

DISPOSABLE STERILE BATTERY-OPERATED CAUTERIES

CE
2797

COMPLIANCE TO STANDARDS: IEC 60601-1: intimal supply device, applied parts type: CF

DIRECTIONS FOR USE:

INDICATIONS:

Cauterization of tissues and capillary vessels during operations. No high frequency generator is required.

DESCRIPTION:

FIAB battery cauterizes are available in 5 different models according to tip shape and to the temperature they can reach. Energy is supplied by built-in alkaline batteries. Each cautery has a safety cap protecting the tip from any damage and preventing any accidental ignition.

F7244 SERIES

High temperature, fine tip cautery

F7277 | F7234 SERIES

High temperature, fine tip cautery, length 125mm, 75mm.

F7255 SERIES

Low temperature, fine tip cautery. Minimizes tissue damage in application area. Particularly recommended for ophthalmologic purposes.

WARNINGS

The product is single use and sterilized with EO gas - do not reuse. ATTENTION 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
- Sterility is not guaranteed if packaging is opened and/or damaged
- After having controlled that packaging is not damaged, verify 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
- Avoid use in presence of flammable anesthetic products and mixtures
- Use only disinfectant in aqueous solutions.
- Do not re-sterilize. Do not dispose in fire
- Devices must be activated by qualified personnel only

PREPARATION AND USE

- Open packing and put the cautery in sterile field.
- Remove protection cap by sliding it up through the body. Carefully avoid contact between cap and tip.
- Before use always do a functioning test as follows:
- Keep away from persons and things and press start button
- For models F7244, F7277, F7234 check that the tip becomes incandescent.
- N.B. Low temperature model F7255 does not feature tip incandescence. For this models the check on correct functioning can be carried out by touching the tip with a sterile gauze dipped in sterile water or a physiological salt solution. 2/3 seconds after activation the evaporation of the water can be observed.
- During use with patients, make short and frequent applications (2-3 seconds). Avoid the prolonged continuous use, that can provoke excessive heating and possible breakup of the tip.
- Don't press the tip too strong in order to avoid possible deformation such to involve its breaking
- Reinsert protection cap after use and destroy the product.

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CONTRAINDICATIONS

- The models F7244, F7277 and F7234 cannot be used for ophthalmologic purposes.
- The electro-cauterizes are not suitable to cauterize heavy hemorrhages.

STORAGE

The package must be stored within the temperature and humidity limits as indicated on the package.

WARNINGS PRINTED ON CAUTERY

- Warning: contains batteries
- Do not autoclave
- Do not dispose in fire
- Do not use in presence of flammable materials

GUARANTEE • NOTICE

- FIAB guarantees that the product complies with Directive 93/42/EEC and has been manufactured according to the procedures of FIAB Quality System certified ISO 13485.
- No responsibility may be ascribed to the producer who shall not be held liable for medical costs, direct or indirect damage due to lacking function or malfunction of the above products, when used differently from the instructions for use. We recommend to report opportunely any malfunction or defect of the product to FIAB Quality Assurance Service.


















WASTE DISPOSAL

- Attention: This product contains batteries. It must be disposed as special hospital waste according to regulations in force. The device may be contaminated by blood and it must be disinfected before disposal. In order to avoid any accidental switching on, please cut the tip with pliers or scissors and cover it with the safety cap.

CAUTION:

U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

SYMBOL LEGEND

	European Conformity 93/42/EEC
	Caution, consult accompanying documents
	Consult instructions for use
	Catalogue Number
	Batch number
	Date of manufacture
	Use by
	Manufactured by
	Temperature limitation
	Humidity limitation
	Keep away from sunlight
	Ethylene Oxide Sterilized
	Do not re-use
	By prescription
	Quantity of pieces per box
	Type CF applied part
	On / Off Switch

