Item Decription:
Iteme Number:

INNOMED, INC.

CE XXXX

Innomed, Inc.
103 Estus Drive
Savannah, GA 31404-USA
Toll free: 1-(800) 548-2362
www. innomed.net
Indicate RMA # on Return Shipments

EC REP

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Devices

These instructions apply to all reusable instruments manufactured for Innomed, Inc. (Innomed). These instructions have been validated as being capable of reprocessing Innomed Inc. reusable surgical instruments. Cleaning and sterilization equipment vary in performance and must be validated accordingly. The reprocessing facility is responsible for routine verification and monitoring of all equipment, materials, and personnel to ensure the desired results are achieved. Any deviations from the following procedures must be evaluated for efficacy by the reprocessing facility to avoid potential adverse consequences.

Instructions for Use

Intended Use

This IFU is intended to assist health care professionals in safe use and handling practices, effective reprocessing and maintenance. Innomed instruments consist of manual surgical instruments and positioners for use in surgical procedures. Instruments should be used by healthcare professionals only in their intended design. Use of these instruments in other than their intended purpose may result in damage to the instrument or may adversely affect the patient. The instruments must be cleaned and sterilized prior to each use.

Innomed surgical devices are supplied non sterile

General Surgical Instrument Care, Handling, Maintenance, Sterilization, Cleaning, and Disinfection

Special instructions apply for the proper care and handling of instruments to ensure longevity.

- Check instruments for smooth action, jaw alignment, and signs of wear.
- Do not autoclave chrome plated instruments with stainless steel instruments.
- Do not use a multipurpose detergent to wash or soak your instruments. Use a specifically compounded low-suds detergent with a neutral pH. A sponge, cloth, or scrub brush can be used to thoroughly clean the instruments. Never use steel wool or abrasives for cleaning.
- Never use an acid rinse or expose bleach to stainless steel instruments.
- Rinse cleaned instruments with clean water to remove any detergent before sterilization.

Detergents designed for surgical instruments are specifically formulated to remove protein, organic debris and blood. The neutral pH balance will not damage stainless steel or tungsten carbide inserts. The solution is gentle enough for manual (hand) as well as ultrasonic cleaning.

Contraindications

None known

Warnings

⚠ Healthcare professions should be familiar with all product support literature and videos to perform procedures

These instructions have not been proven effective for sterilizing instruments contaminated with unconventional transmissible agents such as causative agents and Bovine Spongiform Encephalopathy. It should not be assumed that the methods described here are effective against such agents.

Cleaning is an essential pre-requisite to ensure effective sterilization. Lumens, blind holes, cavities, serrations, and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.

Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions. It is important to wear appropriate protective equipment and follow local infection control policies while handling contaminated instruments. Handle sharp instruments with care to avoid injury.

Caustic substances and those of high hydrogen ion concentration may cause corrosion and diminish instrument life. Instruments having anodized coatings are sensitive to highly alkaline substances, pH>9, and exposure to temperatures greater than 137ºC (279ºF) may promote material degradation. Distilled water is recommended for final rinsing.

Do not allow blood and /or debris to dry on surgical instrument as this may cause corrosion, rusting, or pitting.

Only legally marked medical devices, solutions and accessories should be used for reprocessing. Non absorbent tray accessories that may condensation to pool and extend drying times should not be used.

All non-sterile devices must be cleaned and sterilize prior to use. Always clean and sterilize surgical instruments according to the following instructions before returning to Innomed.

Product should be inspected before each use. Do not use if the product shows signs of damage such as cracking, deformation, and sharp edges.

Instrument Inspection

Visually inspect devices for damage and wear (e.g., corrosion, discoloration, nicks on cutting surfaces). If damage or wear is found, do not use and contact Innomed sales representative for disposition.

Limitations on Processing

Innomed does not define the maximum number of uses appropriate for re-usable instruments. The useful life of device depends on many factors including the method and duration of use, and handling between use. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

Processing/Reprocessing Instructions

Point of Use	• Remove visible debris immediately after use • Modular instruments assembled as part of surgery should be disassembled for cleaning. A modular instrument assembly is any instrument construct having two or more catalog number markings. • Remove visible soil with surgical wipes/sponges moistened with tap water. • Irrigate lumen, blind holes, cavities, serrations and joints with tap water. In order to ensure effective cleaning, do not allow soil to dry on instruments. Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in neutral enzymatic detergent solution or tap water to prevent drying and encrustation of surgical soil.
Preparation Before Cleaning	• No particular requirements
Cleaning -General Instruction	• The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies. Operate equipment in accordance with manufacturer's instructions and in consideration of any limitations of use. This use includes characteristics of certain types of instruments that require special handling, or which may not be adequately cleaned by the equipment. Select, prepare, and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration water temperature

