Lapidus Bunion Correction Instruments

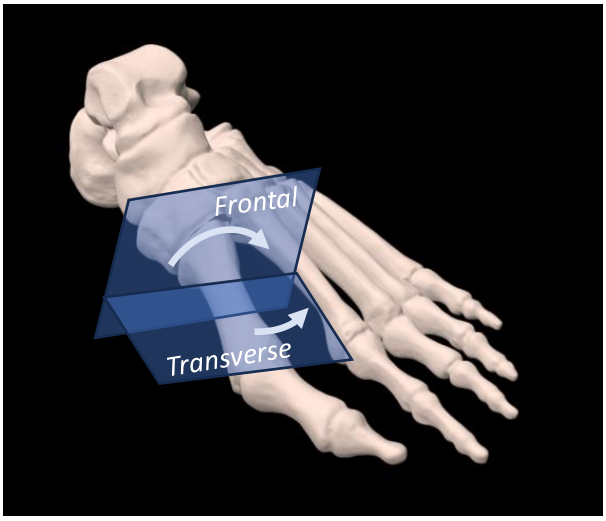
Surgical Operative Technique

GEO-Desis System Overview

GEO-Desis is a new approach to assisting the surgeon in performing a TMT fusion, specifically for Lapidus bunion repair.

Medial displacement of the first metatarsal head is a painful and debilitating condition that may require surgical intervention. The GEO-Desis instruments and surgical technique provide the surgeon with an efficient and repeatable means to return the first ray to the standard anatomic position so that fixation can be applied to fuse the first tarsometatarsal joint.

The surgical procedure includes reducing the intermetatarsal angle in the transverse plane and de-rotation of the first ray in the frontal plane.



NOTE: Metatarsus Adductus must be corrected, or not be present, prior to performing any bunion correction procedure.

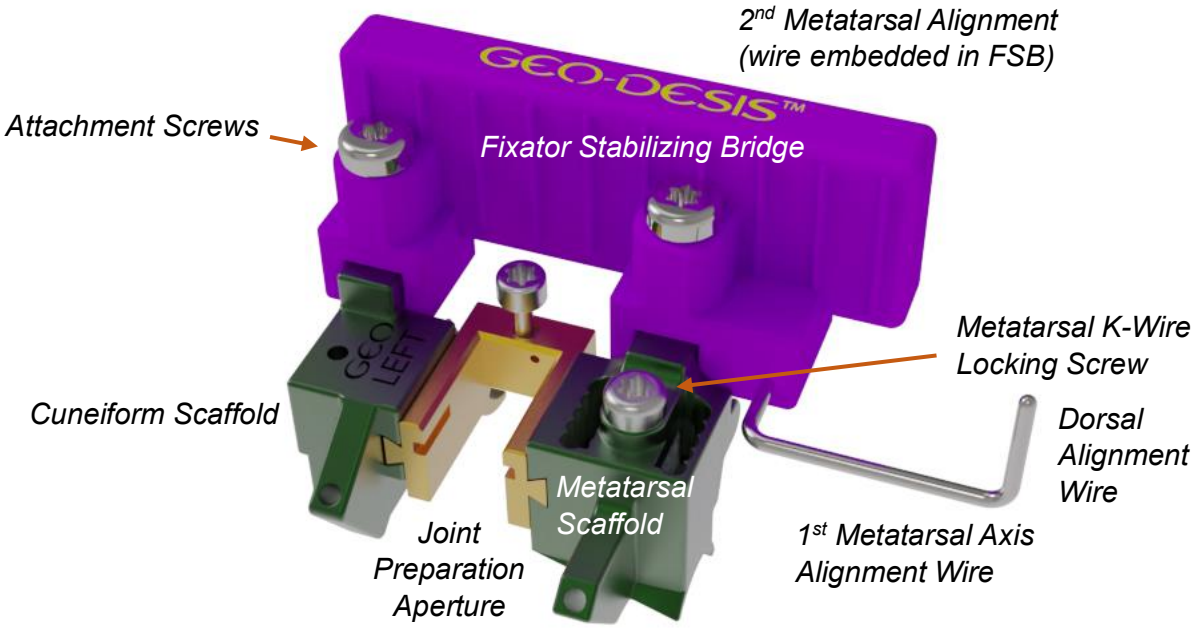
GEO-Desis System Components

First Ray Fixator

The GEO-Desis instrument set includes a First Ray Fixator consisting of three elements. The first component serves as a scaffold for fixation to the metatarsal. The second component is for fixation to the cuneiform. The third element assists with joint preparation.

GEO-Desis First Ray Fixator

GEO-Desis First Ray Fixator Components



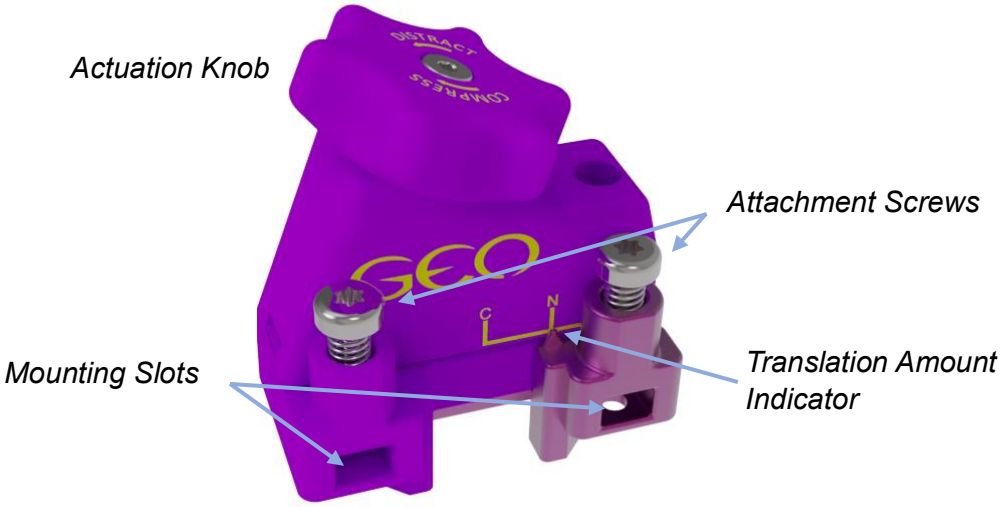
Cut Guides

The system also includes unique interchangeable cut guides that provide for cuts from 1 millimeter to 2.5 millimeters on each bone-end, allowing total joint-cut depth from 2 millimeters to 5 millimeters in half millimeter increments. Each cut guide includes a bone-end positioner to assure the amount of cut.

