



zimmer

Instrument Care, Cleaning and Sterilization Instruction

In accordance with ISO 17664 - 2003

Manufacturer	Zimmer, Inc.
Reusable Instrument Description	Manual orthopedic surgical instruments.
Warnings	<ol style="list-style-type: none">1. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.2. Where applicable, disassemble instruments prior to cleaning3. 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.
Reprocessing Limitations	Repeated processing, according to the instructions below, has minimal effect on Zimmer reusable manual instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS

Point of Use	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.
Containment/ Transportation	<ol style="list-style-type: none">1. Universal precautions for handling contaminated/biohazardous materials should be observed.2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
Preparation of Cleaning Agents	Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
Manual Cleaning Procedure	<ol style="list-style-type: none">1. Use the neutral pH enzyme soaking solution that has been prepared.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). Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).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.4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.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.7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

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Automated Cleaning Procedure	Automated washer/disinfectors 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.
Disinfection	Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.
Inspection/Function Testing	<ol style="list-style-type: none">1. Carefully inspect each device to ensure that all visible blood and soil has been removed.2. Visually inspect for damage and/or wear.3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.4. Check instruments with long slender features (particularly rotating instruments) for distortion.5. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components. <p>Note: If damage or wear is noted that may compromise the function of the instrument, contact your Zimmer representative for a replacement.</p>
Maintenance	Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear.
Packaging	<ol style="list-style-type: none">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 (ANSI/AAMI ST46-1993).
Sterilization	Steam sterilize using a prevacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded. Drying times will vary according to load size and should be increased for larger loads. <p>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).</p>
Additional Information	<ol style="list-style-type: none">1. 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.2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
Customer Service Information	Zimmer, Inc. 1800 West Center Street Warsaw, Indiana 46580 U.S.A. Inside the U.S.A. dial (800) 348-2759 Outside the U.S.A. dial the local international access code followed by +1-574-267-6131

The instructions provided above have been validated by Zimmer as being capable of preparing complex orthopedic surgical instruments for re-use. It is the responsibility of the reprocessor to ensure that reprocessing as 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. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Care, Maintenance and Sterilization

of Zimmer
Orthopaedic
Manual Instruments



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PURPOSE

These procedures are recommended for the care, cleaning, maintenance, and sterilization of orthopaedic manual surgical instruments including “loaner sets.” This document is intended to assist health care personnel in safe handling practices effective cleaning, sterilization, and maintaining the instruments in optimal condition.

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. Instruments are usually supplied in sets which may be subdivided into trays in which the instruments are arranged by size or in the order needed for a specific surgical procedure.

Personnel, including those in the central service department, the operating room, and hospital receiving, may be directly involved in handling instruments on a loan basis. The directors of each of these departments should be informed of this recommendation to help prevent damage or misuse of the instruments.

SCOPE

This manual provides information on the care, cleaning, maintenance and sterilization of manual surgical instruments manufactured by Zimmer, Inc. (Warsaw, Indiana). Products that are distributed by Zimmer, Inc., but manufactured by another original equipment manufacturer, will be packaged with the manufacturer’s Instructions for Use. These instructions should be followed explicitly. Any questions concerning the care, cleaning, maintenance, or sterilization of these instruments should be directed to the manufacturer identified on the Instructions for Use.

CONSIDERATIONS

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips, and marrow. The instruments may also be contaminated with body fluids containing hepatitis or other etiological agents. All health care workers should become familiar with the necessary precautions of preventing injuries caused by sharp instruments when handling these devices after procedures or when cleaning them. It should also be remembered that saline and other irrigation fluids are often used in copious amounts and will exert a corroding effect on instruments.



The hospital must assume the responsibility for decontamination, cleaning, packaging, and sterilizing any instrument set before it is returned to the sales representative. However, the next user must inspect the set to ascertain that the instruments have, in fact, been adequately cleaned before repeating sterilization. Zimmer sales representatives cannot guarantee that sterility was attained by the previous user and has been maintained during transit. Also, they may need to open and inspect the set between users, which will, of course, break sterility.

