

Considerations

- This guide pertains to all JACE Medical devices and should be studied carefully.
- All JACE Medical devices may be safely and efficiently reprocessed using the combination manual/automated cleaning instructions outlined in this manual.
- The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.
- Devices must be thoroughly processed according to these instructions prior to use.

Warnings & Precautions

- Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Do not place heavy instruments on top of delicate devices.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used.
- Instruments must not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricants should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

Limitations & Restrictions

- Automated cleaning using a washer/disinfector alone may not be effective for orthopaedic or cardiovascular instruments. A thorough combination manual/automated cleaning process is recommended.
- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning JACE Medical reusable devices. Alkaline agents with pH < 12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices.
Note: Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.
- Instruments must be removed from metal or polymer trays for manual/automated cleaning procedures. Instrument trays, cases and lids must be cleaned separately. Non-sterile, single-use plate and screw implants are an exception to this rule. Plates and screws may remain in the tray or caddy for reprocessing.
- Repeated processing, according to the instructions in this manual has minimal affect on JACE Medical reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.
- Ethylene oxide (EO), gas plasma and dry heat sterilization methods are not recommended for sterilization of JACE Medical reusable instruments. Steam (moist heat) is the recommended sterilization method for JACE Medical instruments.

Product Care, Cleaning, and Sterilization

Instructions

Point of Use

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a tray of distilled water or cover with damp towels.
- Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation before Cleaning

Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Disassembly, where necessary is generally self-evident. Instructions for more complicated disassembly can be found on the JACE Medical website (www.jacemed.com) under “Product Disassembly and Cleaning Instructions.” Care should be exercised to avoid losing small screws and components.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Manual Pretreatment Procedure

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

- Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
- Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
- Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle.

Automatic Washer/Disinfector

- Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method to the manual cleaning procedure above but is not required. Follow the manufacturer’s instructions if using an automated washer/disinfector.

Inspection, Testing, Maintenance & Lubrication

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that devices assemble readily with mating components.
- Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer’s expiration dates should be adhered to for both stock and use-dilution concentrations.

Product Care, Cleaning, and Sterilization

Instructions Continued

Sterile Packaging

Packaging Individual Devices

- Commercially available, medical grade steam sterilization pouches or wrap may be used to package individual devices. The package should be prepared using the AAMI double wrap or equivalent method.
- Packaging instrument sets in rigid trays and cases with lids and defined, preconfigured layouts.
- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- Trays and cases with lids may also be placed in an approved sterilization container with gasketed lid for sterilization. Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Note: Areas designated for specific devices shall contain only devices specifically intended for these areas.

Note: These validated reprocessing instructions are not applicable to JACE Medical trays that include devices that are not manufactured and/or distributed by JACE Medical. Instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions:

- Any device capable of disassembly must be disassembled prior to placement in the case.
- All devices must be arranged to ensure steam penetration to all instrument surfaces.
- Instruments should not be stacked or placed in close contact.
- The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicon mats may be used to keep devices in place.
- Only devices manufactured and/or distributed by JACE Medical should be included in JACE Medical instrument trays. JACE Medical validated reprocessing instructions are not applicable to JACE Medical trays that include devices that are not manufactured and/or distributed by JACE Medical.

Sterilization

- Disinfection is only acceptable as a precursor to full sterilization for devices.
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces.
- Ethylene oxide or gas plasma sterilization methods should not be used.
- Moist heat/steam sterilization is the preferred and recommended method for JACE Medical instrument sets. Sterilization parameters have been validated by JACE Medical to provide a 10⁻⁶ sterility assurance level (SAL). An FDA cleared sterilization wrap and the following sterilization parameters are recommended:

Cycle:	Pre-vacuum
Temperature:	132°C (270°F)
Exposure time:	4 minutes
Drying time:	30 minutes

Product Care, Cleaning, and Sterilization

Storage

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.

Hospital Responsibilities for JACE Medical Loaner Instruments

- Orthopaedic/Cardiovascular surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to JACE Medical to be discarded. Notify your JACE Medical representative of any instrument problems.
- Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to JACE Medical. Documentation of decontamination should be provided with instruments being returned to JACE Medical.

Important Notice

The instructions provided in this manual have been validated by JACE Medical as being capable of preparing orthopaedic/ cardiovascular devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Customer Service Information

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This JACE Medical reprocessing manual can be found at www.jacemed.com.



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