Reprocessing of Surgical Instruments

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Product	Consensus Orthopedics Inc. (COI) Instruments, Trays and Containers
Warning Notice	Instruments are provided non-sterile. Clean and sterilize before each use. During cleaning, drill holes and other tight areas require special attention.
Reprocessing Limitations	Specific directions listed on product labeling and package inserts take precedence over the information listed herein.
Preparation at the Point of Use	Remove excess debris, blood and tissue from instruments within 30 minutes if possible to assist in their removal. If there is a delay in decontaminating instruments, submerge instruments in water or maintain them moist to prevent drying of contaminants.
Containment/Transportation	If necessary to transport contaminated instruments to processing, they should be covered or closed in containers.
Preparation for Decontamination	If possible, the instruments should be reprocessed in a disassembled or opened state.
Automated Cleaning	Automated washers/disinfectors or ultrasound machines may be used but will not complete all necessary cleaning for effective reprocessing. Manual cleaning will be necessary prior to using automated machines.
Manual Cleaning*	• Manual Cleaning Process a. Open for cleaning by pulling, twisting and locking in the open position b. Neutral PH cleaning solution should be prepared by manufacturers recommendation c. Fully immerse instrument in prepared detergent and allow to soak for minimum of 5 minutes d. Once immersed, scrub instruments with a soft-bristle brush, paying particular attention to crevices and other hard to reach areas e. Use syringe to flush difficult-to-reach areas and a pipe cleaner to brush the lumins of the instrument f. Ensure the instrument is free of cleaning materials such as lint and bristles g. Rinse instrument in running reverse osmosis / deionized water h. Use compressed air to aid in drying • Neutral PH cleaning solutions, such as Enzol or similar, should be used for cleaning. Wires, pipe cleaners and bristle brushes may be necessary and helpful in removing debris and contaminants. Instruments should be free of shredded cleaning material such as lint and bristles. • Some instruments require some disassembly for proper cleaning and/or have hard to reach crevices, moving parts and textures that require attention to detail in cleaning. • Complete rinsing of instruments soaked in cleaning and enzymatic solutions is required. • Instruments should be thoroughly rinsed in deionized water after cleaning. • The use of hydrogen peroxide can assist in inspection and allow assurance that debris is fully removed. Re-clean instruments if necessary. Rinse instruments thoroughly after using hydrogen peroxide. • Thorough cleaning and decontamination procedures are also necessary for organizational containers. *Cleaning validated per AAMI TIR 30 using the contamination method.
Drying	Allow water to drain. Compressed air can be helpful in drying.
Maintenance, Inspection and Testing	1. Visually inspect each device to ensure that blood and soil have been removed. 2. Visually inspect each device for damage. 3. Check all moving parts for smooth operation. 4. Check that devices which are part of a larger assembly assemble with mating components. **Note: If damage or wear is present that may compromise the function of the instrument do not use the instrument, and notify the appropriate responsible person.**
Packaging	Appropriate packaging for the instrument, tray or container should be used. • Individually packaged instruments should be placed in suitable packaging for the sterilization process, i.e., central supply wrap, autoclave pouches etc. • Trays and containers should be double-wrapped in an approved central supply wrap prior to steam sterilization using AAMI double wrap method or equivalent. The case/tray by itself does not provide a sterile barrier. • A towel may be placed beneath the container inside the sterile wrap to absorb condensed moisture.

<table>
<tr><td>Sterilization*</td><td>COI instruments are to be moist heat/steam sterilized only in approved sterilizers. See Table below.
<table>
<tr><th>Cycle Type</th><th>Minimum Temperature</th><th>Pressure</th><th>Minimum Exposure Time</th><th>Minimum Drying Time</th></tr>
<tr><td>High-Temp
Pre-Vac Steam</td><td>270 deg. F
132 deg. C</td><td>4 pulse –
Max-26 psi,
2.8 bars,
Min-10 inHg,
339 mbars</td><td>4 Minute
Exposure
1 Minute Purge</td><td>30 Minutes</td></tr>
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*Steam sterilization validated per ANSI/AAMI ST 79, ISO 17664, and ISO 17665-1 using the half cycle method.</td></tr>
<tr><td>Storage</td><td>Store and maintain in a clean environment free of extreme moisture and temperature, insects and vermin. Instruments should be protected from dust and when transported outside of the facility, un-wrapped and re-processed in the received health care facility.</td></tr>
<tr><td>Additional Advice</td><td>Users and reprocessors should follow all requirements set by their facilities. These recommendations are not intended to supersede facility policies. Differences between these recommendations and user facilities should be resolved. Personnel should follow Universal Precautions when handling all surgical instrumentation due to potential risks of contaminated devices and sharp and potentially harmful instrumentation. Isopropyl Alcohol should not be used on instrument components with silicone.</td></tr>
<tr><td>Manufacturer Contact</td><td>Consensus Orthopedics, Inc.
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