



Manual Orthopaedic Surgical Instruments



Recommendations for Care, Cleaning, Maintenance
and Sterilization



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1. Purpose

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Zimmer orthopaedic manual surgical instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of Zimmer reusable devices.

The manual is intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of Zimmer instrument sets.

Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR) may be directly involved in handling instruments purchased from Zimmer or on a loan basis as consignment instruments. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

2. Scope

This instruction manual provides information on the care, cleaning, disinfection, maintenance and sterilization of manual surgical instruments and is applicable to all reusable medical devices manufactured and/or distributed by Zimmer, Inc.

This information is also applicable to single-use medical devices manufactured by Zimmer 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 (e.g. screws, plates, etc.). This also includes single-use devices packaged and sold sterile but removed from packaging and placed in kits.

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.

Devices that cannot be reused may be labeled with the following symbol:

ISO 15223 3.2



Do not reuse

This information is not applicable to single-use devices that are sold sterile and cannot be resterilized (e.g. osteotome blades).

Devices that cannot be resterilized may be labeled with the following symbol:

ISO 15223 3.25



Do not resterilize

This instruction manual is not applicable to air driven or electrically powered equipment. However, it is applicable to functional attachments (e.g. reamers and drill bits) that are connected to powered equipment for use.

3. Glossary

Chemical: a formulation of compounds intended for use in reprocessing.

Note: This includes detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners and sterilants.

Cleaning: the removal of contamination from an item to the extent necessary for further processing.

Contaminated: State of having been actually or potentially in contact with microorganisms.

Decontamination: the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or items is rendered safe for handling or disposal.

Disinfection: a process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use.

Note: Cleaning and disinfection are often conducted in the same step.

Manual cleaning: cleaning without the use of an automated washer or washer/disinfectant.

Processing/Reprocessing: activity including cleaning, disinfection and sterilization, necessary to prepare a new or used medical device for its intended use.

Sterile: free from all viable microorganisms.

Sterilization: a validated process used to render a device free from all forms of viable microorganisms.

Note: In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.

Washer/Disinfectant: a machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice.

4. Acronyms

BI = biological indicator

CJD = Creutzfeldt-Jakob Disease

CSSD = Central Sterile Supply Department

OR = operating room

PPE = personal protective equipment

SAL = sterility assurance level

TSE = Transmissible Spongiform Encephalopathy

5. Symbols

ISO 15223 3.2



Do not reuse

ISO 15223 3.3



Consult instructions

ISO 15223 3.25



Do not resterilize



Caution or Instructions for Use

6. Considerations

This instruction manual pertains to all Zimmer reusable surgical instruments and should be studied carefully. **This manual supercedes Zimmer and Centerpulse instrument manuals published prior to January 2006.**

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.

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips and marrow. The instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during and after surgical procedures and during reprocessing.

It should be noted that saline and other irrigation fluids are often used in copious amounts during surgical procedures and will exert a corroding effect on instruments.

Orthopaedic surgery requires instruments which are heavy and have multiple components, articulating or rotating parts, removable handles, plastic replacement parts, and series of gauges or other measuring devices in graduated sizes. Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure.

Hospitals must assume responsibility for cleaning, disinfection, packaging and sterilization of all loaner instrument sets before returning them to Zimmer. However, the next user must also inspect the set upon receipt to verify that instruments have, in fact, been adequately cleaned and decontaminated before repeating reprocessing procedures to prepare the loaner set for subsequent reuse. Zimmer cannot guarantee that sterility was attained by the previous user and has been maintained during transit. Zimmer representatives often open and inspect instrument sets between users, which will, of course, compromise sterility and require complete reprocessing prior to subsequent use.






This manual includes instructions for all Zimmer reusable devices including legacy Centerpulse instruments marked with reprocessing category codes [a, a+, b, b+, c]. See Section 7 of this manual for further explanation of reprocessing codes. All Zimmer devices may be safely and efficiently reprocessed using the manual or combination manual/automated cleaning instructions outlined in this manual.

