

| | |
|-----------|---|
| IT | MANIPOLO RIUTILIZZABILE PER ELETTROCHIRURGIA ELETTRODO RIUTILIZZABILE PER ELETTROCHIRURGIA PROLUNGA RIUTILIZZABILE PER ELETTROCHIRURGIA |
| EN | REUSABLE PENCIL FOR ELECTROSURGERY REUSABLE ELECTRODE FOR ELECTROSURGERY REUSABLE EXTENSION FOR ELECTROSURGERY |
| DE | EINMAL-ELEKTRODE FÜR DIE ELEKTROCHIRURGIE WIEDERVERWENDBARE ELEKTRODE FÜR DIE ELEKTROCHIRURGIE WIEDERVERWENDBARE VERLÄNGERUNG FÜR DIE ELEKTROCHIRURGIE |
| ES | MANGO DE ELECTROCIRUGÍA REUTILIZABLE ELECTRODO PARA ELECTROCIRUGÍA REUTILIZABLE EXTENSIÓN PARA ELECTROCIRUGÍA REUTILIZABLE |
| FR | MANCHE RÉUTILISABLE POUR ÉLECTROCHIRURGIE ÉLECTRODE RÉUTILISABLE POUR ÉLECTROCHIRURGIE EXTENSION RÉUTILISABLE POUR ÉLECTROCHIRURGIE |
| RU | АКСЕССУАРЫ ДЛЯ ЭЛЕКТРОХИРУРГИИ, РУЧКА-ДЕРЖАТЕЛЬ ДЛЯ ЭЛЕКТРОХИРУРГИИ |
| PT | PUNHO REUTILIZÁVEL PARA ELETROCIRURGIA ELÉTRODO REUTILIZÁVEL PARA ELETROCIRURGIA EXTENSÃO REUTILIZÁVEL PARA ELETROCIRURGIA |
| CS | OPAKOVANĚ POUŽITELNÁ TUŽKA PRO ELEKTROCHIRURGII OPAKOVANĚ POUŽITELNÁ ELEKTRODA PRO ELEKTROCHIRURGII OPAKOVANĚ POUŽITELNÝ NÁSTAVEC PRO ELEKTROCHIRURGII |

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**REUSABLE PENCIL FOR ELECTROSURGERY
REUSABLE ELECTRODE FOR ELECTROSURGERY
REUSABLE EXTENSION FOR ELECTROSURGERY**

DIRECTIONS FOR USE

INDICATIONS:

Cutting and coagulation of tissues during electrosurgical procedures, with the use of a compatible high-frequency generator.

- **REUSABLE HAND-SWITCH PENCILS WITH VALLEYLAB-TYPE CONNECTION:**
 - MODELS FOR ELECTRODES WITH 2,38mm (3/32").
 - MODELS FOR ELECTRODES WITH 4mm CONNECTION.
- **REUSABLE FOOT CONTROL PENCILS WITH, 4mm PIN CONNECTION.**
- **REUSABLE ELECTRODES WITH 2.38mm (3/32") CONNECTION.**
- **REUSABLE ELECTRODES WITH 4mm CONNECTION.**
- **ELECTROSURGERY ELECTRODES REUSABLE EXTENSIONS WITH 2,38mm (3/32") CONNECTION.**
- **OTHER MODELS OF PENCILS AND ELECTRODES WITH ERBE TYPE CONNECTION 5mm.**

MAXIMUM APPLICABLE VOLTAGE 9kVpp (8kVpp models for electrodes with 4mm connection)

WARNINGS

- STERILISE BEFORE USE those products which are not pre-sterilised;
- Assembly and removal procedures involving the electrode, as well as cleaning, must be carried out only when the hand-switch pencil is disconnected from the generator.
- After controlling the packing for damages, check the hand-switch pencil, electrode, cable, and connector. Do not use the product in the case of damages or visible defects. Instead, return it to FIAB.
- The distal part of the hand-switch pencil can hold all models of electrodes and extensions having a shank diameter of 2.38 mm (3/32") or 4 mm depending on the model. Be sure that the electrode or extension (if present) is firmly inserted in the pencil, and that the insulating coupling of the electrode and extension (if present) is intact.
- Always check the functioning before use. For the hand-switch models, make sure that the two push-buttons make a "click" when they are pressed. Discard defective products.
- Keep a record concerning checks carried out and the results obtained.
- Be sure that the connection of the hand-switch pencil's plug with the generator is firm, and that the metallic part of the connector is completely inserted.
- Do not use clips to secure the cable of the pencil to the surgical cloth, in order to avoid damage to the cable.
- Keep the products away from inflammable materials: their accidental activation and heat could cause fires.
- When the products are not in use, they should be kept in suitable containers.
- High-frequency electrosurgical generators, the grounding plates and accessories to be used with the present product, should conform to existing regulations.
- Refer to the instructions for use supplied with the product regarding use of the generator and the grounding plates.
- The devices are to be used by trained healthcare professionals in electrosurgical procedures.