Bone-End Positioner

Compressor-Distractor

Also included is a unique compressor distractor that attaches to the First Ray Fixator allowing up to 8mm of compression or distraction.



Other Instruments

Other instruments included in the set are a saw blade for use with a Stryker TPS sagittal saw, k-wires, a hand rasp, a tissue protector drill guide and bit, and a T-15 hexalobe driver tip.

GEO-Desis Operative Technique

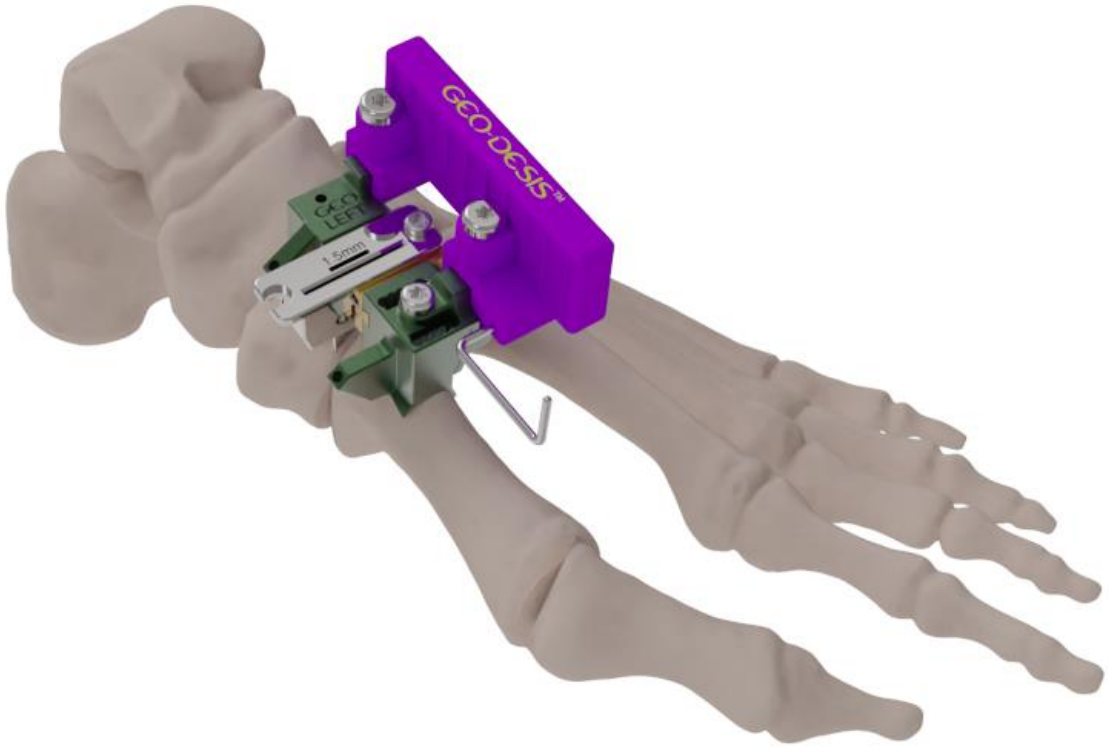
Incision and Joint Preparation

Make an incision on the dorsal aspect of the TMT joint, approximately 20mm proximal and distal to the joint line, or as preferred for accessing the tissue along the first ray. Release the joint capsule tissue and, if required, perform a distal release as preferred for bunion correction.

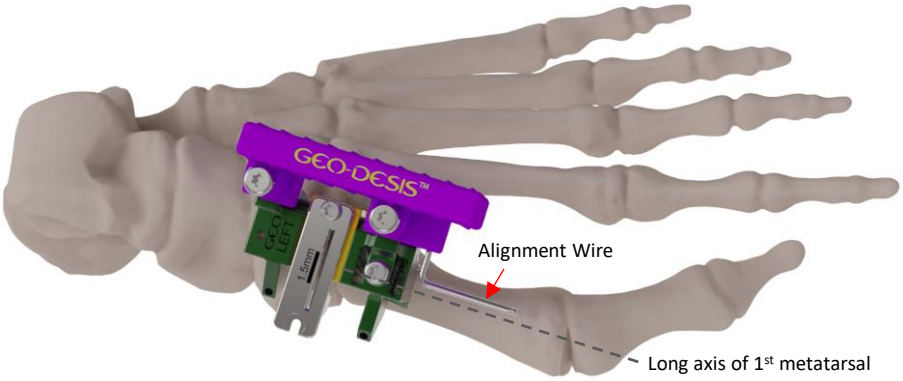
Placement of the First Ray Fixator

After resecting the joint connective tissues, and with the metatarsal in the deformed state, place the First Ray Fixator on the dorsal aspect of the first metatarsal with the bone-end positioner against the metatarsal base.

