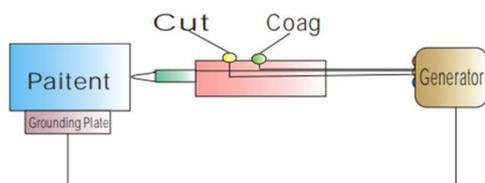


## 2. Structural and operational principles and intended use

Electrosurgical pencil are composed of cable with plugs, an pencil body external shell, a circuit board, switches(button), and electrodes (vary according to the type of surgery; sold separately). The high frequency surgical electrode is actually a switch selection circuit, in which the scalpel is connected to the high frequency device (generator) via the plugs, while the other two terminals of the plugs control the cutting and coagulation functions of the high frequency surgical device via the switches and conduct short circuit terminals on the high frequency surgical electrode. The button nearer the electrode is yellow, and controls the cutting function; the switch further from the electrode is blue, and controls the coagulation function.(see below figure)

Cut: yellow

Coag: blue



Electrosurgical pencil meet ingress liquid safety standards.

## Indication For Use

Electrosurgical pencil is intended to remove tissue and control bleeding by use of high frequency electrical current.

## 4、 Operation Instructions :

- 4.1 Check sealing pouch packing, don not use if have any damage,
- 4.2 Open package and place contents on sterile field, Securely attach the electrode to the electrosurgical pencil
- 4.3 Scrap the tore pouch,
- 4.4 Lock electrode in correct position via the hex lock facility Insert the electrode,
- 4.5 Conjoin the plug to the generator. Refer to the generator instruction manual for proper use
- 4.6 When not in use should be first off the high frequency of the host, pulled out the connecting line operation electrode, and away from the patients.

## 5、 Prohibition:

- 5.1 Don not use this device when the patient has heart pump or metal implant under tissue in operation
- 5.2 Banned for brain and heart surgery

## 6、 Precaution And Warnings

General:

- 6.1 Completely inspect package prior to use. Do not use if the sterile packaging has been opened or damaged.
- 6.2 Inspect the product before use. Do not use electrode if any nicks or cuts are present on the Insulation.
- 6.3 This product is supplied in a sterile package, for single use only, and is not designed for re-sterilization.
- 6.4 Securely attach all components before use.
- 6.5 Prior to use, check the electrode connection to the pencil you are using to ensure proper fit and compatibility. Improper electrode installation may result in injury to the patient or operating room personnel by arcing at the electrode and pencil connection. Ensure that there is no exposed metal in the connection part of the shaft and pencil of the electrode, and the electrical connection is good. Examine all devices to be connected to the electrosurgical generator.
- 6.6 Follow all instructions in the electrosurgical generator's manual. Refer to the generator's manual of instructions for power setting recommendations for various electrosurgical electrode configurations and specifications on voltage output characteristics to ensure that all safety precautions are followed.
- 6.7 Confirm proper electrosurgical generator setting before proceeding with surgery. Power setting guidelines may vary due to differences in surgical techniques, patients, electrodes, and surgical set-up. Use the lowest possible setting to achieve the desired surgical effect. (This is important due to the potential of inadvertent burning at high voltages.)
- 6.8 The electrosurgical electrode should be in contact with tissue prior to turning on the power to the electrosurgical pencil. A complete understanding of the principals of monopolar electrosurgical procedures is necessary to avoid shocks and burns to the patient
- 6.9 This product cannot be used for the cauterization of the mesosalpinx to effect sterilization.

## Fire Hazard:

- 6.10 The use of flammable anaesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a RISK of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.
- 6.11 Do not place them near or in contact with flammable materials (such as gauze or surgical drapes). Use a holster to hold electrosurgical pencils or similar accessories safely away from patients, personnel and surgical drapes. When not using active accessories, place in a holster in a clean, dry, nonconductive and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Notice:**

- 6.12 Loop and wire electrodes are not designed for use in the coagulation mode. Do not activate the generator in coag while using a loop or wire electrode. Loop or wire breakage may occur.
- 6.13 Before inserting or changing an electrode be sure that the active accessory is not connected to an electrosurgical generator or make sure that the generator is off (standby).
- 6.14 Grasp the electrode by using the insulating sleeve and insert the round shank into the electrosurgical accessory until the insulating sleeve is fully inserted. The shank and the insulating sleeve should fit securely into the active accessory. If the shank and./or insulating sleeve does not fit, or the insulation will not insert, use of the pencil is not recommended.
- 6.15 Patients can not contact all connected with the earth objects, such as: use of metal bed. Suggested spread insulating barrier in the patient's body. Patients with limbs to open, can not have cross contact.
- 6.16. In other equipment when used together, please note that the level of protection of other equipment must be of type CF, EMC type of protection into II groups A class.
- 6.17. For the high frequency current may flow through the surgery operation of human small cross-sectional area, is a good use of bipolar technology.
- 6.18. If used with other equipment, pay attention to the connection line and other equipment can not be wound.
- 6.18 If applicable, smoke suction devices should be used whenever possible during surgery with high-frequency electrosurgical device.
- 6.19 Products and expired after the use of the products, prohibit it, in strict accordance with the medical consumables management system for processing Order.
- 6.20 The device should be restricted to be used by a surgeon with relevant electrosurgical training.