trigon®

MTP WEDGE SYSTEM

Surgical Technique Guide

NVISION

BIOMEDICAL TECHNOLOGIES

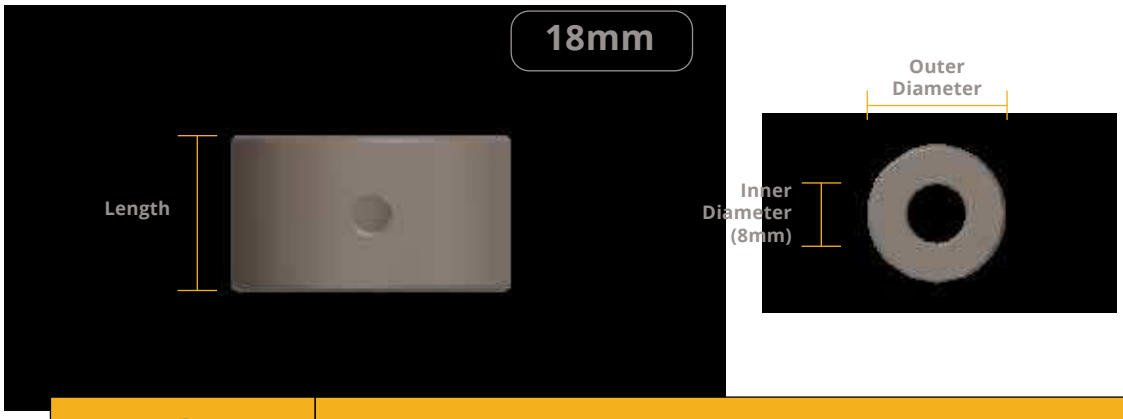
Product Sizes Available

18mm Outer Diameter: 8mm, 10mm, 12mm Length
22mm Outer Diameter: 8mm, 10mm, 12mm Length

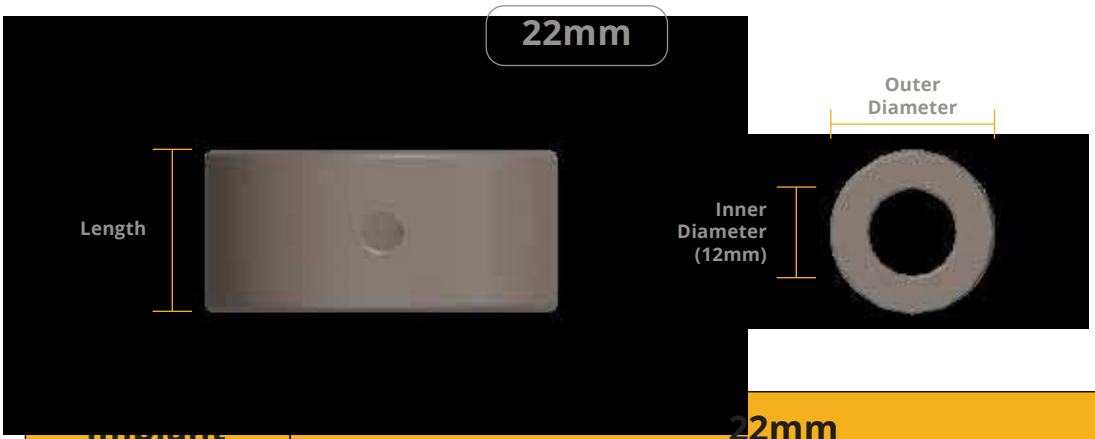
The Trigon MTP Wedge System is made of Fusion Grade PEEK, where hydroxyapatite (HA) is fully integrated throughout the PEEK.

This system is indicated for the lengthening arthrodesis of the metatarsophalangeal joint. 18mm diameter and 22mm diameter footprints are provided, in heights of 8mm, 10mm, and 12mm to accommodate for a wide patient population, allowing for precise and reliable application.

The Trigon MTP Wedge System can be combined with ancillary fixation via the staples provided.



