Instructions for Use

WishBone Medical Decontamination and Sterilization Instructions

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufacturer:

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℞ only	• **Caution: Federal law restricts this device to sale by or on the order of a physician.**
5.1.1	• **Manufacturer**
5.1.3	• **Date of Manufacture**
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
QTY	• **Quantity**
5.4.4	• **Caution: See instructions for use**
STERILE R 5.2.4	• **Sterile – Irradiation**
STERILE EO .2.3	• **Sterile – ethylene oxide**
5.1.4	• **Use by date**
5.2.6	• **Do not resterilize**
LATEX	• **Not made with Natural Rubber Latex**
5.2.8	• **Do Not Use If Package is Damaged**
NON STERILE 5.2.7	• **Non-Sterile**

Symbols: ISO-15223

PURPOSE

These instructions are recommended for the care, maintenance, cleaning, and sterilization of reusable and single-use non-sterile medical devices produced by WishBone Medical. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of WishBone Medical reusable devices. It provides information complementary to the instructions for use in fulfillment of ISO 17664, ANSI/AAMI ST81. The medical devices manufactured and/or distributed by WishBone Medical are safely and effectively decontaminated and sterilized using the instructions and parameters provided in this document **unless otherwise noted in the instructions accompanying the specific medical device.**

These methods were developed using standard equipment and practices common to health care facilities and have been validated to the parameters specified herein. Where user requirements are more stringent than those provided in these instructions, it is the responsibility of the user / processor to comply with local requirements, laws and ordinances.

It is the responsibility of the user, including hospital personnel in receiving, central supply departments, and operating rooms, to ensure these instructions are available, appropriate training is completed, and appropriate equipment and materials are available to process the medical devices safely and effectively, and prevent damage or misuse of the medical devices.

SCOPE

These instructions apply to the reusable devices that are sold by WishBone Medical Inc. that are sold in a non-sterile state. This includes single-use devices that are provided non-sterile and are in trays prior to sterilization (i.e. plates, nails, screws, pins and wires). If not specifically labeled sterile, the components supplied are non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile external fixation devices, remove the original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning is completed prior to sterilization. These reprocessing instructions have been validated as being capable of preparing reusable WishBone Medical instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

DO NOT REUSE implant components or single-use disposable instruments.

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.

DEFINITIONS

- **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.
- **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.**
- **Sterilization Case:** sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.
- **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.

WARNINGS & PRECAUTIONS

- WishBone Medical reusable instruments are provided NON-STERILE and must be cleaned and sterilized according to these instructions prior to use.
- If present, safety caps and other protective packaging material must be removed from the instruments prior to the first cleaning and sterilization.
- Ethylene oxide (EO), gas plasma and dry heat sterilization methods are not recommended for sterilization of WishBone Medical reusable instruments. Steam (moist heat) is the recommended method.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.
- Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth.
- Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and should not be used.
- Failure to completely remove biologic soil and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.
- Do not allow biologic soil to dry on contaminated devices. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used instruments.
- Automated cleaning using a washer/disinfector alone may not be effective for instruments with lumens, blind holes, cannulas, mated surfaces and other complex features. A thorough manual cleaning of such device features is recommended before any automated cleaning process. 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.
- Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of the instruments. Use only soft bristle nylon brushes with different shapes, lengths and sizes to aid with manual cleaning.
- Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.
- When processing instruments do not place heavy devices on top of delicate instruments.

- Use of hard water should be avoided. Softened tap water may be used for most rinsing however purified water should be used for final rinsing to prevent mineral deposits.
- Do not process instruments with polymer components at temperatures equal to or greater than 137 ºC (279 ºF) because severe surface damage to the polymer will occur.
- Oils or silicone lubricants should not be used on surgical instruments.
- Only devices manufactured and/or distributed by WishBone Medical should be included in WishBone Medical instrument trays and cases. These validated reprocessing instructions are not applicable to WishBone Medical trays and cases that include devices that are not manufactured and/or distributed by WishBone Medical.

