Reprocessing of Surgical Instruments

<table>
<thead>
<tr>
<th>Product</th>
<th>Consensus Orthopedics Inc. (COI) Instruments, Trays, and Containers</th>
</tr>
</thead>
</table>

**Introduction**

This document was prepared to provide decontamination and sterilization instructions for the medical devices produced by Consensus Orthopedics, Inc. These methods were developed using standard equipment and practices common to global healthcare facilities. It is the responsibility of the reprocessor to ensure that the reprocessing is performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

**Warning Notice**

- Instruments are provided non-sterile. Clean and sterilize before each use. During cleaning, drill holes and other tight areas require special attention.
- When cleaning instrument sets, the case and instruments should be treated as separate items. For automatic washing, devices must be cleaned separate from the instrument case/tray.
- All cleaning should be performed in a manner designed to minimize exposure to blood-borne pathogens. Manual cleaning should be performed with the instrument immersed.
- It is the responsibility of the user to ensure that the cleaning process, as it is actually performed, achieves the desired result.

**Reprocessing Limitations**

- Specific directions listed on product labeling and package inserts take precedence over the information listed herein.
- Repeated processing cycles that include ultrasonic, mechanical washing and sterilization has minimal effects on device life and function.
- Carefully inspect devices between uses to verify proper function.
- Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.
- Return damaged instruments to a Consensus Orthopedics, Inc. Sales Representative.

**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 a compatible detergent solution or maintain them moist to prevent drying of contaminants.
- Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside.
- Avoid prolonged exposure to saline to minimize the chance of corrosion.
- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

**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**

*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.

Sterilization*

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Minimum Temperature</th>
<th>Pressure</th>
<th>Minimum Exposure Time</th>
<th>Minimum Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-Temp Pre-Vac Steam</td>
<td>270 deg. F</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>
<tr>
<td></td>
<td>132 deg. C</td>
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</tbody>
</table>

*Steam sterilization validated per ANSI/AAMI ST 79, ISO 17664, and ISO 17665-1 using the half cycle method.

Storage

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.

Additional Advice

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.

Manufacturer Contact

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