Surgical Technique

GEO Hammertoe Screw

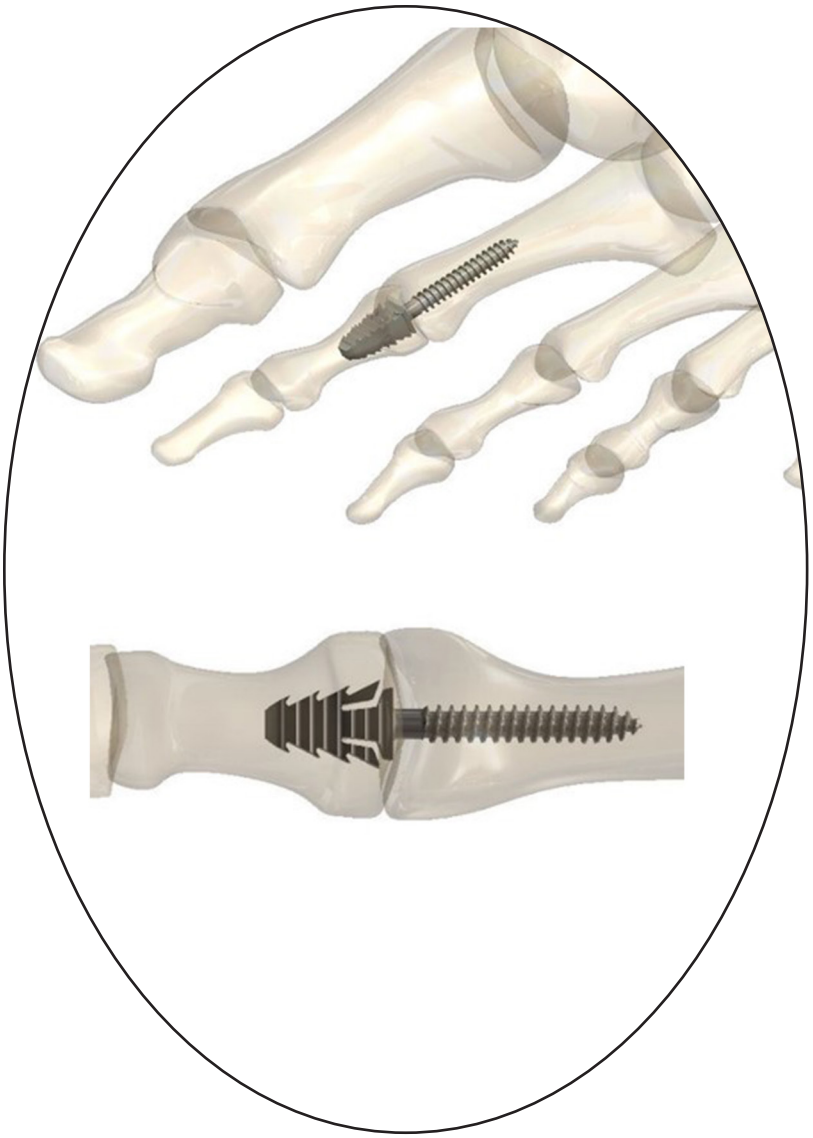
Titanium

Solid & Cannulated Option

Straight & Angled Option

Integrated Instrument Design

Provided Sterile



Contact Customer Service (855) 436-2278

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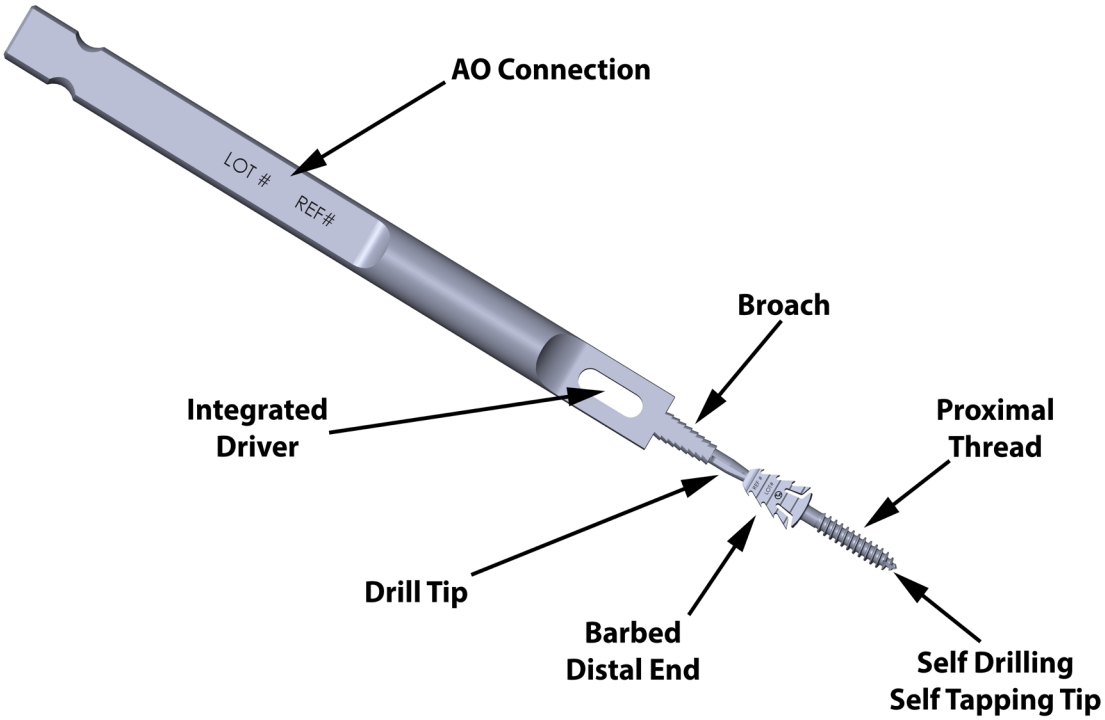
Features and Benefits

The comprehensive GEO Hammertoe Screw was designed to provide the surgeon with speed of the procedure and accurate placement of the screw. The Hammertoe screw exhibits the following advantages:

- No additional instrumentation for a faster procedure
- Built in AO Connection
- Integrated instruments including drill & broach
- Barbed distal end for enhanced bone purchase and fixation
- Screws contain self-drilling and tapping features



Indications and Contraindications

Indications

The GEO Hammertoe Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. Screws are intended for single use only.

Contraindications

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

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

Warnings and Potential Risks

The GEO implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the GEO components should never be re-implanted under any circumstances.

The GEO implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS section for additional warnings.