PROCEDURES FOR MANUAL INSTRUMENTS

The orthopaedic instrument sets must be in good condition to be used correctly. To maintain them properly, it is very important to consider:

- 1) completeness
- 2) functionality
- 3) cleaning and lubrication
- 4) sterility
- 5) special precautions

The instructions below are intended to assist the processing supervisor in developing procedures to attain the above goals, both for hospital-owned and for loaned instrument sets. The information is based on the widely accepted recommendations of the Association of Operating Room Nurses (AORN), the Centers for Disease Control (CDC), the American Society for Testing and Materials (ASTM), the American Association of Medical Instrumentation (AAMI), experience and testing by Zimmer, and advice from consultants in the nursing and central supply field.

Completeness

When receiving an instrument set, either purchased or loaned, inspect it for completeness. Many organizing cases have shadowgraphs, outlines, catalog numbers, and instrument names or sizes silkscreened or otherwise marked on the set or tray. Metallized decals are available from Zimmer to mark certain standard sets or customize specialized ones. (Metallized decals eventually will wear off and should be replaced when the surface shows signs of wear or printed lettering is difficult to read.)

Orthopaedic surgical procedures follow a precise order in which the instruments are used. Also, many instruments have dimensional features which govern bone



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resections, determine implant sizes, and measure intramedullary canal sizes, depth of drill holes, angles of tube/plates, or acetabular cup placements. Thus, it is very important that all sizes of a specific instrument series are available.

Functionality

Markings must be readable on instruments used for measuring anatomical dimensions; these may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and RIGHT/LEFT indications.

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.

Where applicable multicomponent instruments may be disassembled for proper cleaning, taking care not to lose any parts. Always check for specific instructions from Zimmer. If a part is lost, notify the Zimmer representative when the instrument set is returned.

The following plastics used in certain Zimmer instrument sets can be steam sterilized:

- polyformaldehyde (DELFIN, CELCON)
- polycarbonate (LEXAN)
- poly (methyl methacrylate) (PLEXIGLAS, LUCITE)
- nylon
- polyetherimide (ULTEM)

Warning: Currently available plastics will not withstand conditions in washer/sterilizers operating at 285° F (141° C) and above, and using live-steam jets as cleaning features. Severe surface damage to the plastic parts will occur under these conditions.

•All of the above plastic materials have a limited useful life. If plastic surfaces turn “chalky,” show excessive surface crazing or delamination, they should be replaced.

Note: While ethylene oxide sterilization may prolong the service life of certain plastics (e.g., polysulfone), this method of sterilization should only be used if aeration times are provided in the product’s package insert. Large poly - formaldehyde items (DELFIN, CELCON) have been found to require excessively long outgassing times (a minimum of five days at elevated temperatures in a mechanical aerator); therefore, **gas sterilization for polyformaldehyde products is contraindicated.**



CLEANING AND LUBRICATION**Cleaning**

Both loaner and hospital-owned instruments, whether new or contaminated from previous use, must be decontaminated. Traditionally, decontamination is followed by ultrasonic cleaning, lubrication, inspection, preparation, packaging, and terminal sterilization. Cleaning is critical because residual organic material (e.g., blood, bone, proteinaceous material) can inactivate disinfectants; moreover, if a device is not cleaned thoroughly, sterility may not be achieved.

Note: In the past, ultrasonic cleaning before decontamination was not recommended. However, it has been found that, if visible blood, soft tissue, and bone have been removed, ultrasonic cleaning may be used before placing the items into a washer/sterilizer.

Most uncomplicated instruments can be decontaminated in a washer/sterilizer, following standard hospital procedures.

Lubrication

Hinged, rotating, or articulating instruments should be lubricated with a water-soluble product (such as INSTRUMENT MILK or similar lubricant).

Sterility

The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a way that will ensure sterlant penetration and adequate drying steam sterilization (or adequate aeration for ethylene oxide). Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.



PROCESSING OF ORTHOPAEDIC INSTRUMENTS

This section describes the necessary processing steps instruments must undergo to attain sterility.

