GEO Extremity and Ankle Plating System - Instructions for Use

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

GEO Extremity and Ankle Plating System Implants and Instrumentation are provided STERILE and are for Single Use ONLY.

DEVICE DESCRIPTION

The GEO Extremity and Ankle Plating System consists of anatomically contoured Fibula Plates (multiple lengths), general Extremity Plates (multiple lengths and varying geometries), Screws (locking and non-locking of varying lengths and diameters), and Instrumentation to facilitate implantation. Instrumentation includes drill guides, drill guide handle, hook depth gauge, drill bits, hexalobe AO driver tips, plate tack, wire guide/k-wire, plate bender, reamers, reamer templates, plate templates, and AO driver handle.

INDICATIONS FOR USE

The GEO Extremity and Ankle Plating System is indicated for use in the stabilization and fixation of fractures or osteotomies, joint fusion, and reconstruction of the bones in the hand, wrist, foot, and ankle. The System can be used in both adult and pediatric patients. Specific examples include:

Forefoot

- Arthrodesis of the first metatarsal-cuneiform joint (Lapidus Fusion)
- Metatarsal and phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (Weil)
- Fifth metatarsal fractures (Jones fracture)
- First Metatarsal Osteotomies (Hallux Valgus)
- First Metatarsal-Phalangeal Joint (MTPJ) Fusion

Midfoot and Hindfoot

- LisFranc Arthrodesis
- Lapidus Fusion
- Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular- Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusions (including Charcot)
- Lateral Column Fusions (including Charcot)
- Flat Foot (including Evans Osteotomy and Cotton Osteotomy)
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

Ankle

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Pilon Fractures
- Distal Tibia Fractures
- Distal Fibula Fractures
- Medial Malleolar Avulsion Fracture
- Lateral Malleolar Avulsion Fracture
- Supramalleolar Osteotomy
- Fibula Osteotomy

MATERIAL

GEO implants are comprised of titanium alloy (Ti6Al4V) per ASTM F136. Instrumentation is comprised of medical grade stainless steel and anodized aluminum.

CONTRAINDICATIONS

- 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

- 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.

PRECAUTIONS

- Take care to select the proper plate configuration for the patient.
- Plates are offered in different lengths and shapes. Take care to select the proper, desired plate;
- Take care to use the appropriate sized instrumentation for implantation;
- Plate tacks and guide wires should be removed at the appropriate time to avoid insufficient compression;
- Avoid repeated bending of plates as stress fractures in the plate can occur.
- Avoid bending the plates directly over screw/compression holes as damage to the hole can occur and affect the ability to accept the screw;
- Take care to avoid cross threading of components;
- It is the responsibility of the surgeon to consider the clinical and medical status of each patient and be knowledgeable about all aspects of implant procedure and the potential complications that may occur;
- Consult the corresponding Operative Technique for additional information.
- The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery.
- The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices;
- Removal of the implant(s) should take into consideration the potential risk to the patient of a secondary surgical procedure. Device removal should be followed by adequate postoperative management to avoid re-fracture;
- Damage to the Driver Tip or Screw may result from failure to seat the Driver properly with the Screw;
- Handle implants carefully. Scratches, nicks or other damage to implant surfaces can result in harm to soft tissue, and/or give rise to stresses that may reduce the strength and fatigue resistance of the implant and could lead to failure;
- Inspect devices for defects or damage PRIOR to use. If you suspect an implant or instrument to be defective or damaged, DO NOT USE.
- If an instrument is damaged while in use, a new instrument may be required to complete the procedure.

ADVERSE EFFECTS

The following are potential adverse effects that may occur with internal stabilization devices. These effects include, but are not limited to:

- Infection (primary or secondary);
- Pain, inflammation, discomfort, abnormal sensations due to the implant presence;
- Implant fracture, loosening, or dislocation requiring revision surgery;
- Failure or delay of correction, non-union (pseudarthrosis), malunion or malalignment;
- Decrease in bone density due to stress shielding;
- Hematoma and/or impaired wound healing;
- Injury to blood vessels or nerves; necrosis of bone;
- Allergic reaction to implant material(s);
- Untoward histological responses;
- Migration of particle wear debris possibly resulting in a bodily response.

MRI COMPATIBILITY

The GEO Extremity and Ankle Plating 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 GEO Extremity and Fibula Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STERILITY STATUS

All GEO implants and instrumentation are provided **STERILE**. Sterile devices are clearly labeled STERILE. Sterilization is achieved by exposure to a dose of a minimum of 25 kGy of gamma irradiation.

STERILE PRODUCT STORAGE & HANDLING

STERILE devices must be stored in the original unopened packaging away from moisture where temperatures are between ⁻10°to 55°C (14°F and 131°F).

IMPORTANT: Inspect sterile packaging. If package is opened or damaged DO NOT USE. Note: devices should be considered sterile unless the inner tray package has been opened or damaged.

Remove device(s) from package using aseptic OR technique only after the correct type and/or size have been determined and the operative site is prepared for implantation. Handle product with powder-free gloves.

USE BY DATE

Verify the USE BY date on the package labeling. If it is past the USE BY date, DO NOT USE. Re-sterilization of sterile packaged devices is not recommended.

DISPOSAL

Dispose of contaminated device/materials in accordance with institutional biohazard protocol.

CONTACT GEO

For questions, comments, or to report an adverse experience, please call GEO Customer Service at 855-436-2278.

Instructions for Use (IFU) and Operative Technique Guides are available at www.gramercyortho.com or contact GEO Customer Service 855-436-2278 and these materials will be provided to you.

Symbols Use in Product Labeling			
REF	Catalog Number		Manufacturer
LOT	Lot Number		Use By Date (Year/Month/Day)
STERILE R	STERILIZED by Gamma Radiation		Single Use Only
	Storage Temp. Range		Date of Manufacture (yyyy-mm-dd)
	If package opened or damaged do not use	**RX Only**	Prescription Device
	See Instructions for Use	 www	Electronic IFU
IMPLANT	Do Not Implant		