Zimmer Biomet Instrument Care, Cleaning, Maintenance and Sterilization Instructions

ZIMMER BIOMET

Table of Contents

1. PURPOSE

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Zimmer Biomet orthopaedic manual surgical instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of Zimmer Biomet reusable devices. It provides information complementary to the instructions for use in fulfillment of ISO 17664, ISO 16061, ANSI/AAMI ST81, the European Council Directive 93/42/EEC, Annex 1, section 13.6 (h), and the Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex 1, section 23.4(n).

The instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of Zimmer Biomet 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 Biomet 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

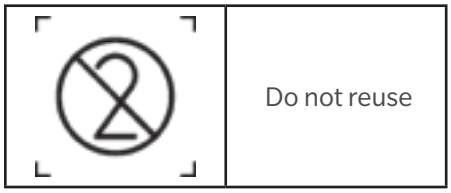
This instruction manual provides information on the care, cleaning, disinfection, maintenance and sterilization of manual surgical instruments and is **applicable** to all reusable medical devices manufactured and/or distributed by Zimmer Biomet.

This information is also **applicable** to single-use medical devices manufactured by Zimmer Biomet that are supplied non-sterile but are intended to be used in a sterile state and single-use devices packaged and sold sterile but may be removed from packaging and placed in kits (e.g., screws, plates, etc.). These devices are single-use but can be reprocessed if **not used.**

Note: not used refers to those single-use components that have not been in contact with blood, bone, tissue, or other body fluids. Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.

Always consult the device labeling and instructions for use for specific recommendations or restrictions on processing within a health care setting.

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



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:

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.

Powered devices included in a manual device case must be cleaned per specific manufacturer's instructions (e.g. Brasseler powered hand pieces).

3. GLOSSARY

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

Note: Chemicals include detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners and sterilants.

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

Contaminated: state of having been actually or potentially in contact with microorganisms or infectious particles.

Containment device (case): reusable rigid sterilization container, instrument case/cassette, or organizing tray and any reusable accessories intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

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

Disinfection: 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 (e.g. washer/disinfector equipment).

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

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

Reusable rigid sterilization Container: sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

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.

Tray: basket, with or without a lid, that has perforated sides or bottom, that holds instruments, and that is either enclosed in sterilization wrap or a pouch or placed inside a container for sterilization.

Washer/disinfector: 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

	Do not reuse
	Consult instructions for use
	Do not resterilize
	Caution (consult instructions for use for important cautionary information)

6. CONSIDERATIONS

This instruction manual pertains to all hip, knee, trauma, and extremity reusable medical devices manufactured and/or distributed by Zimmer Biomet. This manual also pertains to all hip, knee, trauma, and extremity single-use medical devices manufactured by Zimmer Biomet that are supplied nonsterile but are intended to be used in a sterile state. This manual does not pertain to Zimmer Biomet spine or dental devices. This information should be studied carefully. **This manual supersedes Zimmer, Centerpulse, and Implex manual orthopaedic instrument reprocessing instructions and instrument manuals published prior to the issue date of this document.**

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. It is also Zimmer Biomet's recommendation to thoroughly process non-sterile implants (e.g. plates, screws, etc.) prior to use. Single-use devices must be removed from the tray or caddy for the initial cleaning process and returned to the tray or caddy for sterilization. Upon subsequent reprocessing, unused single-use devices may be left in the tray or caddy.

Note: Any unused, single-use device that has been exposed to blood, bone, tissue or body fluids must not be reprocessed and must be discarded.

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone fragments 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 such as Ringers Solution are often used in copious amounts during surgical procedures and may cause corrosion of the 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 the cleaning, disinfection, packaging and sterilization of all loaner instrument sets before returning them to Zimmer Biomet. 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 Biomet cannot guarantee that sterility was attained by the previous user and has been maintained during transit. Zimmer Biomet representatives often open and inspect instrument sets between users, which will, of course, compromise cleanliness and sterility and require complete reprocessing prior to subsequent use. **Zimmer Biomet requires certification of cleaning and disinfection prior to return of loaner sets to Zimmer Biomet.**

