

Single Patient Use Electrosurgical Handpiece

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Description/Intended Use:

These devices are designed to be used as accessories in conjunction with the electrosurgical units and electrodes with which they are known to be compatible. Their use enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Maximum voltage is not to exceed 5.5 KV peak.

These devices are compatible with ConMed disposable standard and UltraClean[®] active electrodes.

Contraindications:

These devices should never be used when:

- There is visible evidence of damage to the exterior of the device such as cracked or damaged plastic or connector damage.
- These devices fail the inspection described herein.
- In the presence of flammable gases, flammable prep solutions or drapes, oxidizing gases such as Nitrous Oxide (N₂O), or in oxygen-enriched environments.
- Do not use monopolar electrosurgery on small appendages, as in circumcision or finger surgery.

Safety Tips:

- **Caution: Make sure to remove tip protector before using.**
- Use lowest possible power setting on the associated electrosurgical unit capable of achieving desired surgical effect. Activation time should be as short as possible.
- 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 associated electrosurgical accessories in a safe insulated location such as a holster when not in use.
- Inspect and test each device before use.
- After use this product may be a potential biohazard. Handle and dispose of as required by hospital policy and applicable law.

Inspection:

These devices should be inspected before 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, abrasions, unusual lumps, significant discoloration.
- Verify that the electrode is fully and securely seated in the handpiece before use.

The ability to effectively clean and re-sterilize this single patient use device has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the device.

Sterility guaranteed unless package has been opened, broken or damaged.

Assembled in Mexico

EC REP