



Bradshaw Medical, Inc. Recommended Care for Surgical Instruments

This document was developed to provide information concerning the recommended care for the cleaning, sterilization, and maintenance of Bradshaw Medical Inc. surgical instruments. This document will also detail the warranty and return policy.

These guidelines are intended to provide a general understanding of the proper care, cleaning, sterilization, and maintenance of Bradshaw Medical surgical instruments. Do not use instruments for anything other than their intended purpose. Avoid using excessive force when handling or cleaning surgical instruments.

It is important to note that all Bradshaw Medical Inc. surgical instruments are shipped in a NON-STERILE condition and require cleaning and sterilization prior to use. DO NOT DISASSEMBLE ANY BRADSHAW MEDICAL SURGICAL INSTRUMENTS unless the included instructions state otherwise.

Manual Cleaning

All instrument must be cleaned immediately after each use. Bradshaw Medical, Inc. recommends that each instrument be manually cleaned following the recommended procedure below:

1. Submerge the instrument(s) in an enzymatic detergent safe for use with medical devices. Prepare the detergent according to the manufacturer's recommendations. Soak the instrument(s) for five (5) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments(s) with a soft bristled brush. Agitate the instruments(s) in the solution while scrubbing. Use a small cytology brush to clean any internal channels. Actuate any moveable parts to loosen any trapped soil.
3. Rinse the instrument(s) with warm (38°- 49°C or 100°- 120°F) water.
4. Place the instrument(s) into a bath containing warm (38°- 49°C or 100°- 120°F) water. Agitate the instrument(s) by hand for a minimum of three (3) minutes.
5. 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.
6. Rinse the instrument(s) with clean tap water for a minimum of one (1) minute.
7. Dry the exterior of the instrument(s) with a clean, lint-free cloth.
8. Repeat the manual cleaning procedure above (Steps 1-7) if the instrument(s) appear to be soiled after cleaning.

Automated Cleaning

An automatic cleaning device such as an ultrasonic cleaner is always preferred over manual cleaning when available. Bradshaw Medical, Inc. recommends that each instrument be automatically cleaned following the recommended procedure below:

1. Run the Automatic wash cycle with temperatures of 40°C and ultrasonic waves of 35 kHz for 10 minutes. These times and temperatures will vary depending on the equipment and detergent used.
2. Following cleaning, thoroughly rinse the device with demineralized water to remove any debris or detergents
3. Rinse the devices with clean warm (38°-49° C or 100°-120°F) potable water for at least one (1) minute.
4. Allow water to run through device. If the water leaving the device appears to be soiled, repeat the cleaning procedure
5. Dry the exterior of the device(s) with a clean, lint-free cloth.
6. Only use an automatic cleaner that has been properly maintained and cleaned.



Sterilization-Autoclave:

All instruments must be sterilized after cleaning and prior to using. Bradshaw Medical, Inc. recommends that each instrument be steam sterilized following either of the recommended parameters below:

Pre-Vacuum Autoclave (Wrapped)		Gravity Autoclave (Wrapped)	
Temperature:	135°C (275°F)	Temperature:	135°C (275°F)
Exposure Time:	3 minutes	Exposure Time:	10 minutes
Dry Time:	20 minutes	Dry Time:	20 minutes

Note After a steam sterilization cycle, the instruments 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 instrument performance.

Inspection

After each cleaning, carefully inspect each instrument to ensure all visible contamination is removed as well for damage that may have occurred during use or during the cleaning process. Check the actuation of the moving parts to ensure smooth operation. Discard any damaged or defective surgical instruments.

Warranty/Return Policy

All surgical instruments manufactured by Bradshaw Medical Inc. are guaranteed against material defects and malfunction. This warranty is null and void if any of the following conditions apply: the instrument was not properly maintained, was altered in any way, or used in a manner not intended for. In addition, if any repair or recalibration of torque devices is performed by anyone other than authorized Bradshaw Medical personnel, the warranty will be void. Returns are allowed within 90 days of invoice unless product was used in surgery or has been sterilized. A restocking fee of 25% may be incurred based on product complexity and the removal of laser marking. Specialty or customized products/packaging can only be returned for repair and will be shipped back to the customer. All product returns require a Return Material Authorization (RMA) number, which can be requested by calling customer service at 262.925.1374. If instruments are returned to Bradshaw Medical due to malfunction, Bradshaw Medical will review the instrument and make a determination as to how to proceed. Instruments will be repaired or replaced based on the findings during review.

Recalibration/Warranty for Torque Drivers

All Bradshaw Medical, Inc. torque drivers must be recalibrated every six (6) months, or anytime the torque driver is dropped or is used improperly, including, but not limited to, being impacted with a mallet. A torque driver recalibration includes verifying the torque setting of the driver upon arrival at Bradshaw Medical, Inc., disassembly, cleaning, and inspection of all parts. Bradshaw Medical, Inc., will inspect and/or replace worn and/or corroded parts that are associated with the torque limiting driver system. Then the customer torque limiting driver will be lubricated, reassembled, and calibrated per their requirements.

During the first three (3) years of service the torque driver will be covered by Bradshaw Medical, Inc. warranty as long as the torque driver is sent to Bradshaw Medical, Inc. for recalibration every six (6) months. The Bradshaw Medical, Inc. warranty for most torque drivers is ±10% of the set torque value. Torque instruments are generally able to maintain an accuracy of ±10% for the life of the instrument. If a torque driver fails to perform within the tolerance of the set torque value before a required six (6) month recalibration, Bradshaw Medical, Inc. will recalibrate the driver at no charge to the customer.

The warranty for all Bradshaw Medical, Inc. torque drivers is null and void if any of the following conditions apply: the torque driver was not properly maintained, was not recalibrated every six (6) months, was altered in any way, including disassembling of the device, or was used in a manner not intended, including being



impacted with a mallet. The warranty will also be null and void if any repair or recalibration of torque drivers is performed by anyone other than authorized Bradshaw Medical, Inc. personnel.

For all recalibrations, contact Bradshaw Medical, Inc. Customer Service or Service Department for information and fees.

All torque drivers must be recalibrated every six (6) months, regardless of the amount of use the driver was exposed to during the six (6) month period. A standard recalibration fee is applied for servicing torque drivers.

If a torque driver is sent to Bradshaw Medical, Inc. after the six (6) month recalibration period, but before the three (3) year life span of the driver, Bradshaw Medical, Inc. will service and recalibrate the torque driver. Additional service fees may be added to the standard recalibration fee.

Servicing and recalibration of torque drivers after three (3) years will include an analysis of mechanism wear, availability of components, and instrument usage. The Bradshaw Medical, Inc. Service Department will provide a quotation to the Customer for service/recalibration or replacement of the torque driver.

Recalibration will be performed on a manual torque machine (manufactured by CDI) or on a computer controlled rotating torsion testing system (manufactured by Instron) for an additional charge.