Electrode for electrosurgical device
[EUSRA RF Electrode]

CE 0120

User's manual

1. Introduction

The electrode for this electro surgical unit is used by connecting with RF lesion generator from STARmed Co., Ltd. which was designed to coagulate tissues. Electrode to combine Instrument channel of the EUS probe and Scope to access body cavity can be coagulate tissues. Tissues can be coagulated with the supply of radiofrequency energy from electric cautery, which is connected for monitoring resistance of continuous tissues and temperature. The electrode is adjusted by the fixed part of insertion length the screw on handle from 0cm to 8cm units(1cm).

2. Guide for use

User should read all the information before using, and especially the user's guide provided with product should be carefully read. EUSRA RF Electrode is designed to be used by connecting with RF lesion generator from STARmed Co., Ltd. If the guidelines are not properly followed, damages by electricity or heat can be caused and the equipment might not properly operate.

3. Purpose of usage

It is a manually operated, disposable one, used for electrosurgical device like electric surgical unit and medical electric cautery. There are pen type and pencil type.

WARRANTY

STARmed Co., Ltd. warranties sufficient care for the design and manufacture of this device. We can not warrantee any content that is not described in this manual. Handling, storage and operation process of this device and other problems beyond STARmed's management directly affect depending on results obtained from its use.
STARmed's device under this warranty is limited to repair and replacement, and STARmed Co., Ltd. is not responsible for any economic expenditures caused by unexpected, significant loss or demage. STARmed Co., Ltd. is not transferring responsibility and duty related to this device to other parties, and will not take any responsibility regarding reuse, and usage of re-sterilized or expired products.

4. Warning

- Before using this product, check whether any damage exists in packaging.
- The expiration date is 3 years from the sterilization date, and using products after the expiration date is prohibited.
- This device is disposable and reuse is prohibited.
- This device is designed to be used by person who trained and qualified for operation.
- This device should be stored in cool place without sunlight and humidity.
- Do not touch the exposed tip of electrode while power supply is on.
- Do not touch the shaft of electrode with fingers or other tools (insulator and components of metallic response)
- Do not touch hand piece/ electrode cable with metallic materials. Patient or operator might get shocks, fire accident or injury.
- Do not use when cardiac pacemaker is placed within 4(four) meters.
- Do not use near conductive materials such as part of metallic bed or spring embedded mattress.
- Like all other electrosurgical units, do not use in the presence of flammable anesthetics, oxidation-reduction gas or other flammable substances. It might be a cause of fire of electrosurgical unit.
- Flammable gas or other materials with high risk of flames should be prohibited from being place nearby. If flammable detergent has been used for cleaning or disinfection, the liquid should be evaporated before procedure.
- Cloth soaked in oxygen and gauze can be flamed by sparks occurred from normal use of the device, thus

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cautions are required.
- Do not activate electrode while it is in touch with metallic substance or tools because it might be a cause of unexpected injury to patient.
- Do not touch metals or tools with the electrode while the power supply is on. It might be a cause of unexpected injury to patients and damage to electrode or other devices.
- When use the electrode, do not hold tip of electrode by tongs (ex. Kelly), do not pass the electrode through a hole of other device, and do not scratch to the surface on the electrode's tip by sharp things . These action might destroy the insulation of electrode and damage the end of the electrode. It might be a cause of unexpected injury to patients or user.
- Do not access to lesion independently. It might be cause of unexpected injury to patients and damage to electrode.

5. Potential complications

- Burning by overheating of surgical unit.
- Dangers from inexperienced operator's using.
- Side effects or cross infection from reuse.
- Weakness of liver functions.
- Delayed bleeding in the operated body parts.
- Recurrence of cancer.
- Syndromes after RFA treatment such as
- Perforation.
- Respiratory depression or arrest.

(abdominal) pain, fever, nausea, vomit, right shoulder joint pain and chest discomfort and headache might occur.

The Potential complications is not limited of the above, other complications may occur by using endoscope.

6. Before using

(1) Preparation of coolant

- The temperature of the coolant should be maintained at almost 0℃ by keeping IV bag in the refrigerator 4 hours or one day before procedure, and it is used just before performing the procedure.

⚠Caution : Do not put the Cooling liquid in a separate container. It can be blocked interior of the electrode by foreign substance.

(2) Grounding pads

⚠ Caution : Re-using grounding pad is prohibited.

⚠ Caution : Do not attach odd number of ground pad or attach pad in unbalance on the skin. It might burned by regressive current imbalance.

- After removing the transparent plastic protection films, attach the apse lines of grounding pads on the thighs widthwise.

- Be careful not to make air bubbles between grounding pads and skin while attaching, and hair waxing, skin cleaning and dry should be done if necessary.
- Attach the grounding pads at the same distance from treated area.
- The lines connected to grounding pads and electric surgical unit should not be twisted.
- Recommended attachment sites of the grounding pads are as follows- Body parts with clear blood vessels and muscle, convex surface of thigh
- The areas to be avoided for correct attachment of grounding pads are as below.

⚠ Caution : Fire injury, inflammation, fatty areas, protrusion with bones, ECG electrode and electric line, metal implanted part, liquid-containing part, pacemaker.