Note: All subsequent cleaning and sterilization steps are facilitated by not allowing blood, tissue debris, saline, or disinfectants to dry on used instruments.

Preliminary Treatment

- a) As soon as possible after use, open the instruments and set them in a basin of distilled water or in a tray covered with damp towels.
- b) Do not place heavy instruments on top of delicate ones.
- c) **Saline** solution has a corrosive effect on stainless steel and **should not be used**.
- d) Soaking in disinfectants may be a necessary step to control certain viruses. However, these agents may discolor or corrode instruments. (Household bleach forms chlorine and chloride in solution and has a corrosive effect similar to saline.) Disinfectants containing glutaraldehyde may denature proteinaceous contaminants, causing them to harden and making them difficult to remove.

Presoaking

Soaking in a proteolytic enzyme solution can facilitate cleaning, especially for instruments with hard-to-reach areas, such as cannulated and tubular designs. This solution breaks down the protein matter and prevents blood and proteinaceous material from drying on the instruments. Follow manufacturers' instructions for the preparation and use of these solutions.

Processing

- a) If instruments are hand scrubbed, a nonabrasive brush and a blood-dissolving detergent should be used. Scrubbing with a brush should **always** be performed with the instrument under water to prevent potential aerosol formation. The detergent should have a nearly neutral pH to prevent pitting and tarnishing of instruments and skin irritation of the user's hands. Low-sudsing detergents should be used so that the instruments to be cleaned are visible in the cleaning solution. Use of these detergents also helps to reduce the formation of aerosols which may spread contaminants. The detergent should dissolve in cool water; a hot solution will coagulate and harden proteinaceous dirt. The detergent must also be easily and completely rinsable.



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- b) After manual cleaning, instruments should be disassembled, where applicable and subjected to a four-minute exposure at 270° F (132° C) in a sterilizer.
- c) Ultrasonic cleaning, usually with a cleaner recommended by the unit's manufacturer, is intended to remove dirt from box locks, nonseparable hinges, sliding parts, spring-loaded parts, indents, and other hard-to-reach areas. If instruments are stained or corroded, an ultrasonic cleaning with an acidic cleaner may be sufficient to remove the surface deposit. However, an acidic cleaner should not be used on a daily basis. (See also previous NOTE about using ultrasonic cleaning before using the washer/sterilizer.)
- d) A commercial and water-based lubricant should be used to reduce friction and wear. Water-based instrument lubricants contain bacteriostatic agents. To remain effective, the solutions should be used no longer than recommended by the manufacturer. 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: Air-powered or electrical instruments have different requirements; their lubrication should be done strictly according to the manufacturers instructions.

- e) Instruments should be prepared so that all surfaces have direct contact with steam. Hinged instruments should be open, sliding instruments extended, complex instruments taken apart, screw-on handles removed, and all parts firmly but gently immobilized in the sterilization case. Experience has shown that, whenever possible, the weight of any one set should not exceed 16 lb, and the weight should be evenly distributed; however, instrument sets for joint replacements and spinal procedures currently in the field may weigh more.
- f) If sterilization wraps are used, they must be free of detergent residues. Foam sheets should not be reused. They may have trapped impurities from the steam supply, and subsequently may form deposits on the instruments. Textiles that have been scorched by overheating also may form deposits on instruments.



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Special Note: Titanium and titanium alloy devices are especially susceptible to discoloration from steam impurities and detergent residues which form multicolored surface layers of oxide deposits. On repeated sterilization these oxide layers, while not harmful to the patient, may become so dark that they can obliterate graduation marks, catalog and lot numbers, and other stamped or etched information.

g) Manufacturer's recommendations for the sterilizer used should always be followed.

“Flash” sterilization by exposure at 270° F (132° C), unwrapped, in a gravity displacement sterilizer should only be used as an emergency procedure.* Instruments must be cleaned and disassembled. Instruments which contain lumens or which otherwise entrap air should be exposed to steam for a **minimum of 10 min. at 270° F (132° C).**

Steam sterilization is the preferred method for metal instrument sets.

