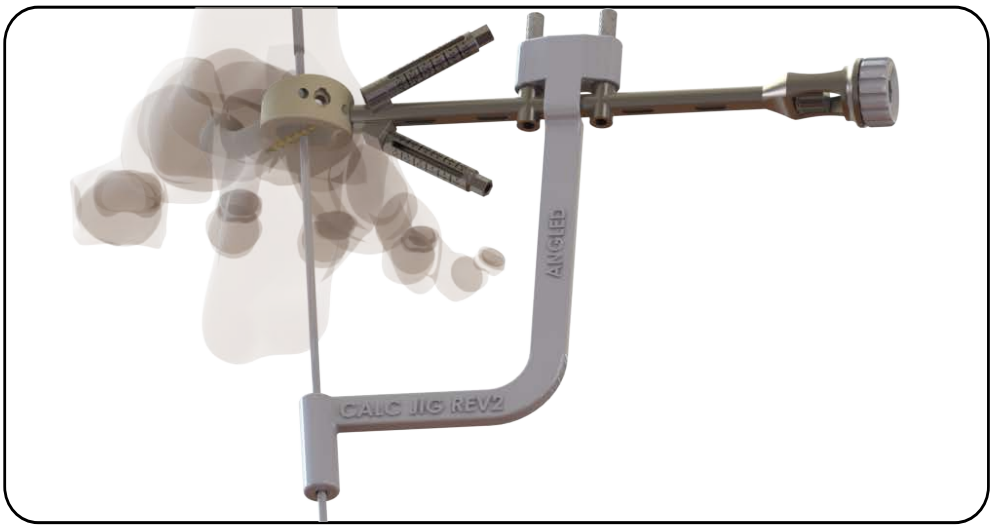


## Step 5 - Additional Fixation (Optional)

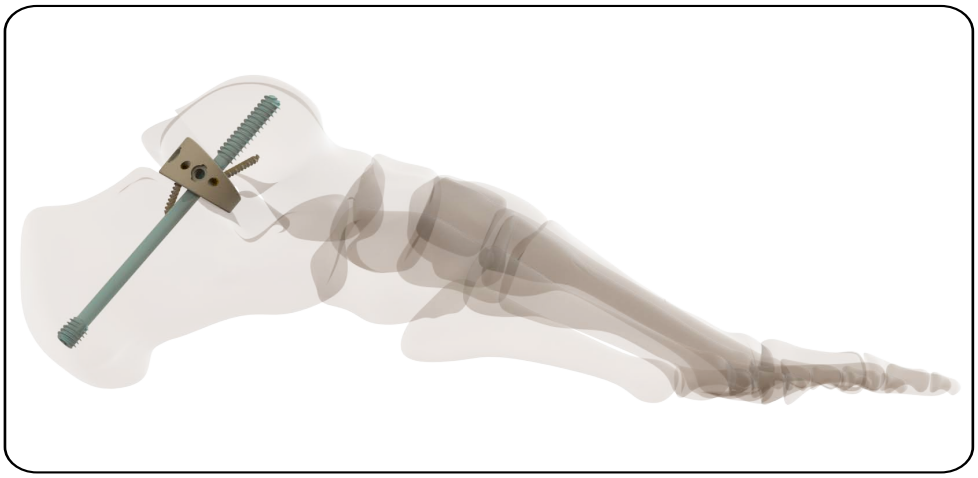
The Trigon HA Subtalar Wedge does not require additional fixation, although it is optional. It is common in a subtalar arthrodesis for a screw to be inserted though calcaneus into the talus for fixation, and the Trigon HA Subtalar Wedge System provides a targeting jig to do so. The targeting jig provides guidance for screw placement through the implanted Subtalar Wedge. The screw and instrumentation required to insert the screw, aside from the targeting jig, are not provided in the Trigon HA Subtalar Wedge System.

**Screw Insertion**

A. Follow steps 1-8 and do not remove wedge inserter from wedge. Attach targeting jig to wedge inserter using the 2 thumb screws.
B. Use desired screw system instrumentation to insert K-wire using the Trigon HA Subtalar Wedge Targeting Jig. Use fluoroscopy to confirm K-wire placement through wedge window.




C. Remove wedge inserter and targeting jig to drill and insert screw over the K-wire.



## Implant Removal

1. If additional fixation was initially used with the Subtalar 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

# ORDERING INFORMATION

trigon® SUBTALAR WEDGE SYSTEM

## Subtalar Implants

| Part Number | Description |
|---|---|
| STP-25-06 | PEEK HA Subtalar Wedge 6mm |
| STP-25-08 | PEEK HA Subtalar Wedge 8mm |
| STP-25-10 | PEEK HA Subtalar Wedge 10mm |
| STP-25-12 | PEEK HA Subtalar Wedge 12mm |
| STP-25-14 | PEEK HA Subtalar Wedge 14mm |
| STP-25-16 | PEEK HA Subtalar Wedge 16mm |

## 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 |

## Instruments

| Part Number | Description |
|---|---|
| WD-1001T-STI | Subtalar Wedge Inserter |
| WD-1000T-SREW | Trigon Screw Inserter |
| WD-1000T-TRI | Trigon Trial Inserter |
| WD-1000T-DRL | Drill for 2.5mm Screw |
| CSRW-1000T-352 | K-Wires (2.4mmx150mm) |
| CSRW-1000T-800 | Pickups |
| CSRW-1000T-501 | Small AO Handle |
| INST-1000T-SPR | Lamina Spreaders |
| INST-1000T-HINT | Hintermann Pin Distractor |
| WD-1000T-SGRB | Subtalar Graft Packing Block |
| WD-1000T-GRFT | Trigon Graft Packing Tamp |
| WD-1000T-CGD | Screw Targeting Guide |

## Trials

| Part Number | Description |
|---|---|
| WD-2506T-ST | Subtalar 6mm Trial |
| WD-2508T-ST | Subtalar 8mm Trial |
| WD-2510T-ST | Subtalar 10mm Trial |
| WD-2512T-ST | Subtalar 12mm Trial |
| WD-2514T-ST | Subtalar 14mm Trial |
| WD-2516T-ST | Subtalar 16mm Trial |


Nvision™ biomedical technologies

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