

Recommendations for Decontamination and Sterilization of gSource Instruments

These reprocessing instructions apply to:

- Non-sterile, reusable surgical instruments supplied by gSource, LLC.
Reusable instrument definition: An instrument intended for repeated use on different patients, with appropriate decontamination and other processing between uses.
- Instruments intended for reprocessing in a health care facility setting.
- Single-use medical devices supplied by gSource, LLC that are supplied non-sterile but are intended to be used in a sterile state. These devices are single-use but can be reprocessed if not used.
Note: “not used” refers to those single-use components that have not been in contact with blood, bone, tissue or other body fluids. Any unused, single-use device that has been exposed to blood, bone, tissue or body fluids must not be reprocessed or resterilized and must be discarded.

The instruments used to implant orthopedic prostheses do not have an indefinite functional life. These instruments are subjected to repeated stresses related to bone contact, impaction and routing, cleaning, and sterilization processes.

Most instrument systems include inserts/trays and a container(s). Many instruments are intended for use with a specific implant. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

CAUTION: These instructions DO NOT APPLY to single-use devices sold as sterile.

These reprocessing instructions have been validated as being capable of preparing gSource instruments for use and are provided to the best of our knowledge at the time of issue. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

Where further information is desired, please contact your gSource distributor.

<p>WARNINGS</p>	<ul style="list-style-type: none"> • Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used. • Do not exceed 140° C (284° F) during reprocessing steps. • Highly alkaline conditions can damage products with aluminum parts. • Complex devices, such as those with tubes, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Manual pre-cleaning of such device features is required before automated cleaning processing. • Avoid exposure to hypochlorite solutions, as these will promote corrosion. • Scratches or dents can result in breakage. • For instruments produced by another manufacturer, reference the manufacturer’s instructions for use. • Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.
<p>Limitations on Reprocessing</p>	<ul style="list-style-type: none"> • Repeated processing has minimal effects on instrument life and function. • End of useful life is generally determined by wear or damage in surgical use. • Carefully inspect instruments between uses to verify proper functioning. • Damaged instruments should be repaired or replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.
<p>Decontamination Considerations – Creutzfeldt-Jakob Disease (CJD)</p>	<p>Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.</p>

Reprocessing Instructions:

<p>Care at the Point of Use</p>	<ul style="list-style-type: none"> • Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergent solution or water to prevent drying and encrustation of surgical soil. • Avoid prolonged exposure to saline to minimize the chance of corrosion. • Remove excessive soil with a disposable wipe.
<p>Containment and Transportation</p>	<p>Reprocess instruments as soon as is reasonably possible after use.</p>
<p>Preparation for Cleaning</p>	<p>For instruments that require disassembly for cleaning, perform disassembly for that instrument.</p>
<p>A. Manual Cleaning: ALL INSTRUMENTS</p>	<ul style="list-style-type: none"> • Clean delicate (microsurgical) instruments separately from other instruments. • Disassemble instruments that are intended to come apart for cleaning. • Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions. • Soak soiled instruments for 5 minutes in the enzymatic solution. • Follow the additional steps in <i>Manual Cleaning</i> sections B, or C, based on the category that most closely matches the type of instrument. • Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices. • Rinse the instrument thoroughly with warm tap water. • Rinse the instrument thoroughly with warm tap water. • Dry the instrument immediately after final rinse.
<p>B. Manual Cleaning – Instruments with cannulations or lumens (i.e. tubes), or holes</p>	<ul style="list-style-type: none"> • Follow the steps in Section A. <i>Manual Cleaning – ALL INSTRUMENTS</i>. • When cleaning, use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the cannula, lumen, or hole. Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic cleaning solution to flush hard to reach internal areas. • Ultrasonically clean the instrument in fully opened position for 10 minutes in neutral pH detergent, prepared in accordance with the manufacturer's instructions. • When rinsing, pay particular attention to flush the cannulations, lumens, or holes with warm tap water. • Dry internal areas with filtered compressed air.
<p>C. Manual Cleaning – Articulating Instruments (those with moveable parts)</p>	<ul style="list-style-type: none"> • Follow the steps in Section A. <i>Manual Cleaning – ALL INSTRUMENTS</i>. • When cleaning, fully immerse the instrument in the cleaning solution to avoid aerosol generation. Brush with a soft non-metallic bristle brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features, to free trapped blood and debris. If the components of the instrument can be retracted, retract or open the part while cleaning the area. For instruments with flexible shafts, bend or flex the instrument under the cleaning solution while brushing the flexible areas. • Ultrasonically clean the instrument in fully opened position for 10 minutes in neutral pH detergent, prepared in accordance with the manufacturer's instructions. • When rinsing; pay particular attention to internal areas and moveable parts. Actuate moveable parts while rinsing. If the components of the instrument can be retracted, retract or open the part while rinsing the area. For instruments with flexible shafts, flex the instrument under the rinse solution. • Dry internal areas with filtered compressed air.

