Spinal & Orthopedic Instrument Specialists

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Instructions for Use: Axial Torque Limiting Driver

This hand torque tool is a high precision and accurate torque limiting device. All hand torque tools must be handled with care. When used within the guidelines of this document, this device will maintain a high level of performance for the life of the device. Failure to abide by these guidelines could significantly compromise torque performance, durability, and cause possible serious injury.

INTENDED USE

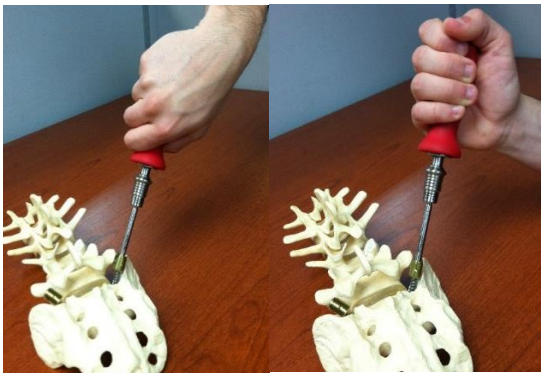
The Bradshaw Medical Axial Torque Limiting Driver is a reusable surgical instrument designed to limit the magnitude of applied (input) torque transferred to an external (output) device or fastener in the clockwise direction. This device is a non-adjustable mechanical 'click' style hand torque tool which presents an audible and tactile 'click' when the maximum desired torque is reached. It is offered from the factory at torque settings between 4 lb.-in to 40 lb.-in (0.45 N-m to 4.5 N-m) and are designed generally able to maintain a torque accuracy of ±10% of the set value through repeated usage and cleaning/sterilization cycles during each recalibration period.

IMPORTANT PRECAUTIONS AND SAFTEY INSTRUCTIONS

1 .Read this instruction manual completely before using this instrument.
2. Use as intended only.
3. Maintain this device in accordance with the Bradshaw Medical Inc. "Recommended Care for Surgical Instruments".
4. The calibration schedule defined by Bradshaw Medical Inc. must be strictly adhered to. Failure to do so may result in unacceptable torque performance.
5. Servicing and calibration of this device shall be performed by Bradshaw Medical Inc. personnel only. Failure to abide by this requirement will void product warranty. This device must be recalibrated every six (6) months.
6. Inspect before every use. Do not use if device is damaged.
7. Discontinue use immediately if abnormal noise or vibration is found to occur or if device appears to be malfunctioning.
8. To avoid damaging the device,
    a. Never use this torque wrench to break fasteners loose. Do not use in the counter-clockwise direction.
    b. Do not impact this device, or use this device to impact other devices.
    c. Do not use as a prying tool.
    d. Do not expose to temperatures less than -23.3°C (-10°F) or greater than 162.8°C (325°F).
    e. Do not use other tools or instruments to aid in rotating the handle. If the device cannot be actuated by hand, discontinue use immediately.
9. This device must be recalibrated if dropped, used improperly, or impacted.

USAGE INSTRUCTIONS

For first time users of the Bradshaw Medical Inc. Axial Torque Limiting Driver, operate the device and become familiar with its function PRIOR to using it in a surgical environment.
1. Fasten the Axial Torque Limiting Driver to the external driving device. Verify that the adaptor is locked and the external driving device is fully secured in the adaptor.
2. Grip the handle as shown with second digit towards the Shaft (Figure 1) or with the 5th digit towards the Shaft of the unit (Figure 2).
3. Orientate the Axial Torque Limiting Driver such that its axis of rotation is parallel to the axis of the external device being driven. (Refer to Figure 3)
    a. Proper orientation is critical: axis of rotation must be aligned with the axis of the external device within approximately 5° in all directions.
4. Apply torque to the handle smoothly and continuously until the device completes one actuation. Completion of 1 actuation can be identified by a single tactile vibration always accompanied with an audible 'click' type of sound.
    a. ROTATION: An actuation (or click) will occur after every 45° of rotation.
    b. SPEED: From start to finish a single actuation should occur within 0.5-1.5 *seconds.*
    c. APPLICATION OF LOAD: Pure torsion in the clockwise direction only.
    d. DO NOT:
        i. Apply any additional loads to the device during an actuation (tension, compression, bending).
        ii. Use this device in the counter-clockwise direction.
        iii. Rotate the handle extremely fast (<0.5 sec/click) or extremely slow (>3 sec/click).
        iv. Continue to rotate the handle if there is any knowledge or suspicion that the device or components within the device are not functioning properly.
5. If multiple actuations are required, release your grip after every actuation and repeat Steps 2-4.



