trigon®

MIDFOOT WEDGE SYSTEM

Surgical Technique Guide

NVISION™

BIOMEDICAL TECHNOLOGIES

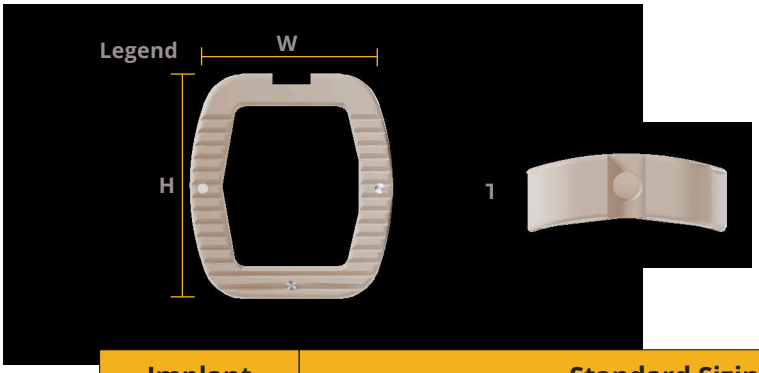
Product Sizes Available

Thickness (T): 6mm
Footprints (HxW): 20x17mm (Standard Small), 21x19mm (Standard Large), 21x33mm (Wide Small), 22x35mm (Wide Large)

The Trigon Midfoot Wedge System is made of Fusion Grade PEEK, where hydroxyapatite (HA) is fully integrated throughout the PEEK.

This system is indicated for a lengthening arthrodesis of the talonavicular or naviculocuneiform joints. Standard and Wide footprints are provided, in small and large sizes, to accommodate a wide patient population, allowing for precise and reliable application.

The Trigon Midfoot Wedge System can be combined with ancillary fixation via the staples provided. A targeting guide is provided for screw fixation if preferred.



Implant	Standard Sizing
MFP-2017-06C	PEEK Small (20x17mm) Standard Midfoot 6mm Wedge
MFP-2119-06C	PEEK Large (21x19mm) Standard Midfoot 6mm Wedge

Implant	Wide Sizing
MFP-2133-06C	PEEK Small (21x33mm) Wide Midfoot 6mm Wedge
MFP-2235-06C	PEEK Large (22x35mm) Wide Midfoot 6mm Wedge

Featured Instruments

Lesser Metatarsal/Midfoot Wedge Inserter Shaft

Trigon Wedge Trial Inserter

2.5mm Drill

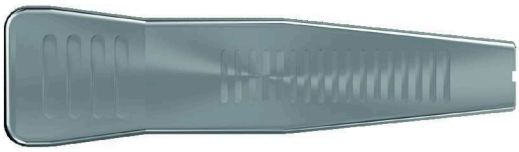
3.0 Drill

Healix Compression Screw K-Wire (1.3mm x 150mm)

