**IFU ID: G870000**
Gebrauchsanweisung
Operating Instructions
操作说明书
Manual de instrucciones
사용 설명서
Instructies voor gebruik
**Rev.: 10-07-2020 REV 01**

CE 0123 NON STERILE Rx only

**medicon**
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

**MONOPOLAR ELECTROSURGICAL ELECTRODES** **EN**

Carefully read the operating instructions and processing instructions prior to clinical application and keep them safe and at hand. The instructions and notes contained therein must be followed.

**Contents**

1 Scope
2 Intended use
3 Safety notices - WARNING!
4 Excerpt from general safety instructions for the application of HF Technology
5 Cleaning, disinfection and sterilization
6 Visual inspection
7 Exclusion of repair and modification
8 Packaging, storage, transportation, handling
9 Returns
10 Liability
11 Disposal
12 Description of symbols and icons

## 1 Scope

Electrosurgical electrodes monopolar Art. No.:
Maximum rated voltage of accessory:

| **Article No.** | **U**max |
|---|---|
| 87.30.70; 87.30.12; 87.30.17; 87.30.25; 87.30.38; 87.30.45; 87.30.60; 87.30.65; 87.32.10; 87.32.08; 87.32.00; 87.32.04; 87.32.06; 87.32.02; 87.32.12; 87.32.14; 87.32.20; 87.32.18; 87.32.16; 87.32.24; 87.32.22; 87.32.32; 87.32.28; 87.32.26; 87.32.36; 87.32.38; 87.32.34; 87.32.30; 87.34.21; 87.34.20; 87.34.27; 87.34.25; 87.34.26; 87.34.15; 87.34.16; 87.34.10; 87.34.11; 87.33.04; 87.33.00; 87.33.06; 87.33.12; 87.33.14; 87.33.32; 87.33.28; 87.33.26; 87.33.30; 87.33.34; 87.33.20; 87.33.18; 87.33.16; 87.33.24; 87.33.02; 87.33.08; 87.33.10; 87.33.53; 87.33.52; 87.31.32; 87.31.37; 87.31.40; 87.31.42; 87.31.45; 87.31.48; 87.31.54; 87.31.56; 87.31.57; 87.31.64; 87.31.65; 87.31.66; 87.31.62; 87.31.67; 87.31.73; 87.31.69; 87.34.12; 87.30.35; 87.30.50; 87.30.72; 87.30.74; 87.30.76; 87.31.63; 87.31.71; 87.31.68; 87.34.02; 87.34.01; 87.34.00; 87.30.39 | 4,3 kVp |
| 87.34.00; 87.34.01; 87.34.02 | 0,5 kVp |
| 87.30.39 | 1,3 kVp |

In any combination with another electrosurgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used. (See also section 2 "intended use").

## 2 Intended use

Only skilled medical professionals are permitted to use the electrosurgical electrodes. The electrosurgical electrodes are intended for open or endoscopic surgery and are used for cutting and coagulating biological tissue. They are not intended for direct contact with the heart or the central circulatory system. The electrosurgical electrodes are connected by a corresponding monopolar electrosurgical cable or a corresponding electrosurgical handle to the monopolar output of the electrosurgical generator. Monopolar electrosurgical electrodes are furnished either with a 1,6 mm, 2,4 mm 4 mm pin. 1,6 mm electrodes can be combined with handle Art. No. 87.33.80/81 or a comparable product. 2,4 mm electrodes can be combined with a handle Art. No87.33.75/77 or comparable product. 4 mm electrodes can be combined with handle Art. No. 87.33.70/72 or comparable product. The voltage of the used generator may not exceed the maximum rated voltage (See section 1 "Scope") of the electrosurgical electrodes and shall not exceed the frequency 4 MHz.
The electrodes are activated by means of a foot-operated switch or electrosurgical handle. It is recommended to use a smoke evacuation system. Monopolar electrosurgical electrodes can be operated with HF-generators of the following manufacturers:

| | |
|---|---|
| ▪ ERBE | ▪ KLS Martin |
| ▪ Covidien | ▪ ValleyLab |
| ▪ EMED | ▪ Tekno |
| ▪ BOWA | ▪ Berchtold |