Figures 1(left) and 2 (right): Gripping the Handle

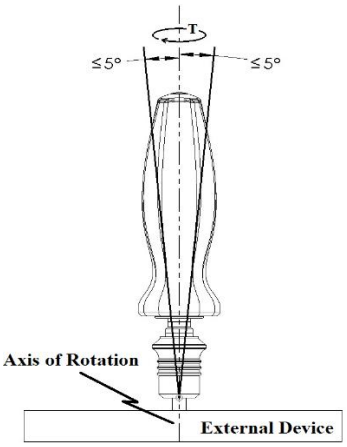


Figure3. Proper Orientation of Device During use

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Recommended Cleaning and Repeated Processing Information

WARNINGS:	• Avoid contact with: Strong Acids such as Hydrochloric acid and Sulfuric Acid, Hydrogen Fluoride, Alkaline and high concentrations of chlorides such as Chlorine Bleach. • No specific enzymatic detergent is endorsed, but the final solution should have a pH between 7.0 and 8.5 according to ASTM F 1744-96. • NEWLY PURCHASED DEVICES MUST UNDERGO DECONTAMINATION PRIOR TO STERILIZATION. • When using any detergent or equipment, always follow the manufacturer's instructions/recommendations for that product. • Long, thin diameter shafts used in conjunction with torque devices will affect the accuracy of the applied torque to the fastener as a certain amount of torque is applied due to the torsional wind-up of the shaft. When these types of shafts are used with torque devices, please inform Bradshaw Medical Inc., engineering personnel at the time of ordering to allow the torque wrench to be calibrated with the shaft attached to provide accurate torque to the fastener.	
Limitations on reprocessing:	• Repeated reprocessing has minimal effects on the performance of this device.	
INSTRUCTIONS		
Recommended Preparations for decontamination:	• Immediately after use, this device should be presoaked in an enzymatic detergent bath safe for medical devices for five (5) minutes. The time and temperature of this soak should follow manufacturer's instruction. • Scrub the submerged device(s) with a soft bristle brush. Agitate the device while scrubbing. Actuate moving parts. Use a small cytology brush to clean internal channels. • Clean the cannulated devices using a small brush through the cannulation. • Ultrasonically clean the instrument(s) for ten (10) minutes in a neutral pH detergent (or acceptable alternative). Prepare the detergent according to the manufacturer's recommendation. • After presoak, the device must be rinsed in demineralized water	
Recommended Cleaning (Manual):	• Use a cleaning brush to remove any remaining soil or debris, paying special attention to small grooves, crevices, and cannulation. • Rinse thoroughly with warm (38-49˚ C (100-120˚F)) tap water. • Place device in a warm bath of tap water (38-49˚ C (100-120˚F)). • Agitate the device for at least three (3) minutes gently by hand. • Ultrasonically clean the instruments(s) for ten (10) minutes in a neutral pH detergent (or acceptable alternative). Prepare the detergent per the manufacturer's recommendation. • Rinse the devices with clean tap water for at least one (1) minute. • Check this device for any visible soil and repeat the cleaning process if soil is found. • Allow water to run through device. If the water leaving the device appears to be soiled, repeat the cleaning procedure. • Dry the exterior of the device(s) with a clean, lint-free cloth. • DO NOT use any abrasive detergents, brushes, or cleaning pads. All brushes used should be designed for use on medical devices.	
Recommended Sterilization	Cycle: Pre-Vacuum, double wrapped Temperature: 135°C (275°F) Exposure Time: 3 minutes Dry Time: 20 minutes	Cycle: Gravity, double wrapped Temperature: 135°C (275°F) Exposure Time: 10 minutes Dry Time: 20 minutes
	Note These sterilization parameters are only valid for a sterilization pouch packaged unit. An equilibration time of 10 minutes is recommended. After a steam sterilization cycle the device must be allowed to cool for a minimum of 40 minutes in (stagnant) open air or 30 minutes under forced air prior to being used. Failure to allow for proper cooling can adversely affect torque performance.	
Inspection:	• Ensure that there are no spots or stains on the device after cleaning/disinfection. • If such spots exist, repeat the cleaning process to remove any protein residues or other stains.	
Packaging:	• Ensure the device has dried and is free of spots prior to packaging. Ensure that the packaging material has been held at room temperature for a minimum of 2 hours before use. • Package the device using standard packaging materials and packaging practices adopted accepted by the institution.	
Storage:	• No particular requirements; follow institution's storage policies.	