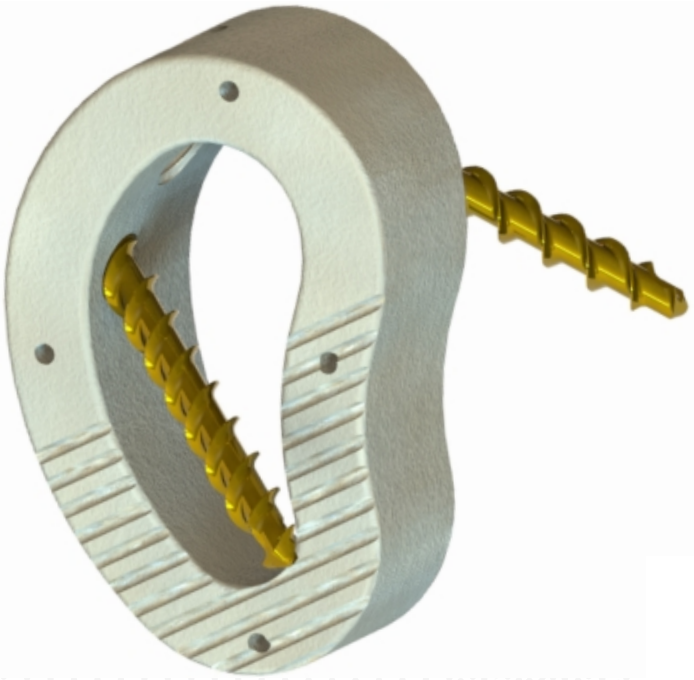
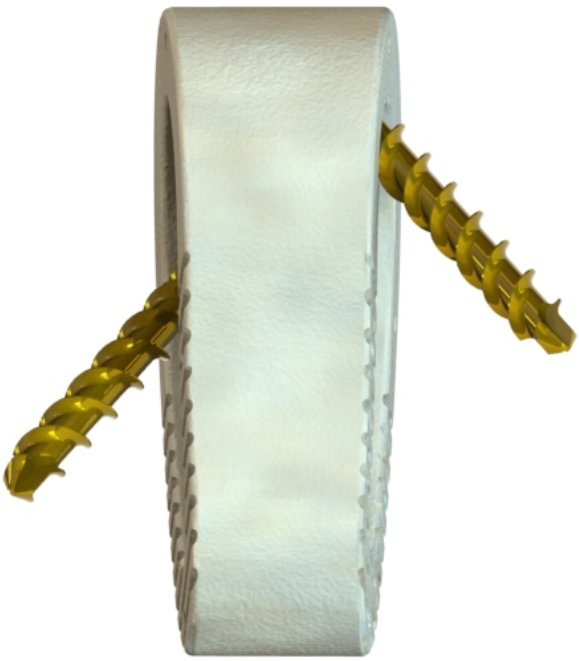
trigon®

LAPIDUS WEDGE SYSTEM

Surgical Technique Guide





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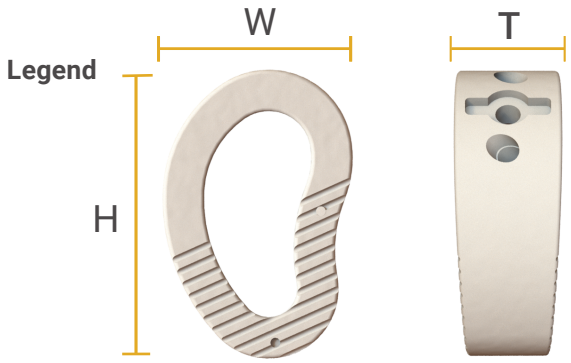
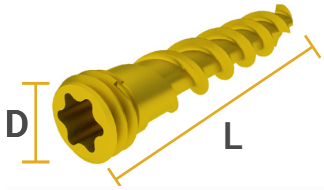
biomedical technologies

trigon®
LAPIDUS WEDGE SYSTEM





Product Sizes Available

Lapidus Footprints (HxW): 24x16mm, 28x18mm, 32x20mm
Lapidus Thickness (T): 5mm, 8mm, 10mm, 12mm

2.5mm Diameter Screws: 10mm-30mm lengths in 2mm increments

The Trigon® HA Wedge Fixation System is made of PEEK-Optima® HA Enhanced, where the HA is fully integrated throughout the PEEK.

The Trigon® Lapidus Wedge is indicated for a first metatarsal-cuneiform lengthening arthrodesis. The wedge is available in a variety of sizes, allowing for precise and reliable correction that accommodate a large patient population.