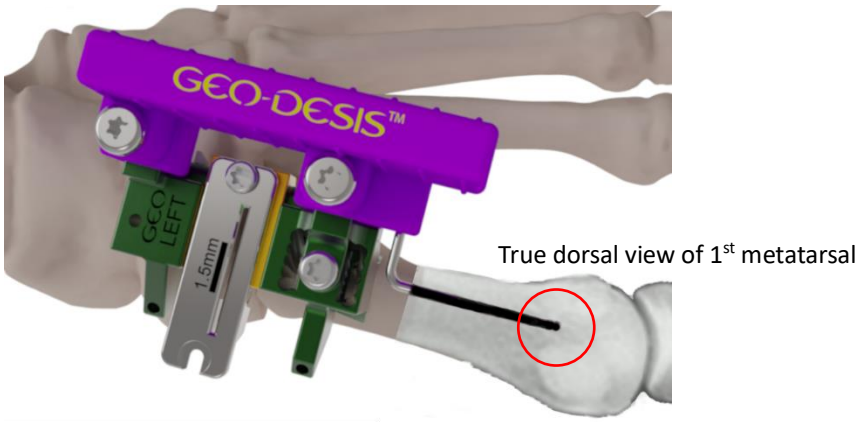
NOTE: Correct alignment of the First Fay Fixator onto the dorsal surface of the first metatarsal is important for ensuring that the joint-cut planes are perpendicular to the first metatarsal axis. Additionally, when the alignment features on the First Ray Fixator correspond with the anatomic axes of the first metatarsal, the First Ray Fixator provides direct visual feedback for correcting the first metatarsal alignment in later steps.



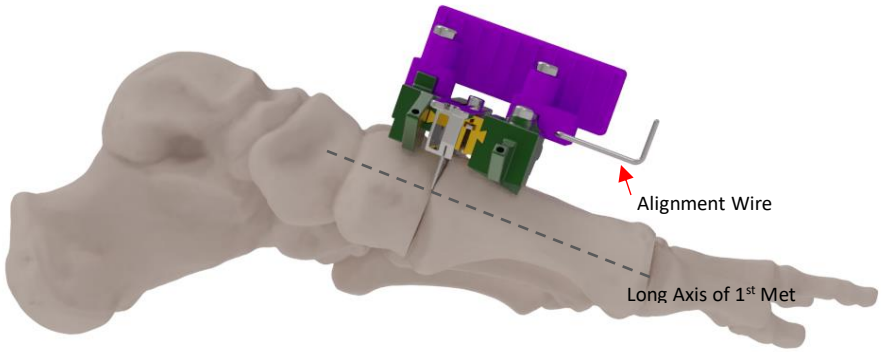
Use the 1st Metatarsal Alignment Wire to aid aligning the First Ray Fixator in a true dorsal orientation of the first metatarsal and aligned with its long axis.



To aid in positioning the First Ray Fixator on the dorsal surface, align a C-arm in a *true dorsal view of the 1st metatarsal* using the sesamoids as a reference. Then, orient the First Ray Fixator until the vertical part of the Dorsal Alignment Wire becomes a "dot" under fluoroscopy.

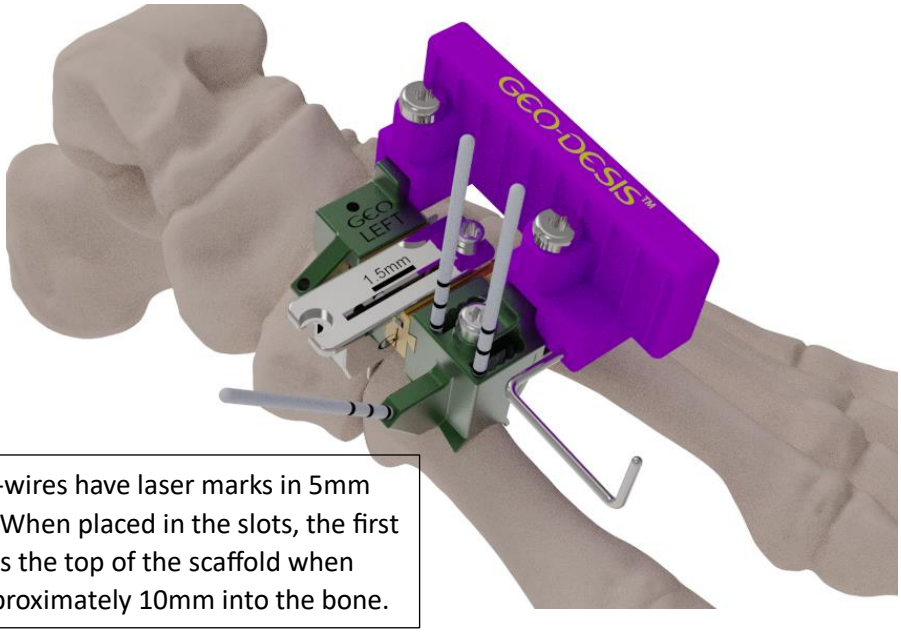


Also check the alignment of the 1st Metatarsal Alignment Wire from a lateral view to ensure it is parallel to the first metatarsal axis.



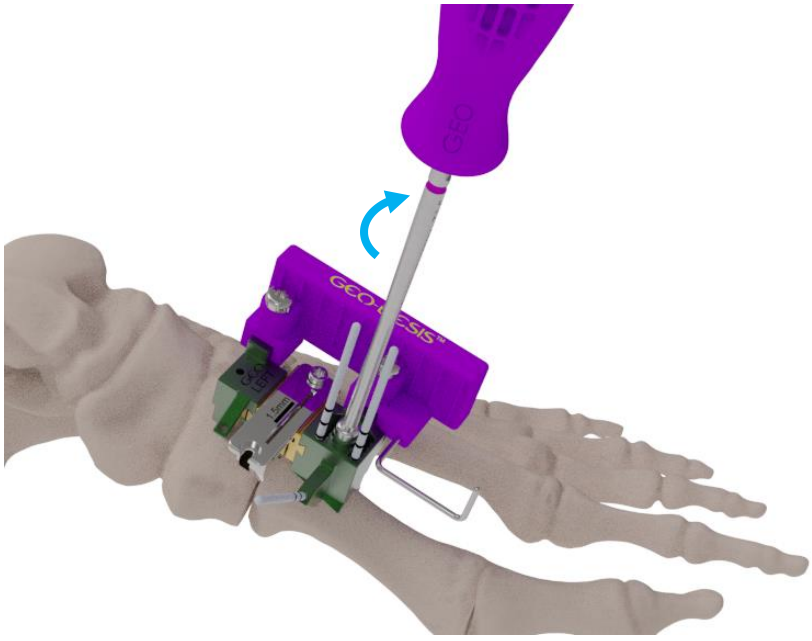
Securing the First Ray Fixator to the Metatarsal

