Instructions for Use (IFU) Bipolar and Monopolar Forceps

1. Device Description

Reusable bipolar and monopolar electrosurgical instruments are designed for grasping, dissecting, and coagulating biological tissue during surgical procedures. These instruments are intended for use with compatible high-frequency electrosurgical generators.

Instruments may include insulated shafts, conductive tips, and various handle configurations depending on the intended surgical application.

Maximum Generator Output Voltage:

- Bipolar instruments: up to 500 Vp (depending on instrument type)
- Monopolar instruments: up to 2000 Vp

Use only with compatible electrosurgical generators.

2. Intended Use

These devices are intended for use by qualified healthcare professionals in surgical procedures requiring electrosurgical energy for coagulation, cutting, or tissue manipulation.

3. User Qualifications

This device is intended for use by trained and qualified healthcare professionals familiar with electrosurgical instrumentation, associated risks, and sterile processing procedures.

4. Device Condition Upon Delivery

Devices are supplied non-sterile and must be cleaned, inspected, and sterilized prior to initial use and before each subsequent use.

5. Warnings and Precautions

- Do not use if insulation is damaged, cracked, or worn.
- Do not use if instrument is bent, corroded, or otherwise damaged.
- Avoid contact with other instruments during activation to prevent unintended burns.
- Ensure proper connection to electrosurgical generator.
- Do not use in flammable or oxygen-enriched environments.
- Use caution in patients with implanted electronic devices (e.g., pacemakers).
- For monopolar operation, ensure correct placement of the neutral electrode to prevent patient burns.
- Activate electrosurgical energy only when the active electrode is in direct contact with target tissue and clearly visible.
- When not in use, place the instrument in an electrically insulated location away from the patient.

Reported Electrosurgical Risks:

- Unintended activation resulting in tissue injury or equipment damage
- Fire involving surgical drapes or flammable materials
- Burns caused by alternate current pathways
- Explosions in the presence of flammable gases
- Organ perforation or severe bleeding

Failure to follow instructions may result in patient injury or device malfunction.

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6. Point-of-Use

Immediately after use, remove gross contamination using a disposable, non-shedding cloth.

Do not allow blood, tissue, or debris to dry on the device.

If immediate cleaning is not possible, keep instruments moist using a cloth dampened with purified water or an approved holding solution.

7. Preparation for Cleaning and Transport

Disassemble instruments as applicable prior to cleaning.

Transport instruments in a closed container to prevent contamination and mechanical damage.

Avoid use of hot water (>40°C) and fixation agents prior to cleaning, as these may cause protein coagulation.

8. Manual Cleaning

Immerse instruments in a neutral pH enzymatic detergent prepared according to the manufacturer's instructions.

Allow instruments to soak for a minimum of 10 minutes.

Clean all external surfaces using a soft-bristled brush.

Clean internal channels or lumens using appropriate non-metallic brushes where applicable.

Flush all lumens thoroughly using a syringe or flushing device with purified water.

Repeat flushing a minimum of three times.

Rinse thoroughly with distilled or deionized water.

9. Ultrasonic Cleaning

Place instruments in an ultrasonic cleaner filled with enzymatic solution.

Ensure instruments are fully submerged and not in contact with each other.

Process for a minimum of 10 minutes.

Rinse thoroughly after ultrasonic processing.

10. Automated Cleaning and Disinfection

Use a washer-disinfector compliant with ISO 15883.

Example washer-disinfector cycle:

- Pre-rinse (cold water) – 1 minute
- Pre-rinse – 3 minutes
- Wash (≤55°C alkaline or 45°C enzymatic) – 5 minutes
- Neutralization – 3 minutes
- Rinse – 2 minutes

Thermal disinfection phase should reach ≥93°C.

Ensure instruments are adequately rinsed and dried at the end of the cycle.

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11. Drying

Dry instruments using a clean, lint-free cloth.

Filtered compressed air may be used to dry internal channels.

Ensure instruments are completely dry prior to sterilization.

12. Inspection and Maintenance

Inspect each instrument prior to sterilization and use.

- Check for cracks, fractures, or deformation.
- Inspect insulation for cuts, burns, or breakdown.
- Check for corrosion or discoloration.
- Verify proper function and alignment.

Do not use instruments that show signs of damage.

13. Packaging

Ensure instruments are clean and completely dry before packaging.

Disassemble instruments as applicable.

Package individually or in trays using validated sterilization packaging systems compliant with ISO 11607.

Protect instruments from mechanical damage during sterilization and storage.

14. Sterilization

Sterilization must be performed using validated steam sterilization cycles in accordance with ISO 17665.

Method	Packaging	Temperature	Exposure Time	Dry Time
Steam – Gravity	Single pouch	132°C (270°F)	15 minutes	20 minutes
Steam – Pre-Vacuum	Single pouch	132°C (270°F)	4 minutes	20 minutes

Discard instrument after suspected Creutzfeldt-Jakob Disease (CJD) exposure. These instruments have not been validated for prion decontamination processes.

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

Healthcare facilities are responsible for validating sterilization processes in accordance with their protocols.

15. Storage

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

Protect from dust, moisture, and mechanical damage.

Maintain sterility of packaged instruments until point of use.

16. Handling and Care

- Handle instruments carefully to avoid damage.
- Do not stack or overcrowd.
- Avoid contact with dissimilar metals.
- Use only compatible cleaning and sterilization processes.

Particular care should be taken to avoid damage to fine tips, insulation, and working ends.

17. Repairs

Repairs must only be performed by qualified personnel.

Instruments must be fully cleaned, disinfected, and sterilized prior to return for repair.

18. Disposal

Dispose of damaged or non-functional instruments in accordance with facility policies and applicable regulations.

19. Responsibility

It is the responsibility of the healthcare facility to ensure that reprocessing procedures are validated and that instruments are safe and functional prior to use.

20. Standards and Guidance

- ISO 17664 – Processing of health care products
- ISO 17665 – Moist heat sterilization
- ISO 15883 – Washer-disinfectors
- AAMI ST79 – Steam sterilization guidance

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