
Reusable Instrument Set

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 approved 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 PURPOSE

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

PERFORMANCE CHARACTERISTICS

The respective BioPoly RS reusable instruments are designed to be used with the corresponding BioPoly RS Partial Resurfacing implants. See Implant IFU.

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 (e.g. CE mark, 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 approved 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 approved 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

- This device is intended to be used by a physician.
- Report any serious incident related to the devices to info@biopolyortho.com and competent authority of Member State.

CLINICAL BENEFITS

The instruments do not provide direct clinical benefits to patient, as it is the implant that provides the clinical benefits. See implant IFU.

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
- HTM-01-01: Management and decontamination of surgical instruments (medical devices) used in acute care

SYMBOL GLOSSARY: **MD** – Medical Device



Knee Set 115-5500

Part Number	Description
115-2010-01	15/20mm Femoral Drill Guide
115-2010-02	15x24mm Femoral Drill Guide
115-2030-03	15mm Cutting Cannula
115-2030-04	15mm Inner Guide Tube
115-2030-05	20mm Cutting Cannula
115-2030-06	20mm Inner Guide Tube
115-2030-07	15mm Reaming Cannula
115-2030-08	20mm Reaming Cannula
115-2040-02	15mm Trial
115-2040-03	20mm Trial
115-2040-04	15x24mm Trial
115-2050-03	15/20/15x24mm Insertion Tamp
115-2060-01	Implant Extractor Tool
115-2070-01	15mm Inserter
115-2070-02	20mm Inserter
115-2070-03	15x24mm Inserter



Patella Set 125-5500

Part Number	Description
115-2020-13	Depth Probe
125-2015-03	15mm Pat. Reaming Cannula Sz 0
125-2015-04	15mm Pat. Reaming Cannula Sz 1
125-2015-05	15mm Patella Trial Drill Guide
125-2020-03	20mm Pat. Reaming Cannula Sz 0
125-2020-04	20mm Pat. Reaming Cannula Sz 1
125-2020-05	20mm Patella Trial Drill Guide



Part Number	Description
125-2015-01	5mm Stem Drill
125-2015-02	15mm Patella Reaming Trial
125-2020-01	7mm Stem Drill
125-2020-02	20mm Patella Reaming Trial

Trochlea Set 115-5600

Part Number	Description
115-2100-01	Trochlea Drill Guide – Standard
115-2100-02	Trochlea Drill Guide – Shallow
115-2100-03	Trochlea Drill Guide – Dysplasia
115-2100-04	Trochlea Size Gauge
115-2100-05	Trochlea Punch
115-2100-06	Trochlear Insertion Tamp
115-2100-07	Trochlea Implant Holder
115-2115-01	15mm Trochlea Guide Tube
115-2115-02	15mm Trochlea Cutting Cannula
115-2115-03	15mm Troch. Ream. Can. – Stand.
115-2115-04	15mm Troch. Ream. Can. – Shal.
115-2115-05	15mm Troch. Ream. Can. – Dys.
115-2115-06	15mm Trochlea Punch Guide
115-2115-07	15mm Trochlea Trial – Standard
115-2115-08	15mm Trochlea Trial – Shallow
115-2115-09	15mm Trochlea Trial – Dysplasia
115-2115-10	15mm Trochlea Inserter
115-2120-01	20mm Trochlea Guide Tube
115-2120-02	20mm Trochlea Cutting Cannula
115-2120-03	20mm Troch. Ream. Can. – Stand.
115-2120-04	20mm Troch. Ream. Can. – Shal.
115-2120-05	20mm Troch. Ream. Can. – Dys.
115-2120-06	20mm Trochlea Punch Guide
115-2120-07	20mm Trochlea Trial – Standard
115-2120-08	20mm Trochlea Trial – Shallow
115-2120-09	20mm Trochlea Trial – Dysplasia
115-2120-10	20mm Trochlea Inserter



Part Number	Description
125-2020-01	3.2mm Pilot Nail Trocar Tip
115-2021-01	3.2mm Pilot Nail Trocar Tip Long
115-2020-03	15mm Cannulated Reamer
115-2020-04	20mm Cannulated Reamer
115-2060-02	2.4mm Extractor Drill

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