



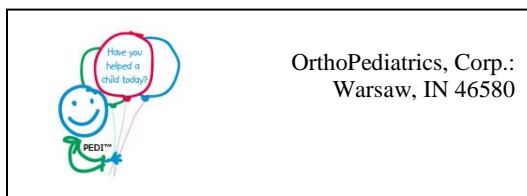
# Instrument Care, Cleaning & Sterilization Instructions

CI-0001

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**Purpose/Scope:** In accordance with ISO 17664:2004, this guide specifies the information for the processing of the medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor. This detailed information is provided so that the medical device can be processed safely and will continue to meet its performance specifications.



**Device(s):** all reusable surgical instruments comprising fixed assemblies (no moving parts) and simple hinged assemblies and all single-use implantable devices supplied non-sterile, but intended to be used in a sterile state supplied by OrthoPediatrics, Corp.

<b>WARNINGS</b>	<ol style="list-style-type: none"> <li>1. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.</li> <li>2. Where applicable, disassemble instruments prior to cleaning.</li> <li>3. Long narrow cannulations and blind holes require particular attention during cleaning.</li> <li>4. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.</li> <li>5. Failure to properly clean the device may lead to inadequate sterilization.</li> </ol>
<b>Limitations on reprocessing</b>	Repeated processing, according to the instructions below, has minimal effect on OPI reusable manual instruments. End of life is normally determined by wear and damage due to use.

<b>INSTRUCTIONS</b>	
<b>Point of Use</b>	Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.
<b>Containment/Transportation</b>	<ol style="list-style-type: none"> <li>1. Universal precautions for handling contaminated/biohazardous materials should be observed.</li> <li>2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.</li> </ol>
<b>Preparation of Cleaning Agents</b>	Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.



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<b>Cleaning: Manual</b>	<ol style="list-style-type: none"><li>1. Use the neutral pH enzyme soaking solution that has been prepared.</li><li>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 (particular attention shall be given 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). <i>Note: The enzyme solution should be changed before it becomes grossly contaminated(bloody and/or turbid).</i></li><li>3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.</li><li>4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.</li><li>5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.</li><li>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.</li><li>7. Repeat step 5 with freshly prepared cleaning solution.</li><li>8. Repeat step 6 for thorough rinsing to remove any cleaning solution residues.</li><li>9. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.</li></ol>
<b>Cleaning: Automated</b>	Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.
<b>Disinfection</b>	Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.
<b>Drying</b>	No particular requirements.
<b>Inspection and Testing</b>	<ol style="list-style-type: none"><li>1. Carefully inspect each device to ensure that all visible blood and soil has been removed.</li><li>2. Visually inspect for damage and/or wear.</li><li>3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.</li><li>4. Check instruments with long slender features (particularly rotating instruments) for distortion.</li><li>5. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.</li></ol> <p><i>Note: If damage or wear is noted that may compromise the function of the instrument, contact your OrthoPediatrics representative for a replacement.</i></p>
<b>Maintenance</b>	Lubricate hinges, threads and other moving parts with a commercial water-based



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	<p>surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Discard blunt or damaged instruments.</p>
<b>Packaging</b>	<p>1. Singly – a standard polyethylene/Tyvek (or equivalent) sterilization pouch of the appropriate size may be used for single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging. 2. In Sets – sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method (AAMI ST79-2006).</p>
<b>Sterilization</b>	<p><b>Warning: Failure to properly clean devices may lead to inadequate sterilization.</b> Steam sterilize using either validated method: a) Gravity cycle for 30 minutes at a minimum temperature of 134°C (273°F). b) Prevacuum cycle for 4 minutes at a minimum temperature of 134°C (273°F). Drying times will vary according to load size and should be increased for larger loads. <b>Note: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a prevacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/APH/2000.3, “WHO Infection Control Guidelines for TSE,” March 1999).</b></p>
<b>Storage</b>	<p>Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.</p>
<b>Additional Information</b>	<p>1. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded. 2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.</p>
<b>Customer Service Information</b>	<p>OrthoPediatrics, Corp. 210 N. Buffalo Street Warsaw, IN 46580 Phone: 877-268-6339 Fax: (574) 268-6302 Email: <a href="mailto:jminaudo@orthopediatrics.com">jminaudo@orthopediatrics.com</a></p>
<p><i>The instructions provided above have been validated by OP as being CAPABLE of preparing complex orthopedic surgical instruments for re-use. It is the responsibility of the processor to ensure that reprocessing as actually performed using the appropriate equipment and materials, and personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences. The recommended sterilization parameters are only valid with sterilization equipment that has been properly maintained.</i></p>	