EXTREMITY ORTHOPEDICS

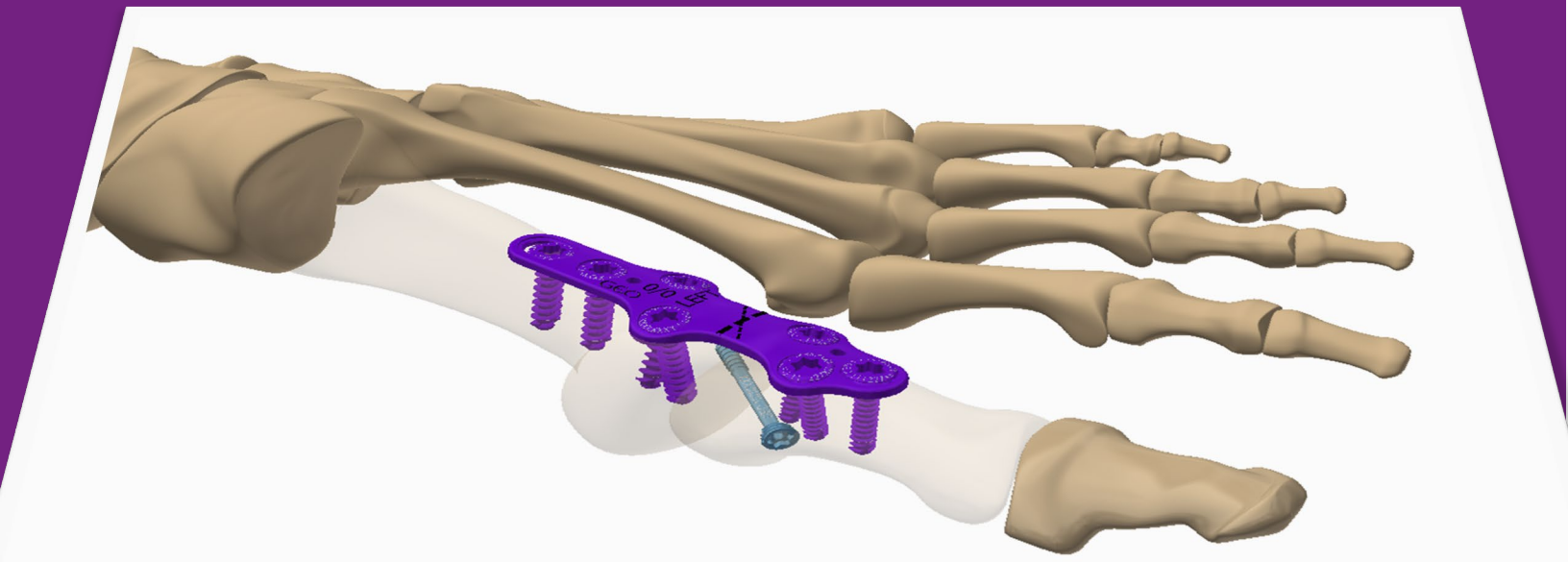
GRAMERCY

GEO®

FirstFUSE

GEO 1st MTP Joint Arthrodesis Plating System

Operative Technique



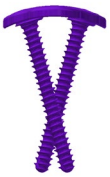
The GEO *FirstFUSE* 1st MTP Joint Arthrodesis Plating System

Features and Benefits

The GEO *FirstFUSE* 1st MTP Joint Plating System consists of a variety of plates and associated instrumentation designed to facilitate optimal sizing, placement and efficiency.

- **Anatomic plate design**
  The GEO *FirstFUSE* 1st MTPJ plates are 1.5mm thick, with a slightly thicker section over the joint for added strength, and anatomically curved and beveled to maintain a low profile. Small, medium, and large plates are available in straight, 5° dorsiflexion, 5° abduction, and combined dorsiflexion/abduction angles with locking screw convergence angles designed to better fit application site.

15° metatarsal locking screw convergence



12° phalangeal locking screw convergence

- **Pre-sterilized packaging, single use instrumentation**
  All GEO implants and instruments are packaged pre-sterilized and are single-use only, eliminating the cleaning and sterility concerns or issues typically associated with standard autoclave steri-trays. The GEO *FirstFUSE* 1st MTPJ Plating System Instruments are packaged to align with the surgical procedure and provide components that are new, sterile, and readily available in a convenience kit.

- **Plate screws**
  The GEO *FirstFUSE* 1st MTP Joint Plating System includes 2.7mm and 3.5mm diameter fixed angle locking and non-locking cortical screws, and 4.0mm diameter cancellous non-locking screws, all available in the GEO CART®. All GEO MTPJ plate screws utilize the same drill bit for increased procedural efficiency.

