

trigon[®]



NVISION[™]
BIOMEDICAL TECHNOLOGIES

Product Sizes Available

Footprints (HxW): 14x14mm, 17x15mm, 14x28mm, 17x31mm

Thickness (T): 6mm, 8mm

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

The Trigon® Lesser Metatarsal Wedge System is indicated for a metatarsal-cuneiform lengthening arthrodesis of the second and/or third TMT joint(s). Both single and double joint options are provided, in parallel or angular correction. The wedge is available in a variety of sizes that accommodate a large patient population, allowing precise and reliable correction.

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



LMP-1414-0600	PEEK Small Single Joint Lesser Metatarsal 6mm Wedge Parallel
LMP-1414-0806	PEEK Small Single Joint Lesser Metatarsal 8mm Wedge 6° Transverse
LMP-1414-0809	PEEK Small Single Joint Lesser Metatarsal 8mm Wedge 9° Transverse
LMP-1715-0806	PEEK Large Single Joint Lesser Metatarsal 8mm Wedge 6° Transverse
LMP-1715-0809	PEEK Large Single Joint Lesser Metatarsal 8mm Wedge 9° Transverse



LMP-1428-0600	PEEK Small Multi Joint Lesser Metatarsal 6mm Wedge Parallel
LMP-1428-0806	PEEK Small Multi Joint Lesser Metatarsal 8mm Wedge 6° Transverse
LMP-1428-0809	PEEK Small Multi Joint Lesser Metatarsal 8mm Wedge 9° Transverse
LMP-1731-0806	PEEK Large Multi Joint Lesser Metatarsal 8mm Wedge 6° Transverse
LMP-1731-0809	PEEK Large Multi Joint Lesser Metatarsal 8mm Wedge 9° Transverse

Featured Instruments

Lesser Metatarsal Wedge Inserter Shaft



Trigon Trial Inserter



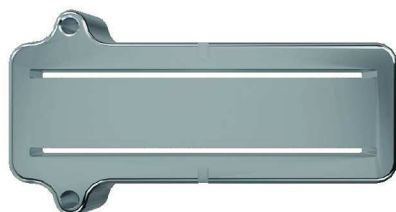
2.5mm Drill



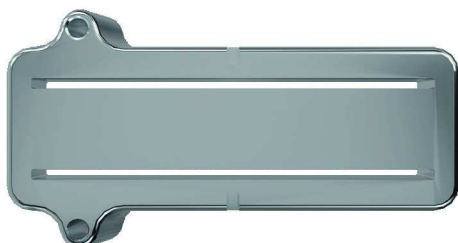
Handle



Lesser Metatarsal 6mm Cut Guide



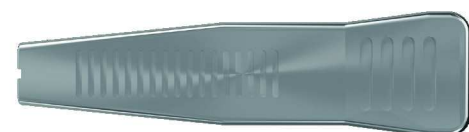
Lesser Metatarsal 8mm Cut Guide



Lesser Metatarsal/Midfoot Cut Guide Handle



Tamp



Lesser Metatarsal Wedge Staple Drill Guide



Staple Distractor



Surgical Technique



1

Incision

Perform a longitudinal dorsal incision over the selected lesser tarsometatarsal joint(s). Retract soft tissue as necessary to aid in ease of cut guide placement.

2

Joint Preparation

Remove cartilage of lesser metatarsal joint(s) to allow for cut guide placement.



3

Cut Guide Placement

Thread the cut guide handle into the cut guide and use it to position the guide over your selected joint(s). Place the paddle of the cut guide into the lesser metatarsal joint(s) and firmly press down on the center of the cut guide to seat it close to the bone. Place k-wires in the designated holes in the cut guide to fixate the guide in its optimal position.



4

Parallel Cuts

Use a sagittal saw and the desired cut guide to make equal cuts through the designated slots on the cuneiform and metatarsal. After the cuts are made, remove the cut guide and k-wires, and subsequently remove the remaining bone slivers. Per surgeon discretion, additional drilling of the raw bone surfaces of the cuneiform and metatarsal can be performed to further enhance the healing environment.



5

Wedge Size Selection

Thread trial inserter into trial 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.