Handle

Midfoot Wedge K-Wire Sleeve

Tamp



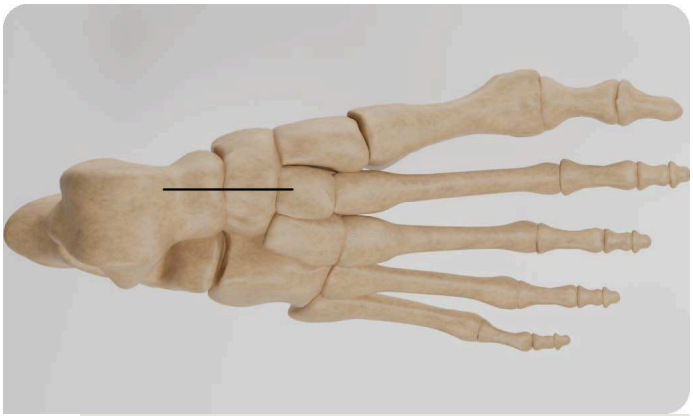
Midfoot Wedge Staple Drill Guide

Midfoot Wedge Wide Screw Targeting Guide

Midfoot Wedge Standard Screw Targeting Guide

Staple Distractor

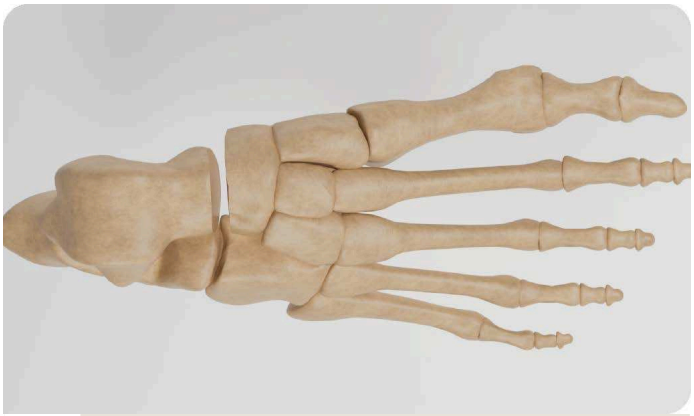
Surgical Technique



1

Joint Preparation

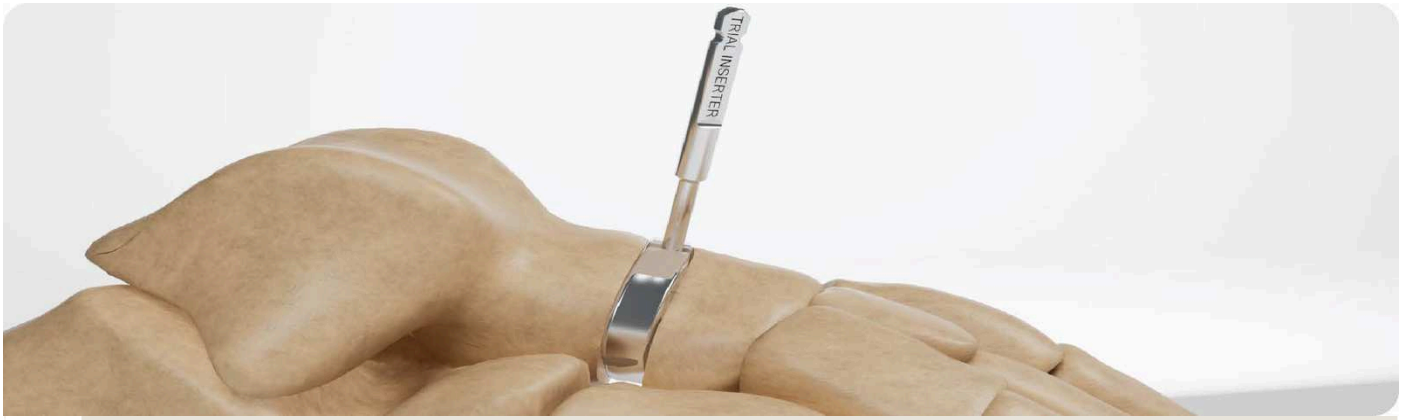
Perform a longitudinal incision over the selected joint. Retract soft tissue as necessary.



2

Joint Cuts

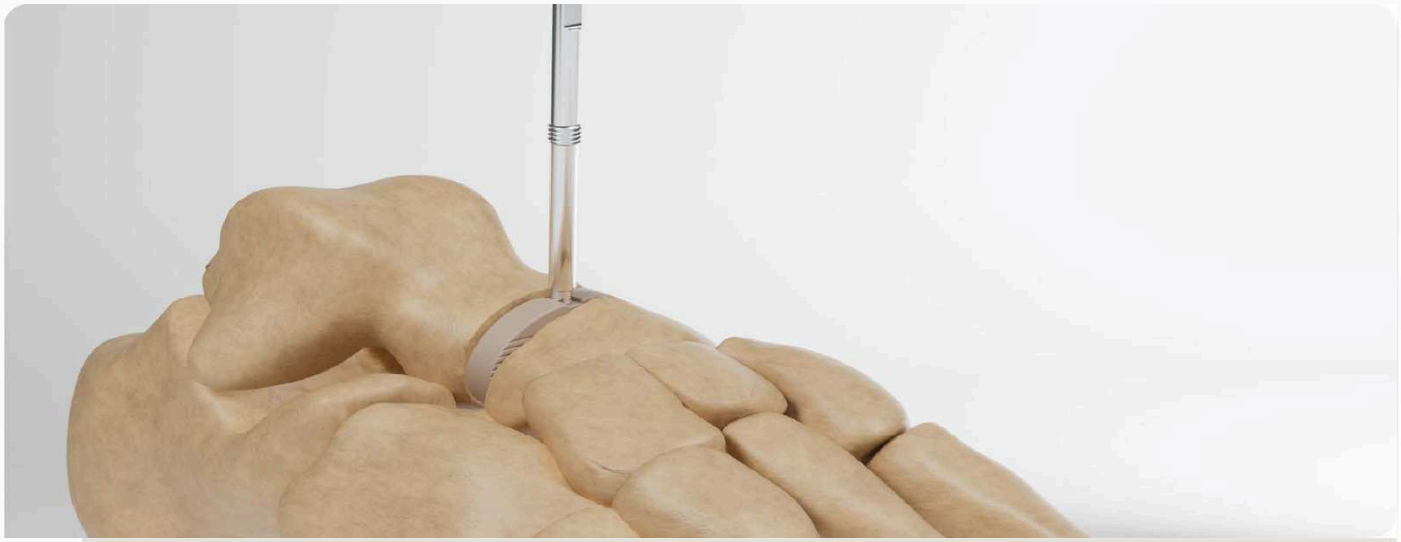
Use a sagittal saw or a burr to make equal cuts on either side of the joint following the curvature of the selected joint. After the cuts are made, remove the remaining bone slivers. Per surgeon discretion, additional drilling of the raw bone surfaces may be performed to further enhance the healing environment.