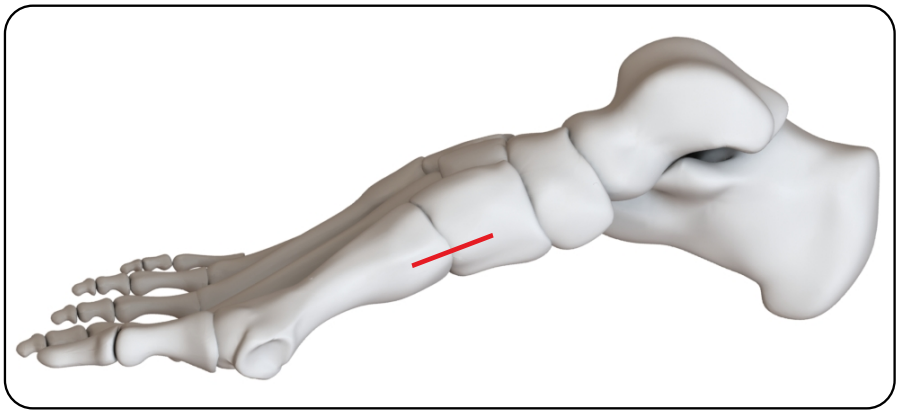
The Trigon® Lapidus Wedge requires ancillary fixation not provided in the Trigon system. Ergonomic instrumentation allow for accurate wedge insertion and precise screw placement.

Footprint	Description	Angulation
24x16mm	PEEK Small Lapidus Wedge 5mm	0-4° Sagittal, 4-10° Transverse
	PEEK Small Lapidus Wedge 8mm	0-4° Sagittal, 4-10° Transverse
	PEEK Small Lapidus Wedge 10mm	0-4° Sagittal, 4-12° Transverse
	PEEK Small Lapidus Wedge 12mm	0-4° Sagittal, 4-12° Transverse
28x18mm	PEEK Medium Lapidus Wedge 5mm	0-4° Sagittal, 4-10° Transverse
	PEEK Medium Lapidus Wedge 8mm	0-4° Sagittal, 4-10° Transverse
	PEEK Medium Lapidus Wedge 10mm	0-4° Sagittal, 4-12° Transverse
	PEEK Medium Lapidus Wedge 12mm	0-4° Sagittal, 4-12° Transverse
32x20mm	PEEK Large Lapidus Wedge 5mm	0-4° Sagittal, 4-10° Transverse
	PEEK Large Lapidus Wedge 8mm	0-4° Sagittal, 4-10° Transverse
	PEEK Large Lapidus Wedge 10mm	0-4° Sagittal, 4-12° Transverse
	PEEK Large Lapidus Wedge 12mm	0-4° Sagittal, 4-12° Transverse

Lapidus Surgical Technique

Step 1 - Site Preparation

Create a dorsomedial incision over the 1st TMT joint to expose the medial aspect of the joint and the base of the metatarsal. The incision should be approximately the length of the cut guide, 3.5 cm long. Retract soft tissue as necessary to aid in cut guide placement.



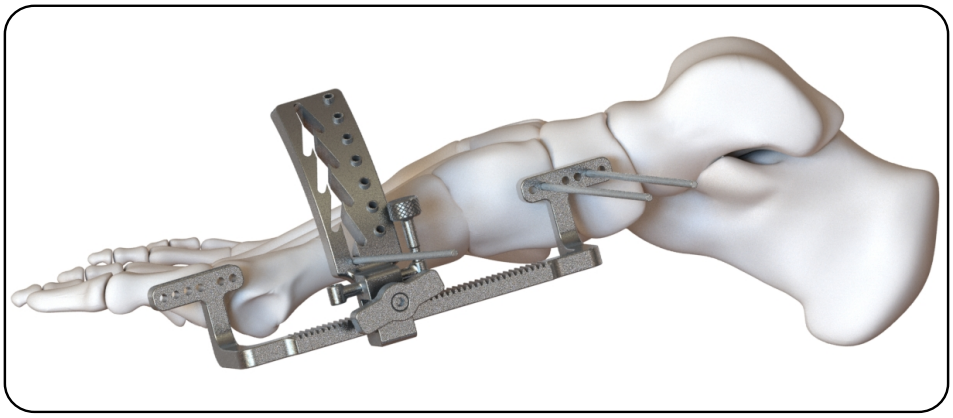
Note: The incision can be extended over the medial metatarsal to expose the MTP joint and preform a capsular and soft tissue release.