- **GEO CART®**
  Because GEO implants, instrument kits, and individual instrument packages are housed in the GEO CART®, the correct implant size, all the necessary instruments, or even additional implant types are immediately available and ready to use.

  All GEO implant and instrument packages are labeled for quick identification so there is no delay in retrieving the exact item needed. All instrument kits identify the specific implant type and are color code matched for convenient and quick selection.

GEO 1st MTPJ Plating System

OPERATIVE TECHNIQUE

Surgical approach

With the patient in a supine position, a dorsal longitudinal incision, proximal to the IP joint extending over the extensor hallucis longus tendon medially and ending 2-3 cm distal to the joint is recommended. As necessary, resect osteophytes using a sagittal saw or osteotome. Use of fluoroscopy is recommended for the procedure.

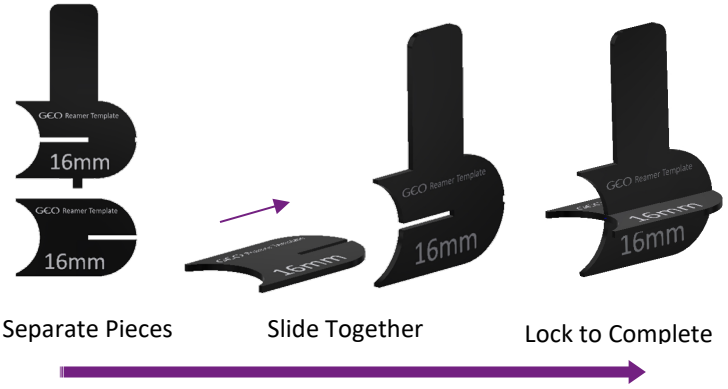
Joint preparation

Expose the 1st MTPJ and prepare the joint for arthrodesis. Cartilage resection is surgeon preference. Refer to steps 1 and 2 if joint reaming is the preferred method for joint preparation. A rongeur or curette can assist in removing additional tissue.

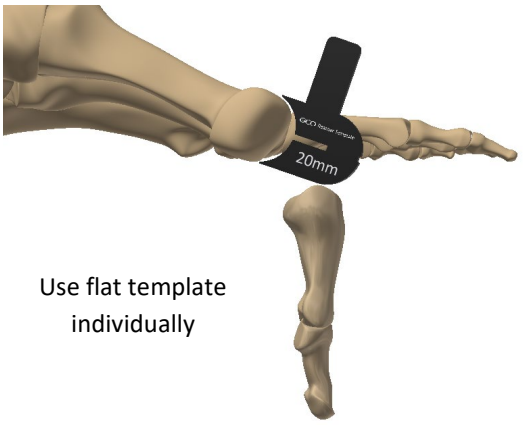
STEP 1

Select Reamer Size

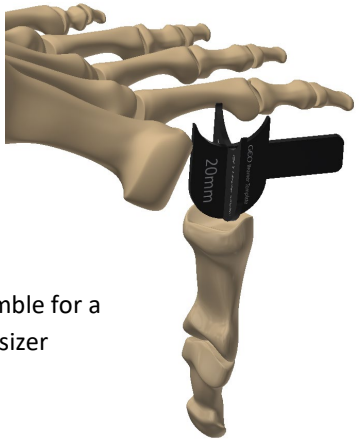
As needed, open one individually packaged and pre-sterilized MTPJ reamer multipack template kit to determine the appropriate reamer size. The GEO reamer template kit contains templates for all reamer sizes and each template consists of two pieces clearly marked with the associated reamer size. Each reamer template can be assembled to provide a 3-dimensional sizing tool or used individually as a 2-dimensional sizer.