Once the position of the First Ray Fixator is satisfactory, insert two k-wires into the medial openings of the metatarsal scaffold scalloped slots. If desired, the proximal k-wire can be inserted first to allow a second alignment check before the distal k-wire is inserted. Insert a k-wire into the oblique k-wire hole to fully secure the First Ray Fixator.



NOTE: The k-wires have laser marks in 5mm increments. When placed in the slots, the first mark reaches the top of the scaffold when the tip is approximately 10mm into the bone.

After both k-wires are inserted, use the T-15 hexalobe driver tip inserted into the driver handle to secure the First Ray Fixator to the k-wires by turning the locking screw clockwise until snug.

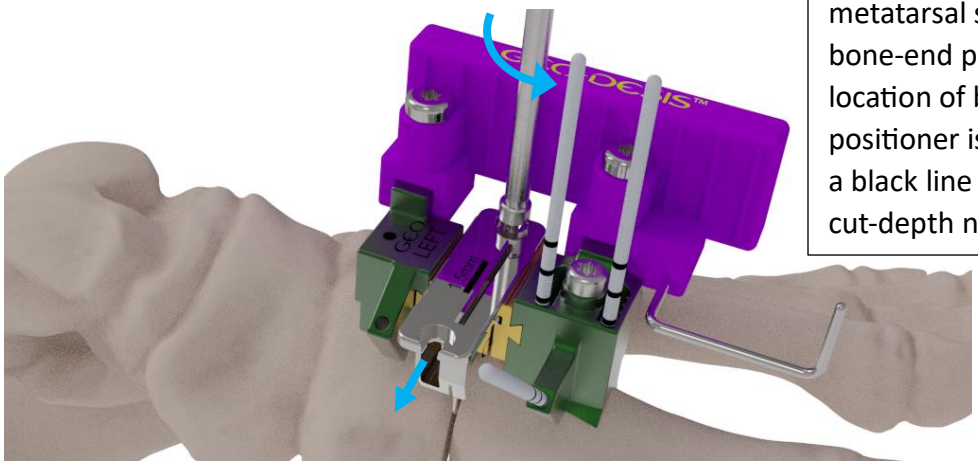


Cut Proximal Cartilage of Metatarsal

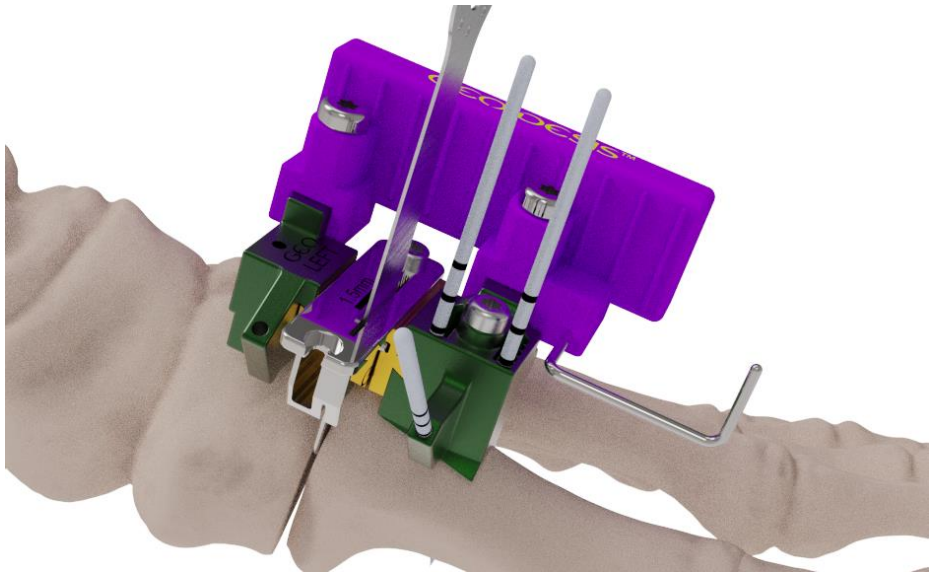
Determine the amount of the metatarsal base to cut. If the cut guide that is pre-installed in the joint preparation aperture is not the correct size, remove it and select one of three other sizes.

To remove the cut guide, use the T-15 driver to turn the securing screw counterclockwise until the screwhead is above the top surface of the cut guide. Slide the cut guide medially then lift out. Reverse the process to insert the guide.