Remove cartilage and prepare the 1st TMT joint for fusion. Utilize a slim osteotome to mobilize the joint and release any plantar soft tissue attachments. Ensure the metatarsal has good mobility to enable rotation by using fluoroscopy to assess the distal metatarsal and sesamoids.

Step 2 - Rotational Correction

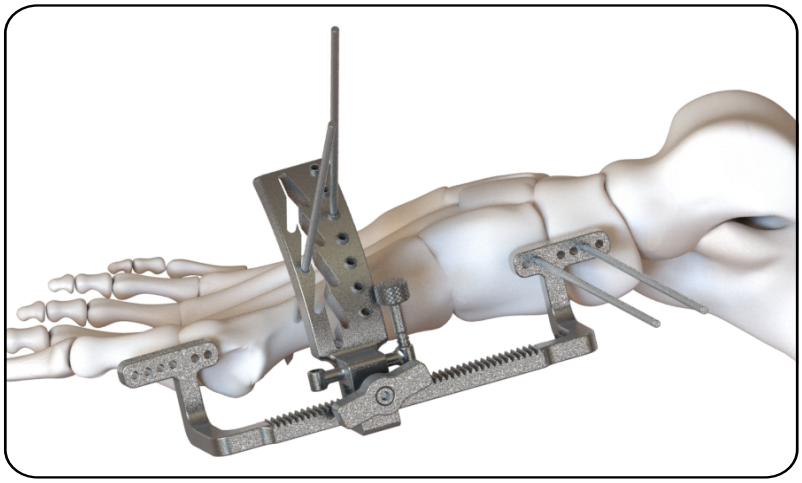
Attach the rotational jig to the medial cuneiform and navicular using two Steinmann pins to ensure rotational stability of the jig.

Position the rotational jig at least 2.5cm distal to the joint. Place another Steinmann pin through the slotted arch of the rotational jig into the medial aspect of the first metatarsal.



Rotate the pin up the center of the arch and position it in the desired slot to perform coronal correction, rotating the sesamoids plantar.

Place a fourth Steinmann pin through one of the holes to the right of the rotational arch to ensure rotational correction does not revert.

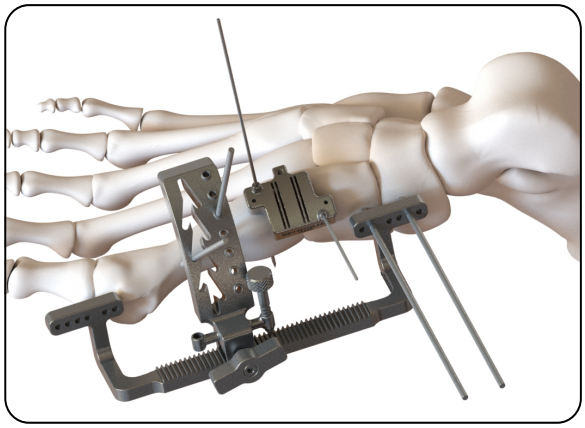


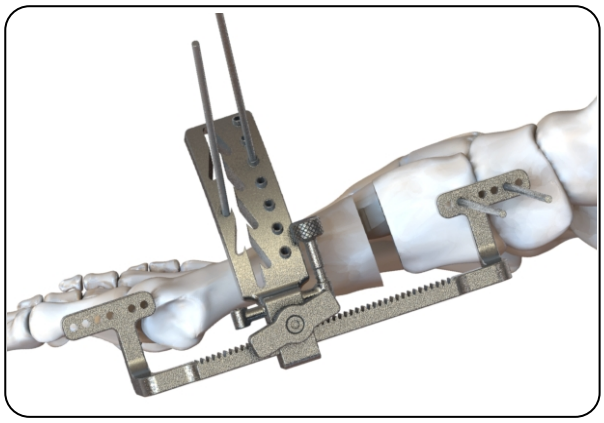
Step 3 - Parallel Cuts

Place the paddle of the cut guide into the first TMT joint and firmly press down on the center of the cut guide to seat it close to the bone.

The trial inserter can be threaded into the cut guide to move the guide dorsally or medially. Place k-wires in the preferred distal and proximal holes of the cut guide to fixate. Ensure both wires are bicortical but not in the 2nd metatarsal.