Implant	18mm
MTP-18-08-00	PEEK MTP 18mm Wedge 8mm Parallel
MTP-18-10-00	PEEK MTP 18mm Wedge 10mm Parallel
MTP-18-12-00	PEEK MTP 18mm Wedge 12mm Parallel



Implant	22mm
MTP-22-08-00	PEEK MTP 22mm Wedge 8mm Parallel
MTP-22-10-00	PEEK MTP 22mm Wedge 10mm Parallel
MTP-22-12-00	PEEK MTP 22mm Wedge 12mm Parallel

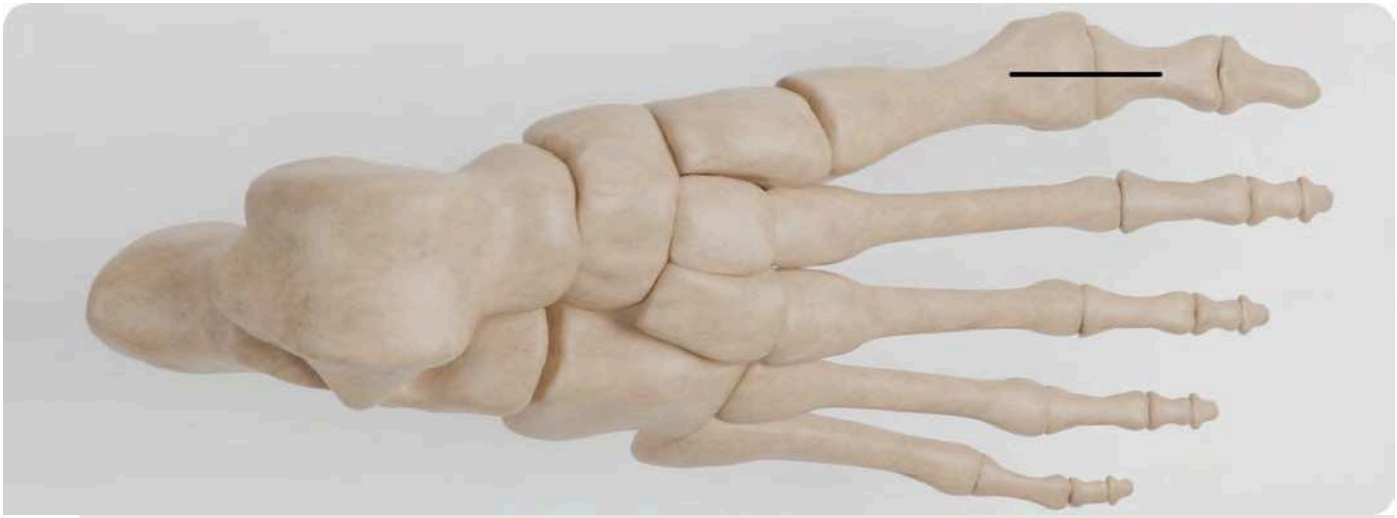
Featured Instruments

MTP Wedge Inserter

Trial Inserter

AO Handle