Precautions

The implantation of screw systems should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized. The GEO Hammertoe Screw System should never be used with dissimilar materials.
Preoperative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of X-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected. Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.
Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The guidewires included in the GEO Hammertoe Screw System are not intended as implants. The guidewires are only intended for use as instruments to facilitate screw insertion.

Bone Preparation

STEP 1 - Implant Sizing

Use an X-Ray template to determine the proper screw size.

STEP 2 - Joint Preparation and Guidewire Insertion

Dissect a clean approach to the joint and resect the joint surface. The use of an oscillating saw is preferred for the joint preparation over a rongeur. Figure 1 shows the PIP joint and lines marking the location for the saw cuts.

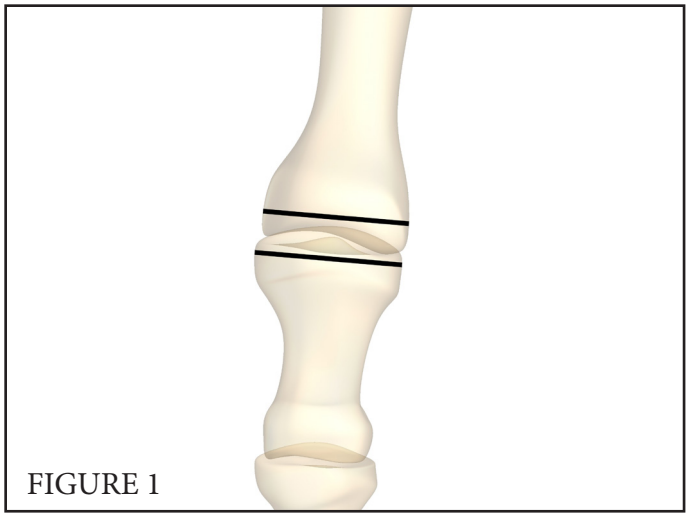


FIGURE 1

The use of a guidewire is possible with the cannulated screw option. Select the correct guiewire for the chosen screw diameter (Table 1). Align the guidewire into the proximal bone. Advance the guidewire until it reaches the distal pole of the desired proximal fixation region (Figure 2).