Follow the instructions for use of the corresponding accessory and of the generator used.
**Improper use will result in immediate loss of warranty. Liability for any damages incurred will not be accepted.**

## 3 Safety notices - WARNING!

See these Instructions for Use, the label or the current product catalog for the maximum rated voltage of the electrosurgical electrodes. If anything is unclear, contact the manufacturer. Prior to each application, electrosurgical electrodes have to be cleaned, disinfected and sterilized according to a validated procedure (DIN EN ISO 17665) (In this regard see Section 5 "Cleaning, disinfection and sterilization"). A visual inspection must be performed before each use (see Section 6 "Visual inspection"). It must be ensured that the electrosurgical electrode is inserted firmly in the handle. This must be done carefully, in order to avoid damage to the electrosurgical electrode and/or injuries to the patient or surgical personnel. The electrode tip may be damaged if excessive force is applied. Prior to each usage, please verify if the designated neutral electrode is put on the patient correctly and whether the neutral electrode is connected with the HF-generator properly. It is not permissible to activate the electrosurgical electrode as long as it is in contact with metal objects and/or optics. Throughout the complete procedure, care must be taken that no flammable substances are present in the immediate vicinity, since otherwise a danger of explosion exists. After the electrosurgical current has been turned off, the electrode tip may still be hot enough to cause burns.

**The high-frequency current used in electrosurgery may interfere with cardiac pacemakers and implanted heart defibrillators, and so affected patients must consult a cardiologist prior to the operation.**

**Contraindication**
This instrument is not designed for use on the central nervous and circulatory system
The application of HF current can damage pacemakers and in vivo cardiac defibrillators
The instrument should not be used in the immediate vicinity of bone, tooth root and metal

## 4 Excerpt from general safety instructions for the application of HF Technology

In addition to the acknowledged benefits of HF surgery, the procedure involves some risks that need to be considered. **Improper use and disregard of the instructions for use may lead to unwanted burns of the patient as well as injury to the user or third parties.** The following is a summary of important general safety notices when using HF technology. Medicon eG recommends continuous advanced training of the staff.

**a) Read and observe the guidelines in the instructions for use.**
Before using the electrosurgical instrument, read the entire instructions for use. This also applies to the instructions for use of the accessories used, including the electrosurgical neutral electrodes to be used during the monopolar application and with the electrosurgical generator. The specifications, safety instructions and warnings of the respective instructions for use must always be kept and followed.

**b) Environment**
It is very important to ensure that no flammable substances (anesthetics, oxidizing gases, endogenous gases, etc.) are present in the immediate vicinity during the complete electrosurgical application; otherwise there is a danger of explosion. Use non-flammable disinfectants agents; do not use e.g. alcohol-based tinctures or similar. All oxygen compounds must be tight and leak-proof during the procedure.

**c) Patient Positioning and Patient Preparation**
Ensure proper patient positioning, i.e. use insulating surgical table supports that are dry, absorbent and impervious to liquids. Isolate conductive surfaces and points of contact with the patient. Dry folds of pulp are required in skin folds, breast creases and between the extremities; fluids accumulated in body cavities, for example, should be removed before starting the procedure. Use non-combustible disinfectants. Use non-conductive rinsing solutions where medically possible. Prior to use, remove any type of body jewelry from the patient.

**d) Circuit Points**
Before starting the application, make sure that the handle or cable used is correctly connected to the electrosurgical generator and that the correct power setting is selected and displayed. Follow the guidelines in the instructions for use of the electrosurgical generator and electrosurgical handle / cable.