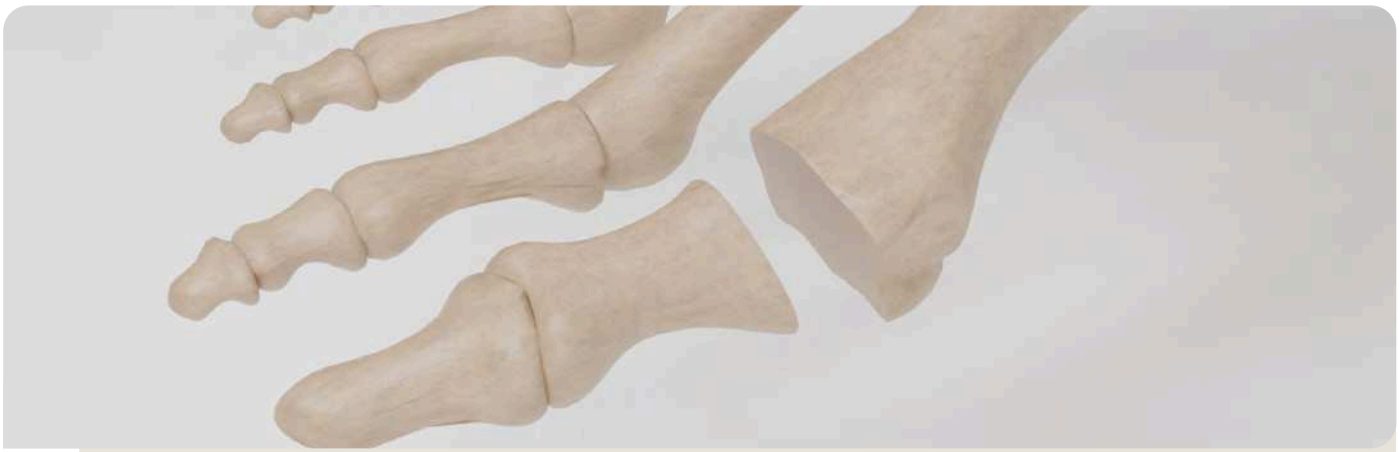
Surgical Technique



1

Site Preparation

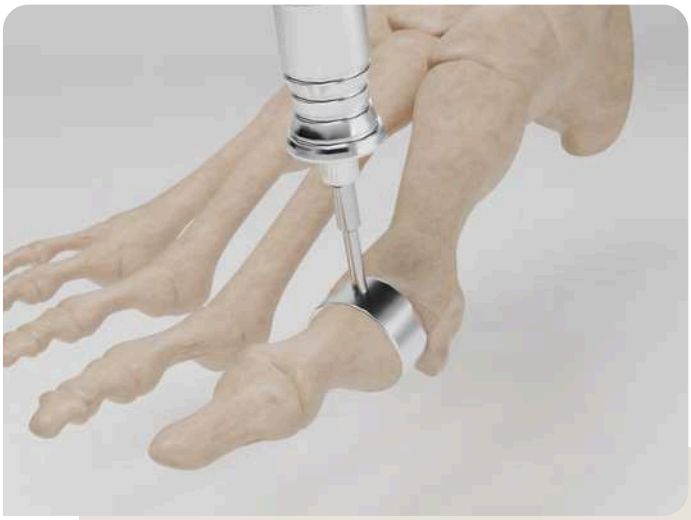
Make a 2-3cm dorsal incision over the metatarsophalangeal joint and retract soft tissue as necessary to expose the desired joint space.

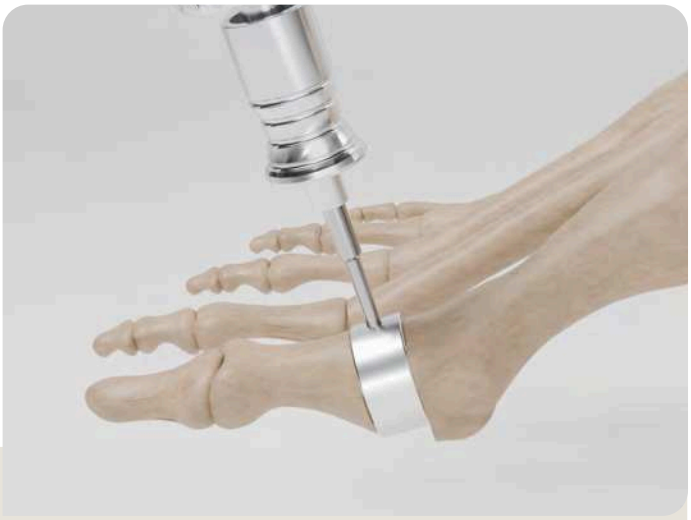


2

Joint Preparation

Once the joint is exposed, make parallel straight cuts on the metatarsal and the proximal phalanx.

