

# Instruction of use

Rubber neutral electrodes



**REF** 70-340-01 - 70-344-02

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## 1 Scope

Rubber neutral electrodes Art No.: 70-340-01 - 70-344-02

## 2 Intended use

Only skilled medical professionals are permitted to use the neutral electrodes that are trained on the product. The neutral electrodes are intended for all monopolar surgical procedures and are used to draw off the electrosurgical current during work with electrosurgical-equipment. They are not intended for direct contact with the heart or central circulatory system. The neutral electrodes are connected by a connection cable to the neutral electrode terminal of the electrosurgical generator.

The following generators can be used to operate the monobloc neutral electrodes:

ERBE VIO - ERBE ICC/ACC - KLS Martin - VallyLab - Olympus PSD20 - Conmed - BOWA - Integra - Medevo Arthro200 - Söring

The following generators can be used to operate the dualistic neutral electrode:

ERBE VIO 300D - Martin Maxium - Sutter Curis - Hartt 300 - VallyLab FXc - Medevo Arthro200 - Covidien Force Triad

It is recommended that a smoke evacuation system is used during electro surgery.

## 3 Safety notice



### WARNING !

Before initial use, new rubber neutral electrodes must be cleaned (In this regard see Section 4 „Cleaning and disinfection“). A visual inspection must be performed before each use (see Section 6 „Visual inspection and function test“). It must be ensured that the neutral electrode is correctly connected to the generator and placed on the patient (see Section 5 „Placing the neutral electrode“). This must be done carefully, in order to avoid damage to the neutral electrode and/ or injuries to the patient or surgical personnel. It is permissible to use the neutral electrode only for persons having a body weight of equal 15 kg [33 lbs] or higher. 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. Fluids have to be kept away from the application area of the neutral electrode.

Neutral electrodes article no. 92316 and 92343 are suitable to be applied for surgeries on children. It is not allowed to use them for high performance surgeries (f.e.. TUR). The aforementioned neutral electrodes only should be used for patients on whom it is not possible to apply larger electrodes.

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

## 4 Cleaning and disinfection

### Preparation for cleaning:

Remove the rubber neutral electrodes from their packaging.

### Manual cleaning:

The rubber neutral electrodes must be disinfected before initial use and prior to each reuse. Immediately after each use the rubber neutral electrodes should be thoroughly cleaned with a soft brush or synthetic fleece pad and thoroughly washed with an alkaline cleaning solution. Afterwards rinse them thoroughly, since otherwise particles or dried secretions may adhere to them. This could make subsequent cleaning difficult or no longer possible. It must be ensured that areas with difficult access are thoroughly cleaned then rinsed several times.

### Automated cleaning:

A mechanical cleaning is not allowed. This can cause failures of the product even after a few cycles.

### Disinfection:

The neutral electrode must be disinfected by a spray or wipe disinfection.

### Limitation of reconditioning:

Due to the design, the materials used and the intended use of the neutral electrodes a maximum limit of cleaning cycles cannot be defined. The life time of the product will depend on natural wear and tear, damage and frequency of reconditioning.

## 5 Placing the neutral electrode



The neutral electrode must be placed on a smooth muscular or well vascularized and unwounded skin area close to the surgical site. The current path between the electrodes should be as short as possible but no shorter than 20 cm. In addition, the area must be chosen such that no liquid at all can reach it. For adults, preferably the thigh or upper arm should be used. Make sure disinfectants are dried completely before the neutral electrode is applied. The part of the body selected for the application has to be shaved, thoroughly cleaned and dried. Remove body jewelry if present. Do not apply on scarred tissue or directly above an implant. If possible, avoid application on tattoos. Now the function test has to be done. The neutral electrode must be applied with its long edge vertical to the current flow. That means the current flow must always hit first the long edge of the neutral electrode. The neutral electrode must be firmly fixed with two rubber bands at the location which is described above. To check that the neutral electrode is overall placed, brush a hand with light pressure over the neutral electrode. Take care that the total surface of the neutral electrode is applied and that kinks are avoided. Then connect the neutral electrode to the generator with the appropriate cable. Do not lead or wrap around the cable among an arm or leg or among a metal object. Do not lead the cable under the patient. Do not place cable

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clips under the patient. Caution! Take care about the correct cable route while relocating the patient. Do not stress mechanically neutral electrode cables that lay on the floor. Do not run over the cables with an instrument or C-cart. After use, unplug the cable from the machine once again. Now detach the neutral electrode gently from the patient.

## 6 Visual inspection and function test



Visual inspection: Before each use, the insulation of the cable of the neutral electrodes must be inspected for pressure points or damage. Additionally verify that the neutral electrode itself is free from damages. It is not permissible to use neutral electrodes or neutral electrode cables exhibiting damage or pressure points. These have to be replaced by new ones.

Function test: Prior to the surgery, proceed with a function test of the neutral electrode. Thereby shortly activate the neutral electrode using the button of the handle. Follow any error reports or alarms.

## 7 Repair and modification

It is not permissible to repair defective neutral electrodes. They must be replaced by new neutral electrodes. Unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty.

## 8 Packaging, storage, transportation, handling

The neutral 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 neutral electrodes must always be handled with the utmost care during transportation, cleaning, upkeep and storage.

## 9 Returns

Returns will be accepted only if they are marked as „hygienically safe“ or „not contaminated“ and have been securely packaged for shipping.

## 10 Disposal

The neutral electrodes, 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.

## 11 About this Instructions for Use

Throughout the period of use of the neutral electrodes, the Instructions for Use must be kept freely accessible for every user. A current version may also be found at [www.AS-Medizintechnik.de](http://www.AS-Medizintechnik.de).

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