**e) Patient Reactions**
All electrosurgical instruments can potentially cause muscle stimulation during use. The design of the products herein has been chosen to minimize the risk of this undesirable effect, but nevertheless, muscle stimulation can cause unexpected movement of the patient in the surgical field.

**f) Handling Electrosurgical Instruments**
Make sure the accessories used are compatible. The tip of the instrument should not be touched during use. After switching off the electrosurgical current, the instrument tip may still be hot and may cause burns. If the electrosurgical instrument is not in use, it should be placed on a dry, clean, non-conductive and well-visible surface that is not in contact with the patient. Inadvertent activation of the instrument may result in patient burns. Mostly, it is advisable to keep the activation times as short as possible or to observe longer pauses between the activation phases and to set the lowest possible performance values.

**g) System integrity confirmation at the end of the operation**
At the end of the operation, the completeness of the system must be confirmed.

## 5 Cleaning, disinfection and sterilization

Medicon eG recommends the validated treatment processes described in the following. Equivalent deviant processes are possible. It is the sole responsibility of the user to safeguard the suitability of the actual applied procedure by suitable means, e.g. validation, routine examination, verification of material compatibility, etc. In view of the design, the materials used and the intended use of the product as well as the respective duration of the use, a maximum limit cannot be defined for the number of cleaning, disinfection or sterilization cycles that may be possible. During proper use of the electrosurgical electrodes, the products are subject to natural wear and tear depending on type and duration of their application. Therefore a visual inspection has to be done prior to each application.

Please also observe the legal regulations applicable in your country and the Hygiene regulations of the medical practice or hospital. This applies to especially for the different specifications (e.g. in Germany according to the KRINKO RKI BfArM recommendation for reprocessing) regarding effective prion inactivation (not applicable to USA).

### 5.1 Preparation for cleaning
Remove the electrosurgical electrodes from their packaging. Place them in a container/ device provided for cleaning/ sterilization. It is not necessary to dismantle the electrosurgical electrodes.

### 5.2 Pre-cleaning
The electrosurgical electrodes must be disinfected immediately after each use. Use mains water (drinking quality) (<40° C) and possibly aldehyde-free, non-fixing disinfectants for pre-cleaning. The electrosurgical electrodes should be thoroughly cleaned with a soft brush or synthetic fleece pad then rinsed, since otherwise particles or dried secretions may adhere to them. This could make subsequent cleaning and sterilization difficult or impossible. It must be ensured that areas with difficult access are thoroughly cleaned then rinsed several times.
Cavities and lumen have to be rinsed intensively using at least 3 x 20 ml cold mains water (<40° C) with the aids of a rinsing adapter (e.g. from the company Medisafe), or with a syringe or with a water pressure pistol (>30 Sec.). **This precleaning step has to be done prior to the further manual cleaning or prior to cleaning with the cleaning and disinfection machine.**

### 5.3 Manual cleaning and disinfection
For cleaning, please prepare an immersion bath with a suitable fluid cleaning agent. Use a disinfection agent that is compatible to the cleaning agent; take care to use a disinfection agent that also can be used for immersion baths. Follow the instructions and recommendations of the manufacturer of the cleaning and disinfection agent. Only use agents that are suitable to clean medical devices made of metal and plastic with a pH-level of between 5.5 and 12.3. We recommend the cleaning agent gigazyme® (Schülke & Mayr). Do not use highly alkaline cleaning agents. Highly alkaline cleaning agents with pH levels above 10 and below 13 have a detrimental influence on the lifetime of the electrosurgical electrodes.

