Reprocessing Instructions for Reusable Surgical Instruments

Manufacturer: Exactech, Inc

Devices: These instructions apply to all reusable surgical instruments manufactured by Exactech® with the exception of AcuDriver® pneumatic-powered handpiece and accessories. For instructions on reprocessing the AcuDriver pneumatic-powered handpiece and accessories, refer to the AcuDriver Instruction Manual.

Reprocessing for surgical instruments distributed by Exactech are not covered by these instructions and must be provided by the manufacturer.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing Exactech reusable surgical instruments for reuse. Any deviations from these procedures must be evaluated for efficacy by the reprocessing facility.

WARNINGS

These instructions have not been proven effective for sterilizing instruments contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It should not be assumed that the methods described are effective against such agents.

Cleaning is an essential pre-requisite to ensure effective sterilization. Lumens, blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.

Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.

Wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. This includes but is not limited to waterproof clothing, robust gloves and eye protection. Avoid splashing and creation of aerosols. Handle sharp instruments with care to avoid injury.

Caustic substances and those containing a chemical make-up of highly acidic or alkaline-based solutions may cause corrosion and shorten instrument life. Instruments with anodized coatings are particularly sensitive to highly alkaline (pH>9) solutions. Exposure to temperatures above 137 °C (279 °F) may accelerate instrument degradation. Water impurities, such as alkali metal, metal and chloride ions may discolor or corrode instruments.

Use purified water for final rinsing and steam sterilization cycles. Saline may cause deterioration of instrument surfaces. Corrosion, rusting and pitting may occur when blood and debris are allowed to dry on surgical instruments.

Only legally marketed medical equipment, solutions and accessories should be used for reprocessing surgical instruments. Do not use non-absorbent tray accessories as these may cause condensation to pool and extend drying times.

All non-sterile instruments must be thoroughly cleaned and sterilized prior to use. Exactech products labeled for “single use only” must not be reprocessed. Always clean and sterilize surgical instruments before returning them to Exactech.

LIMITATIONS ON REPROCESSING

Repeated reprocessing according to these instructions has a minimal effect on Exactech surgical instruments. The useful life is normally determined by a visual and/or functional evaluation prior to use.
## INSTRUCTIONS

### Point of Use
- Remove gross debris immediately after use.
- Disassemble mating components.
- Remove excess soil with surgical wipes/sponges moistened with sterile water.
- Irrigate lumens, blind holes, cavities, serrations and joints with sterile water.
- In order to ensure effective cleaning, do not allow soil to dry on instruments.
- A 2% solution of hydrogen peroxide (which bubbles when it comes into contact with blood or protein) may be used to verify removal of protein debris.

### Preparation before Cleaning
No particular requirements.

### Cleaning – General Instructions
The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.

Operate equipment in accordance with the equipment manufacturer’s instructions and in consideration of any limitations of use. This includes characteristics of certain types of instruments that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer’s instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.

In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7 – 9).

During ultrasonic cleaning combine only instruments made of similar metals in order to avoid ion transfer, which may result in etching and pitting.

Ensure rinsing processes remove all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.

Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.).

### Cleaning – Manual
**Equipment:** Ultrasonic cleaner, cleaning brush, enzymatic detergent (neutral pH), running water (tap, purified)

- Pre-rinse under warm running water for a minimum of two (2) minutes to remove gross debris.
- Completely immerse in an ultrasonic cleaning bath filled with a neutral (pH 7 – 9) enzymatic detergent solution (e.g. Enzol®) prepared according to the manufacturer’s instructions.
- Ultrasonicate for a minimum of ten (10) minutes at or below 35 ºC (95 ºF).
- Remove any remaining debris from crevices using a cleaning brush.
- Rinse for at least two (2) minutes under purified running water to remove cleaning residue.
- Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.

### Cleaning – Automated
- An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Manual pre-cleaning is recommended in cases of dried-on organic material. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies.
- Arrange instruments in the washer such that all surfaces are exposed to the action of the automated washer.
- Sequencing, number and type of stages may vary among washer manufacturers. Washers may use a single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following: cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.
Cleaning Inspection
- After cleaning, visually inspect for cleanliness.
- Removal of all visible organic material and other residue is required prior to steam sterilization.
- Repeat automated cleaning or perform manual cleaning as required.

Disinfection
Instruments must be terminally sterilized prior to surgical use. See sterilization instructions.

Instrument Inspection
- Visually inspect for damage and wear.
- Verify proper assembly of modular components.

Packaging
- Assemble components into their respective tray positions and place lid on tray. Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all instrument surfaces in order to ensure effective sterilization.
- Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States only sterilization wraps cleared for marketing by the Food and Drug Administration (FDA) should be used.

Sterilization
Equipment: Prevacuum steam autoclave, purified water, sterilization wrap

<table>
<thead>
<tr>
<th>Temperature Range</th>
<th>Minimum Exposure Time</th>
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<tbody>
<tr>
<td>132 - 135°C (270 - 275°F)*</td>
<td>Four (4) minutes</td>
</tr>
<tr>
<td>134 - 137°C (273 - 279°F)</td>
<td>Three (3) minutes</td>
</tr>
</tbody>
</table>

* Note: for Exactech Spine instruments, use this cycle [132-135°C (270-275°F), four (4) minutes]

- Ensure autoclave equipment achieves and maintains the proper time, temperature, and pressure.
- Operate equipment in accordance with the equipment manufacturer’s instructions.
- When sterilizing multiple instrument sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.
- Use purified water for steam sterilization.

Storage
- Store and transport sterile instruments in such a way as to maintain sterility and functional integrity.
- Store instrument in dry, clean, well-ventilated environments away from floors, ceilings and outside walls.
- If sterilization is performed by an outside contract facility, protect the wrapped devices from contamination by additional covering.
- Segregate sterile instruments from non-sterile items. Label sterile instruments to identify sterility status and ensure use in a first in, first out (FIFO) order.
- Do not use instruments if the sterilization wrap is opened, damaged or wet.

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