

Instruction for Use (Non-conductive Instruments & Specula)

Description/Intended Use:

These devices are reusable and are supplied non-sterile. Process through cleaning and sterilization prior to initial use.

Reuse:

We guarantee our products to withstand a minimum of 20 sterilization cycles when sterilized in accordance with the validated instructions contained herein. Care in use and handling can extend useful life.

Contraindications:

These devices should never be used when:

- There is visible evidence of damage to the exterior of the device such as cracked plastic or connector damage.
- These devices fail the inspection described herein.
- In the presence of flammable gases, liquids, and/or oxygen enriched environments.

Safety Tips:

- Use lowest possible power setting on electrosurgical unit capable of achieving desired surgical effect.
- Never allow the cables connected to these devices to be in contact with skin of the patient or operator during electrosurgical activations.
- Do not permit the cables connected to these devices to be parallel and in close proximity to the leads of other electrical devices.
- Always place unused electrosurgical accessories in a safe insulated location such as a holster when not in use.
- Inspect and test each device before each use.
- Discard devices that have reached their life expectancy.
- Activation of an electrosurgical device when not in contact with target tissue or in position to deliver energy to target tissue (fulguration) may cause capacitive coupling.

Inspection:

These devices should be inspected before and after each use. Visually examine the devices for obvious physical damage including:

- Cracked, broken or otherwise distorted plastic parts.
- Broken or significantly bent connector contacts.
- Damage including cuts, punctures, nicks, abrasion, unusual lumps, significant discoloration.
- Tips for damage, corrosion or misalignment condition.

Cleaning:

Remove any obvious debris accumulated during use from the device with a soft, non-metallic instrument cleaning brush plus mild detergent and sterile purified water solution. Rinse thoroughly with sterile, purified water until free of detergent residual and debris, then thoroughly dry using a sterile wipe, (Do not fully immerse in fluids).

Precautions:

- Do not scrape or scrub coated surface with abrasives.
- Do not use cervical brush to clean smoke tube.
- Do not overlap instruments in sterilization tray.
- Do not soak coated instruments in CIDEX or other caustic cold sterilization solutions.
- Do not use bleach.
- Do not place coated instruments in ultrasonic cleaner.

Sterilization:

Wrap each pair of instrument separately or place in a container so as to prevent instrument from contacting each other or other instruments.

- Steam: Steam autoclave at 250°F (121°C) for 20 minutes.
- Flash: Steam autoclave at 275°F (134°C) for 10 minutes.
- Gas (ETO): Follow manufacturer's guide for the unit which you are using.
- Pre-Vac: Steam autoclave at 270°-273°F (132°-135°C),
 Exposure Time (4 minutes), Dry Time (20 minutes)

Do not handle the device until they are thoroughly cooled. For maximum life of the product ETO sterilization is recommended.

Storage & Handling:

Non-conductive Instruments & Specula must be stored in a clean, cool and dry area. Protect from mechanical damage & direct sun light. Handle with extreme care.

Warrantv:

These products are guaranteed against material and workmanship. The warranty is null and void should damage occur as a result of improper handling use.

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