SKINTACT® HAND AND FOOT CONTROL PENCILS

PRODUCT DESCRIPTION

SKintact ESD Hand and Foot Control Pencils and Active Electrodes are sterile, single-use, disposable products intended for monopolar cutting and coagulating with various types of ESD generators.

WARNINGS

- Comply with packaging prior to use. Do not use if the sterile packaging has been opened, damaged, or wet. Sterility might be compromised.
- When not using active electrodes, place them in a holder in a clean, dry, noncontaminated and high-voltage area not in contact with the patient. Inadvertent contact with the patient or personnel may result in burns.
- Do not apply or suspend the carbon rod to the ESD generator to ensure there is no contact from one end cause a fire. Do not place them near in contact with inflammable or explosive materials (such as gas or oxygen).

CAUTION

- Do not use product after expiration date.
- Do not reuse.
- Do not reprocess.
- Prior to use, check the integrity of the cable. A breakage in the cable may result in arcing back at the patient or at the active circuit, with the consequences of burns on the patient or the hazard.
- Confirm proper electrical grounding setting before proceeding with surgery. The maximum permissible high frequency voltage for use is 4 kV. Use the lowest possible setting to achieve the desired surgical effect (this is important due to the potential of inadvertent burning at high voltages).
- The electrosurgical electrode should be in contact with tissue prior to turning on the power to the electrosurgical unit. A complete understanding of the principles of monopolar electrosurgical procedures is necessary to avoid shocks and burns to the patient.

INSTRUCTIONS FOR USE

Precautions:
- Confirm proper use: inspect packaging prior to use. Do not use if the sterile packaging has been opened, damaged, or wet. Sterility might be compromised.
- Sterile, single-use, disposable, remove product from package.
- Remove sheath from handle and cable.
- Remove the protection foil electrode. Check electrode for secure and tight fit in the pistol. Be also aware of this when changing the electrodes.
- Temporarily exchange handle, cable and plug for irregularities. Do not use if metal is visible. Defective product may cause arcing, which can result in patient or operator burns or can create a fire hazard.
- Plug the connector into the monopolar connecting adapter at the ESD generator or use the corresponding adapter.
- Never touch the patient’s cable in loops.

Applications:
- How to operate the electrosurgical generator relates to its instructions for use. In particular for power setting recommendations for various electrosurgical electrotechnical configurations, specific indications on output parameters, and activation duration to ensure that all safety precautions are followed.
- Confirm proper electrosurgical generator setting before proceeding with surgery. The maximum permissible high frequency voltage for use is 5 kV. Use the lowest possible setting to achieve the desired surgical effect (this is important due to the potential of inadvertent burning at high voltages).
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- For Hand Control Pencils:
  - To activate the CCG rod, press the yellow button or switch.
  - When not using active electrodes, place them in a holder in a clean, dry, noncontaminated and high-voltage area not in contact with the patient. Inadvertent contact with the patient or personnel may result in burns.
  - Do not place them near in contact with inflammable or explosive materials (such as gas or oxygen) to avoid a fire hazard.

Changing Active Electrodes:
- Before inserting, changing an electrode, be sure that the pencil is not connected to an electrosurgical generator or make sure that the generator is off (plugged).
- Grasp the electrode by the insulating sleeve and insert the round sleeve into the electrosurgical accessory until the insulating sleeve is fully inserted. The sleeve and the insulating sleeve should fit flint tight and securely into the electrosurgical unit. If the sleeve and insulating sleeve do not fit, or the insulator will not insert, do not use the pencil.
- Loops and wire electrodes are not designed for use in the coagulation mode. Do not activate the generator in coagulation mode while using a loop or wire electrode. Loops or wire electrodes may:

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