GEO Staple System: Instructions for Use / Important Medical Information

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

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

DEVICE DESCRIPTION

The GEO Staple System consists of sterile symmetric and asymmetric, barbed and smooth Nitinol staples in varying widths and lengths for internal fixation of small bones. GEO Staple System Instrumentation includes a staple inserter, drill bit, drill guide, tamp and locator pins.

INDICATIONS FOR USE

The GEO Staple System is intended for fixation of small bone fragments, fixation of osteotomies, and joint arthrodesis.

MATERIAL

GEO Staples are comprised of Nitinol per ASTM F2063. Instrumentation is comprised of medical grade stainless steel, aluminum or other biocompatible material.

CONTRAINDICATIONS

- In patients with active local infection or any evidence of latent infection, or localized inflammation.
- In patients with poor or insufficient bone quality or quantity resulting from disease, infection, or other reasons.
- In patients with documented or suspected metal sensitivity or intolerance to foreign bodies.
- In patients having inadequate tissue coverage over the operative site.
- In patients where implant utilization would interfere with anatomical structures or expedited physiological performance such as impinging on vital structures.
- Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
- Use in displaced, non-reduced fractures with bone loss.
- 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.

WARNINGS

- GEO Staples and instrumentation are Single Use Only. DO NOT REUSE.
- Reuse could result in failure of the device to perform as intended, transmission of infectious diseases, and/or harm to the patient or user.
- Implants are for temporary fixation until healing is complete and may not withstand weight bearing or unsupported stress.
- 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 implant and instrumentation may result in loosening, fracture of the device, bone or both, surgical delays and/or additional drilling.
- 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.
- Physical contact with dissimilar metals is not recommended.

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.
- Take care to use the correct sized instrumentation.
- 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.

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 is not limited to the following.

- Infection (primary or secondary).
- Pain, discomfort, abnormal sensations due to the presence of the implant.
- Skin irritation where there is inadequate tissue coverage over the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Clinical failure due to disassembly, fretting, bending, loosening, cracking or fracture of implant, dislocation and/or migration.
- Loss of anatomic position with malunion, malalignment or nonunion.
- Decrease in bone density due to stress shielding.
- Hematoma and/or impaired wound healing.
- Necrosis of bone.
- Injury to blood vessels or nerves.
- Cessation of growth of the operated portion of the bone.
- Implants cutting through the bone especially in soft osteoporotic or cancellous bone.
- Bone forming around the implant making removal difficult or impossible.

MRI SAFETY INFORMATION

The GEO Staple 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 Staple System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

STERILITY STATUS

All GEO Staples and instrumentation are provided sterile and clearly labeled STERILE R Sterilization is achieved by exposure to 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. DO NOT RESTERILIZE.

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.

DISPOSAL

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

Operative Technique

1. Prepare the surgical site and reduce the fracture or osteotomy. Place the drill guide over the site to determine the appropriate size staple.
2. Starting with the most distal location, drill the first staple leg hole with a 2.0 mm drill for staple sizes 8mm-12mm and the 2.7 mm drill for staple sizes 15mm-25m. Depth marks are provided on the drill bit in 5mm increments to assist in drill depth for staple leg length.
3. Place a staple locator pin in the distal drilled hole to maintain drill guide position and then drill the proximal hole.
4. Locate the appropriate sized sterile and preloaded staple. On the GEO Staple Inserter, engage the lever to the full position which will spread the staple legs to a parallel position for insertion. The GEO Staple is packaged and shipped in a compressed (relaxed) state.
5. Remove the GEO Staple Locator Pin and insert the Staple into the predrilled holes until the staple is fully seated to the fixation site.
6. To remove the GEO Staple Inserter, fully disengage the lever and then slide away from the staple. The GEO Staple will remain in situ.
7. Place the Tamp on the Staple bridge and tamp Staple flush to fixation site.
8. Additional GEO Staples may be used if necessary

Note: The 2.0mm drill has a positive stop at 15 mm and is marked with two (2) laser lines at 5 mm intervals distal to the positive stop. The 2.7 mm drill has a positive stop at 20 mm and is marked with one (1) laser line at a 5 mm interval distal to the positive stop.

Symbols Used 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 Temperature 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

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

CONTACT GEO

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