

Non-Conductive Coated Surgical Instruments

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

1. Device Description

Non-conductive coated surgical instruments are reusable manual surgical instruments manufactured from stainless steel and coated with an insulating material designed to reduce electrical conduction when used with electrosurgical devices.

Instrument types may include:

- Specula
- Retractors
- Forceps
- Hooks
- Tenaculums
- Rulers
- Other surgical instruments requiring electrical insulation during electrosurgical procedures

2. Intended Use

Non-conductive coated instruments are intended for use during surgical procedures where electrical insulation of the instrument is required when operating electrosurgical equipment.

Typical uses may include:

- Gynecological procedures
- LEEP procedures
- Colposcopy procedures
- Cervical biopsy procedures
- Other surgical procedures requiring insulated instruments

3. Contraindications

These instruments should not be used if insulation damage, exposed metal, or mechanical defects are present.

Refer to the electrosurgical generator manufacturer's instructions for additional contraindications related to electrosurgical procedures.

4. Warnings

- Excessive heat exposure, repeated sterilization cycles, or improper handling may degrade insulation over time.
- Inspect insulation before and after each use for cracks, nicks, cuts, dents, or exposed metal.
- Never use instruments with damaged insulation.
- Use of damaged insulation may result in electrical burns or shock.
- Avoid contact with sharp objects that may damage the insulation coating.
- If a device has been used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the device must not be reused and should be permanently removed from service.

Non-Conductive Coated Surgical Instruments**5. Precautions**

- Select instruments appropriate for the surgical procedure and patient anatomy.
- Avoid contact between coated instruments and sharp metal instruments.
- Coating wear at pivot points may occur during normal use.
- Inspect the instrument insulation regularly during the instrument life cycle.

6. Inspection Before Use

- Check insulation coating for cracks, tears, voids, or exposed metal.
- Inspect movable parts for proper mechanical function.
- Check for bent tips, burrs, or misalignment.
- Remove damaged instruments from service immediately.

7. Electrosurgical Safety

- Insulated instruments must only be used with properly functioning electrosurgical generators.
- Inspect insulation prior to each use.
- Avoid contact between energized electrodes and exposed metal surfaces.
- Failure to maintain insulation integrity may result in patient or operator injury.

8. Instructions for Use

- Select the appropriate instrument type and size.
- Position the instrument carefully to avoid damage to tissue or insulation.
- Use the instrument only for its intended surgical purpose.
- After the procedure, remove the instrument carefully and begin cleaning promptly.

9. Care and Handling

- Handle instruments individually to avoid damage.
- Do not stack instruments during cleaning or transport.
- Protect insulation coating and instrument tips from sharp objects.
- Keep track of components when disassembling instruments.

10. Pre-Cleaning

- Begin decontamination immediately after use.
- Keep instruments moist and do not allow blood or body fluids to dry.
- Rinse instruments under cool or lukewarm running water to remove gross debris.

Non-Conductive Coated Surgical Instruments**11. Cleaning**

- Wear protective gloves during cleaning.
- Use neutral pH enzymatic detergent.
- Immerse instruments completely during cleaning.
- Clean with a soft bristle brush to remove debris.
- Flush channels or tubing with cleaning solution if applicable.
- Rinse thoroughly with deionized water.
- Repeat cleaning if visible contamination remains.

Cleaning warnings:

- Do not use steel wool, wire brushes, or abrasive detergents.
- Do not soak instruments longer than two hours in any solution.
- Do not use bleach or chlorine-based cleaners.
- Ultrasonic cleaning is not recommended for insulated or coated instruments, as it may damage the coating and compromise electrical insulation.

12. Rinsing and Drying

- Rinse instruments thoroughly with deionized water.
- Dry instruments using a soft lint-free cloth.
- Use compressed air to dry channels or lumens if present.

13. Inspection and Preparation for Sterilization

- Inspect instruments for cleanliness and integrity.
- Verify insulation coating remains intact.
- Check mechanical function of hinges or joints.
- Remove damaged instruments from service.

14. Packaging for Sterilization

- Wrap instruments individually or place in sterilization trays.
- Protect coated surfaces from contact with other instruments.
- Ensure instruments are positioned to allow sterilant contact.

Non-Conductive Coated Surgical Instruments**15. Steam Sterilization Parameters**

Sterilization must be performed using validated steam sterilization cycles in accordance with ISO 17665 and applicable national standards.

Sterilization Method	Temperature	Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	30 minutes
Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes
Pre-Vacuum	134°C (273°F)	3 minutes	30 minutes

The above sterilization parameters are based on recognized steam sterilization practices in accordance with ISO 17665 and are compatible with healthcare facility sterilizers operating under applicable national standards.

16. Storage

- Store sterilized instruments in a clean, dry, dust-free environment.
- Protect insulation coatings from mechanical damage.
- Verify packaging integrity before use.

17. Limitations on Reprocessing

Repeated reprocessing has minimal effect on stainless steel surgical instruments.

However, coated, insulated, or surface-treated instruments may experience gradual degradation over time due to repeated cleaning, handling, and sterilization cycles.

End of instrument life is determined by wear, damage, coating degradation, or loss of function. Instruments must be inspected prior to each use and removed from service if defects are identified.

18. Disposal

Dispose of damaged instruments according to applicable hospital procedures and national regulations.

19. Warranty

These instruments are manufactured to meet high quality standards. Damage resulting from misuse, improper cleaning, or unauthorized modification may void the warranty.