

High-Frequency Surgical Electrode Operation Technical Instruction

Name of registrant/manufacturer: 233(HENAN)
TRADINGCO.,LTD

Product Standard No. : YZB Country /1512-
2014 High-frequency Surgical System

I. Overview

Before installing and using the product, please read the Technical Instruction Manual.

This manual combines "Instruction Manual" and "Technical Instruction Manual" for easy reading.

The performance parameters and safety indexes of high-frequency surgical electrodes are in line with GB9706.1-2007 <Medical Electrical Equipment Part I: General Safety Requirements" >and GB9706.4-2009 <Medical Electrical Equipment Part II: Special Safety Requirements for High-frequency Surgical Equipment>,GB/T16886.1-2011, <Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in the Process of Risk Management>, GB/T16886.5-2003, <Biological Evaluation of Medical Devices Part 5: In vitro Cytotoxicity Test ">, GB/T16886.10-2005 <Biological Evaluation of Medical devices Part 10 Stimulation and delayed hypersensitivity test>.

This product is equipped with high-frequency surgical system, which can be used for tissue dissection, blood vessel and tissue bundle coagulation in various clinical surgical operations.

II. Models and Specifications

The serial number	model	Outer diameter of insertion part (D, unit mm)	Effective length (L, unit mm)	Length of cable (Unit: mm)
1	SM1120	10	200	2800
2	SM1120w	10	200	2800
3	SM1100	10	370	2800
4	SM1100w	10	370	2800
5	SM1520	5	200	2800
6	SM1520w	5	200	2800
7	SM1500	5	370	2800
8	SM1500w	5	370	2800
9	CU1537	5	370	2800
10	CU1537w	5	370	2800
11	CU1517	5	200	2800
12	CU1517w	5	200	2800
13	AM1120	10	200	2800
14	AM1120w	10	200	2800
15	AM1100	10	370	2800
16	AM1100w	10	370	2800
17	AM1520	5	200	2800
18	AM1520w	5	200	2800
19	AM1500	5	370	2800
20	AM1500w	5	370	2800
21	CUT1537	5	370	2800
22	CUT1537w	5	370	2800
23	CUT1517	5	200	2800
24	CUT1517w	5	200	2800
25	SM3099	--	150	2800

III.Working Principle

Bipolar electrode, the tips are the poles of the bipolar, the high-frequency current flows between the two electrodes tips after the high-frequency generator output a certain waveform of high-frequency current , then directly acting on tissue.

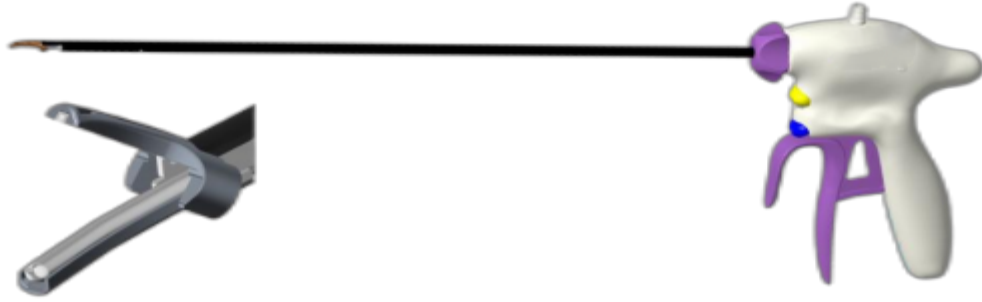
IV. Product components

This product is composed of a clamp core, a handle and a connecting wire.

V.Operation steps

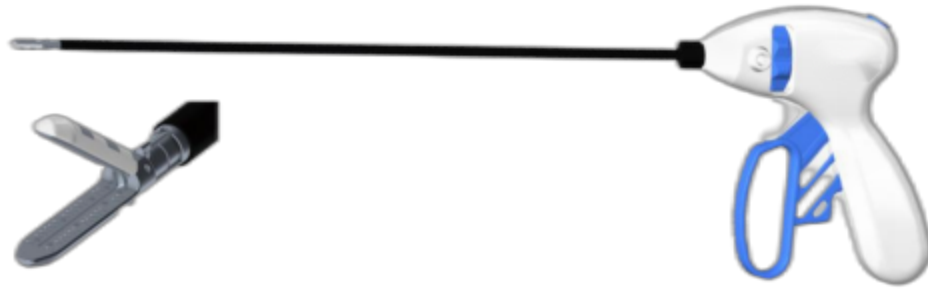
Connect the electrode to each ports on generator, the generator automatically identifies the device.





Operation steps:

- 1、 Connect to generator,if “ SUN ” is displayed on the screen, the identification succeeds;
- 2、 Clamp the blood vessels and tissues between the jaws (The purple rotating wheel can be rotating when the jaw is open or closed until the clamp is in the desired position) , clench the purple handle;
- 3、 Press the yellow/blue button for energy output , yellow one for higher-power sealing and cutting , blue one for low power sealing and cutting ;
- 4、 When the tissue is cut, loosen the purple handle to open the jaws, operation complete.