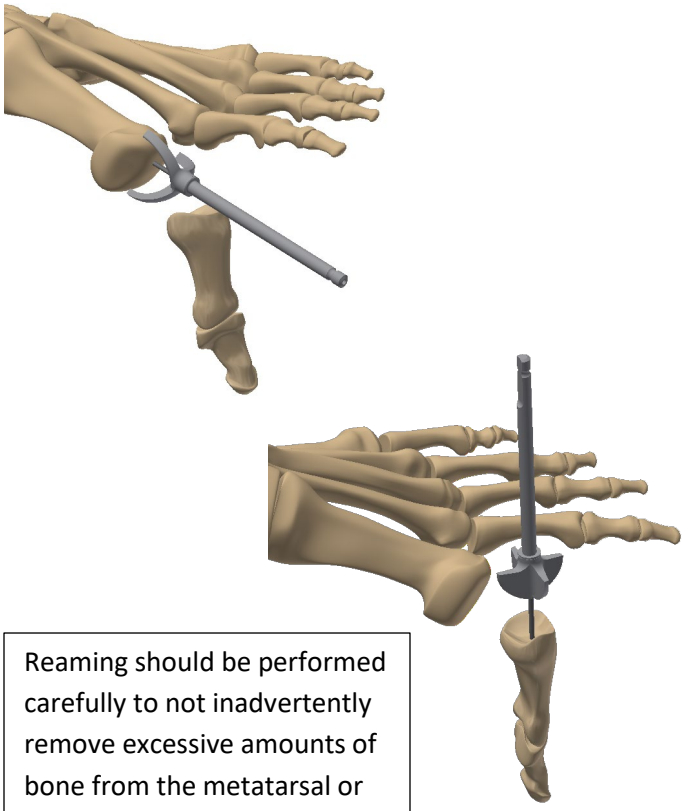
Separate Pieces | Slide Together | Lock to Complete



Use flat template individually



Or assemble for a 3D sizer



Reaming should be performed carefully to not inadvertently remove excessive amounts of bone from the metatarsal or phalanx.

STEP 2

Prepare the Joint

As needed, open the required size of an individually packaged and pre-sterilized MTPJ reamer kit. Each reamer kit contains a 1.6mm guidewire and either a reamer for the phalanx or for the metatarsal.

Insert the included 1.6mm trocar tip guide wire included in the reamer package into the head of the 1st metatarsal. Guide wire should be driven through the center of the 1st metatarsal head, parallel to the long axis of the bone. Slide the cannulated metatarsal reamer over k-wire and remove the cartilage. Ensure all articular cartilage has been removed from the joint surface.

Remove the guide wire and repeat the process on the base of the proximal phalanx with the phalanx reamer.

Plate Application

It is recommended that prior to determining which MTPJ plate will be utilized, and before application of the plate, a trans-articular screw be utilized to compress the joint.

STEP 3

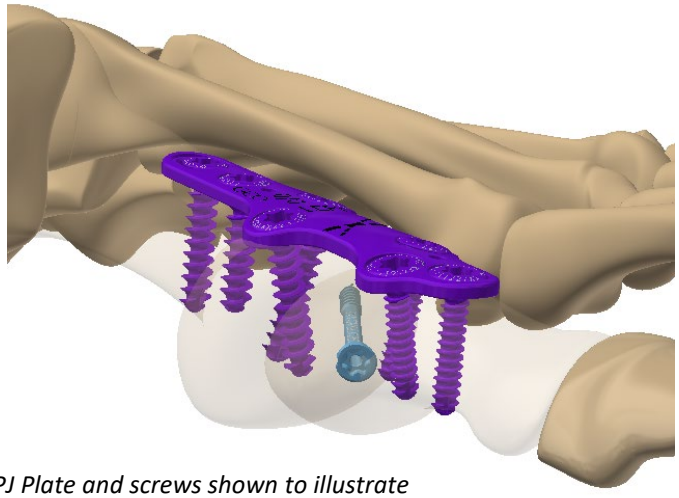
Select Plate Size

As needed, open one individually packaged and pre-sterilized MTPJ plate multipack template kit to determine the appropriate plate size. Each kit contains three template sizes, clearly marked as small, medium, and large, and each template represents both a left and a right side plate by simply turning it over. MTPJ plate templates are flat profiles only. Determine what, if any, dorsiflexion and/or abduction angle may be required based on the anatomy and desired reduction.

STEP 4

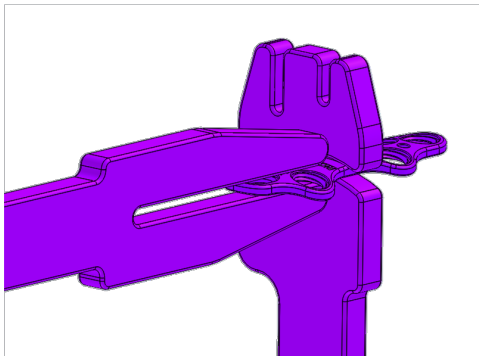
Compress the Joint

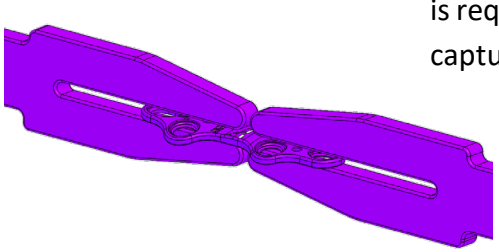
A GEO 3.0mm or 4.0mm headed or headless cannulated bone screw is recommended as a trans-articular screw to compress the joint. The thin angled laser marking on the plate provides a general directional aid for targeting the crossing screw. Surgeon discretion should be used to avoid interference with locking screws adjacent to the joint.