NB: pacemakers may be damaged by electrosurgical current. Do not submit a patient wearing a pacemaker to electrosurgical current without first consulting a cardiologist.

CLEANING

Disconnect the pencil from the generator. Remove the electrode and extension (if present) from the tip of the pencil. To clean the products, it is advisable to use decontaminating solutions and proteolytic detergents for surgical instruments. While cleaning the electrodes, the operator should take care not to wound him or herself with the blades or tips. Follow the relative instructions when using these products. After cleaning, rinse with water and keep the pencil in an upside-down position for at least 30 minutes, so as to enable the exit of any liquids from the tip.

- Do not press the push-buttons during the washing operation.
- Do not make forced entry of liquids or air inside the receptacle of the tip.
- Do not use ultrasound baths
- The use of mechanical washing systems may reduce the product's life.
- Do not immerse the pencil in any sort of solution during the 4 hours following a pre-vacuum treatment.
- Do not use abrasive mechanical systems on the insulation of the electrode or extension to remove biological residue, as such systems could damage it.

STERILISATION

The devices in object of present instructions can be sterilised with ethylene oxide (ETO) or in an autoclave.

NB The sterilisation process used must conform with existing regulations.

- Validation of the process is the responsibility of the user.
- Do not sterilise the pencil when the electrode or extension is inserted in the tip.
- Remove the protective cap from the electrode before autoclave sterilization. After the first use, the treatment cycle of the electrode (decontamination, sterilization) prior to re-use does not require the re-insertion of the protective cap, which can therefore be discarded.
- In repackaging, use adequate protection systems for the tip in order to avoid perforation of the pouch, with the consequent loss of sterility.

For sterilisation with ethylene oxide, the clean products must be packaged in suitable gas-proof pouches. An adequate ventilation time should be respected to ensure total dispersion of the ETO residues.

For sterilisation in an autoclave, package the products in suitable pouches.

Avoid wrapping that is too tight and sharply twisting of the cord.

Advisable temperatures and times for steam autoclave are as follows:

| Cycle | Pre-vacuum | Exposure | Drying |
|---------------|-------------------|-----------------------------------|---------------|
| 134°C (273°F) | 8min | 134°C (273°F) 2,05 bar for 12 min | 9 min |
| 121°C (250°F) | 8min | 121°C (250°F) 1,05 bar for 20 min | 9 min |

NB: The pencils can NOT be sterilised by 137°C (279 °F) cycle.

ATTENTION: Should the products come in contact with the metal supports within the autoclave, their life may be shortened. It is therefore necessary the use of appropriate means spacing or wrapping as gauze.

PRODUCT LIFE

The pencils, properly cleaned and sterilized, handled and stored with care, can be sterilized up to a maximum number of sterilizations indicated on the product label.

Electrodes and extension with 2,38mm connection must be replaced after 20 sterilisations.

Electrodes with 4mm connection must be replaced after 100 sterilisations. Keep track of the number of sterilisations performed.

PREPARATIONS AND CONNECTIONS

Attach the grounding plate to the patient, preferably on the forearm or thigh. Be sure that the skin is free of hair and grease. Do not apply the plate to wounds or scars. Apply conductive gel to the plate (if plates without gel are used). Passage of the current within the patient's body should be as brief as possible, and should proceed diagonally. The current must never flow in a transversal direction across the body, nor cross the chest. The patient must be kept isolated from conductive parts, and the operation table must be suitably "grounded". Use dry gauze to avoid areas of the skin coming in contact

with each other. Be sure that the electrode and extension (if present) is firmly inserted into the housing of the pencil.

Please remember to connect the electrode to the extension before connecting the extension to the pencil. By the way, if you need to replace the electrode, remove the extension from the pencil, then replace the electrode and finally connect again the extension to the pencil.

Connect:

- the grounding plate, by using a suitable connection cable,
- the pedal switch (for pedal-controlled models),
- the connector of the pencil cable (“active” electrode),

to the high-frequency generator.

The active cable must be kept from being in direct contact with the patient’s skin, and must not be twisted. Always refer to the manufacturer’s instruction manual to ensure correct use of the high-frequency generator and to the instructions provided by the manufacturer of the grounding plates, whether these are reusable or disposable.

NB: If changes are made in the patient’s position, always recheck all the connections

OPERATIONAL CHECK

Before each procedure, make a preliminary check of the functioning as follows:

1. Connect the patient to the grounding plate.
2. Connect the pencil to the electrosurgical unit.
3. Turn on the electrosurgical unit and select the 0-Watt outlet in the cutting and coagulation function.
4. Keep the pencil away from persons and objects, and activate the CUT function. Verify that electrosurgical unit signals CUT function activation.
5. Repeat point 4 to verify the COAG function.

During the procedure, always select the lowest possible energy level. If the coagulation capacity of the electrode is less than normal, do not increase the high-frequency output without previously carrying out the following controls:

- the correct positioning of the grounding plate;
- 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.

