EN

REUSABLE GROUNDING PLATES FOR ELECTROSURGERY

INSTRUCTIONS FOR USE

MODEL F7915
Patient plates with single conductive section.
MODEL F7930
Patient plates with separate REM type conductive section.

The product is supplied not sterile

WARNINGS
- Check the packing for damages. Do not use the product in the case of damages or visible defects.
- Select a well-vascularised area of skin close to the area to be operated: do not place the plate over scars or close to metallic prostheses or in the vicinity of ECG electrodes.
- Shave, degrease and dry the selected surface.
- Make sure that the entire surface of the plate is in contact with the patient's skin.
- Connect the plate to the generator using the connector cable.
- 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 pencils and accessories to be used with the present product, should comply with the regulations in force.
- The devices must be connected and put into operation only by qualified personnel.
  N.B. The current must never flow in a transversal direction across the body, not cross the chest.
- Do not submit a patient with implanted pacemaker to electrosurgical current without first consulting a cardiologist.
- For the REM type: Check that the generator alarm system is working before starting the procedure.

PREPARATIONS, CONNECTIONS AND USE
- Attach the neutral plate to the patient in a well-vascularised muscular area close to the area of operation, but distant at least 20 cm.
- Spread with electro-conductive gel all the active conductive surface of the grounding pad.
- Do not apply the plate over wounds or scars, close to metallic prostheses or in the vicinity of ECG electrodes, or in areas of potential liquid flow.

N.B. 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 positioned on a dry and electrically insulated surface. The patient must be kept insulated 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.
Connect the plate to the high-frequency generator using the connector cable. Then connect the pencil and, if any, pedal switch to the generator.

FOR REM TYPE
Connect the plate to an electrosurgical unit developed with a system for checking the continuity of the high frequency current return circuit. Check that the alarm system is working before starting the procedure.

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 of 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.

CLEANING
Wash with running water immediately after the operation, then plunge for around 45 minutes in a solution 2% of a normal disinfection product.
The pads can be reused only if they are correctly used, therefore please make a visual check of the product before use.
In case of visible damages replace the pad.

POSSIBLE CAUSES OF BURNS
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:
- The plate is not well positioned or has been re-positioned.
- 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.

CONTRAINDICATIONS
- The product must not be used:
- If there is visible damage to the plate or the connector cable.
- If the contact between the plate and the skin is not good.
- If the patient wears a pacemaker, unless there has been a prior cardiological consultation.

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

GENERAL NOTES
If, during the use of this device or as a result of its use, a serious incident has occurred, 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
Refuses deriving from health structures must be disposed in according to the regulation in force.

	IT	EN	FR	RU	ES	HR	CS
CE 2797	Conforme alla vigente normativa Europea sui Dispositivi Medici	Compliant with current European legislation on Medical Devices	Conforme à la législation européenne en vigueur sur les dispositifs médicaux	Соответствует действующему европейскому законодательству о медицинских устройствах	Cumple con la legislación europea vigente sobre dispositivos médicos	U skladu s važećim europskim zakonodavstvom o medicinskim proizvodima	Vyhovuje současné evropské legislativě o zdravotnických prostředcích
MD	Dispositivo medico	Medical Device	Dispositif médical	Медицинское устройство	Producto sanitario	Medicinski proizvod	Zdravotnický prostředek
UDI	Identificativo unico del dispositivo	Unique Device Identifier	Identifiant unique des dispositifs	Уникальный идентификатор устройства	Identificador único del producto	Jedinstvena identifikacija proizvoda	Jedinečným identifikátorem prostředku
	Attenzione, consultare la documentazione allegata	Caution, consult accompanying documents	Attention, lire attentivement les instructions	Внимание, обратитесь к сопроводительной документации	Atención, leer atentamente las instrucciones	Pozor, pročitajte popratnu dokumentaciju	Varování, čtěte průvodní dokumentaci
	Consultare le istruzioni d'uso	Consult instructions for use	Instructions d'utilisation	Обратитесь к инструкции по применению	Consulte las instrucciones de uso	Pročitajte upute za upotrebu	Varování, čtěte průvodní dokumentaci
	Fabbricante	Manufacturer	Fabricant	Производитель	Fabricante	Proizvođač	Výrobce
REF	Numero di catalogo	Catalogue number	Code de référence	Каталожный номер	Número de Catálogo	Kataloški broj	Katalogové číslo
LOT	Numero di lotto	Batch code	Numéro de lot	Код партии	Número de Lote	Mnogo	Číslo šarže
	Data di produzione	Date of manufacture	Date de production	Дата изготовления	Fecha de Producción	Datum proizvodnje	Datum výroby
	Scadenza	Use by	Date de péremption	Использовать до	Fecha de Caducidad	Iskoristiti do	Spotřebujte do
	Limiti di temperatura	Temperature limitation	Limites de température	Температурные ограничения	Límites de Temperatura	Temperaturni raspon	Omezení teploty
	Limiti di umidità	Humidity limitation	Limites d'humidité	Ограничения по влажности	Límites de Humedad	Raspon vlažnosti zraka	Omezení vlhkosti
X	Numero di pezzi	Quantity of pieces	Nombre de pièces	Количество штук	Cantidad de piezas	Količina ili komada	Počet kusů