

Recommended Care of Surgical Instruments

Purpose

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

It is important to note that new instruments are shipped in a NON-STERILE condition and require cleaning, sterilization, and lubricating prior to use. DO NOT DISASSEMBLE ANY BRADSHAW MEDICAL SURGICAL INSTRUMENTS unless included instructions state otherwise.

Manual Cleaning

All cleaning agents should be prepared using the manufacturers' recommendations. Clean the instruments as quickly as possible after use. Do not allow soil to dry on the surgical instruments. Submerge the instruments in an enzymatic detergent that is safe for surgical instruments. Soak the instruments for a minimum of five (5) minutes in the detergent. Scrub the submerged surgical instruments with a soft bristled brush. (Note: Using a wire brush or scouring pads will damage the surface finish of the instrument causing corrosion.) Agitate the instruments in the solution while scrubbing. Use a small cytology brush to clean internal channels. Actuate any movable parts to loosen any trapped soil. Rinse the instrument with warm (38-49° C) distilled or deionized water. Place the instruments into a bath containing warm (38-49° C) water. Agitate the surgical instruments by hand for at least three (3) minutes. Dry the exterior of the instruments with a clean, lint-free cloth. Repeat this cleaning procedure if the instruments appear to be soiled after cleaning or ultrasonically clean the instrument.

Ultrasonic Cleaning

Ultrasonic cleaning should only take place after all visible soil has been removed from the instrument(s). Prepare the detergent according to the manufacturer's recommendations. The ultrasonic cleaning machine should be prepared using the manufacturer's recommendations. Separate the surgical instruments into separate batches by type of metal used: aluminum and stainless steel. Ultrasonic cleaning of dissimilar metals causes ion transfer, resulting in etching and pitting. Ultrasonically clean the surgical instruments for ten (10) minutes in a neutral pH detergent (or acceptable alternative). After the cleaning cycle is complete, remove instruments and rinse with distilled or deionized water for at least one (1) minute. Dry the exterior of the instruments with a clean, lint-free cloth. Repeat this cleaning procedure if the surgical instruments appear to be soiled after cleaning the instrument.

Autoclaving

Instruments should be properly prepared and packaged in trays and/or cases allowing steam to make direct contact with instrument surface. Staining or spotting may occur if residual chemicals are not completely rinsed prior to steam sterilization. Steam sterilization must be carried out according to a validated steam sterilization process. The proper care and maintenance of the autoclave apparatus is an

important factor in providing correct instrument operation. Refer to the autoclave manufacturer's instructions.

Inspection/Lubrication

After each cleaning, carefully inspect each instrument to ensure all visible contamination is removed as well as any 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. Using a water-based lubricant, lubricate any actuating parts. Lubricants used must be intended for surgical instruments that require sterilization.

Conclusion

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.

Warranty/Return Policy

All surgical instruments manufactured by Bradshaw Medical 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, 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 shipped back to the customer. All product returns require a Return Material Authorization (RMA) number, which can be requested by calling 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.

Torque instruments are generally able to maintain an accuracy of $\pm 10\%$ for the life of the instrument, which is an average of 2-3 years.

The Bradshaw Medical standard torque wrench warranty is $\pm 5\%$ of set value over the life of the instrument, as long as it is recalibrated every 6 months by authorized Bradshaw Medical personnel. For certain applications, such as torque values below 5 Lbs/in., the warranty range increases to $\pm 15\%$. Over time, the torque wrench mechanism will relax, whether it is sitting on a shelf or being used in daily procedures. **BRADSHAW MEDICAL therefore requires that each torque wrench be returned every six (6) months for a review of all components for wear and recalibration to maintain device accuracy and product warranty.** If the unit falls out of specification before the 6 months, Bradshaw Medical will recalibrate at no charge to the customer. Average turn around on recalibrations is 1-2 weeks after receipt of the torque unit(s).

Contact a Bradshaw Medical Customer Service Representative for the standard recalibration fee. This standard procedure will include verifying the torque at time of arrival, disassembly, review and

replacement of worn parts (as necessary), reassembly and calibration per the customer's requirements. At the time of shipment back to the customer, a new 6 month warranty will go into effect.

Shipping costs: If an item is returned for recalibration, all shipping costs will be incurred by the customer. If the item is returned for defect or malfunction, Bradshaw Medical will be responsible for all shipping charges.