DRAGON CROWN 龙冠

CE 2797

INSTRUCTION FOR USE

Surgical Electrodes

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Surgical Electrodes Instructions

1.Product Name

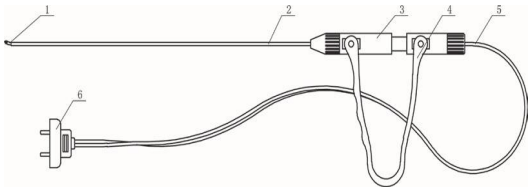
Surgical Electrodes

2.General Description

The Surgical Electrodes is a surgical instrument well-designed by our company's technicians. This product is used in conjunction with high-frequency surgical equipment in clinical practice. The product is in sterile packaging and disposable.

The composition of the surgical electrodes is shown in the figure below. The operator is a doctor who has received relevant training. Before use, it is necessary to carefully read this manual and master the safe operation methods of the product.

Model	DJ-I	DJ-II	DJ-III	DJ-IV
Spec	350	320	230	200



1. Electrode head 2 Outer tube 3 Electrode holder 4 Handle
5 Cable 6 Plug

4.Contraindications

Surgical Electrodes, as accessories for high-frequency surgical equipment, have the same contraindications as high-frequency surgical equipment. Patients who install pacemakers are prohibited from using them.

6.Note

a.The product is provided in a sterile state, please use it within the validity period. It is strictly prohibited to use if the packaging is damaged.

b.The foot switch can only be pressed when the electrode head extends out of the outer tube and the distance from the working channel exceeds 10mm.

c.Low output power should be used as much as possible when the goal can be achieved.

d.Temporarily unused Surgical Electrodes should be placed in isolation from the patient; To prevent contact with other leads of the patient.

e.Patients should not come into contact with grounded or metal objects with significant capacitance to the ground, such as surgical table brackets. Therefore, it is recommended to use anti-static partitions.

f.The skin-to-skin contact should be avoided, e.g., insert a piece of dry gauze between the arm and the body of the patient.

g.Before the operation by using high frequency surgical equipment, the solvent of the flammable detergent or adhesives should evaporate.Draw attention to the risk of the fire caused by the contained gases. Some materials such as the absorbent cotton full of oxygen or gauze may catch fire, caused by the sparks generated during the normal use of the equipment.

8.Warnings

a.The surgical process should be carried out under local anesthesia or conscious sedation conditions, with the aim of monitoring the signs of nerve root stimulation in the patient.

b.The product is not suitable for environments with flammable anesthetics mixed with air or oxygen or nitrous oxide.

c.During the operation, it is necessary to ensure continuous flow of physiological saline for irrigation.

d.This product may cause interference with the operation of pacemakers, other active implants, or other electronic devices carried by patients when used.

e.When connected to high-frequency surgical equipment, there is a hazardous electrical output, therefore, this product can only be used by qualified medical professionals.

f.Random disposal can cause environmental pollution, and should be handled in accordance with relevant national or industry regulations to avoid environmental pollution.

g.The maximum output voltage of high-frequency surgical equipment shall not exceed the maximum voltage of the Surgical

Electrodes.

h.When using high-frequency surgical equipment and physiological monitoring equipment simultaneously on the same patient, any monitoring electrodes should be kept as far away from this product as possible, and needle shaped monitoring electrodes are not recommended.

i.Before each use, it is necessary to check whether there are rough surfaces, sharp edges, or protrusions that pose safety hazards in the parts of the endoscope and endoscope accessories inserted into the human body.

J.When this product is used as an attachment for the endoscope and is interconnected with the endoscope, the eyepiece cover of the interconnected endoscope should be made of non-metallic materials. Before using the device, a compatibility check should be conducted between this product and the endoscope device.

K.When this product is interconnected with an endoscope, there may be a risk of increased leakage current in endoscopic patients.

l.The maximum rated repetitive peak voltage of both the endoscope and endoscope accessories is 750V, and higher repetitive peak voltage should not be used.

m.When this product is used with an endoscope, the insertion part of the endoscope may exceed 41 ℃. It is recommended that users shorten the continuous discharge time, extend the usage interval, and closely observe the surgical site for burns.

n.In all cases, it is recommended to use a monitoring system with high-frequency current limiting devices.

o.For the expected effect, choose the lowest possible output power. Some devices or accessories may pose safety hazards at low power settings.