POSSIBLE CAUSES OF BURNS

Burns may be caused by a high density of current in the patient’s tissues or by the heating of inflammable fluids or gases. Possible causes are:

- The patient has inadvertently been placed in contact with electrically-conductive parts.
- A direct contact has occurred between the cables and the patient’s skin, which has caused a capacitive effect.
- The combustion of inflammable disinfectant agents.
- The combustion of inflammable narcotic gases.

CONTRA-INDICATIONS

The products must not be utilised if:

- there is visible damage to the electrode or extension, to its insulation, to the body and/or connector of the pencil, or to the connection cable;
- the preliminary operational check gave negative results;
- the electrode or extension is not firmly inserted in the distal part of the product.

STORAGE


















The product must be stored in its original package at the environmental conditions (temperature and relative humidity) specified on the pouch’s label. Putting external heavy weights on the package could damage the product.

GENERAL NOTES

If a serious incident occurs while using this device or as a result of its use, please report it to the manufacturer and to your national authority. For any malfunction or defect of the device, inform the Manufacturer's Quality Service.

WASTE DISPOSAL

Waste coming from health facilities must be disposed of according to the regulation in force.

| | IT | EN | DE | FR | ES | RU | PT | CS |
|--|--|--|--|--|--|--|---|--|
|  | Conforme alla vigente normativa Europea sui Dispositivi Medici | Compliant with current European legislation on Medical Devices | Entspricht der aktuellen europäischen Gesetzgebung für Medizinprodukte | Conforme à la législation européenne en vigueur sur les dispositifs médicaux | Cumple con la legislación europea vigente sobre dispositivos médicos | Соответствует действующему европейскому законодательству о медицинских устройствах | Em conformidade com a legislação europeia em vigor sobre Dispositivos Médicos | Vyhovuje současně evropské legislativě o zdravotnických prostředcích |
|  | Dispositivo medico | Medical Device | Medizinprodukt | Dispositif médical | Producto sanitario | Медицинское устройство | Dispositivo médico | Zdravotnický prostředek |
|  | Identificativo unico del dispositivo | Unique Device Identifier | Einmalige Produktkennung | Identifiant unique des dispositifs | Identificador único del producto | Уникальный идентификатор устройства | Identificação única do dispositivo | Jedinečným identifikátorem prostředku |
|  | Consultare le istruzioni d'uso | Consult instructions for use | Gebrauchsanweisung lesen | Consulter les instructions d'utilisation | Consulte las instrucciones de uso | Обратитесь к инструкции по применению | Consulte as instruções de utilização | Čtěte uživatelskou příručku |
|  | Fabbricante | Manufacturer | Hersteller | Fabricant | Fabricante | Производитель | Fabricante | Výrobce |
|  | Numero di catalogo | Catalogue number | Katalognummer | Code de référence | Número de Catálogo | Каталожный номер | Número de Catálogo | Katalogové číslo |
|  | Numero di lotto | Batch code | Posten-Nummer | Numéro de lot | Número de Lote | Код партии | Número de Lote | Číslo šarže |
|  | Data di produzione | Date of manufacture | Herstellungsdatum | Date de production | Fecha de Producción | Дата изготовления | Data de Fabrico | Datum výroby |
|  | Data di scadenza | Use by | Verfalldatum | Date de péremption | Fecha de Caducidad | Использовать до | Prazo de Validade | Spotřebujte do |
|  | Non riutilizzare | Do not reuse | Nicht wiederverwenden | Ne pas réutiliser | No reutilizar | Не использовать повторно | Não reutilizar | Nepoužívat opakovaně |
|  | Numero massimo di sterilizzazioni | Maximum number of sterilizations | Max Anzahl der Sterilisationen | Numero maximum de sterilizations | Numero maximo de esterilizaciones | Максимальное количество стерилизаций | Número máximo de esterilizações | max.počet sterilizací |
|  | Non sterile | Non-sterile | Nicht steril | Non-stérile | No estériles | Нестерильные | Não estéril | nesterilní |
|  | Limiti di temperatura | Temperature limitation | Temperaturbereich | Limites de température | Límites de Temperatura | Температурные ограничения | Limites de Temperatura | Omezení teploty |
|  | Limiti di umidità | Humidity limitation | Feuchtigkeitsbereich | Limites d'humidité | Límites de Humedad | Ограничения по влажности | Limites de Humidade | Omezení vlhkosti |
|  | Proteggere dalla luce solare | Keep away from sunlight | Vor Sonnenlicht schützen | Tenir à l'abri de la lumière du jour | Mantener alejado de la luz solar | Беречь от солнечных лучей | Conservar ao abrigo da luz solar | Nevystavujte slunečnému záření |
|  | Numero di pezzi | Quantity of pieces | Stückzahl | Nombre de pièces | Cantidad de piezas | Количество штук | Quantidade de peças | Počet kusů |
|  | Non contiene lattice di gomma naturale | Does not contain natural rubber latex | Enthält kein Naturlatex | Ne contient pas de latex de caoutchouc naturel | No contiene LÁTEX de goma natural | Не содержит натурального латекса | Não contém latex de borracha natural | Neobsahuje přírodní latex |