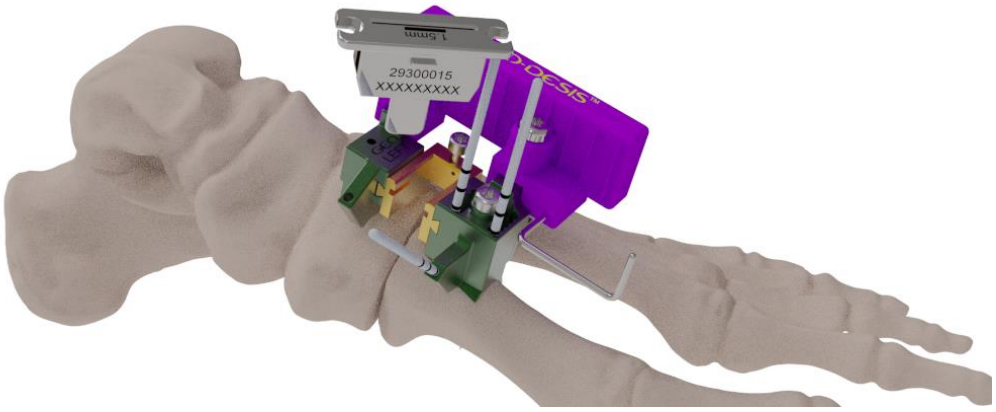
NOTE: Be sure to insert the cut guide so that the cut slot is on the metatarsal side of the bone-end positioner. The location of bone-end positioner is indicated by a black line under the cut-depth number.



Use the sagittal saw blade provided in the GEO-Desis instrument kit. Insert the blade through the cut guide slot and maintain the orientation of the blade so that it remains parallel to the slot walls. This will ensure that the cut plane is perpendicular to the 1st metatarsal long axis.



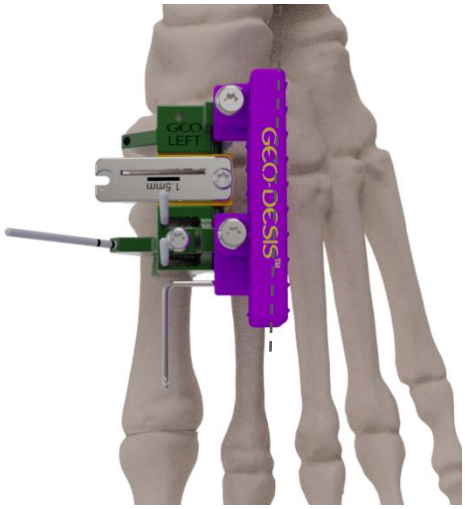
After cutting the desired amount of the metatarsal base, remove the cut guide and remove the cut bone. Rotate the cut guide one-hundred eighty degrees and re insert it into the aperture, or choose a different size cut guide to insert. Be sure the cut slot is on the cuneiform side of the bone-end positioner, then insert the cut guide and secure it to the aperture with the aperture screw making sure the screwhead fully seats in the round opening.

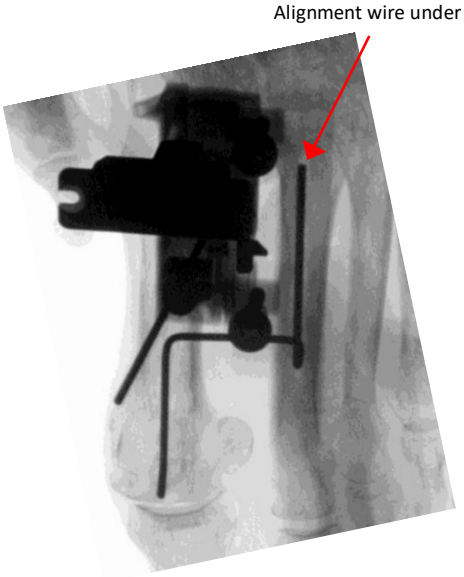


Correct 1st Ray Alignment

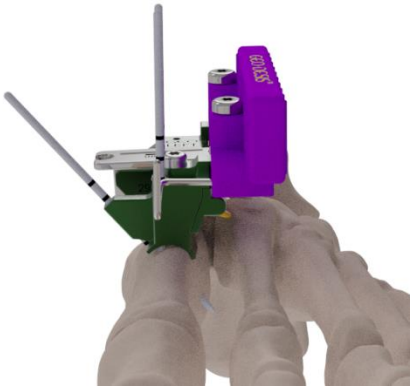
Manually re-position the metatarsal in the desired anatomically correct orientation. Under fluoroscopy, use the 2nd Metatarsal Alignment Wire embedded in the Stabilizing Bridge to orient the first metatarsal with the second metatarsal.

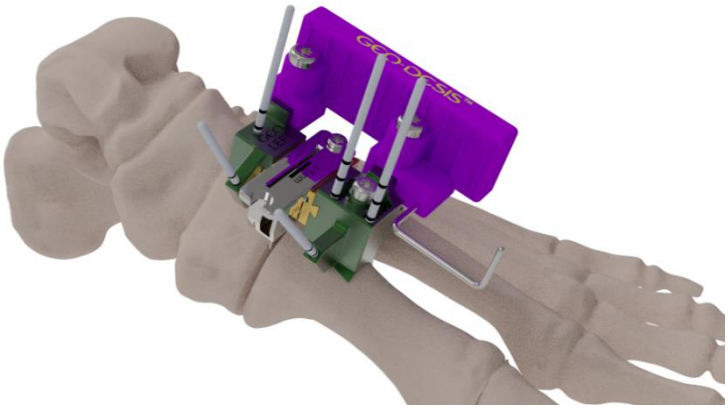
Use the vertical part of the 1st Ray Alignment Wire to visually check the rotational orientation of the first ray in the frontal plane.





Confirm the orientation of the 1st metatarsal under fluoroscopy and when satisfied with the position, insert two k-wires into the medial cuneiform through the two holes in the cuneiform scaffold. Alternatively, place the proximal/dorsal k-wire first to check alignment, adjust as needed, then insert the oblique k-wire to fix the first ray position.