Core orthopaedic instrument sets must be complete and in good condition to be used correctly. Optional devices may be available on request from your Zimmer representative. To maintain instruments properly it is important to consider the following information and processing instructions:

- Warnings and precautions
- Instrument set completeness and functionality
- Reprocessing limitations and/or restrictions
- Preparation for reprocessing at the point of use
- Preparation for cleaning (including assembly/disassembly as necessary)
- Cleaning, disinfection and drying
- Maintenance, inspection, testing and lubrication
- Sterile packaging
- Sterilization
- Storage

7. Processing Category Codes

The following codes are etched on some instruments and provide information useful in the selection of cleaning agents with appropriate pH. Zimmer recommends that all reusable devices (regardless of etching) be processed in accordance with the manual or combination manual/automated cleaning instructions contained in this instruction manual.

	Steel/metal Instruments without cannulated bores/lumens or non-metal/polymer handles, or other components (e.g. retractors, drills, testing trays, rasps, scissors, clamps, exploring hooks, compression forceps, skin bridge elevators, guide wires, etc.). 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 approved for surgical instruments in the presence of rust or corrosion.
	Steel/metal instruments with cannulated bores/lumens but without non-metal/polymer handles or other components (e.g. drills with elongated holes, belt tensioning pulleys, bone joint reamers, extractor cases). 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 approved for surgical instruments in the presence of rust or corrosion. Cannulations and hollow spaces must be cleaned manually.
	Instruments made of polymers or metal instruments paired with polymer components (e.g. testing trays for flat profiles, chisels with non-metal handles, awls, dissectors, femur dilators, pyramidal chisels/rasps). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing.
	Instruments with cannulated bores, made of polymers or metal instruments paired with polymer components (e.g. tibial mallets, flex screwdrivers, tibial dilators, etc.). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. Cannulations and hollow spaces must be cleaned manually.
	Instruments made of titanium or aluminum alloys and/or having assembly/disassembly or other reprocessing aids (e.g. torque spanners, tibial aiming devices, pad cutters, instrument cases, trays and sterilization containers). 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.

8. Processing Instructions

These processing instructions are intended to assist the hospital and central supply management in developing procedures to attain the above goals, both for hospital-owned and for loaned instrument sets. This information is based on Zimmer testing and experience, material science, as well as widely accepted recommendations of the following organizations:

- American National Standards Institute (ANSI)
- American Society for Testing and Materials (ASTM)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Association of Operating Room Nurses (AORN)
- Centers for Disease Control (CDC)
- German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung
- International Standards Organization (ISO)
- International Association of Healthcare Central Service Material Management (IAHCSMM)
- National Health Service (NHS)
- Robert Koch Institute (RKI)
- Swissmedic
- World Health Organization (WHO)

Note: These instructions describe the necessary processing steps that new and used instruments must undergo to attain sterility.

A. Warnings and 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.
- **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.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- **Do not place heavy instruments on top of delicate devices.**
- **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 instruments.
- 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.
- Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays and cases. These validated reprocessing instructions are **not applicable** to Zimmer trays and cases that include devices that are not manufactured and/or distributed by Zimmer.
- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time.

B. Receiving Inspection — Instrument set content and functionality verification

- Upon receipt in the hospital, instrument sets should be inspected for completeness. Inspect for thumb, wing, set, or other types of screws; screw-in or other detachable handles; and auxiliary exchangeable parts such as blades, right/left attachments or heads. Many organizing cases have shadow graphs, outlines, catalog numbers, and instrument names or sizes silk-screened or otherwise marked on the case or tray.
- Orthopaedic surgical procedures follow a precise order in which the instruments are used. Also, many instruments have dimensional features which govern bone resections, determine implant sizes, and measure intramedullary canal sizes, depth of drill holes, angles of tube/plate, acetabular cup placements, etc. Therefore, it is very important that all requested sizes of a specific instrument series are available (specific instruments are routinely omitted from instrument sets due to infrequent use unless requested by the user). Contact your Zimmer representative if requested instruments have been omitted but are required for surgery.
- Markings on instruments used for measuring anatomical dimensions must be legible. These may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and right/left indications. Notify your Zimmer representative if scales and other markings are not legible.

C. Limitations and Restrictions

- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Zimmer reusable devices. Alkaline agents with pH of 12 or less may be used to clean stainless steel and 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 are 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.

Note: It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of fecal matter or other organic contaminants and may not be suitable for use with orthopaedic instruments.