MTPJ Plate and screws shown to illustrate available passageway for trans-articular screw.

STEP 5



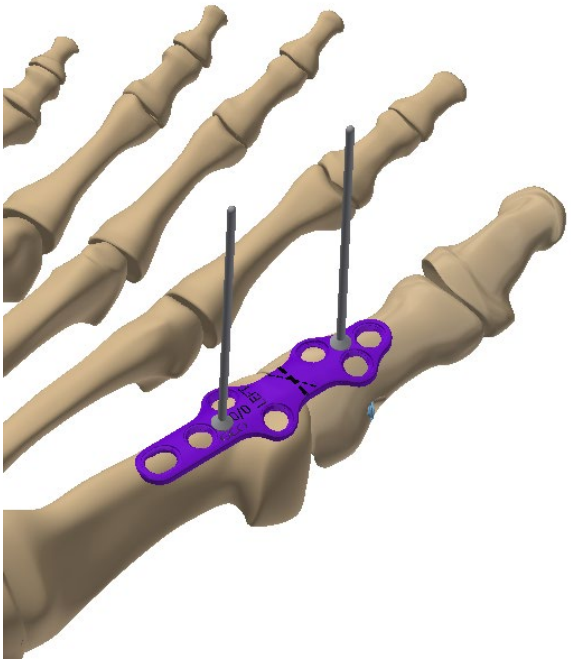


Position the MTPJ Plate

Open the desired, predetermined length and angle plate, ensuring the correct laterality. Position the MTPJ plate over the joint. It may be necessary to remove dorsal osteophytes and exostoses to allow the plate to sit appropriately across the joint.

Plate benders are available in a separate single use multipack kit if slight modification of the plate geometry is required*. The benders feature assorted slot shapes for capturing and bending the plate at various locations.

* Caution: Excessive or repetitive bending of the GEO MTPJ plate may compromise strength and fatigue resistance. Bending the perimeter of a screw hole may impact the ability to insert a locking screw.



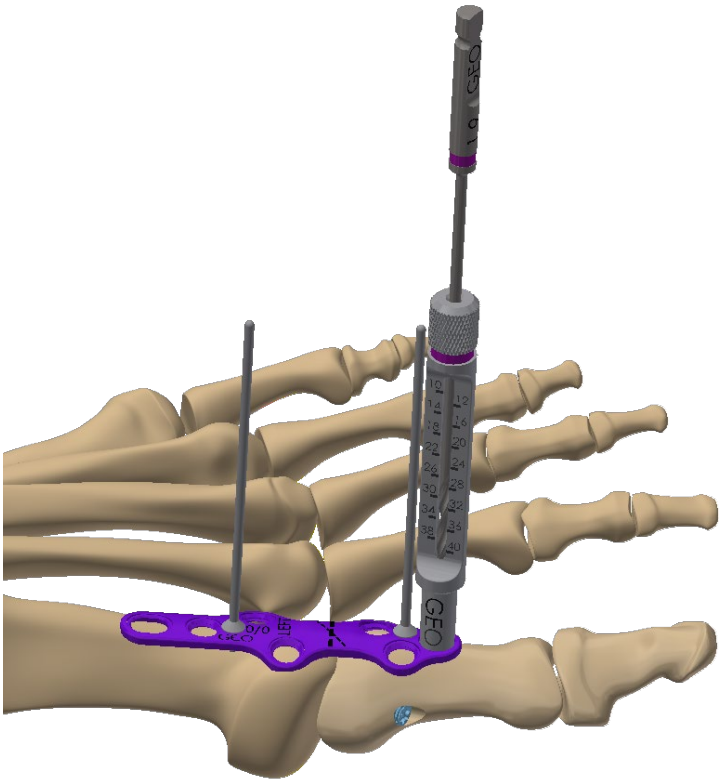
The thick dashed laser mark on the plate can be used as a guide for positioning the plate over the joint center.

Using the plate tacks included in the GEO Plating System instrument kit, temporarily secure the plate by inserting the tacks into the tack holes on both sides of the joint. Once the tacks have been inserted and the plate is secure, it is recommended to obtain fluoroscopic images of the foot (DP and lateral views) to confirm the desired plate location.

