Reusable Instrument Sets

Instructions for Use
Cleaning, Care, and Sterilization

WARNINGS AND PRECAUTIONS

- This product is provided NON-STERILE. Instruments must be properly cleaned and sterilized before each use.
- Automated cleaning might not be as effective as a thorough manual cleaning operation. The manufacturer recommends a manual cleaning process for best results. Any automated cleaning process should be performed in addition to a manual cleaning process.
- Appropriate personal protective equipment must be worn during handling and cleaning. Precautions in accordance with hospital procedures should be followed when handling contaminated or potentially contaminated instruments.
- 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. Only hospital trained personnel should be utilized for cleaning, care, and sterilization of devices.
- User should follow the World Health Organizations guidelines when handling instruments where there is concern of TSE/vCJD contamination.
- User must handle instruments with care to ensure no damage is done to instruments. When processing instruments do not place heavy devices on top of delicate instruments. Extra care should be taken when handling sharp, cutting edges to avoid injury to user as well as avoid damage to cutting surface.
- Do not allow instruments to dry after use and prior to processing.
- Long, narrow lumens require special care and attention during cleaning.
- Cleaning/disinfection agents containing chloride, iodide, bromide, high alkaline, or high pH can be corrosive to stainless steel instruments and should not be used. User must ensure cleaning agent used is acceptable for stainless steel instruments.
- Only use soft bristled brushes and pads for scrubbing instruments. Metal brushes or scouring pads can damage instruments.
- User must ensure that all cleaning and sterilization equipment used for reprocessing has been properly maintained and calibrated.
- Instrument cases and trays do not maintain sterility. An FDA-cleared sterilization wrap must be used in conjunction with case and tray to maintain sterility.
- User must carefully inspect each instrument prior to use to ensure there is no damage that would affect functional use of device.
- Failure to follow cleaning and sterilization instructions may result in inadequate cleanliness and sterility.
- Substitute devices (drills, reamers, etc.) should not be used in lieu of BioPoly instruments.

INTENDED USE

All BioPoly instruments are intended to facilitate the surgical techniques used to implant the BioPoly implantable devices. These instructions apply to all reusable instruments that are initially sold nonsterile and require the user to process them before initial and after subsequent use.

INDICATIONS/CONTRAINDICATIONS

Indications and contraindications are provided in the BioPoly Implant *Instructions for Use (IFU)* package insert

LIMITATIONS ON REPROCESSING AND DISPOSAL

Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use (i.e. dull cutting edge, burrs, etc.). Instruments are not to be reconditioned. For safe disposal, follow cleaning and sterilization per instructions, and then dispose in accordance with local statutes and regulations. Nails, reamers, cutting cannulas, and reaming cannulas should be discarded in a designated sharps container. If damage or wear is noted that may compromise the function of the instrument, contact distributor for a replacement.

POINT OF USE

Instruments should be reprocessed as soon as possible following use. Remove excess body fluids and tissue with disposable cloth. Do not allow body fluids to dry on instrument prior to cleaning. Upon wiping off excess tissue, keep instruments moist until they can be thoroughly cleaned.

CONTAINMENT AND TRANSPORTATION

Used instruments must be transported to the processing location in a closed or covered container to prevent contamination risk.

MANUAL CLEANING/DISINFECTION:

1. Prepare detergent according to manufacturer's recommendations. Submerge the device(s) in the detergent and soak for minimum of 10 minutes. Soak longer if manufacturer recommends a soak time longer than 10 minutes.
2. Scrub the submerged device(s) with a soft sponge and agitate. Use a pipe cleaner/brush to thoroughly clean any lumens. Repeat step 1 and prepare fresh cleaning solutions when existing solutions become grossly contaminated (bloody and / or turbid).
3. Rinse in warm (38°C - 49°C) clean water for 1 minute. Thoroughly flush any lumens using a syringe.
4. Ultrasonically clean the device(s) for 10 minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
5. Rinse the device(s) with deionized or purified water for 1 minute, flushing the lumen using a syringe. Repeat rinse twice. Tap water should not be used for this step.
6. Repeat ultrasonic cleaning and rinse operations in steps 4 and 5.
7. Dry the device(s) thoroughly with a clean, lint free cloth.
8. Visually inspect the device(s) for cleanliness. Repeat this cleaning procedure if the device(s) appears to be soiled or contains residue after the initial cleaning until there is no sign of soil or residue on the device(s).