Note: Remove the guidewire prior to breaking the snap region of the Hammertoe device.

Fluoroscopy should be continuously used to ensure correct guidewire position, alignment, and depth. Do not remove guidewire.

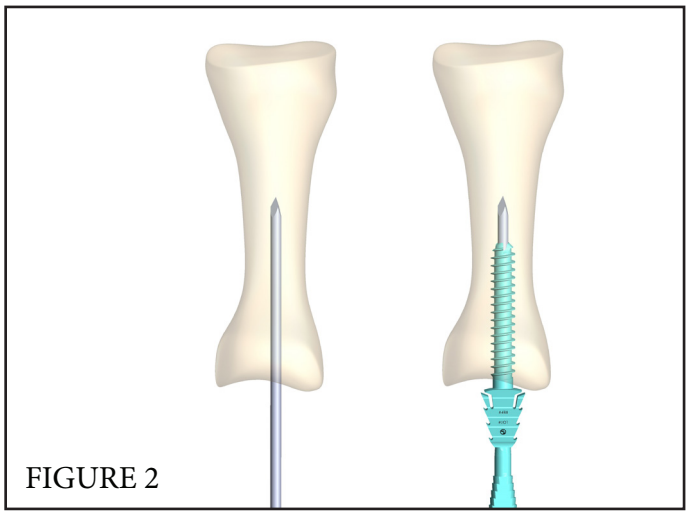


FIGURE 2

TABLE 1 - GUIDEWIRE SIZING

Screw Diameter	Guidewire Diameter
Ø2.0mm	Ø0.9mm
Ø2.5mm	Ø1.1mm
Ø3.0mm	Ø1.1mm

STEP 3 - Proximal Screw Insertion

Align the implant in the proximal bone space. Feed the implant over the guidewire if a cannulated screw is in use. Advance the implant until the beginning of the barbed screw head is fully seated against the bone.

If the screw driver breaks off prior to the implant being fully seated, use the integrated driver to fully advance the screw. If the screw is fully seated against the proximal bone space and has not snapped off, angle the driver handle until the implant is released from the integrated isntrument portion (Figure 3).

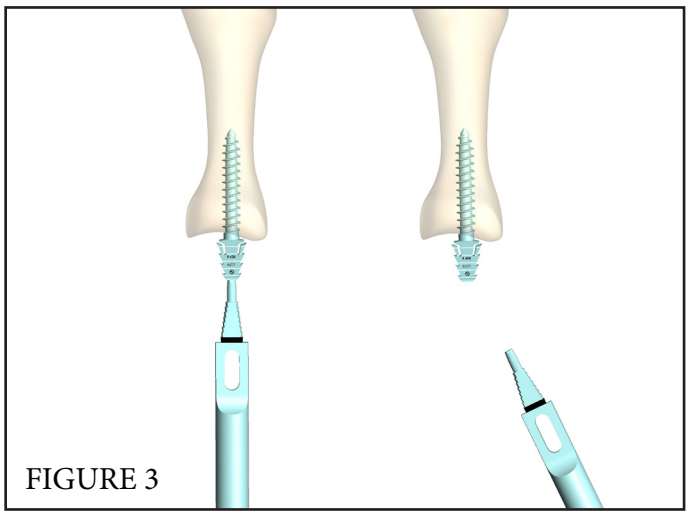


FIGURE 3

STEP 4 - Distal Bone Preparation

Using the integrated drill tip, prepare the distal bone space by hand. After drilling has occured, broach the distal bone space using the integrated broach until the black line is no longer visible (Figure 4). The distal bone space should be prepared such that the barbed head can be fully implanted into the bone space.