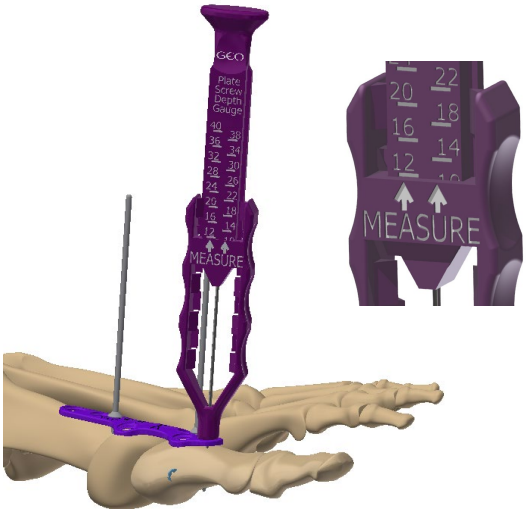
STEP 6

Secure the Plate

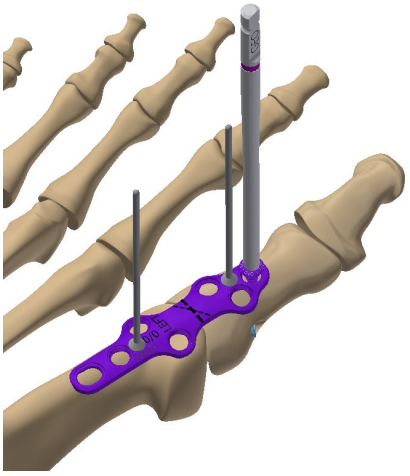
It is recommended to first place a locking screw in the most distal plate hole to secure the plate. Thread the locking drill guide into the distal plate hole threads and drill using the solid AO drill bit included in the kit. Measure for the appropriate screw length using either the laser mark on the drill against the drill guide rule, or with the separate hook-style depth gauge included in the kit.



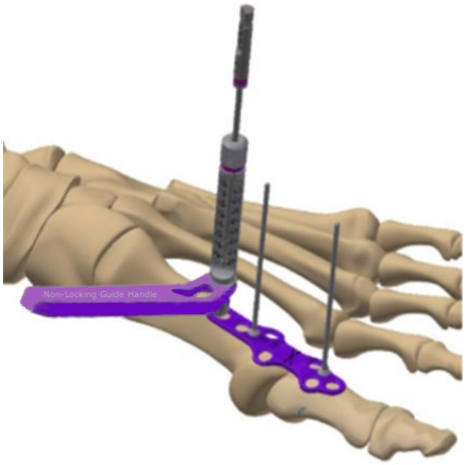
Note: Drill guides, drill bit, and screwdriver tip used with GEO *FirstFUSE* 1st MTPJ plates, and all GEO Extremity Plate System (EPS) Plates and screws, are identified by purple color bands.



The GEO hook-style depth gauge can be used to determine the length of a bi-cortical screw by placing the nose end into the plate hole and sliding the ruler up until the wire hook catches on the plantar surface of the far cortex. Use the marking on the ruler, as shown below, to determine the appropriate length screw.

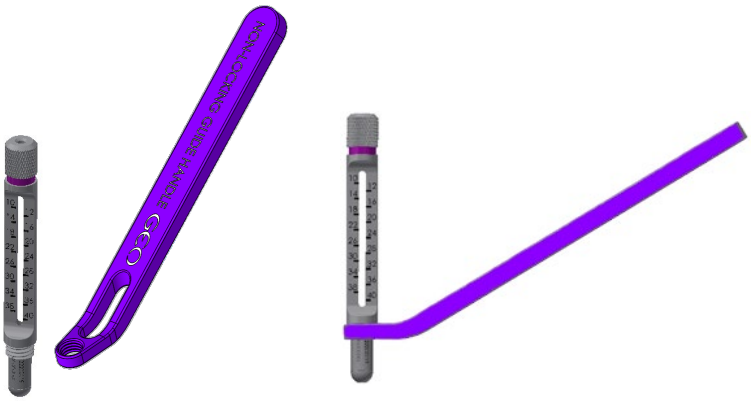


Using the T-15 Hexalobe AO driver tip included in the kit, insert the desired size locking screw and tighten fully. All GEO Extremity Plating System (EPS) screws, identified by color and package labeling, are compatible with GEO MTPJ plates.



