INSTRUCTIONS FOR USE (IFU)

Torque-Limiting Drivers

DESCRIPTION/INDICATIONS

MedTorque, Inc. instruments consist of Class I manual surgical instruments. The torque-limiting drivers designed and manufactured by MedTorque, Inc. are reusable surgical instruments that are intended to limit the applied moment of force, or torque, in the clockwise (CW) direction to a device or fastener during the tightening process. The torque-limiting drivers utilize an internal mechanism that is factory set to actuate at a predetermined value within an accuracy ±10% throughout its duty life which includes use, cleaning, sterilizing, and storage. When actuated, the mechanism produces an audible and tactile click that is noticeable to the user.

IMPORTANT PRECAUTIONS AND SAFETY INSTRUCTIONS

- Read this document prior to using the torque-limiting instrument.
- Only use torque-limiting products as intended.
- The calibration period of six (6) months is established by MedTorque, Inc. and should be closely followed to ensure acceptable performance of product.
- MedTorque, Inc. is the only authorized provider of service and calibration for torque-limiting products. Service provided by non-authorized party will void warranty.
- Inspect prior to use. Do not use or discontinue use if device is damaged, malfunctioning or performance is in question.
- If product has been dropped, impacted or used improperly, a recalibration should be performed.
- To avoid damaging device:
  - Never use torque-limiting drivers in the counter-clockwise (CCW) direction to break loose a fastener.
  - Never impact on torque-limiting drivers or use as an impacting device on other devices.
  - Never use as a prying tool.
  - Never expose torque-limiting drivers to extreme temperatures.

USAGE INSTRUCTIONS

New users of torque-limiting drivers should become familiar with their function prior to using in a clinical setting.

- Engage the torque-limiting driver with the mating shaft and ensure it is secured in the coupling.
- Grip the handle of the torque-limiting driver in such a way that is comfortable in actuating the torque-limiting driver throughout the tightening process.
- Align the axis of the torque-limiter with the axis of the driven fastener. The angle θ° is the deviation symmetrically about the axis of the fastener. This angle, θ°, should not exceed 5° as shown in Figures 1 through 3.
- Apply a rotational force (τ) to the handle in the clockwise (CW) direction along the aligned axes. This force should be applied continuously and consistently until the torque-limiter actuates. The actuation is characterized by an audible and tactile click. The torque-limiter should be actuated in the span of approximately 1 second.
- Do Not:
  - Operate the torque-limiter in a counter-clockwise (CCW) direction.
  - Apply additional compound loads such as bending or compressing to the torque-limiting driver while actuating.
  - Apply rotational force either too rapidly (<0.5 secs per actuation) or too slowly (>2 secs per actuation).
  - Continue to use torque-limiter if there is doubt that it is operating correctly.

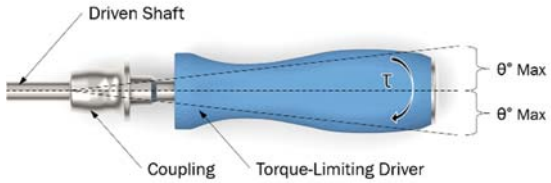

Figure 1 - Axial Torque-Limiter

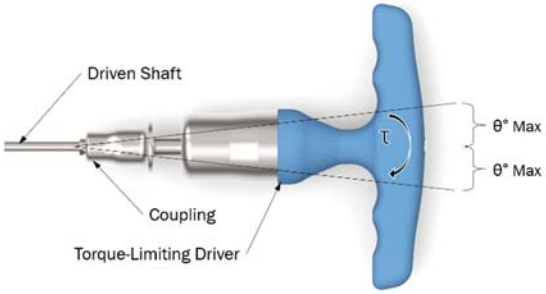

Figure 2 - Axial Torque-Limiter with T-Handle

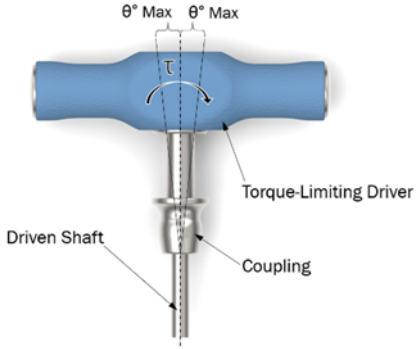

Figure 3 – Mondo T-Handle Torque-Limiter

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. Torque-Limiting Drivers and 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 clothe, 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. Sterilization testing has been performed in accordance with ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1
   a. Gravity: 250°F, 30 min exposure, 45 min dry time
2. After dry time allow a minimum of ten minutes for equilibration period to allow instrument to cool to room temperature.
3. 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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