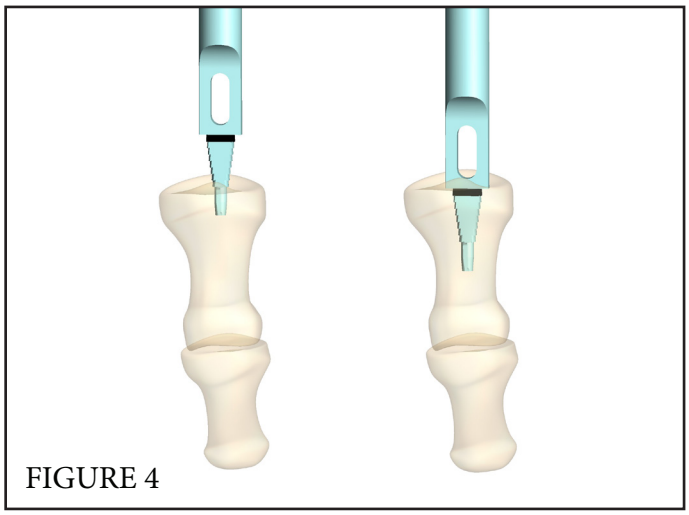


FIGURE 4

STEP 5 - Barbed Screw Head Insertion

Align the barbed head into the distal bone space and advance the head until it is fully seated in the bone space (Figure 5). Apply pressure on the distal phalanx to compress the construct.

Note: When using the 10° implant the lasermarking should be aligned to be facing upward/dorsally.