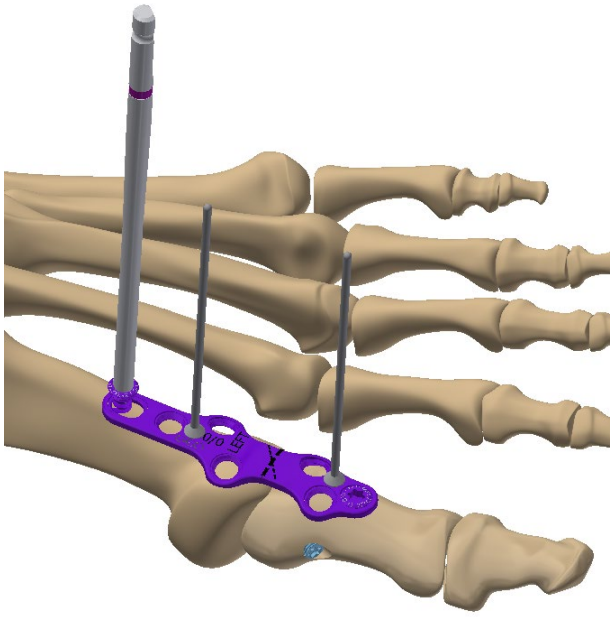
Using the non-locking drill guide and solid AO drill bit included in the kit, drill a screw hole near the proximal end of the compression slot. Measure for the appropriate screw length using either the laser mark on the drill against the drill guide rule, or with the hook-style depth gauge.

If desired, a drill guide handle is provided in the MTPJ plate instrument kit for safety and convenience. It simply threads onto the non-locking drill guide.



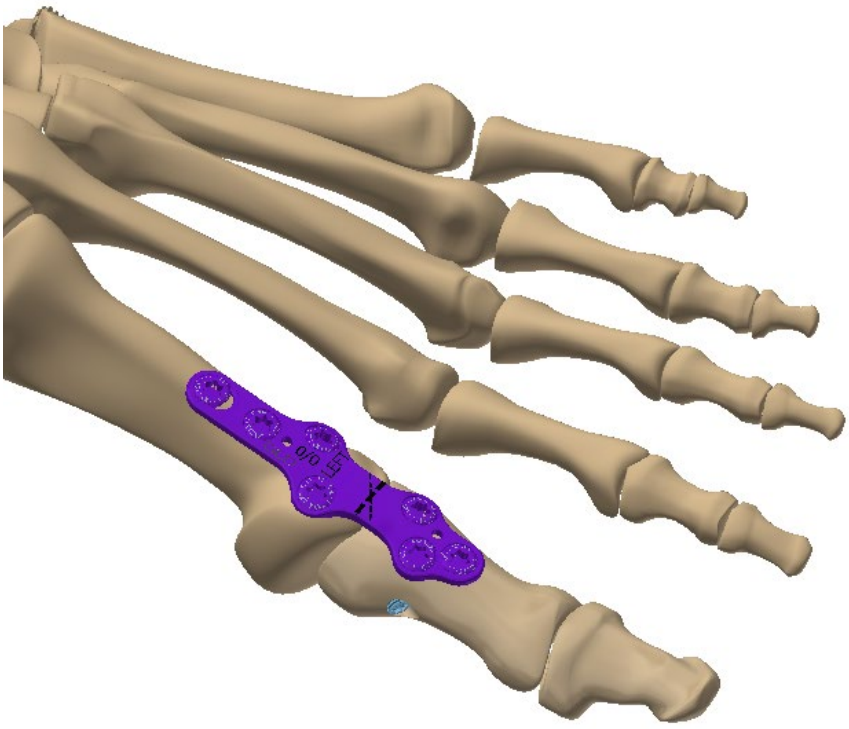
Using the T-15 Hexalobe AO solid driver tip included in the kit, insert a non-locking screw into the compression slot but do not tighten fully.

Remove the plate tacks.



If an independent compression screw was not used in Step 3, manually compress the joint.

Fully tighten the non-locking screw in the compression screw slot to obtain further joint compression.



STEP 7

Insert Remaining Screws

Once the desired plate placement, reduction, and compression is attained, insert screws into the remaining plate holes. It is recommended to insert a minimum of three screws on both sides of the joint. Use the appropriate locking or non-locking drill guide and drill the bone for the intended plate hole.

Note: non-locking screw heads may sit proud if inserted at extreme angles or if the drill guide tip is not properly seated in the screw hole.

MTPJ Plates

GEO *FirstFUSE* MTPJ Plates are part of the GEO Extremity Plating System (EPS) family. For convenience and ease of use, all GEO EPS plates are compatible with all GEO EPS plate screws and instruments. When selecting screws to use with the MTPJ plate, be sure to look for the EPS designation on the label. Screw color will match plate color.