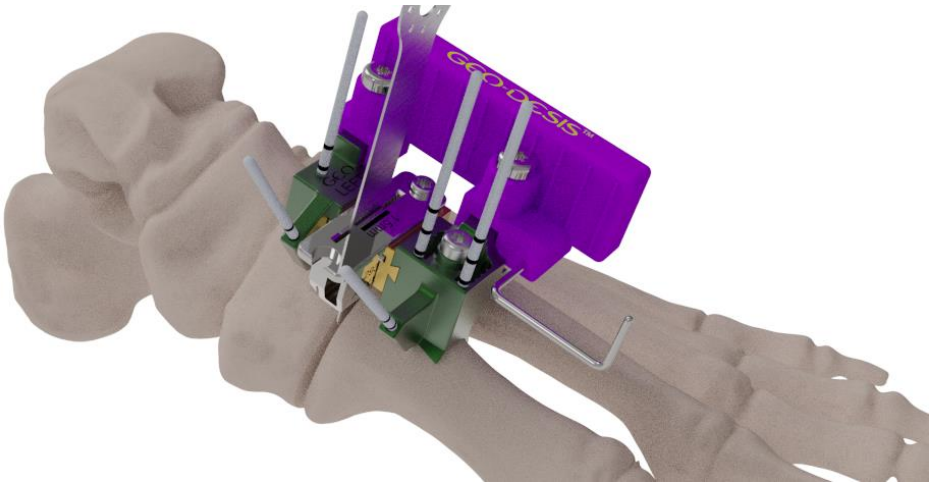




Cut Distal Cartilage of Medial Cuneiform

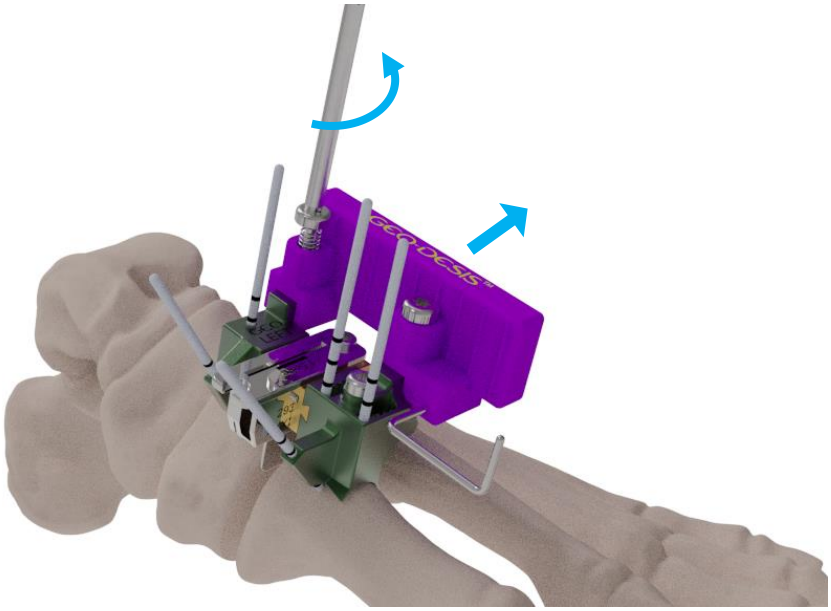
Determine the amount of the medial cuneiform distal bone-end to cut. If the cut guide that is installed in the joint preparation aperture is not the correct size, remove it and select one of three other sizes. Verify that the cut slot is on the cuneiform side of the bone-end positioner.

Cut the distal bone-end of the medial cuneiform.

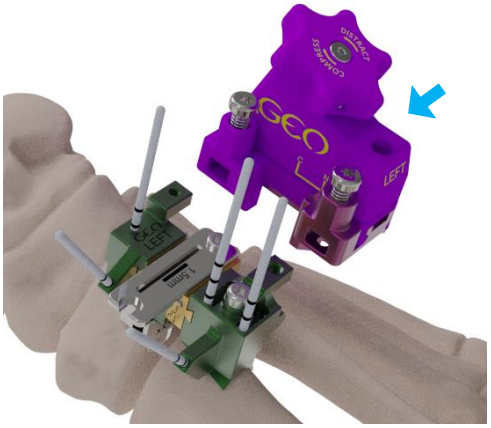


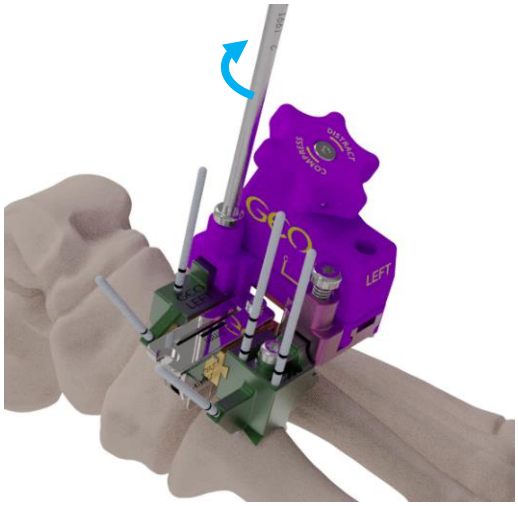
Attach Compressor-Distractor

After cutting the desired amount of the distal medial cuneiform, use the T-15 driver to unscrew each of the screws that are securing the Fixator Stabilizing Bridge until the screws disengage from the First Ray Fixator and turn freely. The screws are captured in the Stabilizing Bridge so they will remain within the holes. Slide the Fixator Stabilizing Bridge laterally off the attachment tabs of the metatarsal and cuneiform scaffolds.