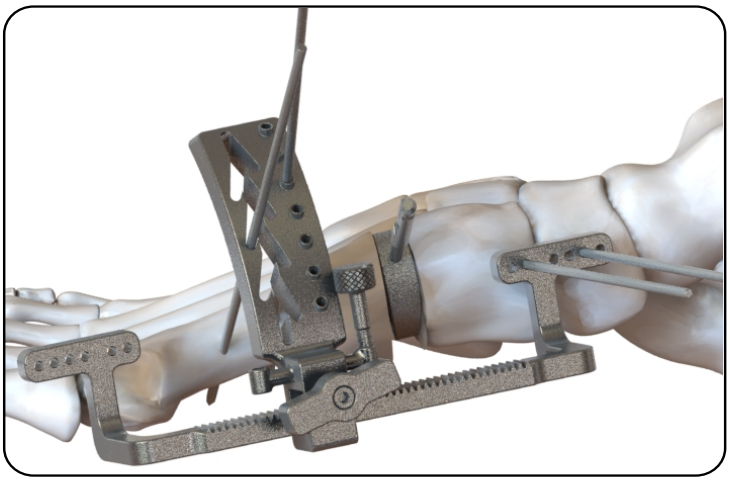
Use a sagittal saw to make equal, parallel cuts through the designated slots on the medial cuneiform and first metatarsal. After the cuts are made, remove the cut guide and k-wires, and remove the resected bone.



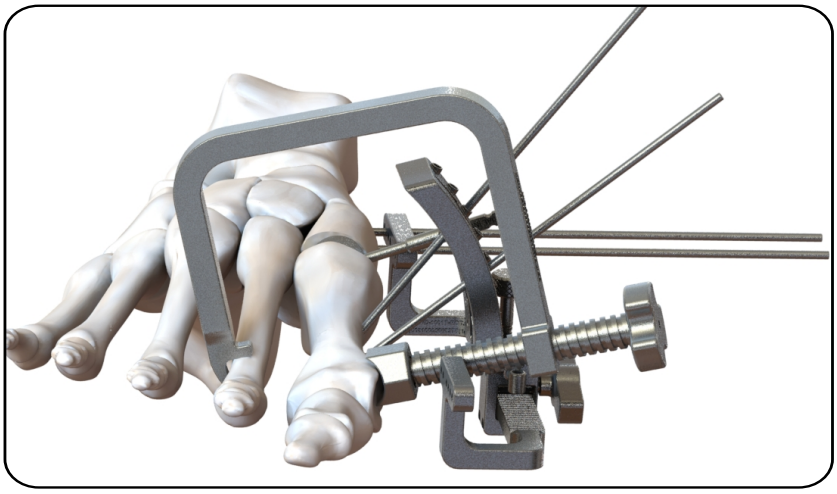


Step 4 - IM Correction and Wedge Selection

While maintaining the correction with the rotational jig, use the provided trial wedges to determine the appropriate implant size. Start with smaller trials and increase the trial footprint, thickness, and biplanar correction as desired.



Make a stab incision in the intermetatarsal space between the second and third metatarsal. Place the lateral hook of the IM angle reducer around the neck of the second metatarsal. Place the medial hook over the skin onto the head of the first metatarsal. Turn the knob clockwise until the bone is compressed to the trial. Use the knob on the rotational jig to further compress around the trial if necessary.



Use fluoroscopy to confirm positioning.

Once satisfied with the correction, distract one or two turns using the rotational jig to prepare for wedge insertion.

Step 5 - Implant Insertion

A. Wedge Insertion

Attach desired implant to the inserter shaft, then slide the wedge screw sleeve over the inserter shaft and secure with threads. Ensure the insertion features on the sleeve are aligned with those on the wedge and are fully seated into the wedge.

Place implant into the joint space until the implant is subflush and/or until stop engages medial cortical wall. Fluoroscopy can be used to confirm the desired correction of deformity is achieved once the 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.