3

Wedge Size Selection

Thread trial inserter and insert trial into joint space. Use the provided trial wedges to determine the appropriate size implant. Start with smaller trials and increase the trial footprint, thickness, and correction as desired. Use fluoroscopy to confirm desired correction. Once satisfied with the correction, remove the trial and prepare for wedge insertion.



4

Wedge Insertion

Use the inserter shaft to insert the selected implant in the joint space. Thread the inserter shaft into the implant until you hit the hard stop. Place the implant in the joint space so that it sits sub-flush of the dorsal cortices.
Fluoroscopy can be used to confirm the desired correction of deformity is achieved once the implant is in place.

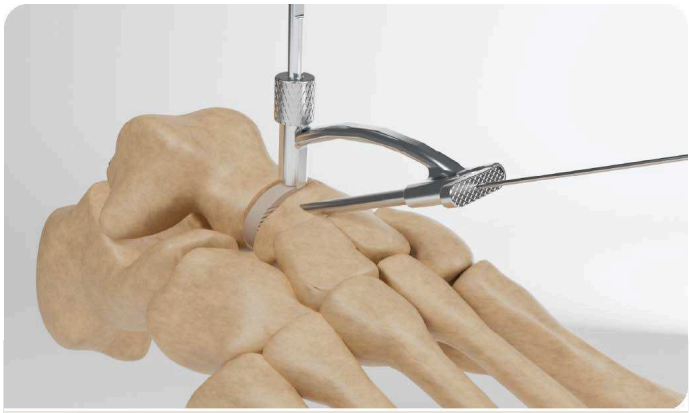
Additional Fixation

Once the wedge is placed, additional fixation is required. The selection of such fixation is surgeon preference. The Trigon HA Midfoot Wedge System provides a drill guide for two distal to proximal compression screws going through the wedge system as well as a staple guide for dorsal fixation. The use of any other ancillary fixation is permitted.

5

To Use the Screw Targeting Sleeve

Slide the screw targeting sleeve down the inserter shaft into the implant ensuring the insertion features on the guide are fully seated into the insertion features of the implant. Turn the knob on the sleeve clockwise onto the inserter shaft to lock the sleeve in place.