This reprocessing manual includes instructions for Zimmer Biomet reusable devices marked with reprocessing category codes [a, a+, b, b+, c]. See Section 7 of this manual for further explanation of reprocessing codes. All Zimmer Biomet devices may be safely and efficiently reprocessed using the combination method cleaning instructions outlined in this reprocessing 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 Biomet representative. To maintain instruments properly, it is important to consider the following information and processing instructions:

- Warnings and precautions
- Instrument set content and functionality verification
- Limitations and restriction on reprocessing
- Initial treatment at the point of use
- Preparation before cleaning
- Cleaning/Disinfection and drying
- Inspection and Maintenance
- Packaging
- Sterilization
- Storage
- Transportation

7. PROCESSING CATEGORY CODES

Zimmer Biomet recommends that all reusable devices (regardless of etching) be processed in accordance with the combination cleaning instructions contained in this reprocessing manual. The following codes are etched on some devices and case components and may provide useful information in the selection of cleaning agents as well as indications for disassembly.

Note: Codes on trays and cases apply only to those components noted and do not apply to the contents of the tray or case.

	Metal devices (excluding aluminum and titanium) and case components without features posing a cleaning challenge 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 neutralization and thorough rinsing. These devices can be treated with rust-removal agents approved for surgical instruments if needed.
	Metal devices (excluding aluminum and titanium) and case components with features posing a cleaning challenge 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 neutralization and thorough rinsing. These devices can be treated with rust-removal agents approved for surgical instruments if needed.
	Devices and case components without features posing a cleaning challenge 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 dilatators, pyramidal chisels/ rasps). These devices are tolerant of alkaline cleaning agents when followed by neutralization and thorough rinsing.
	Devices and case components with features posing a cleaning challenge, made of polymers or metal instruments paired with polymer components (e.g. tibial mallets, flex screwdrivers, tibial dilatators, etc.). These devices are tolerant of alkaline cleaning agents when followed by neutralization and thorough rinsing.
	Devices and case components 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). **The use of alkaline cleaning agents might be corrosive to the surface of these devices.**

Note: Features posing a cleaning challenge include: lumens/cannulated bores, tightly mated surfaces, rough surfaces, ball detents, springs, and multiple component designs.

8. PROCESSING INSTRUCTIONS

These processing instructions are intended to assist the hospital and central supply management in developing procedures to attain safe and effective devices, both for hospital-owned and for loaned instrument sets. This information is based on Zimmer Biomet testing, experience and 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 for Applied Hygiene (VAH)
- Association of Operating Room Nurses (AORN)
- Canadian Standards Association (CSA)
- Centers for Disease Control (CDC)
- Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte)
- 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 generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Dry, soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, 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.
- Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 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 Biomet should be included in Zimmer Biomet instrument trays and cases. These validated reprocessing instructions are not applicable to Zimmer Biomet trays and cases that include devices that are not manufactured and/or distributed by Zimmer Biomet.

- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time. Steam Sterilizers should be descaled in accordance with the manufacturer's instructions.

- Instruments used in suspected or confirmed prion (e.g., TSE/CJD) cases must not be reused and shall be discarded. Notify your Zimmer Biomet Representative if this issue has occurred with loaned instruments. The loaned instrument set must be labeled as being possibly contaminated with prions and returned to the appropriate Zimmer Biomet address with a request for decontamination and disposal.

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 Biomet 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 Biomet representative if scales and other markings are not legible.

C. Limitations and Restrictions on Reprocessing

- Neutral pH, enzymatic, and alkaline (pH ≤12) cleaning agents are recommended and preferred for cleaning Zimmer Biomet reusable devices. Alkaline agents with pH ≤ 12 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. Instruments used in suspected or confirmed prion (e.g., TSE/CJD) cases must not be reused and shall be discarded. It is critical that alkaline cleaning agents are thoroughly neutralized and completely 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 effect on Zimmer Biomet reusable manual instruments unless otherwise noted. Refer to www.zimmerbiomet.com and the Reusable Instrument Life Span Manual 1219 for further information. 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 complex orthopaedic instruments with lumens,

cannulations, blind holes, mated surfaces and other features.