LIMITATIONS ON REPROCESSING

- Repeated processing according to these instructions has minimal effect upon metal WishBone Medical reusable instruments and accessories unless otherwise noted. End of life for stainless steel or other metal surgical instruments is generally determined by wear and damage incurred during the intended surgical use.
- Exposure to temperatures above 137 ºC (279 ºF) may accelerate instrument degradation.
- WishBone Medical instruments comprised of polymers or incorporating polymer components can be sterilized using steam however they are not as durable as their metal counterparts. If polymer surfaces show signs of excessive surface damage (e.g., crazing, cracks or delamination), distortion or are visibly warped they should be replaced. Contact your WishBone Medical representative for your replacement needs.
- Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing WishBone Medical reusable instruments and accessories.
- It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from the devices or degradation may occur that limits the device life.

For the 00-0038-60-WB Rod Cutter, please see https://orthomedinc.com/support/instrument-care for detailed reprocessing instructions.

For the 00-2055-08-WB Torque Limiting Ratchet Wrench, please see https://www.wishbonemedical.com/product/sc/ for detailed reprocessing instructions.

RECEIVING INSPECTION

Upon receipt, medical devices received in non-sterile packaging and/or sterilization cases must be processed by the user to ensure proper decontamination and sterilization. Prior to onsite cleaning and sterilization, medical devices must be inspected to ensure the system's devices are present and in good condition to function properly.

a) **INSPECTION & FUNCTION TESTING**
Devices are inspected prior to cleaning, decontamination, and sterilization. If any damage, deformation, wear, or other lack of function, especially those identified below, the device is to be discarded and not used.

Device type	Inspection / Testing Instruction
(All) Total system devices	Visually inspect and ensure no damage, deformation, or wear.
Hinged / articulating instruments	Check all moving parts to ensure smooth operation throughout the intended range of motion. If the moving part has excessive motion do not use.
Locking mechanism	Ensure device can be locked and unlocked
Cutting features	Ensure devices have a continuous smooth edge and no nicks, cracks or imperfections are visually seen. Jaws / teeth should align properly.
Assembled devices	Ensure the system's components are present and devices are functional when assembled.
Mating interfaces	Ensure all mating parts fit together without complications
Impaction surfaces	Ensure no burrs, large nicks, or cracks
Reamers/ drill bits	Ensure connection ends do not have burrs, distortion, or damage that might hinder insertion into a drill.
Metal devices	Ensure no corrosion
Plastic devices	Ensure no cracks, large nicks, or burrs

DECONTAMINATION

Non-sterile medical devices provided in non-sterile packaging

- Must be opened and placed into an appropriate sterilization case. These instructions were validated for use only in specifically designed WishBone Medical sterilization cases and trays.

Non-sterile medical devices unused in previous procedures

- Any non-sterile medical devices that were unused in a previous procedure must be considered contaminated and reprocessed according to the instructions herein

Point of Use

- It is critical that biologic soil not be allowed to dry on medical devices during and after the procedure as it is difficult and sometimes impossible to clean especially with automated washers.
- All excess biologic soil must be removed from the medical device with a disposable, non-shedding wipe. Close attention should be paid to crevices, joints, cannula, and other hard to clean areas.
- Place devices in a basin with distilled water or cover with damp towels.
- Soaking in enzymatic solutions or other precleaning solutions may be used to break down protein matter and prevent blood/protein-based materials from drying on medical devices. Follow the manufacturer's instructions for preparation and use of these solutions. For optimal results, devices should be cleaned within 30 minutes of use or after removal from solution to minimize drying of biologic soil.

Containment and Transportation

- Follow Universal Precautions for handling and transporting contaminated medical devices to the designated cleaning area.
- Used medical devices must be transported in closed or covered containers to prevent unnecessary contamination risk.
- Devices should not be allowed to dry prior to cleaning.

Preparation for Cleaning

- Medical devices designed to come apart must be disassembled prior to cleaning. See individual medical device instructions for use for specific details, found at www.wishbonemedical.com\IFU
- Devices are designed to be disassembled by hand**, never use tools to disassemble devices unless directed in device specific instructions as this may lead to damage.**
- Prepare all cleaning solutions according to the manufacturer's instructions. 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 devices (e.g., ultra-filter (UF), reverse osmosis (RO), deionized (DI), or equivalent).
- The following agents were used during the validation of these instructions Enzol Enzymatic Detergent, Ref #2252 (Johnson & Johnson), or equivalent.
- **Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated.**