(3) Tubing set-up

- Connect electrode, input/output tubes and pump

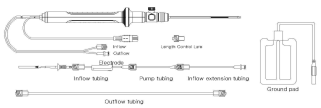
tubing.

⚠ Caution : Must be careful to remove the electrode from the packaging. Patient and the practitioner might be injured by elasticity of the product.

- Open the cover of pump head upside, place pump tube(rubber tube) in the middle of roller, and place the tube precisely at the groove of pump head. Then, fix the tube in the pump by closing the cover down.
- Strain both side of tube from a head and make straight it.
- Hang cold bag at the I.V. pole and poke the bag with the spike of input tube. Roller clamp is temporarily closed until before the procedure.
- Remove the roller clamp during procedure.

(4) Length Control Luer

- Use the Length Control Luer depending on combined length of channel for EUS probe and Scope.



7. During using

(1) Connect the RF lesion generator and electrode parts and check the connection status.

⚠ Caution : Before inserting the electrode in lesion, check if exposed length of the electrode and other specifications are identical with specifications on labels.

(2) Check the location of lesion after the EUS probe and Scope is inserted in the treated lesion.

⚠ Caution : Warning and how to use of the EUS probe and Scope refer to User manual.

(3)The fixed part of the insertion length should be lock the screw to zero point before Electrode is inserted Instrument channel of the EUS probe and Scope.

⚠ Caution : It might be damaged, when EUS Probe and Scope combine to electrode tip that out of sheath

(4) Connect the handle Luer after electrode is put in the Instrument channel of the EUS probe and Scope.

⚠ Caution : Do not control the tip length before the electrode was connected the EUS probe and Scope. It might be damaged.

(5) Adjust electrode to insertion length by loosening screw on handle, and advancing it until insertion reference mark. Tighten screw electrode lock.

⚠ Caution : Do not adjust electrode before tighten screw electrode lock. Tip of electrode might be damaged Perforation to unwanted parts of tissues.

(6) Check the location of lesion to be treated using the EUS probe and Scope, and place the electrode in the lesion.

(7) Once the electrode is placed in the lesion, check that cold liquid is flowing out from electrode's output tube by operating the pump connected with input tube, and then operate RF lesion generator by pressing the output switch.

⚠ Caution : Do not output by High Frequency before the tip of electrode is not cold. It can be occur to carbonization.

(8) Once the procedure is completed, turn off the power switch of the RF lesion generator and pump.

(9) The tip of electrode in sheath pull back into the handle, and the fixed part of the insertion length tighten screw electrode lock to zero point. The electrode separated from the Instrument channel of the EUS probe and Scope.

(10) Be careful to remove disconnected electrode from instrument channel.

⚠ Caution : Be careful the tip of the electrode can be injury to the patient and the practitioner when remove the electrode to the EUS probe and Scope.

(11) Follow the User's manual when remove the EUS probe and Scope from the patient.

8. After using

(1) Grounding pad

- When all the procedure is done, turn off the power switch of RF lesion generator and separate connectors of the grounding pads.
- Slowly remove the ground pads in order to prevent injury on the skin surface,
- Do not remove the ground pads by pulling the electric lines of ground pads,

(2) Upon completion of the procedure, turn off the power switch of RF lesion generator and separate electrode, parts and etc.

(3) Dispose the electrode used according to waste materials disposal procedure.

9. Storage

(1) Keep at room temperature.

⚠ Caution: This device is intended to be sold, used by order of doctor according to the related medical device laws.

10. Action for product demage

⚠ Caution: If any damage on product is visually noticed, do not use to prevent any injury to patient.

11. Expiration date : 3 years from sterilization

12. Symbol

EC REP	Europe deputy
	Temperature for storage
	Refer to users' guide
	Manufacturing Co.
REF	Model No.(Refer to label)
STERILE E.O	E.O. Gas sterilization
⚠	Caution, Refer to indications for use
	Expiration date
LOT.	Lot number
	Prevention of re-use
	Sterilization date

Reuse Precaution Statement

The contents of this product have been sterilized with E.O. gas. If sterilized package is damaged, not use it and call STARmed Co., Ltd.

This product can be used only one time. Reuse, re-treatment or re-sterilization is not allowed.

In case reuse, re-treatment or re-sterilization has been done, it might be a cause of defects in structural functions of electrode, and demage of RF lesion generator which might lead to injury, disease or death to patient. Reuse, re-treatment or re-sterilization can bring dangers of the device contamination, and infections among patients or from other diseases. Contamination of this device might be a cause of patients' injury, disease or death.

13. Descriptions

Manufacturer certificate no. : #2997
Manufactured goods certificate No.: To be written later.
Product name : Electrode for electrosurgical unit
Product name : EUSRA RF Electrode
Type name : Corresponding model number
Manufacture No. : Corresponding number
Date of manufacture : Corresponding year and date

Number of items : 1 set
Sterilization method : E.O. gas
Expiration date : 3 years from sterilization
Method of use : Refer to the manual
Purpose of use : Refer to the manual
Cautions in use : Refer to the manual
Method of storage : In dry place at room temperature
Name of manufacturing Co.: STARmed Co., Ltd.
※ This product is a disposable medical device and reuse is not allowed.

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