	and quality. In order to prevent damage to instruments, use only neutral enzymatic detergents (pH 7-9). • During ultrasonic cleaning combine instruments made of similar metals in order to minimize the risk of ion transfer which may cause etching and pitting. • Modular instruments assembled as part of the surgery should be disassembled for cleaning. A modular instrument assembly is any instrument construct having two or more catalog number markings. • Sterilizations cases and trays must be inspected for soil and cleaned according to cleaning instructions below. • Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, concentration).
Cleaning-Manual	• Instruments must be thoroughly cleaned. Thorough cleaning is an essential prerequisite for effective steam sterilization. Disassemble instruments if applicable. • Rinse under cold running water to remove gross soil and debris. Actuate instruments while rinsing. • Prepare the cleaning Enzol® solutions by using 22.2 mL detergent + 3,785 mL tap water. • Immerse instruments in in prepared Enzol® solution for a minimum of one (1) minute. • Prepare Valsure® Neutral solution by using 5.5 mL +3,785 mL tap water and place in ultrasonic bath. Transfer the instruments to the ultrasonic bath and allow to sonicate while fully immersed for 15 minutes. • After sonication, while the instruments are in Valsure® Neutral solution, scrub the articles thoroughly using a soft bristled brush (Spectrum M-16 or equivalent). Pay close attention to hinges, crevices, seams, lumens, and any hard to reach places. Actuate, while brushing any moveable mechanisms such as hinged joints, box locks, and spring-loaded features to free trapped soil. • Rinse the instruments for a minimum of one (1) minute under running deionized (DI) water until all traces of the cleaning solution is removed. Give particular attention to any cannulations, blind holds, hinges, joints, and other hard to reach places. Actuate instruments during rinsing. • Flush any cannulations, blind spots, joints, and other hard to areas with 50 mL DI water. Perform the flush two (2) additional times for a total of three (3) times. • Dry the instruments with a clean, lint free cloth.

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- Visually inspect each instrument for soil. If any remains, repeat the procedure.

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<tr><td>Cleaning-
Automatic</td><td>

- An automated cleaning process of equal effectiveness to the manual cleaning methods may be used. Manual cleaning prior to automated processing is necessary. Follow the manual cleaning instructions above. Follow instructions for washer manufacturer and detergent manufacturer. Instruments must be thoroughly cleaned. Thorough cleaning is an essential prerequisite for effective steam sterilization.
- Disassemble instruments if applicable, and load in washer so that the design features are exposed to cleaning.
- Devices capable of holding liquids should be loaded do that the design feature can drain.
- Ensure that the washer is filled with dunnage to simulate a full load. Use the following validated guidelines.

<table>
<tr><td>Phase</td><td>Time (MM:SS)</td><td>Temp. (ºC)</td><td>Detergent</td></tr>
<tr><td>Prewash</td><td>2:00</td><td>Cold Water</td><td></td></tr>
<tr><td>Wash</td><td>3:00</td><td>60+/-5ºC</td><td>Enzol®</td></tr>
<tr><td>Rinse</td><td>0:15</td><td>60+/-5ºC</td><td></td></tr>
<tr><td>Final Rinse</td><td>1:00</td><td>80+/-5ºC-DIW</td><td></td></tr>
<tr><td>Dry Time</td><td>6:00</td><td>$\geq$ 80ºC</td><td></td></tr>
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<tr><td>Disinfection</td><td>

- Instruments must be terminally sterilized prior to surgical use. See sterilization instructions.

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<tr><td>Packaging</td><td>

- Assembly components in their respective tray positions and place lid on tray. Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all surfaces in order to ensure effective sterilization.
- Wrap entire tray in sterilization wrap material and apply label to indicate contents. Sterilization wraps must allow adequate steam penetration, aeration, and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States, only sterilization wraps cleared for marketing by the Food and Drug Administration should be used.

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<tr><td>Sterilization</td><td>

- May be accomplished by steam autoclave. Time and temperature parameters required to steam sterilize vary according to type of sterilizer. Refer to the

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	sterilizer's manufacturer's instructions and guidelines. Perform a pre-vacuum steam cycle using one of the following. Temperature — Exposure Time — Drying Time 132°C (270°F) — Four (4) minutes — Thirty (30) minutes 134°C (273°F) — Three (3) minutes — Twenty (20) minutes • Do not stack instrument cases in the sterilizer • Ensure autoclave equipment achieves and maintains the proper time, temperature and pressure • Equipment should be operated in accordance with the manufacturer's instruction • When sterilizing multiple instrument sets in one autoclave cycle, ensure the maximum load stated by the equipment manufacturer is not exceeded.

Storage

 Dry instruments completely prior to storage. Store instrument in in dry, clean, well-ventilated environments away from floors, ceilings, and outside walls. Do not stack instruments.

Equipment Returns: Hospital Responsibilities

All loaner and trial equipment returns must be fully processed before shipping to Innomed, Inc. 103 Estus Drive, Savannah, GA 31404. Hospital must indicate cleaning/sterilization of instruments on return package. RMA must be referenced on outside of package.

Warranty

One year for defective instruments. Innomed's instruments are designed for a specific purpose and should be used accordingly. Warranty is void if instrument has not been properly maintained.

Return Policy

Undamaged instruments are returnable for full credit within thirty (30) days of purpose.

Manufacturer Contact

For additional product information, please contact customer service: info@innomed.net

Symbol Legend:

 Manufacturer	 European Authorized Representative	 Conformity Mark	 Warnings/Precautions	 Supplied Non-Sterile	 Keep Dry/Protect from Moisture