

# Instruction Manual for Electrosurgical Pencil

**Note: Please thoroughly read the instruction before usage of product**

**【Introduction】**

Multifunctional Operational Dissectors is a high-frequency surgical equipment accessory which is adaptable to most brands of electrosurgical generators, it uses high frequency current to do cutting and coagulation which removes tissue and control bleeding. Some models of the electrosurgical pencils can be utilized for suction, remove blood, tissue debris or smoke from the operating area.

**【Product name】**

Multifunctional operational dissectors (electrosurgical pencils)

**【Contents】**

Multifunctional operational dissectors (electrosurgical pencils) is composed of electrodes, insulating material, plastic handle, hand-controlled button switch, cable, plug. Some models also include functional tubes and suction tubes.

**【Sterilization】**

The product is sterilized by ethylene oxide, for single use only.

**【Usage】**

Multifunctional Operational Dissectors are designed to remove tissue and control bleeding by the use of high-frequency current. Some models of the electrosurgical pencils can be utilized for suction, remove blood, tissue debris or smoke from the operating area.

**【Patient population】**

It is suitable for all patients who need to remove tissue and control bleeding.

**【Indications】**

To remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect. Several main models to remove blood, tissue debris, smoke.

**【Contra-indication】**

Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). There is a potential hazard due to the interference with electronic components of the implant, which may damage the implant.

**【Precaution and warnings】**

- 1.Thoroughly inspect the package prior to use. Do not use if the sterile packaging has been opened or damaged.
- 2.Inspect the product before use. Do not use if any nicks or cuts are presented on the insulation.
- 3.This product is sealed in a sterile package, for single use only, and not designed for re-sterilization.
4. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device which may result in patients' injury, illness, or death.
- 5.Multifunctional Operational Dissectors are monopolar electrodes and can only be operated when electrosurgical pad is attached with patients. Pay attention to the monitor during operation, proceed until the electrosurgical pad has been found to avoid a burn.
- 6.Prior to use, check the specs of the electrode being used to ensure a proper fit. Improper electrode installation may result in injuries to the patient or operating room personnel by causing electric arcing at the electrode/pencil connection. Make sure all devices are properly connected to the electrosurgical generator.
- 7.Follow all instruction of the electrosurgical generator's manual. Refer to the generator's manual for power setting recommendations of different type of electrodes.
- 8.Confirm proper electrosurgical generator setting before proceeding with surgery. Use the lowest possible setting to achieve the desired surgical effect. (This is crucial due to the potential of inadvertent burning at high voltage.)
- 9.Deactivate the electrode once the tip leaves the surgical site.
- 10.Regularly inspect cable for possible damage before use.
- 11.Patients should not be grounded or in contact with considerable capacitance to ground metal parts (such as: operating table, stent), therefore the use of anti-static panels is recommend.
- 12.Avoid the skin to skin contact. For instance, put a dry cloth between patient's arm and body.
- 13.The connecting wire of disposable electrode should avoid contact with the patient or other conducting wire. Temporary inactivated electrodes should be located apart from the patient.
- 14.The high frequency current may flow through the lower part of the cross section of the limb, in order to avoid unnecessary condensation, and it is best to use bipolar technology.
- 15.Should choose to be as low as possible to achieve the desired output power. And the ratio of the working time of the product (the longest continuous working time is 10s) to the stop time is 1:3.
- 16.In the normal work settings, the output was significantly reduced or surgical equipment can not work properly, may indicate that the bad or improper use of the neutral electrode.
- 17.If surgery is performed on the chest or head, it should avoid the use of flammable anesthetics and oxygen.
- 18.Patients with pacemakers or pacemaker electrodes, there may be a danger, because it may work for pacemaker interference, or pacemaker damaged, encounter suspicious circumstances, should consult the Department of Cardiology, in order to get help.
- 19.The interference produced by the operation of high frequency surgical equipment may adversely affect the work of other medical electrical equipment.
- 20.Products using ethylene oxide sterilization, the use of products according to the "medical waste management regulations" recycling and processing.

**【Product performance】**

1.Working conditions

Ambient temperature:10 ~ 40℃

Relative humidity: 30%~75%

2.Appearance

Electrode surface should be smooth, no burr, no obvious mechanical damage, deformation, front edge.

3. Safety Requirements

a. The high frequency dielectric strength of the electrode shall be in accordance with the requirements of the high frequency voltage of 1.2 times the rated accessory voltage (3000V) of the insulation used in the IEC60601-2-2.

b. The frequency of dielectric strength electrode with IEC60601-2-2 specified in the operative dissector insulation shall withstand voltage requirements than the rated accessories manufacturers of high frequency operation (3000V) high 1000V DC or peak power frequency voltage requirements.

4.Sterile

The electrodes in a single package are sterilized by an effective sterilization process.

5. Residual ethylene oxide

If the electrode using ethylene oxide sterilization, ethylene oxide residue is not greater than 10 ug/g.

