ELECTRODE - INSTRUCTIONS FOR USE (IFU)

Applicable to:

series 00420.10 / 12 / 14
series 00500.00-00/L-03-D1-D12-D1/S-D12/S-L1-L2-L3-L4-L5-L6-L7-L8-L9-L10-L1/L-L2/L-L3/L
-L4/L-L5/L-L6/L-L7/L-L8/L-L9/L-L10/S05/S10/S15
series 500500.L1-L2-L3-L4-L5-L6-L7-L8-L9-L10-L1/L-L2/L-L3/-L4/L-L5/L-L6/L -L7/L-L8/L-L9/L-L10
series 152-110 / 112 / 120 / 122 / 125 / 130 / 132 / 140 / 142 / 145 / 150 / 152 / 160 / 162 / 165 /
175-10 / 190 -13 / 190-20 / 195

LED SpA Via M.T. Cicerone 138
03100 FROSINONE (FR) ITALY

EN

IA-ELECTRODE_a_EN *ed.2023-02*

CE 0051

INTENDED USE: Devices destined to be connected, for temporary use, to high frequency electrosurgical units for surgical operations in which cutting and / or coagulation of soft tissues is required, with a monopolar and / or bipolar technique, for minor surgery and / or major in open and / or intra-operative percutaneous and / or endoscopic and / or laparoscopic. See attached table.

WARNING: When used as intended, these products are more or less, subject to wear, depending on the intensity of use. Therefore carry out a thorough visual examination and a function test prior each application. In case of defects (example: brittle or defective insulation) not used. For safety information of electrosurgery, please read the manuals of unit. Sterilized in Autoclave before use. Do not use hot air sterilisers. Defective products may not be repaired, always replace with a new one.
The user and/or the patient shall be informed of the need to report any serious incident that has occurred in relation to the device, the manufacturer and the complement authority of the Member State where the user is estalished.

Conditions:
Storage and use conditions:
Temperature: +10°C - +40°C
Relative Humidity : 20 - 80%, non-condensing;
Atmospheric pressure: 700 - 1060 hPa
During stoccage, the products muste be protected from direct sunlight.

Transport conditions:
Temperature: 0 ° C - +50 ° C
Relative Humidity : 20 - 80%, non-condensing;
Atmospheric pressure: 700 - 1060 hPa

Use: Used with an electrosurgical unit for cutting and/or coagulation of soft tissues. Use knife, needle, micro needle and thread shapes for cutting and surface ball and needle knife shapes for coagulation. This product should only be used by medical personnel trained in the fundamentals, application rules and risks of high frequency electrosurgery.

Contraindications: There are no contraindications except those to the use of electro-surgery in general (see IFU of the generator)

This product is supplied NON STERILE in packaging not suitable for sterilization. NON STERILE

Sterilize before use by observing the correct cleaning, disinfection and sterilization procedures. Hot air sterilization is prohibited.

- These electrodes are compatible with 2.4mm handpieces, after insertion, tighten if required and check that they are secure for subsequent use. We recommend the use of LED handpieces that guarantee full compatibility. (codes 00205.00 / 00206.00)
- Check that the expected output characteristics are compatible with the characteristics of the electrodes, the maximum applicable voltage is 3 kV. For 00500.D1 / D12 electrodes the applicable voltage is 1kV. For the wire or loop electrodes of the 00500 or 500500 series the maximum power allowed is 80W and the loop electrodes 152-175-10 / 152-190-XX / 152-195 the maximum power 120 W.

Safety:
- Before use, the product must be checked to check for any damage. In case of damage, do not use the product. There is no repair of this product.
- Do not subject the product to loads greater than its mechanical limits.
- Do not touch the tip of the product immediately after use, it may still be hot to cause burns.
- Do not keep active electrodes close to the patient when not in use to avoid personal injury in case of accidental activation.
- Do not put in contact with other uninsulated tools or objects.
- Always use the minimum power required and do not exceed the recommended voltages and powers.
- The power level must be judged by the user.
- Beware of the risk of injury from sharp parts (e.g. wire electrode or needle).
- To avoid the spread of bacteria and infections, sterilize the product before it leaves the medical environment.
- Follow the regulatory and legal compliance in force in the specific country of use for the disposal of the product and its packaging.

Treatment cycles 30 times MAX 30 CYCLES 75 times (series 00420.XX) MAX 75 CYCLES

Soaking: Soak the tool immediately after use and in any case within 2 hours. Use only aldehyde-free detergents suitable for disinfecting instruments (e.g. CE mark / FDA authorization).

Cleaning / Disinfection: The manual method is not recommended. Use instrument washer.
We recommend the use of neutral to slightly alkaline ((PH 7-9) (1% Clenzyme/ Gigasept GTA) detergents and cleaning and disinfectant products suitable for plastic and metal medical devices. Depending on the concentration it is the use of products with alcohol and / or aldehyde components is allowed. If necessary, blow away with filtered compressed air. Dry the products only with compressed air <3 bar, in order to avoid possible damage.

The manufacturer cannot be held responsible in case of use of detergents and disinfectants other than those recommended. It is mandatory to comply with the recommenda - tions of the manufacturer of the cleaning product.

Before sterilization, the disassembled instruments must be placed in a suitable disposable sterilization package (single or double packaging) and / or a suitable sterilization container.

Autoclave treatment
Fractional vacuum process
Holding time: 3-18 minutes, sterilization temperature: 134 ° C / temperature 121 ° C,minimum 20 minutes. 134°C
The suitability of the products for effective sterilization by means of a fractionated vacuum procedure with the above sterilization times and temperatures has been verified.

This product must be disposed using normative recycling regulations, do not throw away in general disposal containers.