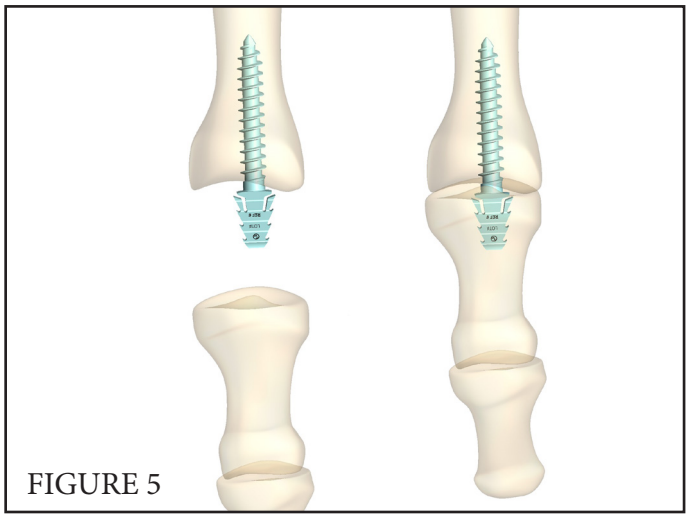


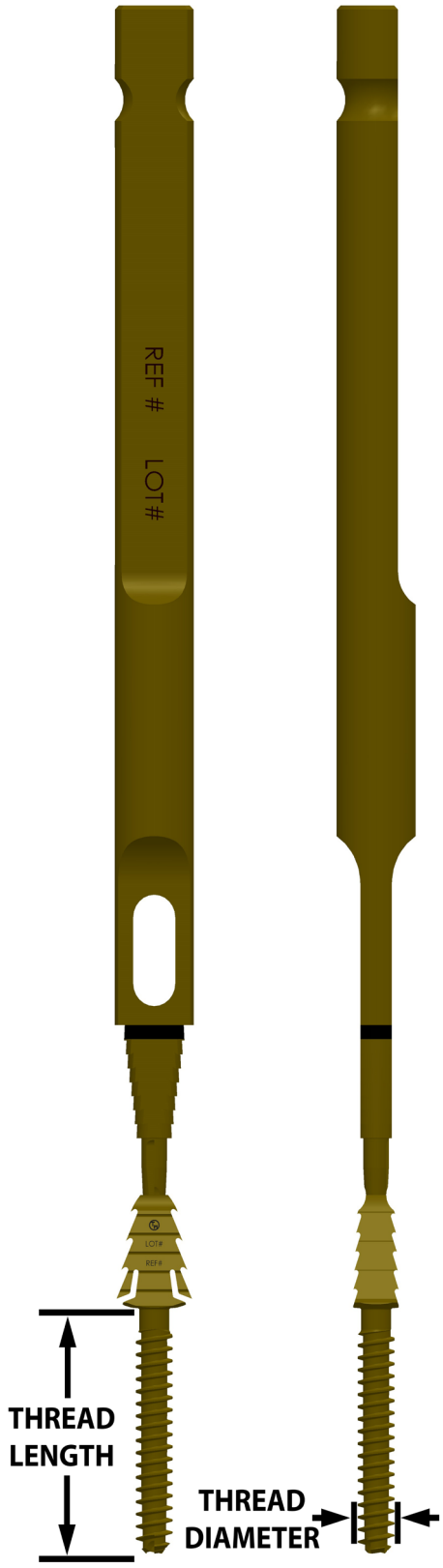
FIGURE 5

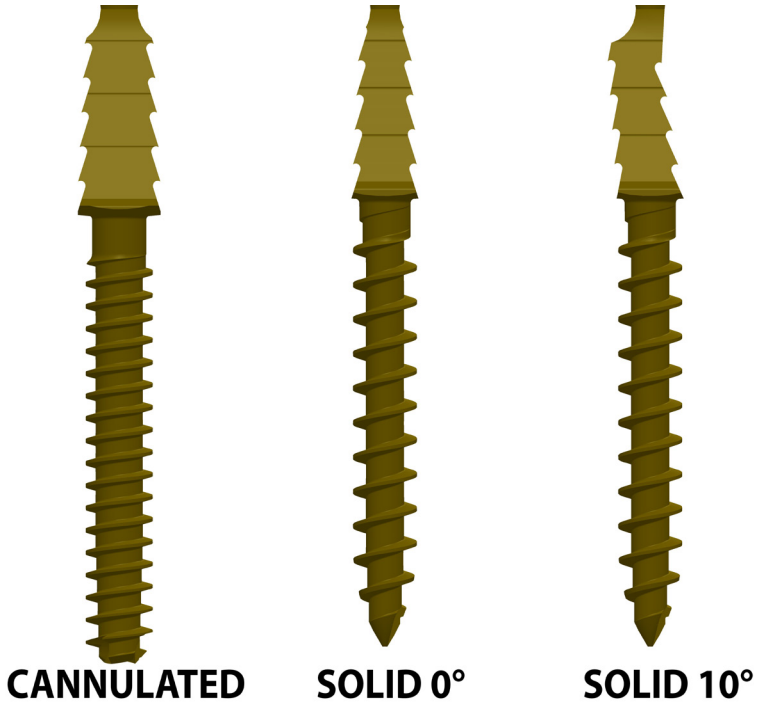
Removal

To remove the implant, distract the bone space exposing the distal end of the implant. The implant can be backed out of the proximal bone space using the integrated driver. If an instrumentation kit is not available, surgical forceps may be used.

Implant - Ø2.0 Screw

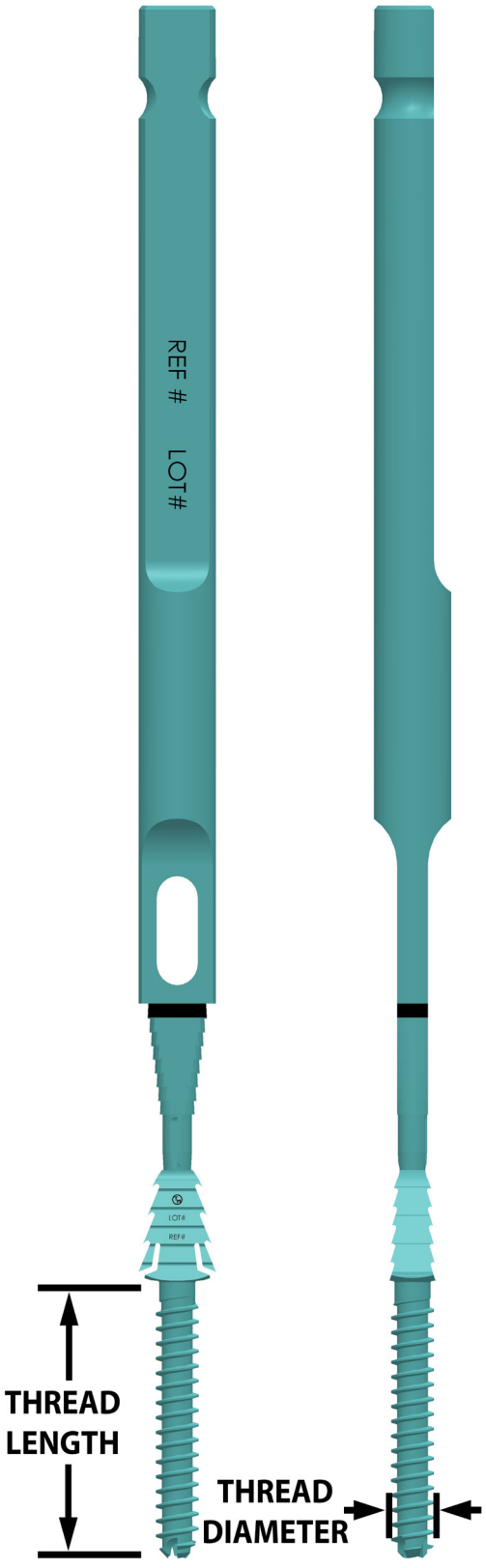
Ø2.0 Screw		
Part #	**Length**	**Description**
15022013	**13mm**	TyFix Cannulated Ø2.0mm x 13mm
15002013	**13mm**	TyFix Solid 0° Ø2.0mm x 13mm
15012013	**13mm**	TyFix Solid 10° Ø2.0mm x 13mm

