Electrode for electrosurgical device
[EUSRA RF Electrode]

User’s manual

1. Introduction
The electrode for this electrosurgical 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. Tissue 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(0cm).

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. warrants sufficient care for the design and manufacture of this device. We can not warrant 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 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 damage. 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 4bus) 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 placed 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 flame 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 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 users.
- 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.
- Synthomes 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 inside of the electrode by foreign substance.

(2) Grounding pads

Caution: Reusing 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 withiwise.

- Be careful not to make air bubbles between grounding pad 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...
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7. During using
(1) Connect the RF lesion generator and electrode parts and check the connection status.
(2) 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.

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.

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

10. Action for product damage
(1) 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

Caution: Warning and how to use of the EUS probe and Scope refer to User manual.
(2) 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.
(3) 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.
(5) Adjust electrode to insertion length by loosening screw on handle, and advancing it until insertion reference marks. Tighten screw electrode lock.
(6) Caution: Do not adjust electrode before tighten screw electrode lock. Tip of electrode might be damaged Perforates to unwanted parts of tissues.
(7) Check the location of lesion to be treated using the EUS probe and Scope, and place the electrode in the lesion.
(8) 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.
(9) Caution: Do not output by High Frequency before the tip of electrode is not cold. It can be occur to carbonization.
(10) Once the procedure is completed, turn off the power switch of RF lesion generator and pump.
(11) The tip of electrode in steath 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.

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Europe deputy
Temperature for storage
Refer to users’ guide
Manufacturing Co.
REF
Model No.(Refer to label)

GAS STERILIZATION
E.O. Gas sterilization
Cautions:
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 damage 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.: A-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
Manufacturer No.: Corresponding number
Date of manufacture: Corresponding year and date
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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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