**【EMC Performance】**

For the product to be taken relating to electromagnetic compatibility (EMC) of special precautions and must be installed and used according to EMC information provided in this manual. Portable and mobile RF communications equipment may have an impact on the product, you must use the mating connector cables and accessories provided by this product. Product should not be close to or stacked with other equipment, or if you must be close to, should be observed to verify normal operation in the configuration can its use.

**Basic properties:**

Name	specific description
CUT	And products supporting high-frequency output power and the actual host icon deviation should not exceed $\pm 20\%$
COAG	And products supporting high-frequency output power and the actual host icon deviation should not exceed $\pm 20\%$

Products meet the following tables 1 to 3 compliance requirements, so use of the product environment must also meet the following requirements, and can not exceed the following standard product testing environments.

( 1 ) EMI Compliance Form :

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	
Voltage fluctuations and flicker	IEC 61000-3-3 Complies	

( 2 ) EMS Compliance Form :

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	$\pm 8kV$ contact $\pm 2kV, \pm 4kV, \pm 8kV, \pm 15kV$ air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Electrical fast transients/bursts	IEC 61000-4-4	$\pm 2kV, 100kHz$ (AC power port) $\pm 1kV, 100kHz$ (signal input/output parts port)
Surges	IEC 61000-4-5	$\pm 0.5kV, \pm 1kV$ (line to line); $\pm 0.5kV, \pm 1kV, \pm 2kV$ (line to ground)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz; 6V in ISM band between 0.15MHz and 80MHz
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Voltage dips	IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT; 1cycle at 0° 70% UT; 25/30 cycles at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles

Table 3 -Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810		
870	800-960	Pulse modulation 18Hz, 28V/m
930		
1720		
1845	1700-1990	Pulse modulation 217Hz, 28V/m
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

**【Method of use】**

1. Insert the cable plug of the Electrosurgical Pencils into the socket hole corresponding to the High Frequency Electrosurgical Generators (see figure) : If the cable plug is olive and single-legged, insert it into the corresponding single-core socket on the panel of the High Frequency Electrosurgical Generators when used; If the cable plug for flat, three feet, insert it into the High Frequency Electrosurgical Generators when using the tripod socket on the panel. If the cable plug is two-pin, insert it into the corresponding two-pin bipolar mode socket on the panel of the high-frequency surgical equipment during use.
2. If it is unipolar working mode, the Electrosurgical Pencils must be used with the Disposable Electrosurgical Pads. Before the operation, please insert the connecting wire plug of the Disposable Electrosurgical Pads into the Disposable Electrosurgical Pads jack of the High Frequency Electrosurgical Generators, turn on the power switch, and check whether the contact is good.
3. When using the Electrosurgical Pencils with suction function, it is necessary to connect the suction tube at the end of the Electrosurgical Pencils with the supporting suction device, and check whether each connection is firm to prevent it from falling off during the operation.
4. Turn on the power switch and check whether the contact is good.
5. According to different surgical needs, set the corresponding power and aim the electrode tip at the body tissue that needs to be operated. Then according to the different functions required in the operation, the operator can start the corresponding function button to carry out the corresponding operation. If the retractable electrode is used, the electrode tip can be extended or retracted according to the needs of the operation to facilitate the doctor's operation.
6. The operation is completed, relevant personnel shall be in accordance with the "regulations on the administration of medical waste recycling and processing finished products use, do not arbitrarily discarded.

**【Product storage and transportation conditions】**

After packaging, the product should be stored in a clean, dark, non-corrosive gas and well-ventilated room.  
 Ambient temperature range:(-20~50)℃  
 Relative humidity range: ≤80%  
 Atmospheric pressure range: (70.0~106.0) kPa

**【Manufactured Date, Expiry Date】**

Manufactured Date: See label  
 Expiry Date: 3 years from the manufacture date.

**【Interpretation of medical device symbols】**

No.	Symbol	Title of symbol
1		Manufacturer
2		Authorized representative in the European Community
3		Date of manufacture
4		Use-by date
5		Batch code
6		Catalogue number

7		Sterile
8		Do not use if package is damaged and consult instructions for use
9		Do not re-use
10		Caution
11		Sterilized using ethylene oxide
12		Do not re-sterilize
13		Non-sterile
14		FRAGILE
15		Keep dry
16		Temperature limit
17		This way up
18		Single sterile barrier system with protective packaging inside
19		Consult instructions for use or consult electronic instructions for use
20		Medical device
21		Unique device identifier
22		This product has passed CE certification

Manufactured for Medical Disposables Corp.  
 6831 Edgewater commerce Pkwy Ste 1101  
 Orlando, FL 32810  
 Tel.(888)863-1112  
 Web:www.MedicalDisposables.us  
 Email: SurgicalDivision@MedicalDisposables.us  
 Made in China

**【Edition】**

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