Operation steps:

- 1、 Connect to generator,if “SMA” is displayed on the screen, the identification succeeds;
- 2、 Push the handle forward to open the jaws completely;
- 3、 Clamp the blood vessels and tissues between the jaws (The blue rotating wheel can be rotating when the jaw is open or closed until the clamp is in the desired position) ;
- 4、 Clench the handle,release after a click sound, the jaw is locked at this point;
- 5、 Press the blue button at the top for energy output,you will hear a “didi” sound when the coagulation is completed;
- 6、 Clench the handle,release after a click sound,push forward the handle so the jaws can be open completely,operation complete.



Operation steps:

- 1、 Connect to generator,if "SMA" is displayed on the screen, the identification succeeds;
- 2、 Clamp the blood vessels and tissues between the jaws, the power output begins when the purple button is triggered,you will hear a "didi" sound when the coagulation is completed;
- 3、 Pull the rotatable trigger to cut the tissues.

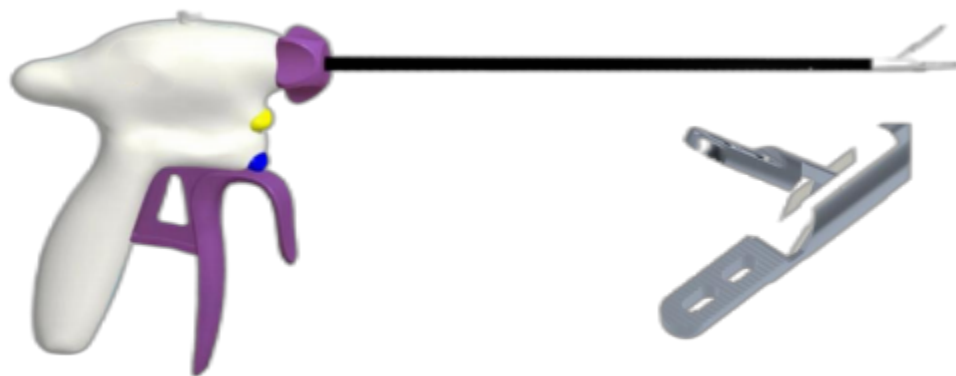


Operation steps:

- 1、 Connect to generator,if "CUT" is displayed on the screen, the identification succeeds;
- 2、 Clamp the blood vessels and tissues between the jaws (The purple rotating wheel can be rotating when the jaw is open or closed until the clamp is in the desired position) , clench the purple handle;
- 3、 Press the yellow/blue button for energy output, yellow one for sealing

and cutting (if press the button and clench the handle at same time ,the cut can be completed very quickly), blue one for sealing (can not cut,seal vessels within 5mm);

4、 When the tissue is cut/sealed, loosen the purple handle to open the jaws,operation complete.



Operation steps:

- 1、 Connect to generator,if “SMA” is displayed on the screen, the identification succeeds;
- 2、 Clamp the blood vessels and tissues between the jaws (The purple rotating wheel can be rotating when the jaw is open or closed until the clamp is in the desired position) , clench the purple handle;
- 3、 Press the blue button for energy output, you will hear a “didi” sound when the coagulation is completed;
- 4、 After the coagulation is completed, loosen the purple handle to open the jaws, operation completed.

VI.Contraindications

- 1) Severe cardiopulmonary insufficiency.
- 2) Blood coagulation disorder.
- 3) Acute diffuse peritonitis.
- 4) Extensive intraperitoneal adhesions.
- 5) Vessels larger than 7mm in diameter.
- 6) Tubal ligation or tubal condensation during sterilization.

VII.Warning

Flammable detergent or binder solvents should be evaporated before performing high-frequency surgery.

- 1) Flammable fluid buildup that exists under the patient's body or in the body cavity must be removed before using the device.
- 2) Some materials, such as cotton wool and gauze filled with oxygen, may be ignited by sparks generated by the normal use of the equipment in normal use.
- 3) If thoracic or cranial surgery is performed, inflammable anesthetics and oxidizing gases (e.g., nitrous oxide N₂O) and oxygen should be prevented.
- 4) Combustible reagents should not be used to clean or disinfect

electrode surfaces during surgery. If combustible reagents must be used for cleaning and disinfection, evaporate them before starting the main engine.

VIII. Disinfection of products

1) Ethylene oxide

Disinfection and sterilization parameters of ethylene oxide

Ethylene oxide action concentration	temperature	Relative humidity	time
450mg/L ~ 1200mg/L	37°C ~ 63°C	40% ~ 80%	1h ~ 6h

2) Low temperature plasma

Parameters of hydrogen peroxide low temperature plasma disinfection and sterilization

Hydrogen peroxide action concentration	Cavity wall temperature	cycle
> 6mg/L	45 ~ 65°C	28min ~ 75min

IX. Transportation and storage conditions

Temperature: -40°C to +70°C.

Relative humidity: 10%-100%.

Atmospheric pressure: 500hPa ~ 1060hPa.