

INSTRUCTIONS FOR USE

Ratcheting Screwdrivers & Fixed Handle Drivers

DESCRIPTION / INDICATIONS

MedTorque, Inc. instruments consist of Class I manual surgical instruments. The Ratcheting Screwdrivers and Fixed Handle Drivers 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 in accordance with ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1.

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

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

STERILIZATION

1. Sterilization testing has been performed in accordance with ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1.
2. 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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