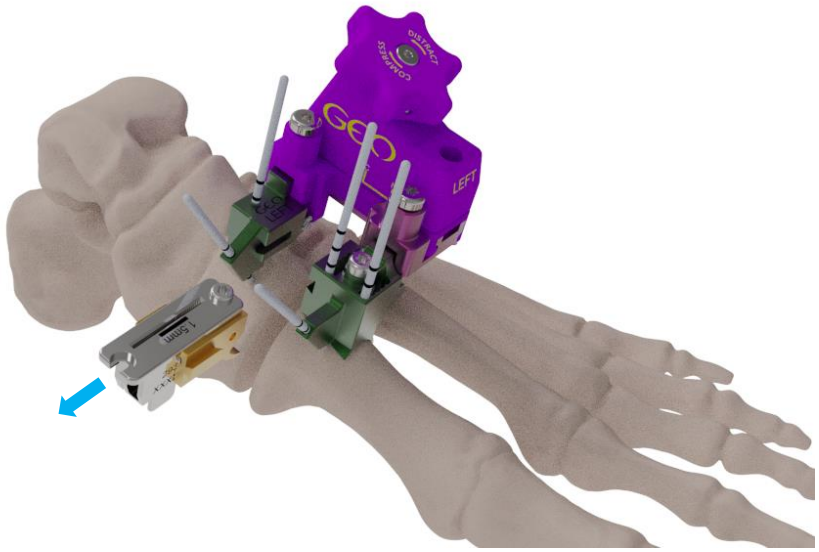


Slide the compressor distractor unit completely onto the attachment tabs. Using the T-15 driver, turn the securing screws clockwise to secure the compressor-distractor to the First Ray Fixator. When the compressor-distractor is fully inserted onto the tabs and both securing screws are tightened, the compressor-distractor is fixed to the metatarsal and cuneiform scaffolds, and the joint preparation aperture is released for removal.



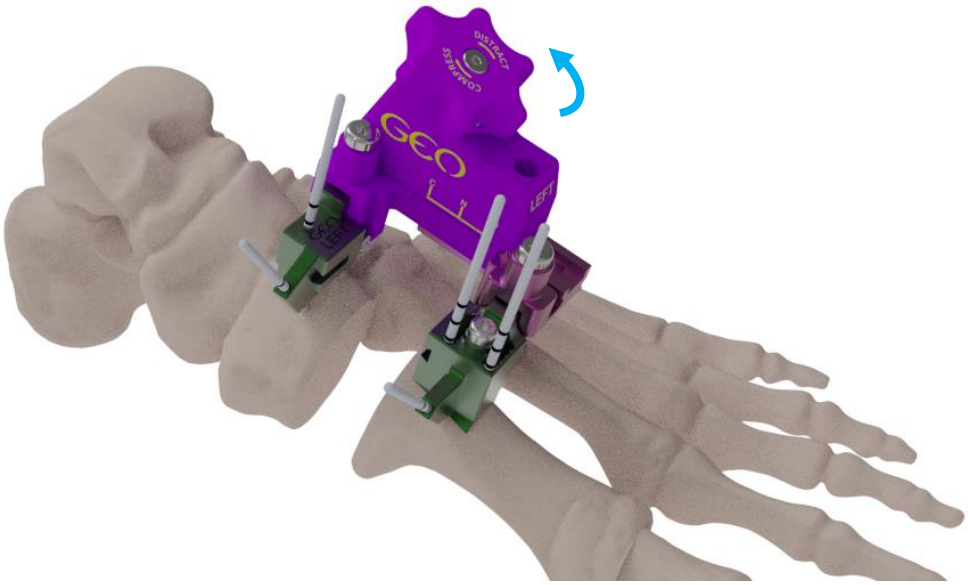


Slide the joint preparation aperture and cut guide medially off the scaffolds. Because the compressor distractor is now locked onto the First Ray Fixator, the first ray alignment will be held securely in place.



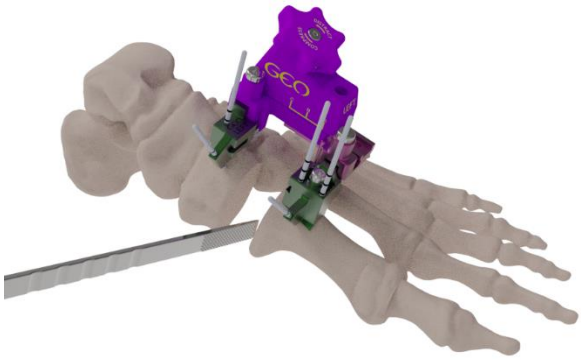
Distract the Joint

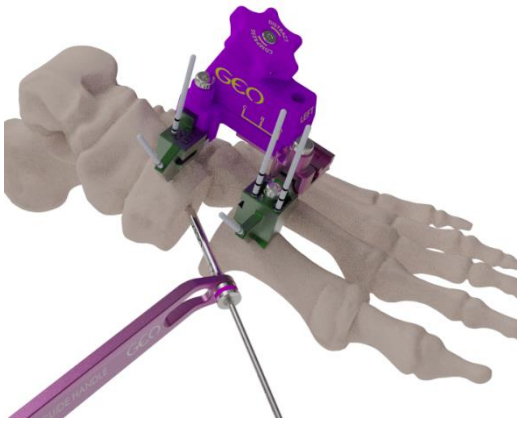
The joint can now be distracted by rotating the knob on the compressor distractor counterclockwise. With the joint distracted, the cut joint surfaces can be fenestrated or otherwise prepared for compression and fusion.



Prepare Joint for Fusion

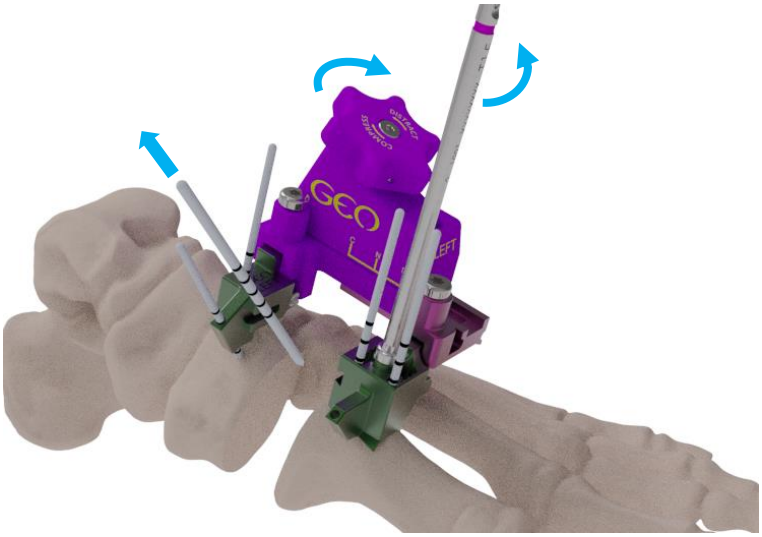
A rasp with an osteotome end is available in the accessory kit if further joint surface clean-up is required. Additionally, a drill guide and drill bit are included to aid fenestration of the joint surfaces.