<p>Automated Cleaning</p>	<ul style="list-style-type: none"> For instrument types with complex design features, such as those described in <i>Manual Cleaning</i> sections B and C above, it is necessary to manually clean prior to automated processing to improve the removal of adherent soil. Follow instructions for <i>Manual Cleaning</i> sections B and C above. Brush the instrument, actuate mechanisms, agitate and/or irrigate under the surface of the cleaning solution to prevent the creation of aerosols. Load instruments so that hinges are open and cannulations and holes can drain. Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments. For instruments with concave surfaces, such as curettes, place instrument with the concave surface facing downward to facilitate draining. Run the automatic wash cycle – minimum cycle parameters: <ul style="list-style-type: none"> - five minute cold prewash - five minute enzyme wash at 43° C minimum temperature - five minute detergent wash at 55° C minimum temperature - one minute rinse at 45° C minimum temperature 						
<p>Cleaning Inspection</p>	<ul style="list-style-type: none"> Inspect all instruments before sterilization or storage to ensure the complete removal of soil from surfaces, tubes and holes, moveable parts. If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments thoroughly after using hydrogen peroxide solution. If soil is still present, reclean the instrument. 						
<p>Disinfection</p>	<p>Instruments must be terminally sterilized prior to surgical use. See <i>Sterilization</i> instructions.</p>						
<p>Maintenance</p>	<p>Between uses, lubricate moving parts with a water-soluble lubricant in accordance with the manufacturer's instructions.</p>						
<p>Inspection and Functional Testing</p>	<ul style="list-style-type: none"> Visually inspect the instrument and check for damage and wear. Cutting edges should be free of nicks and have a continuous edge. Jaws and teeth should align properly. Moveable parts should have smooth movement without excessive play. Locking mechanisms should fasten securely and close easily. Long, thin instruments should be free of bending and distortion. 						
<p>Packaging</p>	<ul style="list-style-type: none"> If desired, use instrument trays to contain instruments that are provided in sets. Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions. Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST46-1993. Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system. 						
<p>Sterilization</p>	<ul style="list-style-type: none"> Use a validated, properly maintained and calibrated steam sterilizer. Effective steam sterilization can be achieved using the following cycles: <table border="1" data-bbox="540 1696 1523 1885"> <thead> <tr> <th data-bbox="540 1696 881 1791">Dynamic Air Removal (Prevacuum) Steam Exposure temperature</th> <th data-bbox="881 1696 1036 1791">Minimum exposure time</th> <th data-bbox="1036 1696 1523 1791">Minimum drying time</th> </tr> </thead> <tbody> <tr> <td data-bbox="540 1791 881 1885">4 pulse - 132°C (270°F) <u>or</u> 3 pulse - 135°C (275°F)</td> <td data-bbox="881 1791 1036 1885">3 minutes</td> <td data-bbox="1036 1791 1523 1885">Wrapped instruments-15 minutes Wrapped containment devices-30 minutes</td> </tr> </tbody> </table> 	Dynamic Air Removal (Prevacuum) Steam Exposure temperature	Minimum exposure time	Minimum drying time	4 pulse - 132°C (270°F) <u>or</u> 3 pulse - 135°C (275°F)	3 minutes	Wrapped instruments-15 minutes Wrapped containment devices-30 minutes
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<p>Storage</p>	<p>Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.</p>						