Manual Cleaning

1. Completely submerge medical device(s) in an enzymatic solution and gently shake to remove trapped air bubbles. Actuate moving parts to ensure full contact of solution, and flush lumen / cannula / blind features with a syringe.
2. Allow medical devices to soak for 10 minutes; using a soft-bristled, nylon brush to remove visible soil. Use an appropriately sized brush to ensure full width and depth of internal features is accessed and use a twisting action.
3. Remove medical devices from the enzyme solution and rinse in softened tap water for a minimum of 1 minute. Aggressively flush and/or use a syringe for lumen / cannula / blind features and actuate moving parts while rinsing.
4. Sonicate devices in enzymatic detergent, fully submerging in solution and shaking/actuating device to remove air bubbles. Sonicate in solution for a minimum of 10 minutes at 45-50 kHz.
   Note: separate stainless-steel devices from other metal devices during ultrasonic cleaning to avoid electrolysis.
5. Rinse devices 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 difficult to access areas or use a syringe and actuate moving parts while rinsing.
6. Check instruments for visible debris and repeat cleaning if debris is visible.
7. Dry devices with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from internal features.

Inspection & Testing

1. After cleaning, devices should be thoroughly inspected to ensure visible contamination was removed. If contamination is present, repeat the cleaning/disinfection process.
2. Visually inspect devices for damage, missing components, and/or excessive wear per **Receiving Inspection** instructions. Contact your WishBone Medical sales representative if replacements are required.
3. Multi-component devices should be checked to ensure the appropriate components are present and the device(s) assemble with mating components.

STERILIZATION

Packaging for Sterilization

- Devices must complete adequate cleaning prior to sterilization (see **DECONTAMINATION** instructions).
- Trauma plates, nails, screws, pins, and wires are implants and considered single-use devices. These devices are sold non-sterile and are often removed by the user from their original packaging and are placed in an appropriate sterilization case for processing. This only applies to single-use non-sterile devices that have NOT come in contact with blood, tissue, or body fluids.
- Single devices should be packaged in an approved (i.e. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap conforming to the recommended specifications for steam sterilization (parameters provided below). Ensure that the pouch / wrap is large enough to contain the device without tearing or applying stress at seals. If sterilization wrap is used, the package should be prepared using the AAMI ST79 double wrap method (or equivalent).
- Reusable wraps are not recommended.
- Medical devices may also be packaged in the designated locations within an approved WishBone Medical sterilization case. Optional / additional instruments should not be added to a preconfigured sterilization case or tray. The case or tray must then be wrapped in an approved medical grade sterilization wrap (double wrap method or equivalent).
- The total weight of a wrapped sterilization case should not exceed 11.4kg/25lbs (other local limits below 25 lbs. may apply).

Sterilization

- Any non-sterile medical devices that was unused in a previous procedure must be considered contaminated and reprocessed according to the instructions above.
- Moist heat / steam sterilization is recommended for all WishBone Medical devices. Ethylene oxide or gas plasma sterilization methods should not be used.
- Follow the manufacturer's instructions; do not exceed the manufacturer's maximum load. Sterilization equipment should have demonstrated efficacy (i.e. FDA clearance, EN 13060 or EN 285 compliance).
- Validated exposure times and temperatures to provide a sterility assurance level (SAL) of 10^{-6}:

Cycle	Temperature	Exposure Time
Pre-vacuum / Pulsating Vacuum	132°C/270°F	4 minutes
Pre-vacuum / Pulsating Vacuum	134°C/273°F	3 minutes

All Cycles	Time
Minimum Dry time	30 minutes
Minimum Cool Time	30 minutes

- Dry times vary according to load size and should be increased for larger loads.
- Cooling times vary according to the type of equipment used, device design, ambient conditions, and type of packaging. Cooling processes should comply with ANSI/AAMI ST79.

Storage

- Sterile packaged/wrapped devices 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.
- Prior to use, inspect each package and wrap to ensure that the sterile barrier is not torn, perforated, wet, or appears to be tampered with. If any of these conditions are present, the device(s) are to be considered non-sterile and must be reprocessed (disinfected and sterilized)

REFERENCES

1. ISO 17664:2017 Processing of health care products
2. ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
3. ANSI/AAMI ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
4. ANSI/AAMI/ST81:2004 - Sterilization of Medical Devices
5. AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities
6. AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
7. ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
8. Food and Drug Administration Guidance for Industry (March 17, 2015) Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

FOR FURTHER INFORMATION

Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.

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