

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





**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:

<b>Cycle</b>	<b>Pre-vacuum</b>	<b>Exposure</b>	<b>Drying</b>
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.

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	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 у 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 reutiliser	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