AUTOMATED CLEANING/DISINFECTION

1. Rinse the device(s) under running cold tap water to remove excess soil.
2. Prepare an enzymatic detergent bath (Valsure Enzymatic Cleaner or acceptable alternative) using warm tap water.
3. Fully immerse the device(s) in the detergent bath for 2 minutes.
    - While immersed, brush the device(s) using a soft bristled brush.
    - While immersed, use an appropriately sized lumen brush to brush the lumen as appropriate.
    - While immersed, use a syringe filled with the detergent solution to flush the lumen as appropriate.
4. Remove the device(s) from the detergent bath and rinse them under running tap water.
5. Visually inspect the device(s) for cleanliness. Repeat this cleaning procedure if the device(s) appears to be soiled or contains residue after the initial cleaning until there is no sign of soil or residue on the device(s).
6. Transfer the devices(s) onto an appropriate rack system contained inside the washer for processing.
    - Arrange instruments so that cannulations are not horizontal and blind holes incline downwards to assist cleaning and drainage.
7. The following minimum parameters are essential for thorough cleaning and disinfection

Phase	Time	Temperature	Detergent
Pre-wash 1	2 min	Cold tap water	N/A
Enzyme Wash**	1 min	Hot tap water	Enzymatic detergent ¼ oz./gallon
Wash 1	2 min	64°C (147.2°F) Tap water (Set Point)	Neutral pH cleaner ¼ oz./gallon
Rinse 1	15 sec	Hot tap water	N/A
Pure Water Rinse	10 sec	64°C (147.2°F) RO/DI water	N/A
Dry Time	7 min	115°C (239°F)	N/A

**Ensure to program an extra enzyme rinse

Note: The washer manufacturer's instructions should be adhered to. Use only cleaning agents recommended for the specific type of automated washer. A washer with approved efficacy (FDA-cleared and validation according to ISO 15883) should be used.

DRYING
Remove excess moisture from the instrument with clean filtered compressed air or a clean, lint free cloth.

INSPECTION AND MAINTENANCE
Inspect all instruments prior to use. If contamination is noted repeat the cleaning/disinfection process. Generally, unmagnified visual inspection under good lighting conditions is sufficient.

PACKAGING
Individual : Place device in standard packaging material (pouch or wrap) that is FDA-cleared for steam sterilization. Ensure pouches are large enough to contain the device without stressing the seals.

Sets: Load devices in designated tray. The sterilization is validated with the instruments placed and positioned in the predetermined placement locations. If devices are added, the user is responsible for validation of the new layout. Trays with lids should be double wrapped in FDA-cleared medical grade steam sterilization wraps.

STERILIZATION
The following are the recommended minimum double-wrapped, steam sterilization procedures validated by BioPoly LLC in accordance with ISO 17665-1 to produce a 10^{-6} sterility assurance level (SAL). It is the responsibility of the user to ensure hospital procedures are validated and can produce equivalent sterility. Sterility testing by BioPoly LLC has been validated with 1 instrument set. If multiple sets are being sterilized at the same time, or if processing conditions, wrapping material, or equipment changes occur, the user must ensure the effectiveness of the sterilization process.

Cycle Type	Minimum Processing Time	Minimum Temperature	Minimum Dry Time
Pre-vacuum	4 minutes	132°C (270°F)	20 minutes

**Steam sterilization is recommended method for all BioPoly reusable devices. Ethylene Oxide, gas plasma, and other sterilization methods should NOT be used.*

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

STORAGE
- Sterile 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.
- Keep away from walls, floors, and ceilings.
- Sterile packaging should be inspected prior to use to ensure packaging has not been damaged and sterile barrier has not been compromised. If there is evidence of damage or tampering, the device(s) should be repackaged and sterilized.
- A maximum shelf life (expiration date) for sterilized reusable instruments should be defined by each healthcare facility based on recommendations of the wrap manufacturer.

CAUTION
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Report any serious incident related to the devices to info@biopolyortho.com

REFERENCES

- AAMI TIR12: Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
- AAMI TIR30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AAMI TIR34: Water for the reprocessing of medical devices
- AAMI ST77: Containment devices for reusable medical device sterilization
- AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI ST81: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

REFERENCES CONTINUED

- ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements
- ISO 15883-1: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
- ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- Center for Disease Control: Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008)
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff
- WHO – World Health Organization: Guidelines on prevention and control of hospital associated infections

SYMBOL GLOSSARY

Symbol	Standard Reference	Symbol Title	Symbol Description
	ISO 15223-1; 5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1; 5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1; 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1; 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1; 5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1; 5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1; 5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109(b)	Prescription only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Standard Reference:

- ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General Requirements
- 21 CFR 801: Labeling

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