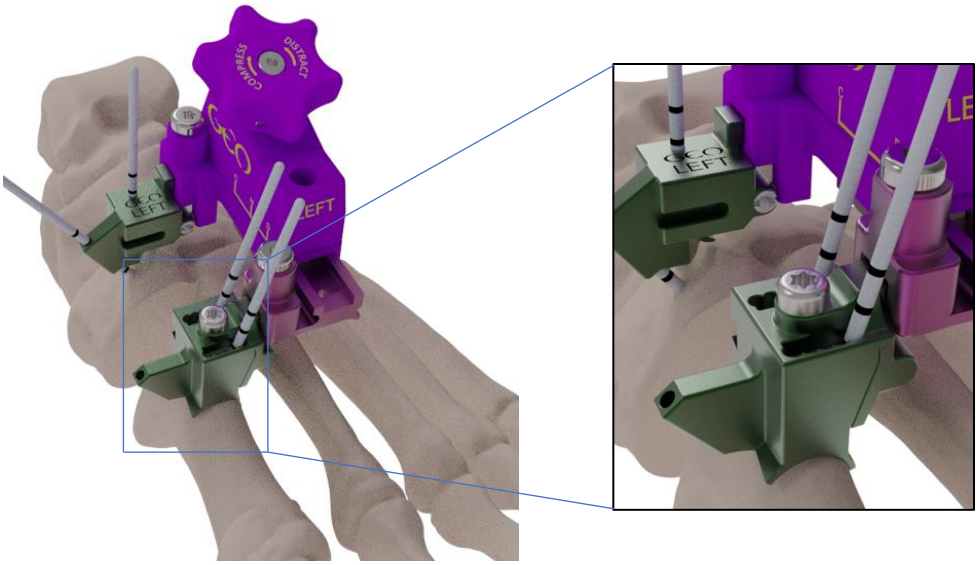


Additional Frontal Plane De-Rotation

If additional frontal plane rotation is needed, relieve the distraction force by rotating the knob on the compressor distractor clockwise, then remove the oblique metatarsal k-wire and fully unlock the parallel metatarsal k-wires by rotating the locking screw counterclockwise. If the rotation in the frontal plane is sufficient, leave the k-wires locked, skip the following step, and proceed to joint compression.



Carefully rotate the metatarsal so the k-wires move in the scalloped slots of the metatarsal scaffold to reach the desired orientation in the frontal plane. The intermetatarsal angle is held in place as the frontal rotation is being performed. Make sure the dorsal surface of the metatarsal remains against the bottom surface of the metatarsal scaffold.



Once the desired rotational orientation is achieved, re-insert the metatarsal oblique k-wire and re-lock the parallel metatarsal k-wires by again turning the locking screw clockwise. Additional preparation of the joint can be done as needed.

Compress the Joint and Apply Fixation

Compress the joint by rotating the knob on the compressor-distractor clockwise.

With the prepared cut planes of the joint are in contact, the fixation of choice can be applied to secure the first metatarsal.

Once the fixation is complete, unlock the parallel metatarsal k-wires, remove all the k-wires, and remove the First Ray Fixator.

GEO Orthopedic Manual Surgical Instruments

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

The preceding procedural overview is specific to GEO products and to be considered as an educational tool for use by licensed medical professionals. Final product usage is to be determined by the medical professional based on their expert opinion, training, clinical experience and appropriate review of medical literature and the product's instructions for use.

INTENDED USE
GEO orthopedic manual surgical instruments are intended for use in the preparation of tissue, and the preparation, manipulation, alignment, and fixation of bone, during orthopedic surgery.

CONTRAINDICATIONS
The GEO Orthopedic Manual Surgical Instruments do not carry any specific contraindications. General contraindications associated with the orthopedic surgeries for which the instruments may be used, include:

- Not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine;
- In patients with active local infection or any evidence of infection;
- In patients with suspected or documented metal allergy, intolerance; or sensitivity or allergic reaction to foreign bodies;
- In patients with insufficient quality or quantity of bone to permit stabilization of the arthrodesis;
- In the presence of clinical or functional abnormalities that would preclude the potential of achieving a good outcome for the patient.

WARNINGS

- The GEO Orthopedic Manual Surgical Instruments are for Single [Patient] Use Only. DO NOT REUSE. Reuse could result in failure to perform as intended, transmission of infectious diseases, and/or harm to the patient or user.
- Take care to select the proper type and alignment geometry of any instrumentation used in conjunction with the GEO Orthopedic Manual Surgical Instruments. Failure to utilize the appropriate instrumentation may result in breakage of instrumentation and/or surgical implant, patient injury and/or surgical delays.
- Use of the GEO Orthopedic Manual Surgical Instruments for purposes other than intended may result in breakage, injury, and/or the need for medical intervention.
- Pre-operative and operating procedures, surgical techniques and proper patient selection are important considerations for the successful use of the GEO Orthopedic Manual Surgical Instruments.

For full prescribing information, refer to the GEO Orthopedic Manual Surgical Instruments Instructions for Use located on:
www.gramercyortho.com

Gramercy Extremity Orthopedics, LLC
www.gramercyortho.com
info@gramercyortho.com
855-436-2278

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