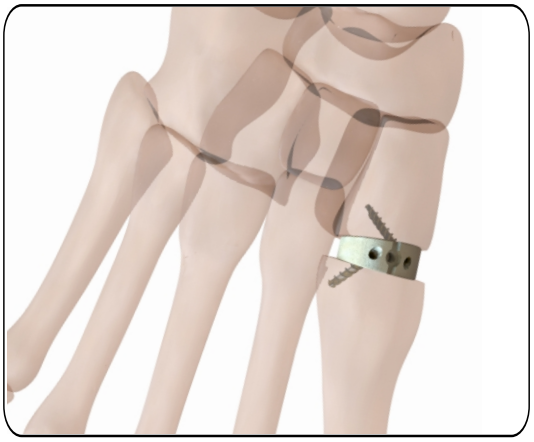
B. Wedge Insertion

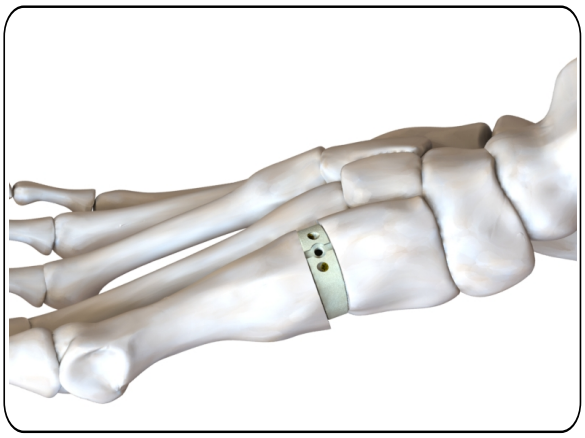
Keeping the wedge in position, drill through the drill guide towers and refer to the depth indicator lines to determine screw length. Then advance the appropriate screw until the screw inserter reaches the stop on the wedge tower. Repeat the same for the remaining screw.

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 inserter shaft counterclockwise to disengage from the wedge. If needed, further drive the wedge screws until they are subflush with the implant.



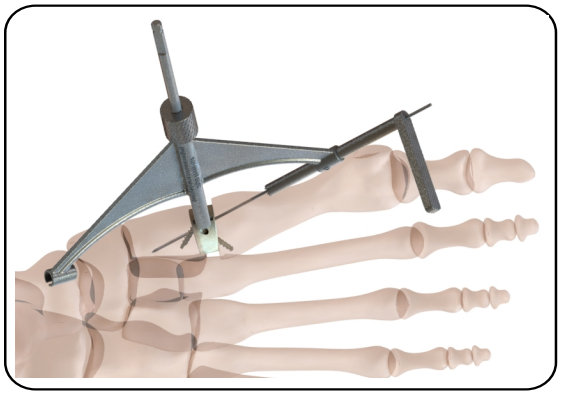


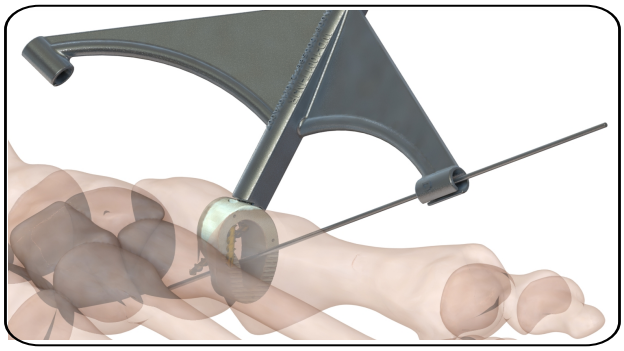
Step 6 - Additional Fixation

Once the wedge screws are placed, additional fixation is required, and the selection of such fixation is surgeon preference. The Trigon HA Lapidus Wedge System provides a drill guide for two opposing interfragmentary screws going through the wedge system, but the use of any other ancillary fixation is permitted.

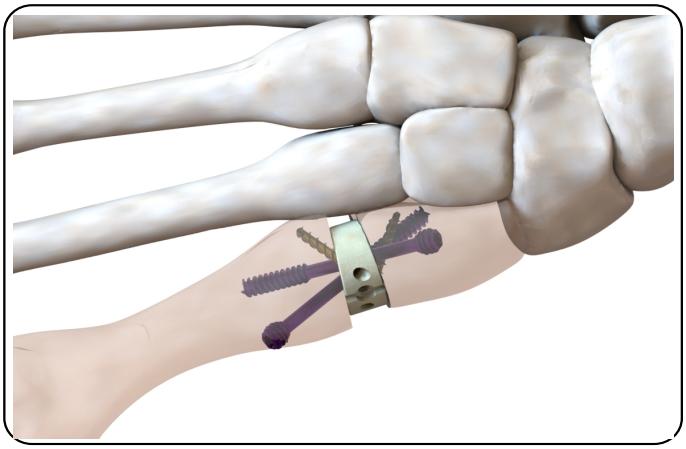
To use the interfragmentary screw sleeve:

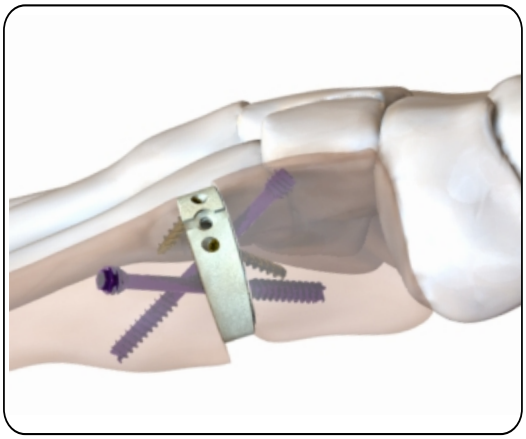
Remove the wedge screw sleeve, while maintaining the position of the inserter shaft within the wedge. Slide right (R) or left (L) interfragmentary screw sleeves onto the inserter shaft and thread the knob in the same manner as before to lock in place. Ensure the arm marked with a ‘D’ is facing distally, and confirm the sleeve is fully seated into the insertion feature of the wedge. Use K-wire sleeve to insert K-wire.





Use fluoroscopy to confirm trajectory of interfragmentary screws. Remove all guides and inserter shaft. Drill over the K-wires and insert interfragmentary screws. Remove K-wires.





Implant Removal

1. Remove the additional fixation that was initially used with the Lapidus Wedge. Remove this with corresponding instrumentation (screw, plate, or staple removal 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 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 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

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.

Notes

ORDERING INFORMATION

trigon® LAPIDUS WEDGE SYSTEM

Lapidus Implants

Part Number	Description
LDP-2405-XXXX	PEEK HA Small Lapidus Wedge 5mm
LDP-2408-XXXX	PEEK HA Small Lapidus Wedge 8mm
LDP-2410-XXXX	PEEK HA Small Lapidus Wedge 10mm
LDP-2412-XXXX	PEEK HA Small Lapidus Wedge 12mm
LDP-2805-XXXX	PEEK HA Medium Lapidus Wedge 5mm
LDP-2808-XXXX	PEEK HA Medium Lapidus Wedge 8mm
LDP-2810-XXXX	PEEK HA Medium Lapidus Wedge 10mm
LDP-2812-XXXX	PEEK HA Medium Lapidus Wedge 12mm
LDP-3205-XXXX	PEEK HA Large Lapidus Wedge 6mm
LDP-3208-XXXX	PEEK HA Large Lapidus Wedge 8mm
LDP-3210-XXXX	PEEK HA Large Lapidus Wedge 10mm
LDP-3212-XXXX	PEEK HA Large Lapidus Wedge 12mm

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-1000T-SHFT	Lapidus Wedge Inserter Shaft
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-320	K-Wires (1.0mmx150mm)
CSRW-1000T-501	Small AO Handle
WD-1000T-LGRB	Lapidus Graft Packing Block
WD-1000T-LCGXX	Lapidus Parallel Cut Guide [05-12mm]
WD-1001T-ROTJ	Lapidus Rotational Jig
WD-1001T-WSLV	Lapidus Wedge Screw Sleeve
WD-1001T-INJR	Lapidus Interfrag Screw Targeting Sleeve (R)
WD-1001T-INJL	Lapidus Interfrag Screw Targeting Sleeve (L)
WD-1001T-INRS	Interfrag Screw Targeting Sleeve (R) 24mm
WD-1001T-INLS	Interfrag Screw Targeting Sleeve (L) 24mm
WD-1001T-IMAR	Lapidus IM Angle Reducer
WD-1001T-KWSL	Lapidus Kwire Sleeve
CSRW-1000T-200	Interfrag Screw Depth Gauge

Trials

Part Number	Description
LDP-2405-XXXX	Small Lapidus Wedge 5mm Trial
LDP-2408-XXXX	Small Lapidus Wedge 8mm Trial
LDP-2410-XXXX	Small Lapidus Wedge 10mm Trial
LDP-2412-XXXX	Small Lapidus Wedge 12mm Trial
LDP-2805-XXXX	Medium Lapidus Wedge 5mm Trial
LDP-2808-XXXX	Medium Lapidus Wedge 8mm Trial
LDP-2810-XXXX	Medium Lapidus Wedge 10mm Trial
LDP-2812-XXXX	Medium Lapidus Wedge 12mm Trial
LDP-3205-XXXX	Large Lapidus Wedge 6mm Trial
LDP-3208-XXXX	Large Lapidus Wedge 8mm Trial
LDP-3210-XXXX	Large Lapidus Wedge 10mm Trial
LDP-3212-XXXX	Large Lapidus Wedge 12mm Trial

NVISION™ biomedical technologies

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