- Where applicable, multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. More specific instructions can be found in the instruction for use, the Instrument Disassembly and Assembly Manual 1258, and at www.zimmerbiomet.com. Care must be taken to avoid losing small parts. If a part is lost, notify your Zimmer Biomet representative when the instrument set is returned.
- At point of use, soiled instruments must be removed from metal or polymer trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Do not clean soiled instruments while in polymer or metal trays. Single-use devices must be cleaned separately from soiled instruments.

Note: Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.

- Polymers used in Zimmer Biomet 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 Biomet representative if polymer devices need to be replaced.
- Most currently available polymers will not withstand conditions in washers/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 may 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 Biomet devices.
- Ethylene Oxide (EO), Hydrogen Peroxide Gas Plasma, Vaporized Hydrogen Peroxide, and dry heat sterilization methods are not recommended for sterilization of Zimmer Biomet devices.
- Instruments 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 for Zimmer Biomet devices. 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, EO 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 dark and obscure graduation marks, item and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration as needed.
- Stainless steel instruments may be treated with rust-removal agents approved for surgical instruments if needed.
- 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 (e.g. ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent).

D. Initial Treatment at the Point of Use

- 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 or other precleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays 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.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution 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 Biomet representative when the instrument set is returned.
- Instructions for instrument assembly/ disassembly and device specific cleaning aids can be found at www.zimmerbiomet.com and the Instrument Disassembly and Assembly Manual 1258.
- Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended by Zimmer Biomet.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.

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.

- Only agents with proven efficacy (FDA approved, VAH listed, or CE mark) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Zimmer Biomet does not recommend any specific brand.
- Agents used during the validation of these processing instructions are as follows:

  1. Enzymatic and Neutral Detergents: Steris®, Prolystica™ 2X Enzymatic Pre Soak and Cleaner and Steris® Prolystica™ 2X Concentrate Neutral Detergent.
  2. Alkaline Detergent and Neutralizer: neodisher® FA Alkaline Detergent and neodisher® Z Acid Neutralizer.

- 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 and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).
- The combination manual and automated cleaning instructions in Sections F or G shown in Table 1

must be used to clean the instruments and the tray, case, and lid components. Instruments must be removed from the tray or case during the cleaning.

Table 1. Cleaning/Disinfecting Options		
Method	Description	Section
Combination of Manual and Automated Cleaning Using Enzymatic and Neutral Detergents	Enzymatic soak and scrub, followed by enzymatic sonication, followed by automated washer/disinfector cycle with enzymatic and neutral detergents.	F
Combination of Manual and Automated Cleaning Using Alkaline Detergent and Neutralizer	Alkaline soak with sonication followed by automated washer/disinfector cycle with alkaline detergent and neutralizer.	G

F. Combination Cleaning/Disinfection Instructions Using Enzymatic and Neutral Detergents

1. Rinse soiled instruments, trays, cases, and lids under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush.

2. Completely submerge the instruments, trays, cases, and lids in an enzyme solution and allow to soak for 10 minutes. Instruments must be removed from the trays or cases during the cleaning. Use a soft nylon-bristled brush to gently scrub the device for a minimum of one minute and 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 syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

3. Remove instruments, trays, cases, and lids from the cleaning 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.

4. Completely submerge the instruments, trays, cases, and lids in an enzyme solution and sonicate for 10 minutes at 40±5 kHz. Instruments must be removed from the trays or cases during the cleaning.

5. Remove instruments, trays, cases, and lids from the cleaning 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.

6. Place instruments, trays, cases, and lids in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. Instruments must be removed from the trays or cases during the cleaning. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2. Typical U.S. 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.

Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE

mark, FDA approval, and validation according to ISO 15883) should be used.

7. Proceed to Section H, Inspection and Maintenance.

G. Combination Cleaning/Disinfection Instructions Using Alkaline Detergent and Neutralizer

1. Rinse soiled instruments, trays, cases, and lids under running cold tap water for a minimum of one minute. Remove gross soil and debris using a soft bristled, nylon brush.

2. Completely submerge the instruments, trays, cases, and lids in an alkaline (pH ≤12) solution and allow to sonicate for 10 minutes at 40±5 kHz. Instruments must be removed from the trays or cases during the cleaning.