- 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.
- Automated cleaning using a washer/disinfector alone **may not** be effective for orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other complex features. A thorough, manual or combination manual/automated cleaning process is recommended.
- Where applicable, multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self evident. Care must be taken to avoid losing small parts. If a part is lost, notify your Zimmer representative when the instrument set is returned.
- Instruments **must** be removed from metal or polymer trays for manual and/or automated cleaning procedures. **Do not** clean instruments while in polymer or metal trays. Instrument trays, cases and lids must be cleaned separately from instruments. 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.
- Polymers used in Zimmer instrument sets can be sterilized using steam/moist heat. Polymer materials have a limited useful life. If polymer surfaces turn "chalky," show excessive surface damage (e.g. crazing or delamination), or if polymer devices show excessive distortion or are visibly warped, they should be replaced. Notify your Zimmer representative if polymer devices need to be replaced.
- Most currently available polymers will not withstand conditions in washer/sterilizers that operate at temperatures equal to or greater than 141°C/285°F, and use live-steam jets as cleaning features. Severe surface damage to polymer devices will occur under these conditions.

- Soaking in disinfectants may be a necessary step to control certain viruses. However, these agents may discolor or corrode instruments (household bleach contains or forms chlorine and chloride in solution and has a corrosive effect similar to saline). Disinfectants containing glutaraldehyde, or other aldehydes, may denature protein based contaminants, causing them to harden and making them difficult to remove. Where possible, soaking in disinfectants should be avoided.
- Steam/moist heat is the recommended sterilization method for Zimmer instruments.
- Ethylene Oxide (EO), Gas Plasma Sterilization and dry heat sterilization methods are not recommended for sterilization of Zimmer reusable instruments.
- Instrument with removable polymer sleeves **must** be disassembled for sterilization (e.g. acetabular reamer shaft with sleeve, side cutters, etc.)
- During initial steam sterilization runs some formaldehyde from polyformaldehyde surfaces may vaporize and become noticeable. This should not cause concern. After a few sterilization cycles, the odor should be no longer evident.
- While ethylene oxide sterilization may prolong the service life of certain polymers (e.g. polysulfone), this method of sterilization is not recommended unless aeration times are provided in specific package inserts. Large polyformaldehyde items (DELRIN, CELCON) have been found to require excessive outgassing times (a minimum of five days at elevated temperatures in a mechanical aerator); therefore, **gas sterilization for polyformaldehyde products is contraindicated.**
- Titanium and titanium alloy devices are especially susceptible to discoloration from steam impurities and detergent residues which form multi-colored surface layers of oxide deposits. Upon repeated sterilization these oxide layers, while not harmful to the patient, may become so dark that they can obscure graduation marks, catalog and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration. Avoid frequent use of these agents.
- 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.

D. Point of Use Preparation for Reprocessing

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- 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.

E. 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. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your Zimmer representative when the instrument set is returned.
- Published instructions for use and surgical techniques and/or procedures may provide a supplemental source to illustrate assembly/disassembly instructions for specific Zimmer instruments.

F. Preparation of Cleaning Agents

- Neutral pH enzymatic and cleaning agents with low foaming surfactants are preferred and recommended by Zimmer. Alkaline agents with pH of 12 or less may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and thorough rinsing.
- 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.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Table 1. Cleaning/Disinfection Options

Method	Description	Section
Manual	Enzymatic soak and scrub followed by sonication	G
Combination Manual/Automated	Enzymatic soak and scrub followed by automated washer/disinfector cycle	H
Automated (Washer/Disinfector)	Washer/disinfector cycle - not recommended for use without manual precleaning	I

G. Manual Cleaning/Disinfection Instructions

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon 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-bristled brush (i.e. pipe cleaner brush).
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.
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
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.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

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.

H. Combination Manual/Automated Cleaning and Disinfection Instructions

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 (i.e. pipe cleaner).

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.

2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2. Typical Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93°C/176-200°F)
8	10 second purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7 to 30 minute hot air dry (116°C/240°F)
Note: The washer/disinfector manufacturer's instructions should be strictly adhered to.	

I. Automated Cleaning/ Disinfection Instructions

1. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Orthopaedic instruments should be cleaned following the manual or combination manual/automated cleaning procedure outlined in this manual except where specifically indicated.
2. An automated washer/disinfector may be used as follow-up to the manual cleaning procedure above but is not required.
3. Simple instruments without multiple components, lumens/cannulations, blind holes, mated surfaces, connectors and internal mechanisms or other complex features may be successfully cleaned and disinfected using a typical washer/disinfector cycle for surgical instruments as outlined in Table 2 of this manual. Devices should be thoroughly inspected prior to sterilization to ensure effective cleaning.

