

Introduction

These guidelines are not intended for use with electrical, pneumatic or other powered surgical instruments. All instruments are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling

Use instruments only for their intended purpose, such as cutting, holding, retracting, torqueing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that de-ionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

Cleaning

1. Use a neutral pH enzyme soaking solution that has been prepared per the manufacturers recommendations
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. (Use a soft-bristled brush to gently clean the device paying particular attention to crevices, lumens, mated surfaces and other hard-to-clean areas until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft bristled brush (i.e. pipe cleaner brush).
Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following process: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream
7. Visually inspect instruments for any damage or remaining contaminants. Instruments should be visibly clean.
8. Repeat step 5 with freshly prepared cleaning solution.
9. Repeat step 6 for thorough rinsing to remove any cleaning solution residues.
10. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
11. Contact BioPro if instruments are damaged.

Sterilization

Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

Either validated method

Gravity cycle for 30 minutes at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290° F)

Pre-vacuum cycle for 10 minutes exposure at minimum 132° C (270° F), maximum 143° C (290° F)

Dry times will vary according to load size and should be increased for larger loads.

Examination Prior to Use

All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.

Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of the manufacturer.

Warnings and Precautions

- Devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in breakage of the instrumentation during operation. Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.



BioPro, Inc.
2929 Lapeer Rd.
Port Huron, MI 48060
Toll Free: (800) 252-7707
Fax: (810) 982-7794
www.bioproimplants.com



STG000401 09