3. Remove instruments, trays, cases, and lids from the cleaning 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.

4. Place instruments, trays, cases, and lids in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. Instruments must be removed from the trays or cases during the cleaning. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 3. Typical European Automated Washer/ Disinfector Cycle for Surgical Instruments

Step	Description
1	5 min pre-rinse with cold tap water
2	10 min alkaline cleaning agent wash at 55°C
3	2 min rinse with neutralizer
4	1 min rinse with cold tap water
5	Disinfection at 93°C with hot purified water until A0 3000 is reached (approx. 5 min)
6	40 min hot air drying at 110°C

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to.

Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

5. Proceed to Section H, Inspection and Maintenance.

H. Inspection and Maintenance

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 Biomet 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. If necessary, hinged, rotating, or articulating instruments can be lubricated with an instrument product (e.g. Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization. Make sure to spray an adequate amount of lubricant on the instrument, especially in hard to reach spaces. Properly rub in the lubricant for a few seconds afterwards and wipe off.

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.

Note: Lubricants not specifically designed for compatibility with steam sterilization should not be used because they may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

5. Check instruments with long slender features (particularly rotating instruments) for distortion.

6. Where instruments form part of a larger assembly, consult www.zimmerbiomet.com and the Instrument Disassembly and Assembly Manual 1258 if necessary for reassembly and check that the devices assemble readily with mating components.

I. Packaging

Packaging individual instruments

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in the table below. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- The sterilization pouch or wrap used should be FDA cleared and compliant to ISO 11607-1.
- 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. Instrument cases may be placed in an approved sterilization container with gasketed lids at the user's discretion. Consult the Zimmer Biomet website www.zimmerbiomet.com or your Zimmer Biomet representative for the full list of approved sterilization containers. The total weight of the instrument set, case, and sterilization container, must not exceed 11.4kg/25lbs (other local limits below 25 lbs. may apply).

- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- The sterilization wrap used should be FDA cleared and compliant to ISO 11607-1.
- Trays and cases with lids may also be placed in an approved and FDA cleared sterilization container with gasketed lid for sterilization.
- The following list contains the approved rigid sterilization containers for use using these steam sterilization instructions.
    - Aesculap® SterilContainer™
    - Case Medical SteriTite®
    - OneTray®

Note: If using the OneTray® sterilization container, the only cycle that was validated by Zimmer Biomet was the cycle using the 132 °C temperature for a four minute exposure time. In addition, the drying time using the OneTray® sterilization container was not validated by Zimmer Biomet, because customers do not utilize a drying time when using the OneTray® in accordance with the OneTray® instructions for use.

- 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 Biomet 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 Biomet should be included in Zimmer Biomet instrument trays. These validated reprocessing instructions are not applicable to Zimmer Biomet trays that include devices that are not manufactured and/or distributed by Zimmer Biomet.

Instrument trays with reconfigurable layouts

- Brackets designated for specific devices shall contain only devices specifically intended for them.
- Optional Zimmer Biomet instruments should not be added to a reconfigurable tray unless a dedicated universal space or compartment has been included in the layout and the guidelines described below for universal trays without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Zimmer Biomet should be included in Zimmer Biomet instrument trays. These validated reprocessing instructions are not applicable to Zimmer Biomet trays that include devices that are not manufactured and/or distributed by Zimmer Biomet.
- Brackets designed to force disassembly of a complex device must not be altered to allow the assembled device to be inserted into the tray or case.
- To ensure devices are fully seated in their corresponding brackets and to prevent damage to tray contents, individual brackets should not overlap one another when inserted into the tray floor.

Note: Some individual brackets may be designated for assembly onto other "host" brackets. In these instances, the mating relationship between the brackets will be graphically depicted on the face of the "host" bracket.

- Bracket fasteners should be fully engaged with the tray floor to prevent unintended migration, damage and/or loss of tray contents.
- Wave springs positioned over the shaft of the bracket fasteners are intended to stabilize brackets by minimizing free-play between them and the tray floor. To ensure intended function, periodically inspect brackets for damaged and/or missing springs which can be replaced by contacting your Zimmer Biomet representative.
- Identification tags and associated labels on trays should correspond to tray contents to ensure correct trays are available for use in surgery.
- Any manual tools provided by Zimmer Biomet to aid in the removal of individual brackets must not remain in the instrument trays during reprocessing and are not intended for use in surgery.

