



EN	Torque Limiting Drivers Instructions for Use
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Torque Limiting Drivers Instructions for Use

Manufacturer

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European Representative

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Description

The Torque Limiting Drivers are reusable manual orthopedic surgical instruments that are used to engage surgical engage surgical implants and instruments and allow the user to apply a specific amount of torque. The instruments are provided non-sterile without a storage container.

Intended Use

A hand-held manual surgical instrument designed to attach to the proximal end of a surgical instrument (e.g., a screwdriver shaft) to allow the surgeon to perform manipulations with the instrument, typically manual rotation of a bone screw or setscrew, whilst providing a torque-limiting function to ensure that the screw is not over tightened, during an orthopaedic procedure. The device is typically made of metal/synthetic material (e.g., polysulphone) and may have a T-shaped handle grip. It will normally provide an indication to the surgeon when the pre-set torque level is reached with an audible click and release of rotational traction.

Rx Only

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Indications

The Torque Limiting Drivers are indicated for any scenario where a clinician desires to apply a specific torsional load to fastener or implant in a surgical setting.

Contraindications

There are no known contraindications for this instrument at this time.

Precautions

Instrument is provided non-sterile. Clean and sterilize prior to each use.

Neutral pH cleaners are recommended.

Prior to use, care must be taken to protect nerves, vessels and/or organs from damage that may result from the use of these instruments.

Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.

Point of Use

Remove excess bodily fluids and tissue with a disposable wipe.

Instrument should not be allowed to dry prior to cleaning.

Containment / Transportation

Follow hospital protocols when handling contaminated and or biohazardous materials. Instrument should be cleaned within 30 minutes after use to minimize the potential of staining, damage, and drying after use.

Device Life

The Torque Limiting Drivers have an expected life of 5 years with a re-calibration period of 1 year. Each year the device should be returned to the manufacturer for a re-calibration cycle to ensure device performance is maintained.

Reprocessing Limitations

Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing reusable instruments and accessories.

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

These reprocessing instructions have been validated as being capable of preparing the instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

Remove all accessory instruments, implants, or other medical devices from the Torque Limiting Driver before re-processing.

Manual Cleaning Procedure

1. Prepare a proteolytic enzyme solution according to the manufacturer's instructions.
2. Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.
3. Soak instruments for a minimum of 10 minutes. While soaking, scrub surfaces using a nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, instrument teeth, rough surfaces, and areas with moving components or springs. Lumens, blind holes, and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole, or cannula with a twisting motion while pushing in and out multiple times.

NOTE: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.

4. Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas, and other difficult to access areas.
5. Prepare an ultrasonic cleaning bath with detergent and de-gas according to the manufacturer's recommendations. Completely submerge instruments in the cleaning solution and gently shake them to remove any trapped bubbles. Lumens, blind holes, and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. Sonically clean the instruments at the time, temperature, and frequency recommended by the equipment manufacturer and optimal for the detergent used. A minimum of ten (10) minutes is recommended.

NOTES:

- **Separate stainless steel instruments from other metal instruments during ultrasonic cleaning to avoid electrolysis.**
- **Fully open hinged instruments.**
- **Use wire mesh baskets or tray designed for ultrasonic cleaners.**
- **Regular monitoring of sonic cleaning performance by means of an ultrasonic activity detector, aluminum foil test, TOSITM or SonoCheckTM is recommended.**

6. Remove the instruments from the ultrasonic bath and rinse in purified water for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas, and other difficult to access areas.
7. Dry instruments with a clean, absorbent, non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas, and difficult to access areas.

Automated Cleaning Procedure

A validation study for Automatic Cleaning has not been performed for these instruments. Please consult an appropriate responsible person or hospital protocol for direction. Automated cleaning using a washer/disinfector alone **may not** be effective for instruments with lumens, blind holes, cannulas, mated surfaces, and other complex features. A thorough manual cleaning of such device features is recommended before any automated cleaning process.

Disinfection

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.

Drying

Dry instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.

Inspection / Functional Testing

1. Carefully inspect each device to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features (particularly rotating instruments) for distortion.
5. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

***NOTE: If damage or wear is noted that may compromise the function of the instrument, do not use the instrument and notify the appropriate responsible person.**

Lubrication

After cleaning and before sterilization, instruments may be lubricated with a water-soluble lubricant such as Preserve®, Instrument Milk or equivalent material intended for surgical application. Always follow the lubricant manufacturer's instructions for dilution, shelf life and application method.

Sterilization

The Instrument must be cleaned prior to sterilization.

Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn. Devices should be wrapped using the double wrap or equivalent method (ref: AAMI ST79, AORN Guidelines).

Reusable wraps are not recommended.

Moist heat/steam sterilization is the recommended method for the instruments. Use of an approved chemical indicator (class 5) or chemical emulator (class 6) within each sterilization load is recommended.

Always consult and follow the sterilizer manufacturer instructions for load configuration and equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance,). Additionally the manufacturer's recommendations for installation, validation, and maintenance should be followed.

Validated exposure time and temperature to achieve a 10^{-6} sterility assurance level (SAL) is listed below.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.

Method – Pre-Vacuum Steam Sterilization

Set parameters at 4 minutes exposure at a temperature of 132°C (270°F) with a minimum of four (4) vacuum pulses prior to actual exposure.

A minimum dry time of 30 minutes is recommended. Longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.

Storage

Store sterile, packaged instruments in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

Instructions for Use

Do not use the instrument if accessories, implants or other medical devices do not properly fit with the instrument.

The user of the instrument set should ensure that the instrument has no more than 60 minutes of direct exposure to the patient. The user of this set should ensure that no instruments/parts of instruments be left in the patient during and following the surgical procedure.

Inspect instrument for damage or wear prior to use. Failure to do so could result in the damaging of instrument, implant, accessory, or other medical devices.

***Note: If damage or wear is noted that may compromise the function of the instrument, do not use the instrument and notify the appropriate responsible person.**

Insert accessory instrument, implant, or other medical device into the Torque Limiting Driver by moving the collar of the adaptor towards the proximal end of the device and inserting. Ensure appropriate fit of the Torque Limiting Driver and the accessory instrument, implant, or other medical device. If there is not appropriate fit, do not use. Once the accessory instrument, implant, or other medical device is inserted, release the collar to create engagement. Manually pull on the accessory instrument, implant, or other medical device to ensure proper engagement.

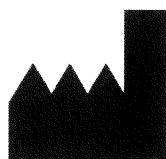
Insert the instrument into the wound site further engaging other implants, medical devices or the patient as needed. Rotate the silicone handle of the torque limiting driver in a clockwise manner to insert implants as needed. When the set torque limit is reached the Torque Limiting driver will audibly and physically actuate. This signifies the pre-set torque limit has been achieved.

The Torque Limiting Driver can be used in a counter-clockwise manner but **will not actuate at the pre-set torque limiting setting**. Additionally, care should be taken as to not subject the Torque Limiting Driver to an excessive amount of torque in the counter-clockwise direction.

Once finished using the Torque Limiting Driver remove all accessory instruments, implants, or other medical devices before re-processing.



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