1. According to the instructions of the manufacturer and using the appropriate cleaning agents, prepare two immersion baths separately, one for cleaning and one for disinfection.
2. Place the electrosurgical electrodes completely in an ultrasonic bath with a cleaner (e.g. 0.5% gigazyme®). The electrosurgical electrodes must be cleaned in an ultrasonic bath applying a sonication time of 5 min and a frequency of 35 kHz. Follow the instructions of the manufacturer of the cleaning agent. Furthermore, follow the instructions of the manufacture of the ultrasonic bath. Make sure that the products do not touch any other parts in the ultrasonic bath. Take care that sonic shadows are avoided inside the ultrasonic bath.
3. Then, clean the electrosurgical electrodes with a soft brush under cold mains water (drinking quality) (<40° C). Cavities and lumen have to be rinsed intensively by using a water pressure pistol (>30 Sec.) or similar for 1 minute. Afterwards rinse the HF electrodes thoroughly for at least 1 minute under mains water (<40° C) in order to remove any residues of the cleaning agent.
4. Inspect the electrosurgical electrodes visually regarding remaining soiling/stain. In case soiling/stain is still detectable visually, repeat the aforementioned steps until all soiling/stain is removed.
5. Afterwards put the electrosurgical electrodes into the disinfection bath completely with e.g. Korsolex Plus 3% for 15 min. The exposure time according to the Manufacturer information must be followed. Make sure that all areas and parts of the electrosurgical electrodes are covered by the disinfectant. Cavities and lumen have to be rinsed with the disinfectant for several times using a syringe and at least min. 3 times using 20 ml.
6. Then, rinse the electrosurgical electrodes thoroughly for at least 1 minute with cold demineralized water in order to remove any and all residues of the disinfectant.
7. In addition, all narrow and hard-to-reach areas on the electrosurgical electrodes, all cavities and lumens must be rinsed several times with a syringe (at least 3 times using 20ml) of cold demineralized water.
8. Dry the electrosurgical electrodes with a lint free wipe and sterile compressed air. Dry the cavities and lumen with sterile compressed air as well.

### 5.4 Automated cleaning and disinfection
Only apply cleaning and disinfecting machines that are efficiency tested according to DIN EN ISO 15883. Please refer to the information of the manufacturer of the cleaning or disinfecting agent, and only use agents that are suitable to be applied for medical devices made from metal and steel and have a pH-value between 5,5 and 12,3. It is recommended to use neodisher ® mediclean forte (Dr. Weigert GmbH & Co. KG). Select the program for thermal disinfection. Regarding the program course, follow the instructions of use of the manufacturer of the agents. The electrosurgical electrodes must be mounted securely and protected against mechanical damage during machine cleaning/ disinfection.
Do not clean electrosurgical electrodes together with sharp-edged or pointed objects.
Put the electrosurgical electrodes in a suitable rinsing device. Start the program course of the following features:

- Pre rinse with cold water for 1 Min.
- Emptying
- Pre rinse with cold water for 3 Min.
- Emptying
- Wash at 55° C for 5 Min. with a 0.5% alkaline cleaner
- Emptying
- Neutralisation with warm mains water(>40° C) and Neutraliser (0.1% Neodisher®Z) for 3 Min.
- Emptying
- Intermediate rinsing: rinse with warm demineralised water (>40° C) for 2 Min.
- Emptying

### 5.5 Disinfection
Proceed with the automated Thermic Disinfection according to the national requirements regarding the AO-value (see ISO 15883, AO-value >3000): 5 Min. for 92° C +/- 2° C.

### 5.6 Drying
- 30 Min. at 90° C
- Remove rinsing adapter

After the course of the program is completed, remove the electrosurgical electrodes and verify if there are any staining residues. If staining/bonded residues are present, repeat the automated cleaning and disinfecting process as long as no visible residues are present. Dry any cavities and insufficiently dried areas with sterile compressed air < 2 bar. After the electrosurgical electrodes are taken out (after additional re-drying on a clean place), immediately pack them in a single-use sterilization package (double package) made of paper/foil or put them in a sterilization container (according to DIN EN ISO 11607 and DIN EN 868).

