

Fig.1

EN REUSABLE ELECTROCAUTERY

TIP FOR REUSABLE ELECTROCAUTERY

DIRECTIONS FOR USE

INDICATIONS

Cauterisation of tissues and small blood vessels during surgical operations. No high frequency generator is required. Specially suitable for ambulatory care surgery.

DESCRIPTION

F7297 and F7299 are reusable electrocauteries which allow battery and tip replacement. Inserting a disposable sterile tip (F7298 series) on the anterior part, reusable electrocautery becomes a self-powered system for cauterisation of small vessels, and it provides an excellent alternative to the radio frequency electrocautery unit. F7297 and F7299 cauteries are intended for different fields of application: F7297 is specific for ophthalmology, while F7299 can be used for gynaecology, orthopedics, Otorhinolaryngology, urology and dermatology. Anyhow, they can be both used in specialities where an accurate and quick cauterisation is required. Since the electrocautery body is supplied non-sterile (only tips are sterile) these models can be used for ambulatory procedures only. Tips are supplied with a sterile protection sheath in PE, which must be used to protect the electrocautery body when in use.

Depending on the need, three different tips can be supplied: fine long (F7298FG), fine short (F7298F) and fine large (F7298L). F7297 cautery must be used with the fine short one (F7298). The working temperatures reach 600°C/1100°F for F7297 cautery and 1.200°C/2200°F for F7299 cautery.

WARNING

- Power is supplied by batteries.
- Use only alkaline batteries SIZE AA 1,5V LR6.
- It is advisable to replace batteries after every application.
- The tips, and the supplied protections, are single-use and sterilized with ethylene oxide gas – do not reuse – Reusing the product may lead to:
 - Possible presence of biological residues that may cause cross-infections;
 - Alteration of materials;
 - Loss of initial functional features of product;
- The tips and protections may not be sterile if the package has been opened and/or damaged.
- After having controlled that packaging is not damaged, verify the cautery body; in case of visible damages or defects, do not use the product and send it back to FIAB.
- Avoid direct contact of cautery with liquids.
- To clean the body use only water-based disinfectants (containing no alcohol).

- Do not sterilise with steam.
- The body has a safety cap-closing system guaranteeing protection when the tip is not inserted.
- The equipment is to be prepared and used by specialized personnel.
- **Avoid use in presence of flammable anaesthetic products and mixtures.**
- Replace the protection when replacing the tip.
- After use always reinsert protection cap before disposal.
- If needed, the body may be sterilized (without tip and batteries) with ethylene oxide for up to 10 times (validation of sterilization is under the responsibility of each end user). After sterilization, the end user should operate in order to avoid any contamination in replacing batteries.
- As concerns disposal, please follow what explained in the paragraph "DISPOSAL".

Caution: remove the tip when the equipment is not used or it may cause a fire.

PREPARATION AND USE

- Open the package containing the tip.
- Extract the protection cap from the handle by making it slide in parallel to the long axis.
- Insert the transparent protection (Fig. 1) on the stem, inserting the handle between the white strip and the paper, thus protecting the tip lodgings.
- Remove the protection package.
- Insert the tip on the front of the stem, piercing the transparent protection.
- For a preliminary control of the electrocautery, follow these instructions:
 - Keep the equipment far from things or people, and press the start button;
 - Make sure the tip becomes incandescent; NB As concerns the low temperature model, since its tip does not become incandescent, you can verify the right functioning as follows: press start button and touch a wet gauze (wet with sterile water or saline solution), then wait 2/3 seconds before noticing water evaporation;
 - If needed, replace the batteries (see corresponding paragraph);
- When using the equipment on the patient, make short (2-3 seconds) and repeated applications. Do not keep the equipment on for too long.
- Do not exert pressures that may misshape the tip.
- Once the application is over, remove the tip from the handle, remove the transparent protection and throw away; if needed, clean the handle and insert the cap.