Universal 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. Silicone mats may be used to keep devices in place.
- Only devices manufactured and/or distributed by Zimmer Biomet should be included in Zimmer Biomet instrument trays. Zimmer Biomet validated reprocessing instructions are not applicable to Zimmer Biomet trays that include devices that are not manufactured and/or distributed by Zimmer Biomet.

J. Sterilization

- See Table 4 for recommended minimum sterilization parameters that have been validated by Zimmer Biomet 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 Biomet reusable devices.
- 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 cases should not be stacked during steam sterilization.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- Autoclaves must fulfill the requirements of EN ISO 17665 series, EN 13060 and / or EN 285.
- Ethylene oxide, hydrogen peroxide gas plasma, and vaporous hydrogen peroxide 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.
- Flash (immediate-use) steam sterilization by exposure at 132-134°C/ 270-273°F for the exposure times listed in Table 4 without the recommended dry time should only be used as an emergency procedure. Instruments must be cleaned and disassembled. Flash (immediate-use) sterilization is not available for users in the European Market.

Table 4. Recommended Steam Sterilization Parameters

Cycle Type	Temperature[2]	Exposure Time[1,5]	Minimum Dry Time[9]	Minimum Cool Time[10]
		Wrapped[6,7] and Unwrapped[8]		
Prevacuum/Pulsating Vacuum[3]	134°C / 273°F	3 minutes	30 minutes	30 minutes
Prevacuum/Pulsating Vacuum[3]	132°C / 270°F	4 minutes		
Prevacuum/Pulsating Vacuum[4]	134°C / 273°F	18 minutes		

1. Validated exposure time required to achieve a 10^{-6} sterility assurance level (SAL).
2. Validated exposure 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. Exposure temperatures below 134°C are not for use in Europe.
4. This cycle is not for use in the United States. These are disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination. However, this sterilization cycle alone is not effective for the inactivation of prions. Instruments used in suspected or confirmed prion (e.g., TSE/CJD) cases must not be reused and shall be discarded.
5. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable. Country specific minimum exposure times of 3, 4, 5, 10 or 18 minutes may be applicable in Europe. Please regard the local ordinances.
6. Medical grade steam sterilization compatible wrap that is FDA cleared and compliant to ISO 11607-1.
7. Approved rigid sterilization container per these instructions may be used.
8. Flash (immediate-use) steam sterilization by exposure at 132-134°C / 270-273°F for the exposure times listed without the recommended dry time is not available in Europe and should only be used as an emergency procedure. Instruments must be cleaned and disassembled.
9. Drying times vary according to load size and should be increased for larger loads.
10. Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

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

K. 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.
- 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 cleaned, 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.

L. Transportation

- The instruments are supplied in their designated instrument trays.
- The trays ensure that every instrument is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

9. HOSPITAL RESPONSIBILITIES FOR ZIMMER BIOMET LOANED INSTRUMENT 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 Biomet to be discarded. Notify your Zimmer Biomet representative of any instrument problems. Refer to www.zimmerbiomet.com and the Reusable Instrument Life Span Manual 1219 for further information.
- Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and sterilization before being returned to Zimmer Biomet. Documentation of decontamination should be provided with instruments being returned to Zimmer Biomet.
- 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 Biomet representative to ensure that the next hospital will receive a complete set of instruments in good working condition.
- The instructions provided in this reprocessing manual have been validated by Zimmer Biomet 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: 1-800-253-6190 Outside USA: local international access code +1-574-267-6131
Zimmer GmbH Sulzer allee 8 CH-8404 Winterthur, Switzerland	+41 (0) 58 854 80 00
Zimmer Switzerland Manufacturing GmbH Sulzer allee 8 CH-8404 Winterthur, Switzerland	+41 (0) 58 854 80 00
Biomet France SARL Plateau de Lautagne 26000 Valence France	+33 4 75 75 91 00
Biomet Orthopedics 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581 USA	Inside USA: 1-800-253-6190 Outside USA: local international access code +1-574-267-6131
Biomet Sports Medicine 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581 USA	
Biomet Trauma 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581 USA	
Biomet Biologics 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581 USA	
This Zimmer Biomet reprocessing manual and device specific cleaning and assembly/disassembly instructions can be found at www.zimmerbiomet.com.	