### 5.7 Sterilization:
The electrosurgical electrodes are exclusively designed for steam sterilization in autoclaves (fractionated pre-vacuum method with sufficient product drying). They must be sterilized at a minimum of 134° C and maximum 137° C in saturated

medicon®
MEDICON eG
Gänsäcker15,78532 Tuttlingen
Germany
Tel.: (49) 7462 / 2009-0
Fax: (49) 7462 / 2009-50
E-Mail: sales@medicon.de
Internet: http://www.medicon.de

steam with holding time of at least 5 minutes to a maximum of 20 minutes and vacuum drying for at least 10 minutes. Sterilizer (Class B) must be in accordance with applicable national standards and regulations (e.g. DIN EN 13060 or DIN EN 285). The sterilization standards DIN EN ISO 17665 (Sterilization of health care products - Moist heat) must be observed. Electrosurgical electrodes shall not be sterilized with hot air, EtO gas, gamma radiation or plasma.

**NOTE:** Before use, the electrosurgical electrodes must be cooled to room temperature. It is the sole responsibility of the user to safeguard and maintain the sterile condition of the electrosurgical electrodes after the sterilization process. In case the aforementioned described and recommended chemicals and machines for manual pre-cleaning and/or automated cleaning and disinfection are not available, it is the responsibility of the user to validate their procedure. Also, if another sterilization procedure is chosen, the procedure deviant from the procedure described in paragraph 5 has to be validated by the user accordingly.

**Limitation of reconditioning:**
The lifetime of the product will depend on wear, handling, and duration of use, damage and frequency of reconditioning.

## 6 Visual inspection

Prior to each use, a visual inspection must be carried out on the electrosurgical electrodes. In particular the insulation of the electrosurgical electrodes must be inspected for pressure points or damage. Electrosurgical electrodes with damage or pressure points shall not be used and must be replaced by new ones.

## 7 Exclusion of repair and modification

Defective electrosurgical electrodes shall not be repaired. They must be replaced by new electrosurgical electrodes. Furthermore, unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty.

For service and repair please contact your national representative of MEDICON eG

## 8 Packaging, storage, transportation, handling

The electrosurgical electrodes must be stored in a clean and dry environment. They should be individually stored in a protective container with individual compartments or heat-sealed in film. The electrosurgical electrodes must always be handled with the utmost care during transportation, cleaning, disinfection, upkeep, sterilization and storage. This applies in particular for fine tips and other sensitive areas. It is the operator's responsibility to ensure that the sterile condition is preserved after the sterilization process.

## 9 Returns

Returns will be accepted only if they are marked as "hygienically safe" or "not contaminated" and have been securely packaged for shipping. Use our Return Form for returns.

## 10 Liability

CAUTION: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription!
In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version shall be authoritative. Only the latest revision of the operating instructions applies.
Due to constant technical development, the content of these MEDICON operating in-structions is updated regularly. Please use the IFU-Website ifu.medicon.de to ensure that you are using the current version. The version date of the respective edition of the operating instructions is included in the printout. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions. MEDICON eG will not accept liability either for changes or repairs made to the product without the prior written authorisation of MEDICON eG, nor for repairs that were not carried out by workshops authorised by MEDICON eG or the
MEDICON Repair Service (MRS).

## 11 Disposal

Disposal of damaged instruments or of instruments that are not functionally reliable: To avoid a risk of infection to third parties, the instruments must be cleaned and sterilised before disposal.
In addition, the instruments must be disposed of in specific and appropriately labelled containers, in order to protect third parties from cutting injury. Observe the applicable national laws when disposing of reusable surgical instruments!
The product, the packaging material and the accessories must be disposed of in accordance with the regulations and laws specific to the country in which they are used.

## 12 Description of symbols and icons

| Icon | Description |
|---|---|
| | Manufacturer |
| LOT | Production lot number, batch |
| REF | Item number |
| NON STERILE | Non-sterile |
| | Caution |
| | Observe the operating instructions |
| CE 0123 | CE label acc. to Directive 93/42/EEC |
| MD | Medical device |
| | Store in dry conditions |
| | Protect from sunlight |