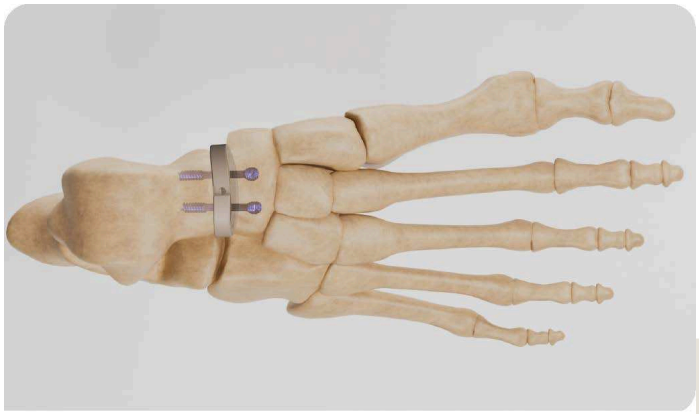


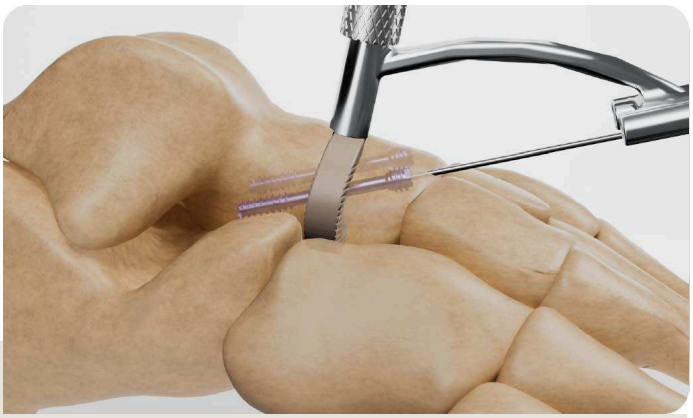
6

Slide the k-wire sleeve into the appropriate holes of the drill guide aligning the chamfered edge so it is fully seated on the bone.
Once the sleeve is in place, drive k-wires through the holes of the k-wire sleeve. Use fluoroscopy to confirm trajectory of k-wires.

7

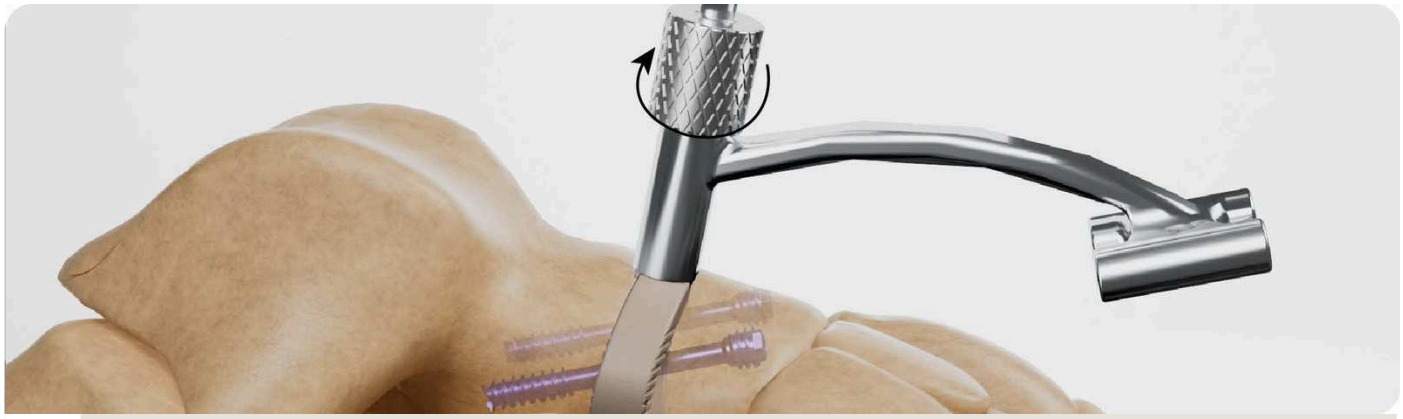
Remove k-wire sleeve and drill over the k-wires.





8

Slide cannulated screws onto the wire and advance to desired depth. If preferred, remove k-wires and insert solid screws.