Instrument sets should be properly prepared and packaged in a case or tray that will allow steam to penetrate and make direct contact with all surfaces. The following charts summarize **exposure times** and **temperatures** that are customarily recommended by manufacturers of steam sterilizers for metal instruments sterilized alone or in combination with porous materials. Time and temperature relationships indicate holding time after the specific temperatures have been reached and do not include heating or drying times.

Sterilizer	Unwrapped	Wrapped*
Gravity Displacement (250° F) (121° C)	NA	30 min. ^{††}
Gravity Displacement (270° F) (132° C)	10 min.	15 min. ^{††}
Prevacuum or Pulsating Vacuum (270° F) (132° C)	4 min.	4 min. [†]

Note: Where there is concern of TSE/CJD contamination, autoclaving at 273° F (134° C) for 18 minutes is recommended by the WHO.

*In the equivalent of four thicknesses of 140-thread-count muslin.

* ANSI/AAMI ST37-1996



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Instrument sets with unusual density or design characteristics that may create moisture problems (i.e., wet packs) from condensation may need special packaging and/or extended exposure and/or drying times.

^{**}Where rigid container systems are used in place of wraps, gravity displacement cycles are not recommended, because cycle times are too long to be practical.

^{***}Additional sterilization information is available upon request. In the USA call 1-800-348-2759. For calls outside the USA call the local international access code + 1-574-267-6131.

Thick-walled plastic items, such as mallet or driver heads or acetabular gauges, may have poor heat conductivity. To prevent condensation of steam on their surfaces, these items require an extended exposure time to attain the required temperature.

If the interior of the case is wet after the sterilization cycle, do not attempt to remedy the situation by:

- a) opening the case immediately after sterilization
- b) increasing only the drying time, unless testing shows that the exposure time was adequate to attain sterility
- c) drilling additional holes into the case for added drainage

During initial sterilization runs some formaldehyde from the gauge surfaces may vaporize and become noticeable. After a few sterilization procedures, the odor should be no longer apparent.

CONCLUSIONS

Orthopaedic instruments in general have a long service life, but 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 discarded. Notify the company representative of any instrument problems.

Hospital Responsibilities for Zimmer Loaner Sets

- 1) Loaner sets should undergo all steps of decontamination, inspection, and terminal sterilization prior to their return to the sales representative.
- 2) 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 the Zimmer representative to ensure that the next hospital will receive a complete set in workable condition.



Zimmer Representatives' Responsibilities for Loaner Sets

- 1) Ascertain that instrument sets are complete before delivery to, and following return from, the hospital.
- 2) Make sure that instruments are in good working condition.
- 3) Replace damaged or missing instruments and spare parts.
- 4) Take care that instruments are properly immobilized and protected during transit.
- 5) Inform hospital personnel that care instructions are available.



REFERENCES**References on Instrument Processing**

- 1) American Society for Testing and Materials: ASTM F565-00 – *Standard Practice for Care and Handling of Orthopaedic Implants and Instruments*.
- 2) Association for the Advancement of Medical Instrumentation: *Good Hospital Practice: Steam Sterilization and Sterility Assurance*. ANSI/AAMI. ST46 – 1993.
- 3) Association of Operating Room Nurses, Inc.: *AORN Standards and Recommended Practices and Guidelines*, Denver, CO, 2000
 - a) Recommended practices for selection and use of Packaging Systems pp 299-304.
 - b) Recommended practices for Sterilization in Perioperative Practice Settings. pp 347-358
 - c) Recommended practices for care of instruments and powered surgical equipment. pp 283-288
- 4) ANSI/AAMI ST37-1996; Flash Sterilization
- 5) ANSI/AAMI ST35-1996; Safe Handling and Biological Decontamination of Medical Devices in Healthcare Facilities.
- 6) Reichert M., Young J.; *Sterilization Technology for the Health Care Facility*, Aspen Publishers Inc., Gaithersburg, Maryland 1993



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