

GEO Bone Screw System - Instructions for Use/ Important Medical Information




Gramercy Extremity Orthopedics, Inc.

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CAUTION:

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

GEO Bone Screw System Implants and Instrumentation are provided STERILE and are for  Single Use ONLY.

DEVICE DESCRIPTION

The GEO Bone Screw System consists of STERILE stand-alone headed and headless, cannulated and solid threaded Bone Screws, Washers, and Instrumentation. The Bone Screws are available in varying lengths and diameters including partially and fully threaded designs to accommodate application in varying bone sizes. Instrumentation is provided to facilitate implantation and includes K-Wires, Drill Bits, Depth Gauge, Countersink, Hexalobe Driver Tips and Driver Handles.

INDICATIONS FOR USE

The GEO Bone Screw System is indicated for bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment.

MATERIAL

GEO implants (Bone Screws and Washers) are comprised of titanium alloy (Ti6Al4V) per ASTM F136. Instrumentation is comprised of medical grade stainless steel, plastic, 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 metal sensitivity or allergic reaction to foreign bodies;
- In patients with poor or insufficient bone quality or quantity;
- In the presence of any clinical or functional abnormalities that would preclude the potential of achieving a good outcome for the patient;
- Other conditions that may place the patient at risk physiologically;
- Irreparable tendon system.

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 and 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 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;
- Patient sensitivity to implant materials should be considered and assessed prior to surgery;
- Implants are for temporary fixation until healing is complete and may not withstand weight bearing or unsupported stress.

PRECAUTIONS

- 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;
- The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery. Revision surgeries with implants are common;
- 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;
- Take care to use the appropriate sized Instrumentation for Bone Screw implantation;
- Damage to the Driver 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 cause damage 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.

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ADVERSE EFFECTS

The following are potential adverse effects that may occur with internal stabilization devices that should be understood by the surgeon and explained to the patient. These effects include, but are not limited to:

- Infection (primary or secondary);
- Pain, discomfort, abnormal sensations due to the presence of the implant;
- Clinical failure due to bending, loosening, wear and tear, implant fracture, loss of fixation, dislocation and/or migration;
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;
- Hematoma and/or impaired wound healing;
- Loss of anatomic position with malunion or malalignment;
- Necrosis of bone;
- Injury to blood vessels or nerves;
- Metal sensitivity or allergic reaction to a foreign body;
- Clinical failure due to bending, loosening, wear and tear, implant fracture, loss of fixation, dislocation and/or migration;
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;
- Hematoma and/or impaired wound healing;
- Loss of anatomic position with malunion or malalignment;
- Necrosis of bone;
- Injury to blood vessels or nerves.

MRI COMPATIBILITY

The GEO Bone Screw 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 Bone Screw 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 from package using aseptic OR technique only after the correct size has 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.

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			
	Catalog Number		Manufacturer
	Lot Number		Use By Date (Year/Month/Day)
	STERILIZED by Gamma Radiation		Single Use Only
	Storage Temp. Range		Date of Manufacture (yyyy-mm-dd)
	If package opened or damaged do not use		Prescription Device
	See Instructions for Use	 www	Electronic IFU