

Gramercy Extremity Orthopedics

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GEO NON-STERILE HANDLE (ratcheting and fixed)

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

GEO Non-Sterile Ratcheting and Fixed Handles are provided **NON-STERILE** and require cleaning and sterilization prior to use.

DEVICE DESCRIPTION

The GEO non-sterile Ratcheting and Fixed Handles are considered manual orthopedic instruments and are designed for use with other instrumentation featuring Hudson and AO mating geometries for use in orthopedic surgery.

INDICATIONS FOR USE

The GEO non-sterile Ratcheting and Fixed Handles indicated for use with other instrumentation featuring Hudson and AO mating geometries for use in orthopedic surgery.

MATERIAL

GEO non-sterile ratcheting and fixed handles are comprised of medical grade silicone and stainless steel.

CONTRAINDICATIONS

There are no known contraindications for this instrumentation.

WARNINGS

- Instrumentation is provided NON-STERILE and must be cleaned and sterilized prior to initial use and before each subsequent use.
- Failure to follow specified cleaning and sterilization instructions could result in infection.
- Surgical Instrumentation should only be used and reprocessed by qualified healthcare practitioners.
- Do not disassemble Handles for cleaning.
- Cleaning of small holes and cannulation requires special attention.
- To avoid damage including pitting and rusting, do not use highly aggressive agents (e.g., NaOH, NaOCL), and salt solutions.
- Do not use aldehyde fixating detergents because they can cross-link the proteins residues, making it difficult to remove soiling.

PRECAUTIONS

- Inspect instrumentation for defects or damage PRIOR to use. If you suspect the instrument to be defective or damaged, DO NOT USE. (Instruments that are damaged should be reprocessed prior to returning to GEO.)

NON-STERILE INSTRUMENT CLEANING & HANDLING

GEO Ratcheting and Fixed Handles are supplied NON-STERILE unless otherwise labeled and MUST BE CLEANED and STERILIZED before each use. After use, Instruments must be, at a minimum, properly decontaminated, cleaned and stored. NON-STERILE instruments should be stored clean, decontaminated and completely dry in a clean, dry environment.

LIMITATIONS AND RESTRICTIONS OF REPROCESSING

Surgical instruments are designed for their durability and ability for reuse. GEO Instrumentation is manufactured from medical grade stainless steel, silicone and other biocompatible materials that permit a long life when properly handled and maintained.

End of functional life is normally determined by wear and damage due to use, handling, diminished performance, etc.

GEO does not accept responsibility or liability for any instrument for which repairs and/or modifications have been attempted or made expect for authorized GEO Representatives.

INSTRUMENT CLEANING

Clean Instrument as soon as possible after each use. Do not allow blood or debris to dry on the instrument. Clean all instruments whether or not they were used in case of inadvertent contact with blood or saline solution.

Point of Use

Rinse each Instrument in running water for at least 30 seconds. Use a soft cloth, moistened with water to remove any visible soil. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solution to delay drying.

Preparation for Cleaning

Individuals performing the cleaning should be properly gowned with appropriate gloves and personal protective equipment.

Cleaning Equipment Required:

Water	Room temperature deionized water
Detergent	Enzymatic (pH neutral) cleaning agent or detergent (pH <8.5) solution
Manual Cleaning Accessories	Brushes, pipe cleaners, syringes, gloves, absorbent disposable cloth, soft lint-free cloth

STEPS FOR MANUAL CLEANING

1. Prepare the enzymatic cleaning agent or detergent according to the manufacturer's instructions.
2. **Submerge instruments** in a basin containing the enzymatic detergent or cleaning agent for at least 10 minutes.
3. At the end of this time, use a soft bristled brush to remove visible blood, soil and debris from the instruments paying close attention to uneven surfaces, small holes, and cannulation.
4. **Brush** each Instrument for at least 30 seconds.
5. Submerge the Instrument(s) again in the enzymatic detergent basin for a minimum of 1 minute.
6. **Rinse** with de-ionized or sterile, purified water (~20° C) for a minimum of 2 minutes. Use a syringe to apply rinsing solution under pressure to hard to reach areas such as cannulations and small holes.
7. Ensure all areas are thoroughly rinsed and visible detergent is removed.
8. Visually inspect the instruments to verify that they are free of remaining soil/debris. If soil is still visible following cleaning, repeat the cleaning and rinsing steps as necessary.
9. Dry the Instruments with a soft, clean, lint-free cloth.

STEAM STERILIZATION INSTRUCTIONS

1. Visually inspect instruments before sterilization for soiling, corrosion, cracks, splitting, delamination and/or damage. This is typically done under normal lighting and without magnification.
2. Functionally inspect adapters (if equipped) to ensure they connect onto the mating shafts. Check function of ratcheting drivers in both directions (forward and reverse).
3. Notify appropriate personnel regarding damage and malfunctioning components.
4. The recommended steam sterilization cycle for GEO Handles in FDA cleared sterilization wrap/pouch is as follows:

Steam Sterilization Cycle – 10⁻⁶ SAL

GEO Handles (Ratcheting & Fixed)	Cycle	Temp	Exposure Time	Dry Time
1. <i>Wrap the instrument in FDA cleared sterilization wrap for gravity steam sterilization; and</i> 2. <i>Place the wrapped device in an FDA cleared sterilization pouch for gravity steam sterilization</i>	<i>Gravity displacement</i>	270°F (132 °C)	15 min	30 min

This recommendation is consistent with ANSI/AAMI/ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1 and ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012/ A4:2013/(R)2014 and AAMI TIR30 and has been validated using specific equipment. **If processing conditions, wrapping materials or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.**

INSTRUMENTATION, INSPECTION & MAINTENANCE

GEO Instrumentation is susceptible to damage from prolonged use and/or through misuse or harsh handling. Care must be taken to avoid compromising their performance. To minimize damage, note the following:





1. Inspect the Instruments for damage when received and after each use and cleaning. If any component appears damaged, do not use.
2. After cleaning, Instruments should be stored clean, decontaminated and completely dry in a clean, dry dust-free environment at temperatures between 5 °C – 40 °C. Avoid areas of humidity to reduce risk of corrosion.
3. Only use an Instrument for its intended purpose.

End of functional life is normally determined by wear and damage due to use, handling, diminished performance, etc. **A visual and functional inspection** should be performed prior to use. Visually inspect for cracking, splitting and/or delamination of the silicone handle or any other feature that appears defective. Functionally inspect for: 1) restriction or binding of the spring-loaded retention collar; 2) binding or locking of the directional collar of ratcheting handles prohibiting the choice of driving or removing screws (ratcheting handles should move forward and in reverse easily); 3) ability of instrument to lock into the handle. If instrumentation appears damaged or defective, do not use and contact GEO.

Contact GEO

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

Instructions for Use (IFU) are available at www.gramercyortho.com. Or contact GEO Customer Service at 855-436-2278 and the IFU will be provided to you at no charge.

Symbols Use in Product Labeling			
	Catalog Number		Manufacturer
	Lot Number	RX Only	Prescription Device
	Temperature range		