EndoGuidance Monopolar Electrode Instruction for Use

The following information should be read before using this device.

INTENDED USE

The EndoGuidance Laparoscopic Monopolar Electrode is provided with unipolar electrosurgical capacity. This device is used in a variety of laparoscopic procedures to coagulate tissue, and does not contain latex.

SCOPE OF APPLICATION: This device is used for coagulate in minimally invasive surgery with high frequency surgical equipment. But except the following patient population: Patients with severe cardiopulmonary insufficiency, patient with blood coagulation disorders, patient with acute diffuse peritonitis, patient with abdominal adhensions.

CONTRAINDICATIONS:

This device is not intended for contraceptive coagulation on fallopian tissue. It may be used to achieve homeostasis following transaction of the fallopian tube.

DIRECTIONS FOR USE:

Insert the Hook through the desired 5mm trocar sheath to close to the tissue needing to be coagulated.

The device is equipped with a standard 4mm male plug connector. To operate the unipolar electrosurgical feature, please follow instructions provided by electrosurgical generator manufacturer. When the endoscopic procedure is complete, dispose this device in accordance with local regulations.

CAUTIONS/WARNINGS:

1. This device is single-used and can't be re-used or re-sterilized. Do not used if package is opened or damaged.
2. Only physicians with adequate training and knowledge of these procedures should perform endoscopic procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications, and complications prior to the performance of these procedures.
3. Before Endoscopic instruments and accessories from different manufacturers are utilized together in a procedure, verify compatibility and ensure that electrical isolation of grounding is not compromised.
4. A thorough understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.
5. This instrument should be used with U.L recognized unipolar electrosurgical generators, with capability of being activated with a foot control switch.
6. Keep the voltage power as low as possible to achieve the desired end effect. Refer to use instructions provided by the electrosurgical generator to ensure that all safety precautions are followed.
7. Using a metal trocar sheath in conjunction with a plastic site stability device creates a potential hazard when using electrosurgical instruments.
8. Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.
9. The highest voltage of the high frequency generator connected with the product is not more than

2500V.

10. suggested parameter adjustment:
    10.1 In the single cut mode, the generator is 50-100W, and the maximum is not more than 150W.
    10.2 In the single setting mode, the generator is 30-60W, and the maximum is not more than 100W.
    10.3 In the mixing mode, the generator is 40-80W, and the maximum is not more than 120W.
11. If it is found that the shell of the product or the insulating cortex is damaged or abnormal, do not use it.

Performance Spec:

Insert working length: 33±0.5cm

Max insert diameter: 5±0.15mm

Appearance roughness: Ra≤0.8um

Corrosion resistance: b level (YY/T 0149-2006)

Specification parameters of primary device High Frequency Generator：

General parameters:

Power supply：220V~ 50Hz

Rated Accessory Voltage: 3000Vp

Rated power：≤1100VA

Classification: Class I Type CF

Working mode: intermittent load and continuous operation. Duty cycle 10s/30s。

Maximum Power：350W， 500Ω load

Technical Parameter:

Normal operation:

Ambient temperature：5℃~40℃

Relative humidity：≤80

Atmospheric pressure：86.0~106.0Kpa

Power supply：220V±22V，50Hz±1Hz

Working frequency：416kHz

Rated output power：

cutting：1W~350W（500Ω load）；

dissecting 1：1W~250W（500Ω load）；

dissecting 2：1W~150W（500Ω load）；

spaying：1W~150W（500Ω load）；

soft coagulating：1W~120W（500Ω load）；

strong bipolar coagulating：1W~70W（500Ω load）；

power supply：5A 220V~±10%，50±1%Hz

Overall power consumption：≤1100VA （Dissection 300W）

EMC：

Guidance and manufacture's declaration – electromagnetic emission		
The active medical device is intended for use in the electromagnetic environment specified below. The customer of the user of the active medical device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The active medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic
RF emission CISPR 11	Class A	The active medical device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

1.This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3.Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4.Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

5. Active Medical Devices include below models:

EndoGuidance Laparoscopic Monopolar Electrodes: MDMPJ-33, MDMPL-33

Guidance and manufacture's declaration – electromagnetic immunity			
The active medical device is intended for use in the electromagnetic environment specified below. The customer or the user of active medical device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output ines	±1 kV for input/ output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%, 70%, 0% of UT	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	50Hz,60Hz 30A/m	50Hz:30A/m 60HZ:30A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The active medical device is intended for use in the electromagnetic environment specified below. The customer or the user of the active medical device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	150KHz to 80MHz 3Vrms ISM bands between 150KHz to 80MHz 6Vrms	3 Vrms 6Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the active medical device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80MHz to 2700MHz 10V/m (rms) 385MHz 27V/m (rms) 450MHz 28V/m (rms) 710MHz, 745MHz, 780MHz 9V/m (rms) 810MHz, 870MHz, 930MHz 28V/m (rms) 1720MHz, 1845MHz, 1970MHz 28V/m (rms) 2450MHz 28V/m (rms) 5 240MHz, 5500MHz, 5785MHz 9V/m (rms)150kHz~8	10V/m, 80% Am at 1kHz 27V/m PM at 18Hz 28V/m FM ± 5 kHz deviation at 1kHz sine 9V/m PM at 217 Hz 28V/m PM at 18Hz 28V/m PM at 217 Hz 28V/m PM at 217 Hz 9V/m PM at 217 Hz	recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35√p d=1.2√p 80MHz to 800MHz： d=1.2√p 800MHzto 2.5GHz： d=2.3√p Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the active medical device is used exceeds the applicable RF compliance level above, the active medical device should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the active medical device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the active medical device.

The active medical device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the active medical device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the activemedical device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance dinmetres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by

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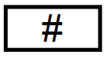
EndoGuidance
LAPAROSCOPIC MONOPOLAR

Symbol	Definition	Symbol	Definition
	No Latex		Expiry Date
	EO Sterilized		unique device identifier
	Do Not Reuse		Indicates the medical device manufacturer
	Do not use if package is damaged.		DEHP Free
	Do not reuse		Indicates a medical device is non-pyrogenic
	Consult Instruction for Use		Indicates the item is a medical device
	Model Number		This device is prescription only
	Lot Number		Indicates a single sterile barrier.
	Manufacture Date		Single sterile barrier system with protective packaging outside