



Quick Reference Guide

Instrument Care, Cleaning and Sterilization

In accordance with ISO 17664

Considerations

- Additional information is available in Zimmer document 97-5000-170-00 R3 which should be used in conjunction with this *Quick Reference Guide*.
- This guide pertains to all Zimmer reusable instruments and should be studied carefully. This manual supercedes Zimmer and Centerpulse instrument manuals published prior to January 2006.
- This guide includes processing instructions for all Zimmer reusable devices including legacy Centerpulse instruments marked with processing category codes [a, a+, b, b+, c]. All Zimmer devices may be safely and efficiently reprocessed using the manual or 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.
- New and used instruments 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 instruments.** A thorough, manual or combination manual/automated cleaning process is recommended.
- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Zimmer reusable devices. Alkaline agents with pH \leq 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 and/or 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 Zimmer 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 Zimmer reusable instruments. Steam (moist heat) is the recommended sterilization method for Zimmer instruments.

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

- 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. Care should be exercised to avoid losing small screws and components.

Preparation Before Cleaning

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

Table 1. Cleaning/Disinfection Options

Method	Description
Manual (Table 2)	Enzymatic soak and scrub followed by sonication.
Combination Manual/Automated (Table 3)	Enzymatic soak and scrub followed by an automated washer/disinfector cycle.
Automated (washer/disinfector) (Table 4)	Automated cycle – Not recommended without manual pre-cleaning.

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Manual Cleaning/Disinfection 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.

Table 2. Manual Cleaning Steps

Step 1	Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.
Step 2	Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 3	Place prepared cleaning agents in a somication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
Step 4	Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 5	Repeat the sonication and rinse steps above.
Step 6	Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Manual Cleaning/Disinfection Procedure

Table 3. Combination Manual/Automated Cleaning Steps

Step 1	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.
Step 2	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.
Step 3	Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

Automatic Washer/Disinfector Cycle

Table 4. Automated Washer/Disinfector Cycle Steps

Step 1	Pre Wash; Cold Softened Tap Water; 2 minutes
Step 2	Enzyme Spray, Hot Softened Tap Water; 20 seconds
Step 3	Enzyme Soak; 1 minute
Step 4	Rinse (X2); Cold Softened Tap Water; 15 seconds
Step 5	Detergent Wash; Hot Softened Tap Water; (64-66°C/146-150°F); 2 minutes
Step 6	Rinse (X2); Hot Softened Tap Water; 15 seconds
Step 7	Thermal Rinse; Hot Softened Tap Water; (80-93°C/176-200°F); 2 minutes
Step 8	Purified Water Rinse; (64-66°C/146-150°F), 10 Seconds
Step 9	Hot Air Dry; (116°C/240°F); 7 to 30 minutes

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.

Processing Category Codes

Processing codes listed in Table 5. are etched on some instruments and provide information useful in the selection of cleaning agents with appropriate pH. Zimmer recommends that all devices (regardless of etching) are processed in accordance with the manual or combination manual/automated cleaning instructions contained in this reprocessing guide.

Table 5. Processing Category Codes

a	Steel/metal Instruments without cannulated bores/ lumens or non-metal/ polymer handles, or other components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices may be cleaned with rust-removal agents.
a+	Steel/metal instruments with cannulated bores/lumens but without non-metal/polymer handles or other components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices can be cleaned with rust-removal agents. Cannulations and hollow spaces must be cleaned manually.
b	Instruments made of polymers or metal instruments paired with polymer components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing.
b+	Instruments with cannulated bores, made of polymers or metal instruments paired with polymer components. These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. Cannulations and hollow spaces must be cleaned manually.
c	Instruments made of titanium or aluminum alloys and/or having assembly/ disassembly or other reprocessing aids. These devices should be cleaned using the manual or combination manual/automated cleaning procedures provided in this manual. These devices should not be exposed to alkaline cleaning agents.

Sterile Packaging

Packaging Individual Instruments

- Commercially available, medical grade steam sterilization pouches or wrap may be used to package individual instruments. 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.

Safety Precaution: The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs for the safety of the personnel handling instrument sets. When placed in a sterilization container with gasketed lid, the total package should not exceed 16kg/35lbs.

- 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 Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer. Instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions:

- The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total sterilization package should not exceed 16kg/35lbs.
- 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 Zimmer should be included in Zimmer instrument trays. Zimmer validated reprocessing instructions are **not applicable** to Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer.

Sterilization

- Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments. See Table 6 for recommended minimum sterilization parameters that have been validated by Zimmer to provide a 10⁻⁶ sterility assurance level (SAL).
- 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.
- Moist heat/steam sterilization is the preferred and recommended method for Zimmer orthopaedic instrument sets.
- 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 unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.
- Gravity displacement sterilization cycles are **not recommended** because cycle times are too long to be practical.

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 Zimmer Loaner Instruments

- Orthopaedic 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 Zimmer to be discarded. Notify your Zimmer representative of any instrument problems.
- Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Zimmer. Documentation of decontamination should be provided with instruments being returned to Zimmer.

Table 6. Recommended Steam Sterilization Parameters

Cycle Type	Temperature	⁵ Pressure	⁶ Exposure Time	⁷ Dry Time
^{1,3} UK Prevacuum	134°C 273°F	3bar 28.5psi	3 minutes	30 minutes
^{2,3} Prevacuum	132°C 270°F	1.86bar 27psi	4 minutes	30 minutes
^{3,4} Prevacuum	134°C 273°F	3bar 28.5psi	18 minutes	30 minutes
⁸ Prevacuum	132°C 270°F	1.86bar 27psi	8 minutes	30 minutes
⁹ Gravity	Not recommended due to excessively long sterilization cycles which are not practical.			

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| <ol style="list-style-type: none"> 1 Minimum validated steam sterilization <u>time</u> required to achieve a 10⁻⁶ sterility assurance level (SAL). 2 Minimum validated steam sterilization <u>temperature</u> required to achieve a 10⁻⁶ sterility assurance level (SAL). 3 Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table. 4 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination. | <ol style="list-style-type: none"> 5 Sea level 6 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable. 7 Drying times vary according to load size and should be increased for larger loads. 8 For Universal Instrument Cases without defined load configurations. 9 Gravity cycle parameters are available on request from Customer Service. |
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Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Important Notice

- The instructions provided in this Quick Reference Guide have been validated by Zimmer as being capable of preparing orthopaedic 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

Address	Telephone
Zimmer, Inc. 1800 West Center Street Warsaw, Indiana 46580, USA	Inside USA: 1-800-348-2759 Outside USA: Local International Access Code +1-574-367-6131
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This Zimmer reprocessing manual and the associated <i>Quick Reference Guide</i> can be found at www.zimmer.com under the "Medical Professional" heading.	