J. Inspection, Maintenance, Testing and Lubrication

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your Zimmer representative for a replacement.

3. 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.
4. 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. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

Note: 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.

Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

5. Check instruments with long slender features (particularly rotating instruments) for distortion.
6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

K. Sterile Packaging

Packaging individual instruments

- Commercially available, medical grade steam sterilization pouches (e.g. paper, Tyvek™ or equivalent) of the appropriate sizes may be used to double package single instruments. Ensure that the inner pouch is large enough to contain the instrument without stressing the seals or tearing the packaging but small enough to be placed in a secondary pouch without compromising the integrity of the total package.
- Standard medical grade, steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

Note: If sterilization wraps are used they must be free of detergent residues. Reusable wraps are not recommended.

Packaging instrument sets in rigid trays and cases with lids

Safety Precaution: 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 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 a gasketed lid for sterilization.

Note: Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Instrument trays and cases with defined, preconfigured layouts

- Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Optional Zimmer instruments should not be added to a preconfigured instrument tray or case unless a dedicated universal space or compartment has been included in the design and the guidelines described below for trays and cases without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays. These validated reprocessing instructions are **not applicable** to Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer.

Universal 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.

L. Sterilization Instructions

- See Table 3 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.

Table 3. Recommended Steam Sterilization Parameters

Cycle Type	Minimum Temperature	Pressure	Minimum Exposure Time		Minimum Dry Time
			Wrapped	Unwrapped	
^{1,3} UK Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5psi	3 min	3 min	30 minutes
^{1,3} Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27psi	4 min	4 min	
^{3,4} Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5psi	18 min	18 min	
⁵ Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27psi	8 min	8 min	
¹² Gravity/Gravity Displacement	Not recommended due to excessively long sterilization cycles which are not practical.				

- 1 Minimum validated steam sterilization time required to achieve a 10⁻⁶ sterility assurance level (SAL).
- 2 Minimum validated steam sterilization temperature 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.
- 5 For Universal Instrument Cases without defined load configurations.
- 6 Sea level
- 7 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.
- 8 Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin.
- 9 Rigid sterilization container that complies with ANSI/AAMI ST46.
- 10 Flash (unwrapped) sterilization by exposure at 132°C /270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled.
- 11 Drying times vary according to load size and should be increased for larger loads.
- 12 Gravity steam sterilization cycle parameters are available on request from Customer Service.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

M. Storage Instructions

- 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.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be repackaged and sterilized.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set resterilized.

9. Hospital Responsibilities for Zimmer Loaner Sets

- 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.
- Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to your Zimmer representative to ensure that the next hospital will receive a complete set of instruments in working condition.
- The instructions provided in this manual have been validated by Zimmer in the laboratory and are 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.

10. Customer Service Information

Mailing 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
Zimmer GmbH Sulzer-Allee 8 CH-8404 Winterthur, Switzerland	+41 (0)52 262 60 70
This Zimmer reprocessing manual and the associated Quick Reference Guide can be found at www.zimmer.com under the "Medical Professional" heading.	

11. References

1. AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
2. AAMI TIR13, *Principles of industrial moist heat sterilization*
3. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
4. ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities*
5. ANSI/AAMI ST35, *Safe handling and biological decontamination of reusable medical devices in healthcare facilities and in nonclinical settings*
6. ANSI/AAMI ST37, *Flash sterilization – Steam sterilization of patient care items for immediate use*
7. ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
8. ANSI/AAMI ST67, *Sterilization of health care products – Requirements for products labeled “Sterile”*
9. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
10. ANSI/AAMI/ISO 15223 and Amendments 1 and 2, *Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied*
11. AORN, *Standards, Recommended Practices and Guidelines*
12. ASTM F 565, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*
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Appendix 1. Cleaning/Disinfection Processes

Chart 1. Manual Cleaning/Disinfection Procedure

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 sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
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.

Chart 2. Combination Manual/Automated Cleaning/Disinfection Procedure

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.

Chart 3. Typical Automated Washer/Disinfector Cycle for Cleaning/Disinfection of Surgical Instruments

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

Contact your Zimmer representative or visit us at www.zimmer.com