REPLACING BATTERIES

To replace the batteries, press the cap at the bottom of the handle, turn clockwise and pull it out. Replace the batteries, inserting them with the positive pole towards the inside of the handle. Put the cap back in place by pressing it and turning it anticlockwise until it stops.

CONTRAINDICATIONS

- F7299: Don't use for intra-ocular applications.
- The electro-cauteries are not suitable to cauterize heavy haemorrhages.
- If the stem protection is not used during applications, there is the risk of infections since the stem is not sterile.

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.

The batteries must be disposed of in line with current regulations. Do not burn batteries.

	IT	EN	FR	ES	DE	RU
	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	Cumple con la legislación europea vigente sobre dispositivos médicos	Entspricht der aktuellen europäischen Gesetzgebung für Medizinprodukte	Соответствует действующему европейскому законодательству о медицинских устройствах
	Dispositivo medico	Medical Device	Dispositif médical	Producto sanitario	Medizinprodukt	Медицинское устройство
	Identificativo unico del dispositivo	Unique Device Identifier	Identifiant unique des dispositifs	Identificador único del producto	Einmalige Produktkennung	Уникальный идентификатор устройства
	Attenzione	Caution	Attention	Precaución	Vorsicht	Предостережения
	Consultare le istruzioni d'uso	Consult instructions for use	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Gebrauchsanweisung lesen	Обратитесь к инструкции по применению
	Seguire le istruzioni per l'uso	Follow instructions for use	Consulter les instructions avant utilisation	Siga las instrucciones de uso	Befolgen Sie die Gebrauchsanweisung	Следуйте инструкциям по применению
	Numero di catalogo	Catalogue number	Code de référence	Número de Catálogo	Katalognummer	Каталожный номер
	Numero di lotto	Batch code	Numéro de lot	Número de Lote	Posten-Nummer	Код партии
	Data di produzione	Date of manufacture	Date de production	Fecha de Producción	Herstellungsdatum	Дата изготовления
	Data di scadenza	Use by	Date de péremption	Fecha de Caducidad	Verfalldatum	Использовать до
	Fabbricante	Manufacturer	Fabricant	Fabricante	Hersteller	Производитель
	Limiti di temperatura	Temperature limitation	Limites de température	Límites de Temperatura	Temperaturbereich	Температурные ограничения
	Limiti di umidità	Humidity limitation	Limites d'humidité	Límites de Humedad	Feuchtigkeitsbereich	Ограничения по влажности
	Proteggere dalla luce solare	Keep away from sunlight	Tenir à l'abri de la lumière du jour	Mantener alejado de la luz solar	Vor Sonnenlicht schützen	Беречь от солнечных лучей
	Sterilizzato con ossido di etilene	Sterilized using ethylene oxide	Stérilisé à l'oxyde d'éthylène	Esterilizado con oxido de etileno	Sterilisiert mit Ethylenoxid	Стерилизовано с использованием оксида этилена
	Sistema di barriera sterile singola	Single sterile barrier system	Système de barrière stérile unique	Sistema de barrera estéril simple	Einfaches steriles Barrierensystem	Единая стерильная барьерная система
	Non usare se la confezione è danneggiata	Do not use if package is damaged	Ne pas utiliser si l'emballage est endommagé	No utilizar si el bulto está dañado	Bitte nicht benutzen wenn die Verpackung beschädigt ist.	Не использовать, если упаковка повреждена
	Non risterilizzare	Do not resterilize	Ne pas restériliser	No esterilizar nuevamente	Nicht wieder sterilisieren	Не стерилизовать повторно
	Non riutilizzare	Do not reuse	Ne pas reutiliser	No reutilizar	Nicht wiederverwenden	Не использовать повторно
	Dispositivo di tipo CF	Type CF device	Appareil de type CF	Aparato de tipo CF	Geräte vom Typ CF	Устройства CF-типа
	Numero di pezzi	Quantity of pieces	Nombre de pièces	Cantidad de piezas	Stückzahl	Количество штук