

The reprocessing instructions provided in this document were developed in accordance with ISO 17664 and are compatible with healthcare facility practices described in ISO 15883 (washer-disinfectors) and ISO 17665 (moist heat sterilization).

IMPORTANT INFORMATION

This device is intended for use by trained healthcare professionals. The treating physician is responsible for the clinical application. The manufacturer does not provide recommendations regarding specific surgical techniques.

Failure to follow these instructions may compromise device performance and patient safety.

1. Device Description

Reusable endoscopic micro instruments are intended for minimally invasive surgical procedures. Instruments may include scissors, graspers, dissectors, and electrosurgical devices. Components may include handle, shaft, insert, and insulated outer tube.

2. Intended Use

Intended for cutting, grasping, dissection, and coagulation of tissue during endoscopic procedures.

3. Contraindications

- Do not use outside intended endoscopic procedures
- Do not use in flammable or explosive environments
- Use caution in patients with implanted electronic devices

4. User Qualifications

For trained healthcare professionals experienced in endoscopic procedures.

5. Device Condition Upon Delivery

- Supplied non-sterile
- Must be cleaned, inspected, and sterilized before use

6. Warnings and Precautions

General Warnings

- Do not use damaged or malfunctioning instruments
- Inspect insulation before each use
- Ensure proper grounding and equipment setup

Electrosurgical Safety

- Use the lowest effective power setting
- Avoid activation in an open circuit
- Avoid contact with other instruments during activation
- Ensure proper neutral electrode placement
- Use compatible high-frequency (HF) equipment

Risks of Electrosurgery

- Thermal damage, including burns or tissue necrosis
- Increased collateral tissue damage compared to scalpel use
- Electrical injury due to insulation failure

7. Reprocessing Instructions

Reprocessing instructions developed in accordance with ISO 17664 and compatible with ISO 15883 washer-disinfectors.

7.1 Pre-Cleaning

- Remove gross debris immediately
- Do not allow soil to dry
- Rinse with cold water

7.2 Disassembly

- Disassemble all components prior to cleaning

7.3 Manual Cleaning

Prepare a detergent solution in accordance with the detergent manufacturer's instructions.

1. Immerse the disassembled instruments in the prepared detergent solution for a minimum of 1 minute.
2. Clean all external surfaces using a soft, non-metallic brush. Pay particular attention to joints, interfaces, serrations, and hard-to-reach areas.
3. Remove instruments from the detergent solution.
4. Rinse thoroughly under lukewarm running potable water to remove detergent residues.
5. Repeat the rinsing process a minimum of three times to ensure complete removal of cleaning agents.
6. Visually inspect all components for residual soil.
7. Allow all components to drain completely.
8. Dry using a soft, single-use, lint-free cloth or sponge.
9. Ensure all internal lumens and cavities (if applicable) are dried using filtered compressed air.

7.4 Automated Cleaning

Place the pre-cleaned and disassembled instruments in a washer-disinfector compliant with ISO 15883.

The following cycle parameters are recommended:

1. Pre-rinse with cold potable water for a minimum of 2 minutes.
2. Enzymatic wash using detergent at manufacturer-recommended concentration for approximately 4 minutes at elevated temperature.
3. Neutralization phase for approximately 2 minutes at approximately 65°C.
4. Rinse with potable water for a minimum of 15 seconds.
5. Thermal disinfection at a minimum temperature of 93°C with appropriate holding time.
6. Drying phase for a minimum of 6 minutes at approximately 98°C.
 - Visually inspect all instruments for cleanliness
 - If visible soil remains, repeat the cleaning process
 - Ensure complete drying before sterilization

7.5 Drying

- Ensure complete drying before sterilization
- Use compressed air for lumens if required

7.6 Inspection and Functional Testing

- Inspect for damage, wear, and insulation defects
- Do not use if defects are present

7.7 Packaging

Ensure all instruments are clean, dry, and properly inspected prior to packaging.

Package instruments individually or in sets using suitable sterilization packaging systems, such as wraps, pouches, or rigid containers, in accordance with ISO 11607.

Packaging must allow for adequate sterilant penetration and effective drying.

Arrange instruments to prevent contact damage, bending, or stress during sterilization and handling.

Protect delicate components, tips, and insulated surfaces from mechanical damage.

Ensure packaging integrity is maintained throughout sterilization, storage, and handling. Do not use if packaging is torn, compromised, or wet.

8. Sterilization

The following steam sterilization parameters are recommended for reprocessing this device:

Method	Temperature	Exposure Time	Dry Time	Configuration
Pre-vacuum Steam Sterilization	132°C (270°F)	4 minutes	≥30 minutes	Wrapped

Devices must be thoroughly cleaned, rinsed, and completely dried prior to sterilization.

Sterilization should be performed using steam sterilization processes in accordance with ISO 17665 and applicable national standards.

The above parameters are based on recognized steam sterilization practices for reusable surgical instruments.

Healthcare facilities are responsible for validating sterilization processes in accordance with their equipment, institutional procedures, and applicable regulations.

9. Storage

Store instruments in a clean, dry, and controlled environment.

Maintain sterility of packaged devices until point of use. Packaging integrity must be inspected prior to use. Do not use if packaging is damaged, compromised, or wet.

Protect instruments from mechanical damage, dust, moisture, and direct sunlight.

Avoid exposure to extreme temperatures and humidity.

Store in a manner that prevents contact with other instruments or materials that may cause damage or contamination.

10. Maintenance

- Inspect after each cycle
- Lubricate moving parts if required
- Remove damaged instruments from service

11. Limitations on Reprocessing

Repeated reprocessing may result in wear and insulation degradation. End of life is determined by condition and functionality.

12. Responsibility

It is the responsibility of the healthcare facility and reprocessing personnel to ensure that all cleaning, disinfection, packaging, and sterilization procedures are performed in accordance with:

- Validated equipment and processes
- The facility's internal protocols and quality systems
- Applicable national regulations and recognized standards

The healthcare facility is responsible for:

- Validating reprocessing methods when alternative equipment or parameters are used
- Ensuring that instruments are clean, functional, and free from damage prior to use
- Verifying that sterilization conditions are appropriate for the load configuration

Failure to follow these responsibilities may result in ineffective reprocessing, device damage, or patient injury.

13. Standards and Guidance

Reprocessing, cleaning, disinfection, and sterilization of reusable medical devices should be performed in accordance with applicable healthcare facility policies and recognized industry standards.

The following standards provide guidance for the safe and effective processing of reusable medical devices:

- ISO 17664 – Information to be provided by the manufacturer for processing of medical devices
- ISO 17665 – Moist heat sterilization of healthcare products
- ISO 15883 – Washer-disinfectors
- AAMI ST79 – Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities

These standards are intended to support the development, validation, and routine control of reprocessing procedures.

Healthcare facilities are responsible for ensuring that their processes are compliant with applicable standards and regulatory requirements.