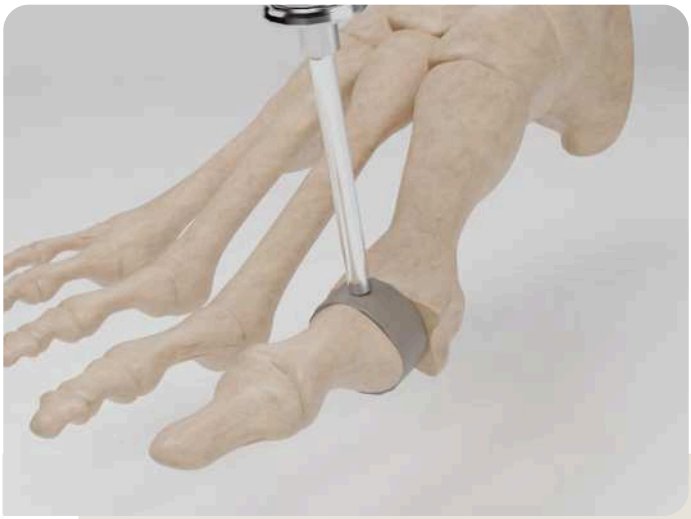


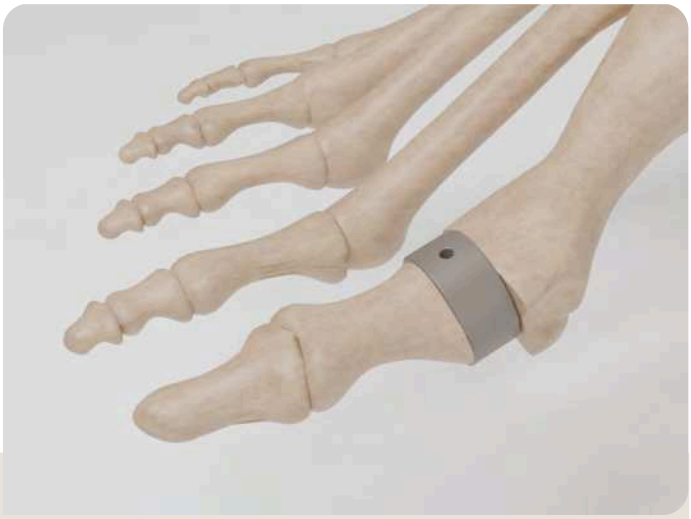


3

Trial/Implant Selection

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





4

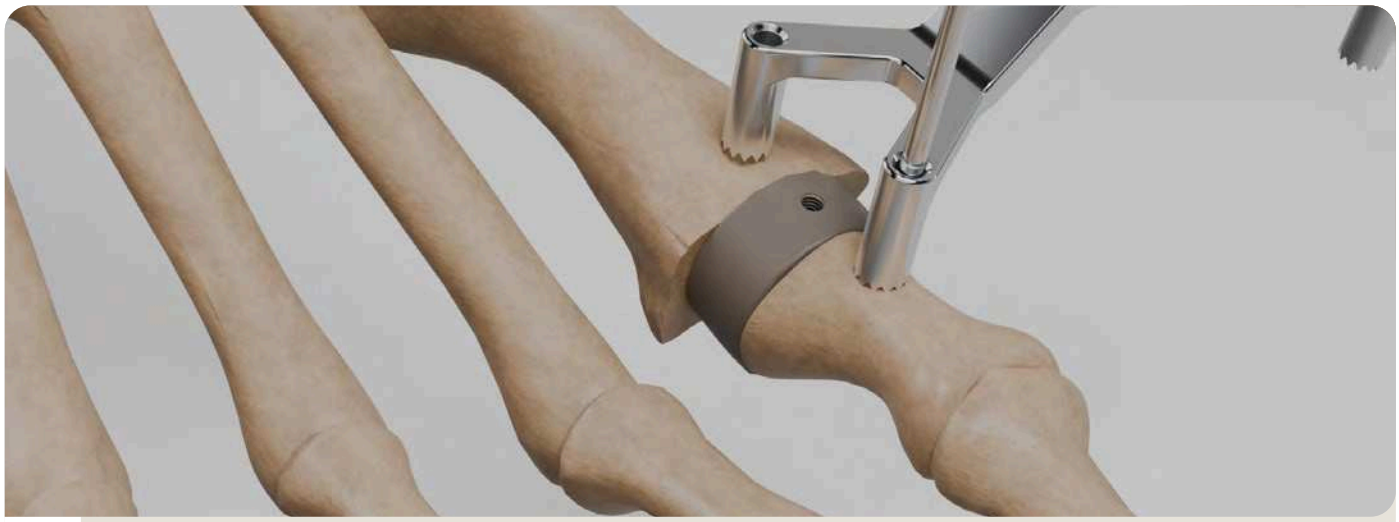
Implant Insertion

Thread the inserter into the selected implant and insert into the joint space. Fluoroscopy can be used to confirm desired correction of deformity is achieved once implant is in place.

Additional Fixation

The Trigon MTP Wedge requires additional fixation. Additional fixation to be used, such as plates or staples, is surgeon preference.