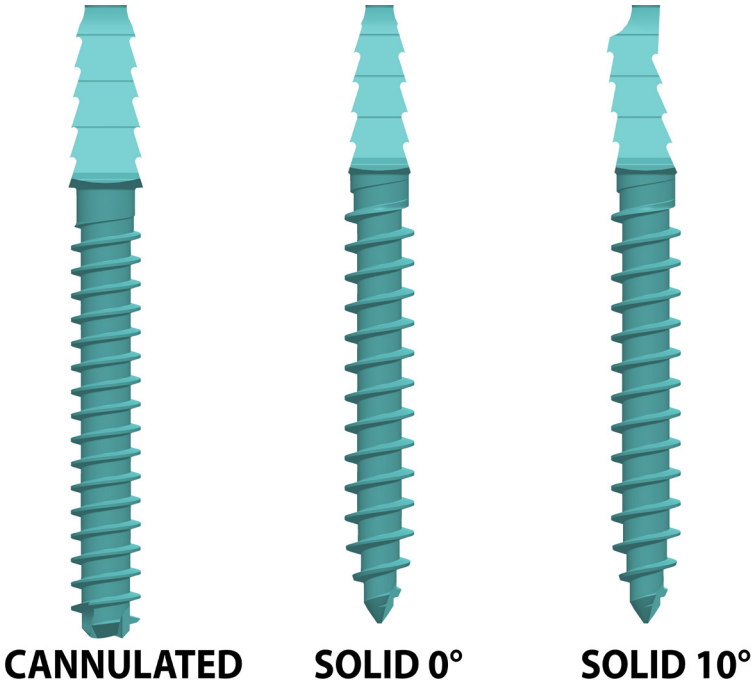




Implant - Ø2.5 Screw

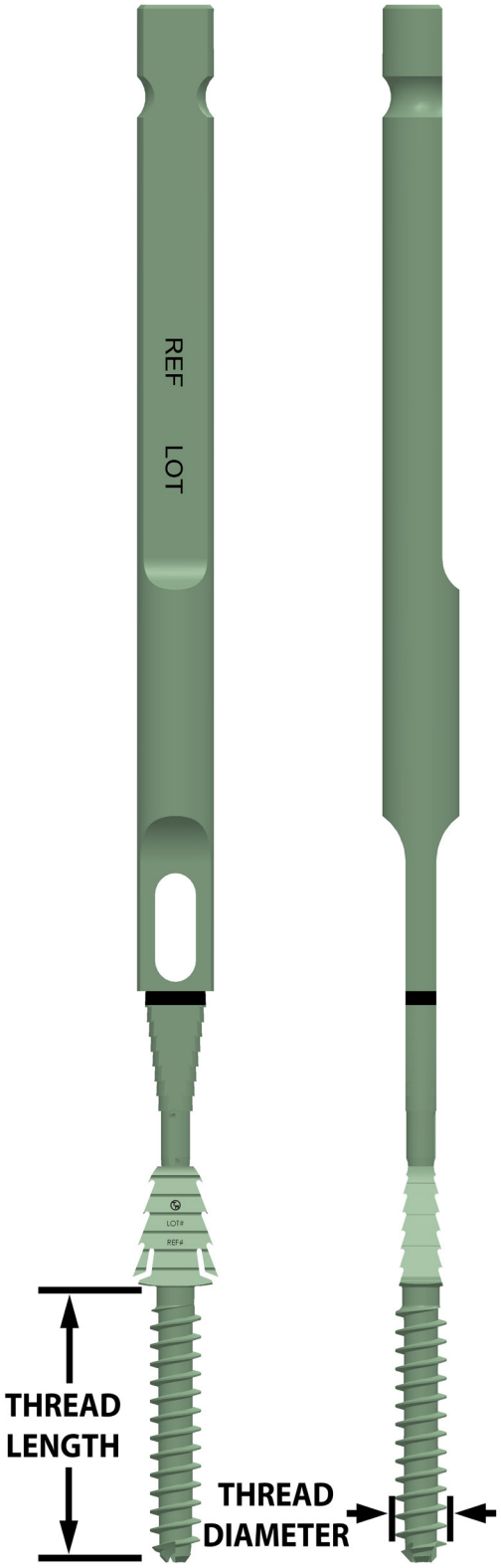
Ø2.5 Screw		
Part #	**Length**	**Description**
15022515	**15mm**	TyFix Cannulated Ø2.5mm x 15mm
15002515	**15mm**	TyFix Solid 0° Ø2.5mm x 15mm
15012515	**15mm**	TyFix Solid 10° Ø2.5mm x 15mm