9

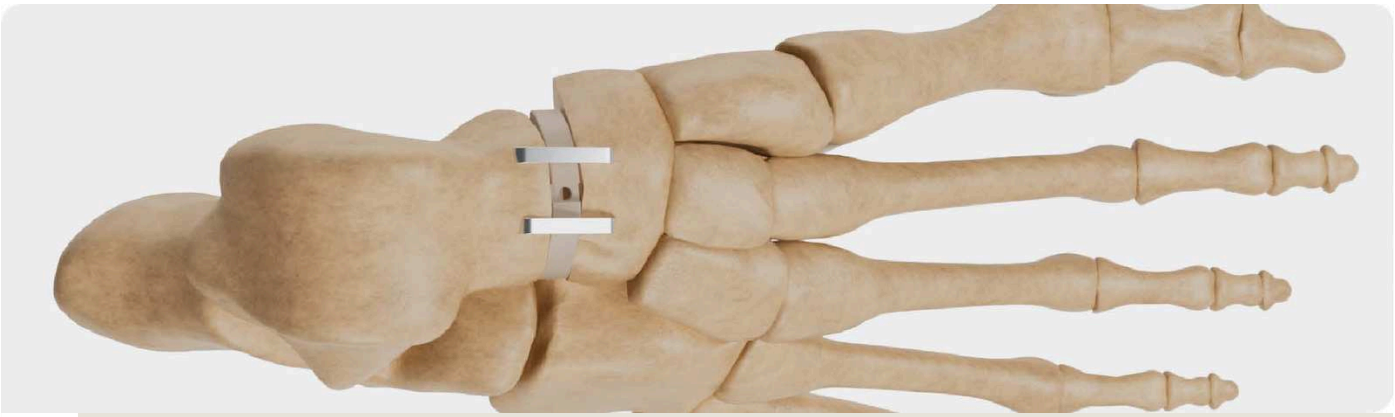
Inserter Disengagement

Turn the distal knob on the screw targeting sleeve counterclockwise to disengage the targeting sleeve from the inserter shaft.

10

To Use the Staple Drill Guide

Once the implant is fully seated, use the staple drill guide and place the drill guide holes over your desired placement of the staple. Drill through the staple drill guide and place the selected staple into the holes.



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Tamp on the staple to place it subflush to the bone.

Implant Removal

1. Remove the additional fixation that was initially used with the Lesser Metatarsal Wedge. Remove this with corresponding instrumentation (screw, plate, or staple removal instrumentation).
2. 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 osteotomy if wedge is tightly positioned.

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 exists. 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

MR Safety Information:

The Trigon HA Stand-Alone Wedge Fixation 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 Trigon HA Stand-Alone Wedge Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Ordering Information

Wedges STANDARD

Part Number	Description
MFP-2017-06C	PEEK Small (20x17mm) Standard Midfoot 6mm Wedge
MFP-2119-06C	PEEK Large (21x19mm) Standard Midfoot 6mm Wedge

Wedges WIDE

Part Number	Description
MFP-2133-06C	PEEK Small (21x33mm) Wide Midfoot 6mm Wedge
MFP-2235-06C	PEEK Large (22x35mm) Wide Midfoot 6mm Wedge

Staples

Part Number	Description
STK-20-20-20	20mm Bridge Staple, 20mm x 20mm Legs
STK-25-20-20	25mm Bridge Staple, 20mm x 20mm Legs

Trials STANDARD

Part Number	Description
MF-2017T-06C	PEEK Small (20x17mm) Standard Midfoot 6mm Trial
MF-2119T-06C	PEEK Large (21x19mm) Standard Midfoot 6mm Trial

Trials WIDE

Part Number	Description
MF-2133T-06C	PEEK Small (21x33mm) Wide Midfoot 6mm Trial
MF-2235T-06C	PEEK Large (22x35mm) Wide Midfoot 6mm Trial

Ordering Information

trigon® MIDFOOT WEDGE SYSTEM

Instruments

Part Number	Description
WD-1000T-MSHFT	Lesser Metatarsal/Midfoot Wedge Inserter Shaft
WD-1000T-MSSG	Midfoot Wedge Standard Screw Targeting Guide Assembly
WD-1000T-LMKB	Midfoot Wedge Standard Screw Targeting Guide Assembly
WD-1000T-MWSG	Midfoot Wedge Wide Screw Targeting Guide
WD-1000T-LMKB	Midfoot Wedge Wide Screw Targeting Guide
HAN-1000T-AOSM	Handle
WD-1000T-MKSL	Midfoot Wedge K-Wire Sleeve
WD-1000T-MSDG	Midfoot Wedge Staple Drill Guide
WD-1000T-TRI	Trigon Wedge Trial Inserter
KWIRE-13-150S	Healix Compression Screw K-Wire (1.3mm x 150mm)
STK-1000T-030	3.0mm Drill
STK-1000T-011	2.5mm Drill
STK-1000T-DIS1	Staple Distractor
STK-1000T-TMP	Tamp

NVISION BIOMEDICAL TECHNOLOGIES™

NVISION Biomedical Technologies
12449 Silicon Drive
San Antonio, TX 78249

210-545-3713 ext. 112
orders@nvisionbiomed.com
www.nvisionbiomed.com

Scan to visit our website.

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