Size	Dorsiflexion	Abduction	Side	Part Number
Small 	0	0	R	12020000
	5	0	R	12020050
	0	5	R	12020005
	5	5	R	12020055
	0	0	L	12320000
	5	0	L	12320050
	0	5	L	12320005
	5	5	L	12320055
Medium 	0	0	R	12020100
	5	0	R	12020150
	0	5	R	12020105
	5	5	R	12020155
	0	0	L	12320100
	5	0	L	12320150
	0	5	L	12320105
	5	5	L	12320155
Large 	0	0	R	12020200
	5	5	R	12020255
	0	0	L	12320200
	5	5	L	12320255

All plate package labels and part markings include the plate size and dorsiflexion/abduction angles. Example, 0/5 indicates a plate with 0° dorsiflexion and 5° abduction.

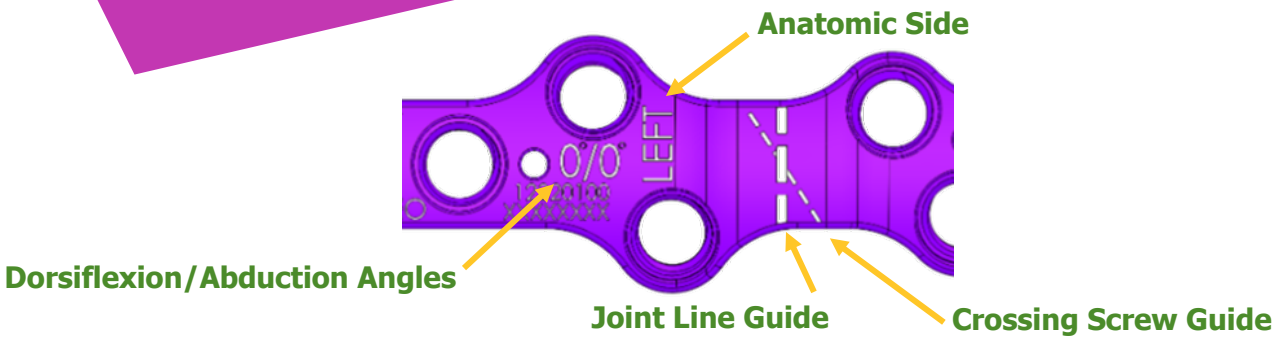


Plate Screws

As part of the GEO Extremity Plating System (EPS), the following EPS screws can be used with all MTPJ Plates.

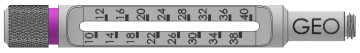
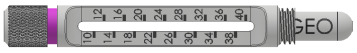
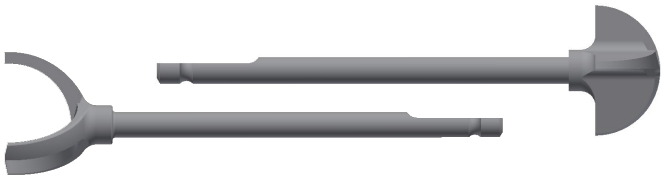
Diameter	Length	Part Number	Diameter	Length	Part Number
Fixed Angle Locking Cortical (EPS)					
2.7 mm 	10 mm	11122710	3.5 mm 	10 mm	11123510
	12 mm	11122712		12 mm	11123512
	14 mm	11122714		14 mm	11123514
	16 mm	11122716		16 mm	11123516
	18 mm	11122718		18 mm	11123518
	20 mm	11122720		20 mm	11123520
	22 mm	11122722		22 mm	11123522
	24 mm	11122724		24 mm	11123524
	26 mm	11122726		26 mm	11123526
	28 mm	11122728		28 mm	11123528
	30 mm	11122730		30 mm	11123530
	32 mm	11122732		32 mm	11123532
	34 mm	11122734		34 mm	11123534
	36 mm	11122736		36 mm	11123536
	38 mm	11122738		38 mm	11123538
	40 mm	11122740		40 mm	11123540
Non-Locking Cortical (EPS)					
2.7 mm 	10 mm	11022710	3.5 mm 	10 mm	11023510
	12 mm	11022712		12 mm	11023512
	14 mm	11022714		14 mm	11023514
	16 mm	11022716		16 mm	11023516
	18 mm	11022718		18 mm	11023518
	20 mm	11022720		20 mm	11023520
	22 mm	11022722		22 mm	11023522
	24 mm	11022724		24 mm	11023524
	26 mm	11022726		26 mm	11023526
	28 mm	11022728		28 mm	11023528
	30 mm	11022730		30 mm	11023530
	32 mm	11022732		32 mm	11023532
	34 mm	11022734		34 mm	11023534
	36 mm	11022736		36 mm	11023536
	38 mm	11022738		38 mm	11023538
	40 mm	11022740		40 mm	11023540