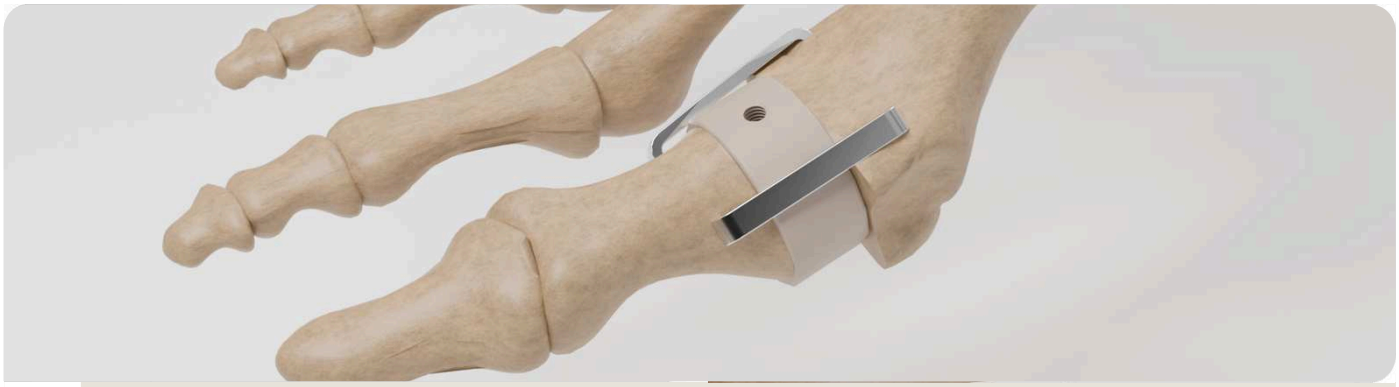
The Nvision Vertex System provides staples to be inserted over the wedge as desired.



5

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.



6

Tamp on the staple to place it subflush to the bone. A staple may be placed dorsally and/or medially over the implant as shown.

Removal:

1. Remove additional fixation with corresponding system instrumentation.
2. 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
• Subtalar Fusion
• First Metatarsal-Cuneiform Lengthening Arthrodesis
• Calcaneocuboid Arthrodesis
• Calcaneal Z Lengthening Osteotomies
• MTP Lengthening Arthrodesis
• Lesser Metatarsal-Cuneiform Lengthening Arthrodesis
• Navicular-Cuneiform Arthrodesis
• Talonavicular 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.

DEVICE DESCRIPTION

The Trigon HA Stand-Alone Wedge Fixation System is a family of PEEK Optima HA Enhanced (HA PEEK) wedges with tantalum markers used for angular correction of small bones of the foot. The wedges incorporate an inserter-receiving hole and/or two screw-receiving holes and an area to contain grafting material. The wedges are designed in rectangular, kidney, circular, oval, and teardrop shaped footprints in a range of sizes and in multiple thicknesses. The associated 2.5mm diameter titanium screws are designed in lengths of 10 to 30mm. When used with the provided screw fixation the Trigon wedges may be used with or without ancillary plating. Lapidus, Calcaneocuboid, MTP, Lesser Metatarsal, and Midfoot Wedges require additional fixation not provided in the Trigon System.
When used without the provided screws, Trigon wedges are intended for use with ancillary fixation.

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.
• Patients with high level of activity.
• 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.

MR (Magnetic Resonance) Safety Information:

The PEEK Trigon HA Stand-Alone Wedge Fixation System is MR Safe.

Potential Adverse Events:

Potential Complications and 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

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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® MTP WEDGE SYSTEM

Implants 18mm

Part Number	Description
MTP-18-08-00	PEEK MTP 18mm Wedge 8mm Parallel
MTP-18-10-00	PEEK MTP 18mm Wedge 10mm Parallel
MTP-18-12-00	PEEK MTP 18mm Wedge 12mm Parallel

Implants 22mm

Part Number	Description
MTP-22-08-00	PEEK MTP 22mm Wedge 8mm Parallel
MTP-22-10-00	PEEK MTP 22mm Wedge 10mm Parallel
MTP-22-12-00	PEEK MTP 22mm Wedge 12mm Parallel

Trials 18mm

Part Number	Description
MTP-18-08T-00	18mm Diameter 8mm Length 0 Degree Trial
MTP-18-10T-00	18mm Diameter 10mm Length 0 Degree Trial
MTP-18-12T-00	18mm Diameter 12mm Length 0 Degree Trial

Trials 22mm

Part Number	Description
MTP-22-08T-00	22mm Diameter 8mm Length 0 Degree Trial
MTP-22-10T-00	22mm Diameter 10mm Length 0 Degree Trial
MTP-22-12T-00	22mm Diameter 12mm Length 0 Degree Trial

Instruments

Part Number	Description
HAN-1000T-AOSM	Handle
WD-1000T-TRI	Trial Inserter
WD-1000T-MWIS	MTP Wedge Inserter

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