



DISPOSABLE NEUTRAL ELECTRODE FOR ELECTROSURGERY

INFORMATION FOR SAFETY AND PERFORMANCES

INTENDED USE

Electrodes (plates) for adult and pediatric patients with conductive adhesive gel to be used as neutral reference during electrosurgical procedures.

CONTRAINDICATIONS

- Do not use pediatric plates for high-power procedures (such as trans-urethral resection –TUR).

PRECAUTIONS AND WARNINGS

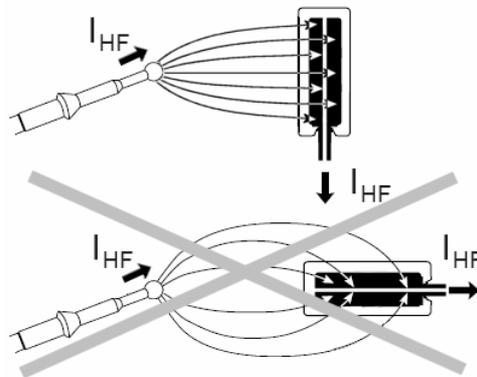
- This is a disposable product - do not re-use.
- The product is supplied not sterile - do not sterilize.
- Do not re-position or cut the plate, do not add gel.
- Do not use the product in case:
 - The packaging is not complete
 - There are evident damages on the plate or on the connection cable
 - Gel is not homogeneous or is dry.
- During procedure always select the lowest energy level which is possible. If the coagulation ability of the electrode is lower than usual don't increase the high frequency output before making following controls:
 - Correct positioning of the neutral plates (perfect adherence on the entire surface)
 - The correct connection of the cables and their connectors
 - The correct activation of the starting keys (hand-switch or foot-control)
 - That there is no damage to the insulation of the cables
 - That the electrode is not dirty.
- If the patient is "re-positioned" check the contact of the plate with the patient's skin and the cable connections.
- For connections and correct functioning, follow the instructions for use supplied by the manufacturer of the ESU unit and pencil being used.
- High-frequency electrosurgical generators, the neutral electrodes and accessories to be used with the present product, should conform to existing regulations.
- The devices are to be used by trained healthcare professionals in electrosurgical procedures.
- Do not submit a patient with implanted pacemaker to electrosurgical current without first consulting a cardiologist.
- For the pediatric version: use only on children of less than 15 Kg (33 pounds) weight.
- For the neonatal version: use only on children of less than 5 Kg (11 pounds) weight.
- Incorrect positioning of neutral electrode can cause burns: follow the instructions.
- For the "REM" type (F7x20 series): Check that the generator alarm system is working before starting the procedure.

- For neutral electrodes of series F7805x: The use of this plate does not allow to activate the “REM” control system of the ESU device.
- In cases where the contact impedance is high (eg. Patients with dry skin, adipose tissue and / or poor vascularization) or for long-duration or high power is recommended to increase the contact surface to reduce the risk of burns skin. Please refer to the instructions of the generator and of each device used for the connections and the use of each accessory.

ATTENTION

SELECTION OF THE APPLICATION AREA AND PATIENT PREPARATION

- Select a well convex area (muscle) next to the area to be operated but at least 20 cm far from it, possibly on the forearm, on the thigh or on a whip. Eventually move the plate in order that the longer side is perpendicular to the area of the operation (see the picture). Avoid that the plate is superimposed.



NB Current should flow in parallel to the body surface and never pass through the thorax. The patient must be placed on a dry and perfectly isolated surface. The patient must be kept isolated from conductive parts and the operating bed must be earthed. Use dry gauzes to avoid that different areas of the body come into contact with each other.

- Do not place the plate on wounds and scars, near bone projections, very adipose tissues, close to metallic prosthesis or to ECG electrodes or on areas, where liquids can flow.
- Do not place the plate on areas, where it can be subjected to pressure or under patient's weight.
- Rader Shave the selected area, clean carefully and skim in order to remove eventual remaining of cream or cosmetics. Dry the selected area.

NB Do not use inflammables during the patient's preparation. Do not use alcoholic substances or benzoine tinture.

- Eventual shave remaining or hair can cause burns.

FOR “REM” TYPE

- Check that the alarm system is working before starting the procedure.

- At the end of the procedure, disconnect the connections, take hold of a corner of the plate and pull gently to slowly remove the plate.

NB A brusque or rapid removal can cause skin traumas – Do not remove the plate by pulling on the cable connector section (tongue).

POSSIBLE CAUSES OF BURNS

This product has been developed using materials which reduce heating, and therefore the risk of burning, to a minimum. Burns can be caused by a high current density in the patient's tissue, or by the heating of fluids or inflammable gases; the causes can be the following:

- Wrong choice of the application area and patient's preparation.
- The plate is not well placed (low adherence, presence of air bubbles) or it has been placed back.
- The patient has been inadvertently positioned in contact with electrically conductive parts.
- There has been a direct contact between the cables and the patient's skin which has provoked a capacitive effect.
- The combustion of inflammable disinfectant agents.
- The combustion of inflammable narcotic gases.



Via Costoli, 4 - 50039 - Vicchio
(Florence, Italy) - www.fiab.it