

**SKINTACT ESU HAND AND FOOT CONTROL PENCILS****PRODUCT DESCRIPTION**

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

WARNING

- Completely inspect package prior to use. Do not use if the sterile packaging has been opened, damaged or wet. Sterility might be compromised.
- When not using active accessories, place them in a holster in a clean, dry, nonconductive and highly visible area not in contact with the patient. Inadvertent contact with the patient or personnel may result in burns.
- Fire Hazard: Electro-surgical accessories that are activated or hot from use can cause a fire. Do not place them near or in contact with inflammable or explosive materials (such as gauze or drapes).

CAUTION

- Do not use product after expiration date !
- Do not reuse !
- Do not re-sterilize !
- 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 electro-surgical generator setting before proceeding with surgery. The maximum permissible high frequency voltage for use is 9 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 electro-surgical electrode should be in contact with tissue prior to turning on power to the electro-surgical pencil. A complete understanding of the principals of monopolar electro-surgical procedures is necessary to avoid shocks and burns to the patient.

INSTRUCTIONS FOR USE**Preparation:**

- Completely inspect package prior to use. Do not use if the sterile packaging has been opened, damaged or wet. Sterility might be compromised.
- Open the peel pouch and aseptically remove product from package.
- Remove sleeve from handle and cable.
- Remove tip protection from electrode. Check electrode for secure and tight fit in the pencil. Be also aware of this when changing the electrode.
- Thoroughly examine handle, cable and plug for irregularities. Do not use if product is defective. Defective product may cause arcing, which can result in patient or operator burns or can create a fire hazard.
- Plug the connector into the corresponding monopolar socket of the ESU generator or use the corresponding adaptor.
- Never lay the pencil's cable in loops.

Application:

- Prior to operating the electro-surgical generator refer to its instructions for use, in particular for power setting recommendations for various electro-surgical electrode configurations, for specifications on voltage output characteristics, and for activation duration to ensure that all safety precautions are followed.
- Confirm proper electro-surgical generator setting before proceeding with surgery. The maximum permissible high frequency voltage for use is 9 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 electro-surgical electrode should be in contact with tissue prior to turning on power to the electro-surgical pencil. A complete understanding of the principals of monopolar electro-surgical procedures is necessary to avoid shocks and burns to the patient.
- For Hand Control Pencils:
 - To activate the CUT mode, press the yellow button or switch.
 - To activate the COAG mode, press the blue button or switch.
- When not using active accessories, place them in a holster in a clean, dry, nonconductive and highly visible area not in contact with the patient. Inadvertent contact with the patient or personnel may result in burns.
- Do not place them near or in contact with inflammable or explosive materials (such as gauze or drapes) to avoid a fire hazard.

Changing Active Electrodes:

- Before inserting or changing an electrode, be sure that the pencil is not connected to an electro-surgical generator or make sure that the generator is off (standby).
- Grasp the electrode by the insulating sleeve and insert the round shank into the electro-surgical accessory until the insulating sleeve is fully inserted. The shank and the insulating sleeve should fit tightly and securely into the electro-surgical pencil. If the shank and/or insulating sleeve do not fit, or the insulation will not insert, do not use the pencil.
- Loop 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. Loop or wire breakage may occur.

	Do not use if the product sterilization barrier or its packaging is compromised		Do not reuse		Follow instructions for use		Sterilized Using Ethylene Oxide		Keep Away From Sunlight		Keep Dry		Temperature Limitation
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