APPENDIX 1- CLEANING AND STERILIZATION VALIDATION PROCESS

Zimmer Biomet cleaning methods are validated using at least two relevant test markers and visual inspection criteria. The reusable devices or device features are exposed to test soil prior to cleaning. After cleaning, test samples are inspected for any sign of visible soil and extracted to determine the quantitative amount of extractable soil. The data are compared to test protocol requirements to determine if the acceptance criteria are met. The cleaning processes outlined in these instructions have been validated per the following standard and FDA guidance document.

ISO 17664, Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff

Steam sterilization cycles are validated using the "overkill" method to demonstrate a 10^{-6} sterility assurance level (SAL). Studies are conducted using disposable steam sterilization wrap and/or approved rigid steam sterilization containers. Recommended dry time is validated by demonstrating that there is no visible moisture at the end of the full sterilization cycle. Durability studies are also performed using multiple cycles at maximum temperature and time parameters to ensure that the instrument case and contents can withstand repeated processing. The sterilization parameters outlined in these instructions are validated per the following standards.

ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ANSI/AAMI/ISO 17665, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

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 TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
3. AAMI TIR34, *Water for the reprocessing of medical devices*
4. ANSI/AAMI ST67, *Sterilization of health care products – Requirements for products labeled "Sterile"*
5. ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*
6. ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
7. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
8. ANSI/AAMI/ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General Requirements*
9. AORN, *Standards, Recommended Practices and Guidelines*
10. Association for Applied Hygiene (VAH) Verbund für Angewandte Hygiene, *List of Disinfectants*
11. ASTM F 565, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*
12. European Commission, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
13. Regulation (EU) 2017/745 of the European Parliament and of the Council
14. German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung, *Proper Maintenance of Instruments, 10th Ed,2012.*
15. IAHCSMM, *Central Service Technical Manual*
16. ISO 15883, *Washer/Disinfectors: General Requirements, Terms and Definitions and Tests*
17. ISO 17664, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices*
18. ISO 17665-1, *Sterilization of health care products –moist heat, Part 1*
19. ISO 17665-2, *Sterilization of health care products –moist heat, Part 2*
20. Robert Koch Institute (RKI), *Hygiene Requirements for Reprocessing Medical Devices* Federal Health Gazette, 10/2012
21. Robert Koch Institute (RKI), *Hospital Supplies and Instrument Sterilization in Light of CJD Patients and Suspected CJD Cases,* Federal Health Gazette, 7/1998
22. UK Department of Health, published by The Stationary Office, London: *Health Technical Memorandum (HTM) 01-01: Decontamination of reusable medical devices. Parts A and B*
23. World Health Organization (WHO), WHO/CDS/CSR/APH 200.3, *WHO Infection Control Guidelines for TSE*
24. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - *Guidance for Industry and Food and Drug Administration Staff, 2015*
25. ISO 11607-1, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
26. ISO 16061, *Instrumentation for use in association with non-active surgical implants – General Requirements*
27. EN 13060, Small steam sterilizers
28. EN 285, Sterilization - Steam sterilizers -Large sterilizers

This material is intended for health care professionals.

MC255323 | 97-5000-170-00 Rev. 8, ©1987, 1988, 2002, 2006, 2010, 2012, 2013, 2015, 2021

Legal Manufacturer
Zimmer, Inc.
1800 West Center Street
Warsaw, IN 46801-0708
USA

Legal Manufacturer
Biomet Trauma
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet Sports Medicine
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Zimmer Switzerland
Manufacturing GmbH
Sulzerallee 8
8404 Winterthur
Switzerland

Legal Manufacturer
Zimmer GmbH
Sulzerallee8
8404 Winterthur
Switzerland

Legal Manufacturer
Biomet Biologics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

Legal Manufacturer
Biomet France SARL
Plateau de Lautagne
26000 Valence
France

ZIMMER BIOMET

CE 0123
CE 2797

3455.2-GLBL-en-Issue Date 2022-07

www.zimmerbiomet.com