



# Electrode for electrosurgical device

[ELRA Electrode]



## 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.

Flow RF energy, and ablate tissue by using heat according to electrode or contact resistance. The current flowing through tissue using an electrode with high energy is delivered to a small area of tissue. Especially if electricity concentrated in small dots or lines, movement of water molecules in the tissue is increasing and then generates heat. The tissue instantaneously heat by the explosion, and ablate it.

### 2. Guide for use

User should read all of the following information and also the provided user's guide of generator before use. ELRA RF Electrode is designed to be used in conjunction with RF lesion generator from STARmed Co., Ltd. If the guidelines are not properly followed, damages from electricity or heat can be caused and the equipment may malfunction.

### 3. Purpose of usage

It is a manually operated, disposable used for electrosurgical device such as electric surgical unit and medical electric cautery.

### 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 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 there is any damage to the packaging.
- The expiration date is 3 years from the sterilization date. Use of the products after the expiration date is prohibited.
- This device is disposable and reuse is prohibited.
- This device is designed to be used by a qualified and trained Medical doctor.
- This device should be stored in a 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 meters.
- Do not use near conductive materials such as part of metallic bed or spring embedded mattress.
- Do not use in the presence of flammable anesthetics, oxidation-reduction gases or any other flammable substances. It might be a cause of fire in the electrosurgical unit.
- Flammable gases or other materials with a high risk of flames should be prohibited from being place nearby. If a flammable detergent has been used for cleaning or disinfection, the liquid should have evaporated before the procedure.
- Cloth soaked in oxygen and gauze can possibly be ignited from sparks which occur from normal use of the device, please use with caution.
- Do not activate electrode while it is in touch with



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metallic substance or tools 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 also damage the electrode or other devices.
- Do not hold the tip of the electrode by tongs (ex. Kelly), do not pass the electrode through a hole of other devices, and do not scratch the surface on the electrode's tip by sharp things. These actions can destroy the insulation of the electrode and damage the end of the electrode. It might be a cause of unexpected injury to patient 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 use.
- Side effects or cross infection from reuse.
- Weakness of liver functions.
- Delayed bleeding in the operated body parts.
- Recurrence of cancer.
- Symptoms after RFA treatment include.
- Perforation.
- Respiratory depression or arrest.


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

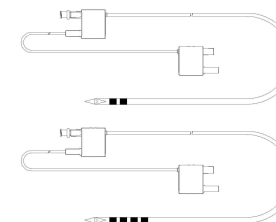
The Potential complications is not limited of the above, other complications may occur by using endoscope.

### 6. Before using




- (1) Check whether damaged of the package status.
- (2) When open the electrode from package, be careful the sterilization state is not damaged according to the


electrode (because the shape is long and flexible electrode) to be contacted inappropriate part.

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



### 7. During using

- (1) Connect the RF lesion generator and electrode parts and check the connection status.
- (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) Insert the guide wire into the instrument channel and position it exactly on the lesion so that the electrode can be easily placed on the lesion.  
 Caution: The maximum outer diameter of the guide wire with this product is 0.035 inch.  
 Caution: Please refer to the operating method and the cautions in the user manual for the relevant guide wire product.

- (4) Make sure to place the electrode's tip exactly on the lesion by connecting it to the guide wire that is already placed on the lesion through the instrument channel of the EUS probe or other scope.  
 Caution: After placing the electrode on the lesion, pay attention not to have an ablation occur in unwanted zone by moving the electrode during RF procedures.



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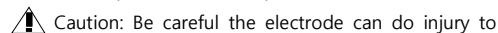
(5) Perform RF procedures using the RF lesion generator under proper condition of operating circumstance (output, temperature, and time)

(6) When the RF procedures are over, stop generating power output by pressing the Finish button on the RF lesion generator.

### 8. After using

(1) Upon completion of the procedure, turn off the power switch of RF lesion generator.

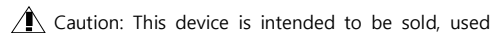
(2) Separate the electrode from the instrument channel of the EUS probe, other Scope, and etc.

 Caution: Be careful the electrode can do injury to the patient and the practitioner when remove the electrode from the EUS probe and other Scope, be follow the User's manual when remove the EUS probe and other Scope from the patient.


(3) Dispose of the electrode according to the 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 damage

 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



Europe deputy



Temperature for storage



Refer to users' guide



Manufacturing Co.



Model No.(Refer to label)



E.O. Gas sterilization



Caution,  
Refer to indications for use



Expiration date



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, do not use and call STARmed Co., Ltd.

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

If the electrode is reuse, re-treated or re-sterilized it might cause defects in the structural form, and damage the RF lesion generator which might lead to injury, disease or death to patient. Reuse, re-treatment or re-sterilization can bring dangers such as 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 : ELRA Electrode

Type name : Corresponding model number

Manufacture No. : Corresponding number

Date of manufacture : Corresponding year and date

Number of items : 1 set



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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.



STARmed Co., Ltd.

Address : # 901-1 Ilsan Techno Town, 1141-1,  
Baekseok-dong, IlsanDong-gu, Goyang-si Gyeonggi-do

T E L : +82 506 816-3546

F A X : +82 506 816-4546

<http://www.STARmed4u.com>

E-mail : [Info@STARmed4u.com](mailto:Info@STARmed4u.com)



EC Authorised Representative  
DongBang Acuprime

1 The Forrest Units, Hennock Road East  
Marsh Barton, Exeter, EX2 8RU U.K.

Tel. +44 1392 829500

Fax. +44 1392 823232

Date of issue: 2013. 05