PROGRESSIVE® MEDICAL

PMI PTFE Coated Disposable Electrosurgical Electrodes

WARNING

Danger: Explosion Hazard. Do not use electrosurgery in the presence of flammable anesthetics.
Fire Hazard. Both oxygen (O_2) and nitrous oxide (N_2O) support combustion. Watch for enriched O_2 and N_2O atmospheres near the surgical site, especially during head and neck surgery. Enriched O_2 atmospheres may result in fires and burns to patients or surgical personnel.

WARNING

Fire/Explosion Hazard: The following substances contribute to increased fire and explosion hazards in the operating room:

- Oxygen enriched environments.
- Oxidizing agents such as nitrous oxide (N_2O) atmospheres.
  - Verify all anesthesia circuit connections are leak-free before and during use of electrosurgery.
  - Verify endrotracheal tubes are leak-free and that the cuff seals properly to prevent oxygen leaks.
  - If an uncuffed tube is in use, pack the throat with wet sponges around the uncuffed tube.
  - If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.
- Alcohol-based skin prepping agents and tinctures.
  - Activate the electrosurgical unit only after vapors from skin prep solution and tinctures have dissipated.
- Naturally occurring flammable gases (such as methane) that may accumulate in body cavities.

WARNING

Fire Hazard: The sparking and heating associated with electrosurgery can provide an ignition source.
Observe fire precautions at all times:

- When using electrosurgery in the same room with flammable substances, prevent pooling of fluids and the accumulation of gases under surgical drapes or near the surgical site.
- Tissue build up (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen enriched environment such as in throat or mouth procedures. Eschar plus high oxygen may create embers. Keep the electrode clean and free of all debris.
- Facial and other body hair is flammable. Water soluble surgical lubricating jelly may be used to cover hair close to the surgical site to decrease flammability.

The electrode must fit completely and securely into the pencil. An incorrectly seated electrode may result in burns to the patient or surgical personnel.

WARNING

Fire Hazard: Always place the active electrode in a clean, dry, insulated safety holster when not in use.

- Electrosurgical accessories that are activated or hot from use can cause unintended burns to the patient or surgical personnel.
- Electrosurgical accessories may cause fire or burn if placed close to or in contact with flammable materials such as gauze or surgical drapes.

Confirm proper electrosurgical settings prior to and during a procedure. Use the lowest power settings to achieve the desired effect. If increased power settings are requested, check the patient return electrode and all accessory connections before major power setting adjustments.

CAUTION

This product is designed for non-continuous operation, with a duty cycle of 10 seconds ON, and 30 seconds OFF. Always use the lowest possible power setting that achieves the desired surgical effect. Use the active electrode for the minimum time necessary in order to reduce the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small appendages.

WARNING

Before use, examine the electrosurgical unit and accessories for defects. Do not use cables or accessories with damaged (cracked, burned, or taped) insulation or connectors.

WARNING

Do not modify or add to the insulation of active electrodes. Prior to and during operation, it is strictly prohibited to use metal instruments to grip the product's insulated layer, as this can damage the insulation and cause potential burns.

Activate the electrosurgical unit **only** when you are ready to deliver electrosurgical current and the active tip is in view (especially if looking through an endoscope).

Deactivate the electrosurgical unit **before** the tip leaves the surgical site.

The electrodes are intended for single use only. Safely **discard after use** to prevent injury to hospital personnel. These electrodes are not designed to withstand resterilization. **Do not resterilize.**

NOTICE

This electrode has a coating to reduce sticking of eschar. Cleaning the electrode with a scratch pad or other abrasive object, scraping with a sharp object, or bending beyond 90 degrees may damage the electrode. If the electrode is damaged, discard it.

Using coated electrodes at high power settings may cause damage to the coating. If the coating is damaged, discard the electrode.

Electrosurgical generators with contact quality monitoring technology to control output power, produce desired surgical effects at lower cut mode settings than conventional electrosurgical generators. The electrode coating may deteriorate when used with contact quality monitoring generators at higher power settings.

IMPORTANT

Wipe the electrode often with moist gauze or other non-abrasive material.

Instructions for Use –

1. Ensure the pencil is not connected to the generator.
2. Grasp the insulating sleeve on the electrode. Insert the electrode into the pencil.
3. Ensure the insulating sleeve fits securely inside the nose of the pencil so that the nose overlaps the insulating sleeve by at least 0.3cm (1/8").
4. A tip protector covers the coated end of some electrodes. If a tip protector is present, remove it before use.

Warranty

Progressive Medical Inc. warrants that this device meets all written specifications. **This warranty is in lieu of and excludes any and all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise.** Progressive Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly, arising from the use of this device. Replacement of a defective device is Progressive Medical's sole obligation and liability hereunder. Terms of sale, price, specifications and model availability are subject to change without notice.

PROGRESSIVE MEDICAL®

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CONSULT INSTRUCTIONS FOR USE

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