Diameter	Length	Part Number
Non-Locking Cancellous (EPS)		
4.0 mm 	10 mm	11034010
	12 mm	11034012
	14 mm	11034014
	16 mm	11034016
	18 mm	11034018
	20 mm	11034020
	22 mm	11034022
	24 mm	11034024
	26 mm	11034026
	28 mm	11034028
	30 mm	11034030
	32 mm	11034032
	34 mm	11034034
	36 mm	11034036
	38 mm	11034038
	40 mm	11034040

Instrument Kits

For Use With	Part Number	Kit Components
All MTPJ Plates and Screw Diameters	70120001	Locking Drill Guide
		Non-Locking Drill Guide
		Non-Locking Drill Guide Handle
		Hook-Style Depth Gauge
		Drill Bit
		T-15 Hexalobe Driver Tip
		Plate Tack (2 in kit)
		Trocar K-wire
	70260001	Reamer Instrument Kit, 16mm, Phalanx, 1.6mm K-wire
	70260002	Reamer Instrument Kit, 16mm, Metatarsal, 1.6mm K-wire
	70260003	Reamer Instrument Kit, 18mm, Phalanx, 1.6mm K-wire
	70260004	Reamer Instrument Kit, 18mm, Metatarsal, 1.6mm K-wire
	70260005	Reamer Instrument Kit, 20mm, Phalanx, 1.6mm K-wire
	70260006	Reamer Instrument Kit, 20mm, Metatarsal, 1.6mm K-wire
	70260007	Reamer Instrument Kit, 22mm, Phalanx, 1.6mm K-wire
	70260008	Reamer Instrument Kit, 22mm, Metatarsal, 1.6mm K-wire

Individual Instruments

EPS Plate Locking 1.9mm Drill Guide PN: 22200019	EPS Plate Locking 2.3mm Drill Guide PN: 22200023	
EPS Plate Non-locking 1.9mm Drill Guide PN: 22210019	EPS Plate Non-locking 2.3mm Drill Guide PN: 22210023	
Non-locking Drill Guide Handle PN: 30120001		
Hook Depth Gauge PN: 27141001		
Drill Bit, 1.9mm AO PN: 21119135	Drill Bit, 2.3mm AO PN: 21123135	
T-15 Hexalobe AO Driver Tip PN: 20019915		
Plate Tack, 1.6mm PN: 13416075		
Wire Guide / K-Wire, 1.6mm PN: 13016135		
Plate Bender PN: 24000003		
Reamer Kits – Phalanx and metatarsal, each with one 1.6mm wire guides PN: see kit table above		
MTPJ Reamer Template Kit, 4 sizes PN: 71270002		
MTPJ Plate Template Kit, 3 sizes PN: 71270001		
Single Use AO Driver Handle PN: 20080000		

GEO *FirstFUSE* 1st MTP Joint Arthrodesis Plating System

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.

INDICATIONS FOR USE

The GEO *FirstFUSE* 1st MTP Joint Arthrodesis Plating System is indicated for use in the stabilization and fixation of the first metatarsal-phalangeal joint in the foot for surgical fusion (arthrodesis), osteotomy, nonunion, malunion or revision surgery.

CONTRAINDICATIONS

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

WARNINGS

- GEO implants and instrumentation are SINGLE USE ONLY;
- Reuse could result in failure of the device to perform as intended, transmission of infectious diseases, and/or harm to the patient or user;
- The implant can fail due to excessive load or fatigue;
- A successful result may not be obtained in each case. Corrective surgery may be required;
- Pre-operative, operating procedures, surgical techniques and proper patient selection are important considerations for the successful use of this System.
- Selection of the proper type and size of implant is extremely important. Failure to utilize the appropriate size and shape implant and instrumentation may result in loosening, fracture of the device, bone or both.
- The use of implants for purposes other than indicated may result in implant breakage, injury, reoperation and/or removal;
- Where material sensitivity is suspected, appropriate tests should be made prior to implantation;
- Implants are for temporary fixation until healing is complete and may not withstand weight bearing or unsupported stress.

For full prescribing information, refer to the GEO *FirstFUSE* 1st MTP Joint Arthrodesis Plating System Instructions for Use located on www.gramercyortho.com

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