



REPROCESSING SURGICAL INSTRUMENTS TRI-GEAR™ Ratcheting Screwdrivers & Driver Handles

DESCRIPTION / INDICATIONS

MedTorque, Inc. instruments consist of Class I manual surgical instruments. The TRI-GEAR™ ratcheting screwdrivers and driver handles are designed to install and remove threaded product and to interface with Class I shafts manufactured by MedTorque, Inc.

WARNING

- 1 - Instruments are provided **non-sterile** and must be cleaned and **sterilized** prior to use.
- 2 - Surgical instruments should only be used and reprocessed by qualified healthcare practitioners.
- 3 - Ratcheting Screwdrivers and Driver Handles are not designed for disassembly before cleaning.
- 4 - Cleaning of small holes and cannulation requires special attention.
- 5 - To avoid damage, (pitting, rusting), avoid highly aggressive agents, (NaOH, NaOCL), and salt solutions.
- 6 - Clean and sterilize before first use and before returning them to service.

INFORMATION

- 1 - Instruments that are damaged should be reprocessed prior to return to the manufacturer for repair.
- 2 - These cleaning methods have been validated by a third-party lab. Other means of cleaning may be suitable; however, it is advisable that the cleaning method(s) be validated in accordance with the equipment manufacturer's recommendations.

POINT OF USE

- 1 - Wipe instruments to remove visible soil.
- 2 - Keep instruments moist, preferably submerged in cold water (<40°C) immediately after use.

MANUAL CLEANING

- 1 - Submerge instruments in a pH neutral enzymatic cleaning agent or detergent (pH <8.5) solution for 10 to 15 minutes. Do not use aldehyde fixating detergents because they can cross-link the protein residues, making it difficult to remove soiling. Follow detergent manufacturer's instructions for mixing ratios and temperature.
- 2 - Use a soft bristle brush if needed to remove visible soil from surfaces. Give special attention to uneven surfaces (such as knurled handles) and drilled holes/cannulation. Use flexible bottle brush, syringes, or aspiration for hard to reach places such as cannulation.

RINSE IN RUNNING WATER

- 1 - Thoroughly rinse with de-ionized or sterile, purified water, (<40°C), until it is no longer slippery to the touch, for a minimum of 2 minutes. Use a syringe to apply rinsing solution under pressure to hard to reach areas such as cannulations and drilled holes.
- 2 - Visually inspect instruments for remaining debris, paying special attention to hard to reach areas. Repeat rinsing steps if needed until no visible soiling remains.
- 3 - Drain instruments on single-use drying paper or lint-free towel.

ULTRASONIC CLEANING

- 1 - Submerge instrument in ultrasonic bath with pH neutral enzymatic cleaning agent or detergent, (pH <8.5), solution. Follow detergent manufacturer's instructions for mixing ratios and temperature.
- 2 - Soak at 25 to 45 kHz for 10 to 15 minutes. Visually ensure complete immersion of instruments.



RINSE IN RUNNING WATER

- 1 - Thoroughly rinse with de-ionized or sterile, purified water, (<40°C), until it is no longer slippery to the touch, for a minimum of 2 minutes. Use a syringe to apply rinsing solution under pressure to hard to reach areas such as cannulations and drilled holes.
- 2 - Visually inspect instruments for remaining debris, paying special attention to hard to reach areas. Repeat rinsing steps if needed until no visible soiling remains.
- 3 - Drain instruments on single-use blotting paper.

DRY INSTRUMENTS

- 1 - Thoroughly dry instruments with a soft, lint-free cloth, with single-use drying paper, or with medical grade, filtered, compressed air. Hard to reach areas such as drilled holes and cannulations should be dried with medical compressed air.

INSPECT INSTRUMENTS

- 1 - Visually inspect instruments before sterilization. This is typically done under normal lighting and without magnification.
- 2 - Visually inspect for soiling, corrosion, cracks, and damage to components.
- 3 - Functionally inspect adapters (if equipped) to ensure they connect onto mating shafts. Check function of ratcheting screwdrivers in both directions, (forward and reverse).
- 4 - Notify appropriate personnel regarding damage and malfunctioning components.

STERILIZATION

- 1 - See Implant / Instrument System manufacturer's Instructions.

MAINTENANCE

- 1 - Lubricate moving parts and threads with a water-based surgical grade instrument lubricant. Follow lubricant manufacturer's instructions.

STORAGE / HANDLING

- 1 - Handle instruments with care. Scratches and surface damage can minimize the usable life of the instrument and increase the risk of corrosion.
- 2 - Store sterilized instruments in a clean, dry, dust-free environment at temperatures between 5°C and 40°C. Avoid areas of humidity to reduce the risk of corrosion.



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