6

Use fluoroscopy to confirm desired correction.

7

Once satisfied with the correction, remove the trial and prepare for wedge insertion.



8

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.

9

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, and the selection of such fixation is surgeon preference. The Trigon Lesser Metatarsal Wedge System provides a staple guide for dorsal fixation, but the use of any other ancillary fixation is permitted.



1

To use the Staple Drill Guide

Once the implant is fully seated, place the staple drill guide over the desired placement of the staple (ideally over the grooves in the wedge) and drill through the guide.

2

Place the selected staple into the drilled holes and tamp it flush 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 Insert to reattach and secure to wedge. Pull or slide wedge out of osteotomy.
 - Use burr or sagittal saw to remove any bone growth on or through wedge.
 - 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.
-

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 SINGLE JOINT

Part Number	Description
LMP-1414-0600	6mm Wedge Parallel PEEK Small Single Joint Lesser Metatarsal
LMP-1414-0806	8mm Wedge 6° Transverse PEEK Small Single Joint Lesser Metatarsal
LMP-1414-0809	8mm Wedge 9° Transverse PEEK Small Single Joint Lesser Metatarsal
LMP-1715-0806	8mm Wedge 6° Transverse PEEK Large Single Joint Lesser Metatarsal
LMP-1715-0809	8mm Wedge 9° Transverse PEEK Large Single Joint Lesser Metatarsal

Wedges MULTI JOINT

Part Number	Description
LMP-1428-0600	6mm Wedge Parallel PEEK Small Multi Joint Lesser Metatarsal
LMP-1428-0806	8mm Wedge 6° Transverse PEEK Small Multi Joint Lesser Metatarsal
LMP-1428-0809	8mm Wedge 9° Transverse PEEK Small Multi Joint Lesser Metatarsal
LMP-1731-0806	8mm Wedge 6° Transverse PEEK Large Multi Joint Lesser Metatarsal
LMP-1731-0809	8mm Wedge 9° Transverse PEEK Large Multi Joint Lesser Metatarsal

Staples

Part Number	Description
STK-20-14-14	20mm Bridge Staple, 14mm x 14mm Legs
STK-20-18-18	20mm Bridge Staple, 18mm x 18mm Legs
STK-20-20-20	20mm Bridge Staple, 20mm x 20mm Legs

Trials SINGLE JOINT

Part Number	Description
LM-1414T-0600	6mm Trial Parallel PEEK Small Single Joint Lesser Metatarsal
LM-1414T-0806	8mm Trial 6° Transverse PEEK Small Single Joint Lesser Metatarsal
LM-1414T-0809	8mm Trial 9° Transverse PEEK Small Single Joint Lesser Metatarsal
LM-1715T-0806	8mm Trial 6° Transverse PEEK Large Single Joint Lesser Metatarsal
LM-1715T-0809	8mm Trial 9° Transverse PEEK Large Single Joint Lesser Metatarsal

Trials MULTI JOINT

Part Number	Description
LM-1428T-0600	6mm Trial Parallel PEEK Small Multi Joint Lesser Metatarsal
LM-1428T-0806	8mm Trial 6° Transverse PEEK Small Multi Joint Lesser Metatarsal
LM-1428T-0809	8mm Trial 9° Transverse PEEK Small Multi Joint Lesser Metatarsal
LM-1731T-0806	8mm Trial 6° Transverse PEEK Large Multi Joint Lesser Metatarsal
LM-1731T-0809	8mm Trial 9° Transverse PEEK Large Multi Joint Lesser Metatarsal

Ordering Information



Instruments

Part Number	Description
HAN-1000T-AOSM	Handle
WD-1000T-LMCG06	Lesser Metatarsal 6mm Cut Guide
WD-1000T-LMCG08	Lesser Metatarsal 8mm Cut Guide
WD-1000T-LMSDG	Lesser Metatarsal Wedge Staple Drill Guide
WD-1000T-MCGH	Lesser Metatarsal/Midfoot Cut Guide Handle
WD-1000T-TRI	Trigon Trial Inserter
STK-1000T-011	2.5mm Drill
STK-1000T-DIS1	Staple Distractor
STK-1000T-TMP	Tamp



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