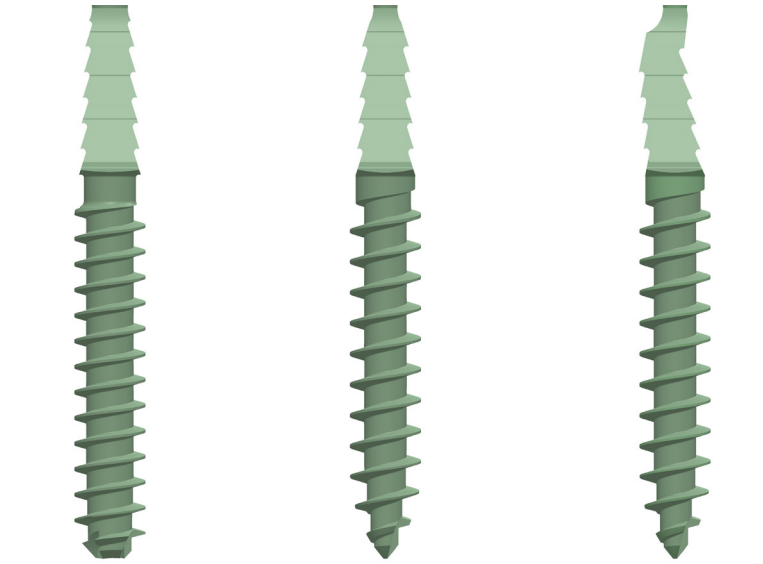




Implant - Ø3.0 Screw

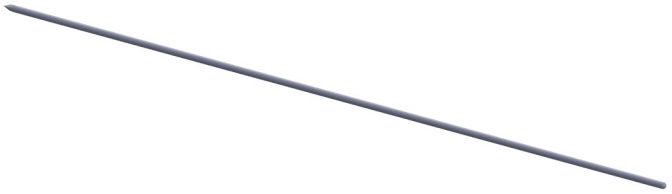
Ø3.0 Screw		
Part #	**Length**	**Description**
15023015	**15mm**	TyFix Cannulated Ø3.0mm x 15mm
15003015	**15mm**	TyFix Solid 0° Ø3.0mm x 15mm
15013015	**15mm**	TyFix Solid 10° Ø3.0mm x 15mm





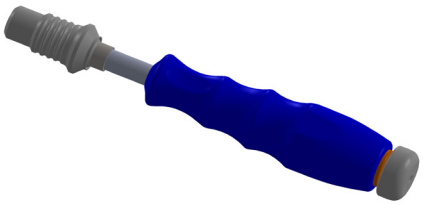
Guidewire

001-000002	Ø0.9mm Guidewire (6”)
001-000003	Ø1.1mm Guidewire (6”)



Handle

GC-00008	Mini Fixed AO Handle



X-Ray Template

013-000001	X-Ray Template

Caddies

013-000000	Hammertoe Non-Sterile Implant

Sterilization

The GEO Hammertoe Screw is provided sterile. All sterile implants will be clearly marked "STERILE". The sterile implant is gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize. Where specified, do not use the device after expiration date.

The GEO Hammertoe Screw instrumentation are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to use.

The following steam sterilization parameters are recommended:

Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Time: 4 minutes
Drying time: 20 minutes
NOTE: Allow For Cooling

Consult the GEO Hammertoe Screw Package Insert for additional cleaning and sterilization instructions.

Individuals not using the recommended method temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Notes

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Rx Only. Patent and Patent Pending.

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