The interference generated during the operation of high-frequency surgical equipment may have adverse effects on the operation of other electronic devices.

q.This product is for signal use only.Repeated sterilization poses a risk of equipment damage or cross-infection.

r.The device cannot cause death of any user or serious deterioration in health status.

s.This instruction manual must be read carefully before use.

t.The visible exposed metal parts at the connection between the electrode rod and the handle should avoid physical contact. Poor coordination or electrical connection between the handle and the electrode rod may have adverse effects on the operation of the equipment.

u.Do not allow modification of this equipment.

v：Please do not use if the packaging is damaged. Opening the packaging too early may pose safety hazards

9.Complications/Side Effects

a. Postoperative infection

b. Nerve damage

10. Storage

a.Work and operation

The product should be used in an environment with atmospheric pressure ranging from 70kPa to 106kPa, temperature ranging from 5 ℃ to 40 ℃, and relative humidity not exceeding 80%.

b.Storage and Transportation

The product should be stored indoors with atmospheric pressure ranging from 70kPa to 106kPa, ambient temperature ranging from -15 ℃ to 45 ℃, relative humidity not exceeding 80%, no corrosive gases, and good ventilation.

Transport under conditions of atmospheric pressure ranging from 70kPa to 106kPa, ambient temperature ranging from -15 ℃ to 45 ℃, and relative humidity not exceeding 80%. Protect from rain, avoid placing sharp objects together, and ensure that the packaging is undamaged.

11.Main technical parameters

a.Telescopic stroke: 13mm Maximum deviation of electrode head: ≥ 7mm

b.Working part size: Length: 350mm Diameter: 2.5mm、Length: 320mm Diameter: 2.5mm、Length: 230mm Diameter: 2.5mm、Length: 200mm Diameter: 2.5mm

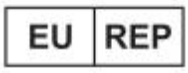
c.Product type: BF type

d.Operating mode: Not applicable (related to the accompanying high-frequency surgical equipment)

13.Adapted device parameter requirements

Parameters of high-frequency surgical equipment used in conjunction: the corresponding gear output power: ⩽ 120W Maximum output voltage: 750V Frequency: 100KHz-4MHz.

14.Explanation of graphics, symbols, abbreviations, etc. used in medical device labels/

Symbols	Explanation of graphics	Symbols	Explanation of graphics
	Model number		Temperature limit
	Manufacturer		Humidity limitation
	Ethylene oxide sterilization		Date of Manufacture
	Medical device		Batch Code
	Caution		Use-by Date
	Consult instructions for us		Storage atmospheric pressure limit
	Authorized representative in the European Community		Do not use if package is damaged
	Do not resterilize		Do not re-use
	BF type application part		Handle with care
	Be afraid of rain		Upward
	Avoid sun exposure		Single sterile barrier system

16.CMR or endocrine-disrupting substances

Cobalt above 0.1% (w/w) .

17. Warning information/

⚠ Warning/

Active medical devices are subject to special EMC precautions and therefore must be installed and used in accordance with these guidelines

⚠ Warning

Surgical Electrodes need to be installed and used based on the electromagnetic compatibility information provided in the accompanying documents.

⚠ Warning

Except for transducers and cables sold as spare parts for internal components by surgical electrodes manufacturers, the use of accessories, transducers, and cables outside of regulations can lead to an increase in equipment or system emissions or a decrease in immunity.

⚠ Warning

The device or system should not be used in close proximity or stacked with other devices. If it is necessary to use in close proximity or stacked, it should be observed and verified that it can operate normally in the configuration in which it is used. The use of surgical electrodes may cause interference with the operation of other electronic devices.

⚠ Warning

Portable and mobile communication RF devices may affect the use of medical electrical equipment.

⚠ Warning

Strong electromagnetic radiation sources may affect the normal operation of surgical electrodes, and should be kept away from strong electromagnetic radiation sources during use.

⚠ Basic performance

N/A

EU REP

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