

## **DISPOSABLE STERILE ELECTROCAUTERY**





# DIRECTIONS FOR USE

## **COMPLIANCE TO STANDARDS**

EN 60601-1: Internal supply device, applied parts type: CF

## INDICATIONS

Cauterisation of tissues and small blood vessels during operations. No high frequency generator is required. Specially suitable for ambulatory care surgery in outpatients' and emergency departments, gynaecologic, ophthalmologic, dermatological and cardiologic departments, for pacemakers implantation and cardiovascular surgery.

#### **DESCRIPTION**

FIAB battery cauteries 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 (1200°C/2200°F). It is particularly recommended when precise and efficacious haemostasis is required, as in cardiovascular surgery, dermatology and microsurgery.

#### F7266 SERIES

High temperature, large tip cautery (1200°C/2200° F). Due to its larger contact surface, it is particularly recommended when bleeding must be kept under strict control. Especially suitable for general surgery and orthopaedics.

#### F7277 - F7234 SERIES

High temperature model (1200°C/2200°F) fine tip length 125mm, 75mm. It is particularly indicated when precise haemostasis in particular recesses or areas with limited access is required. It is particularly useful during pacemaker implantation and in outpatients gynaecology.

#### F7288 SERIES

Medium temperature, thick tip cautery (800°C/1400°F). This model is characterised by its thick, rigid tip and is recommended for removal of haematoma under the nails.

#### F7255 SERIES

Low temperature, fine tip cautery (600°C/1100°F). Minimises tissue damage in application area. Particularly recommended for ophthalmologic purposes.

# WARNINGS

- The product is disposable and sterilised with EO gas Do not reuse Reusing the product may lead to:
  - o Possible presence of biological residues that may cause cross-infections;
  - o Alteration of materials;
  - o Loss of initial functional features of product;
- Sterility is not guaranteed iFpackaging 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 anaesthetic products and mixtures.
- Use only disinfectant in aqueous solutions.
- Do not sterilise with steam. Do not dispose in fire.
- Devices must be activated by qualified personnel only.
- After use <u>always</u> reinsert protection cap before disposal.

### 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 medium and high temperature models 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.

## CONTRAINDICATIONS

- The medium and high temperature models cannot be used for intra ocular use.
- The model F7288 can be used only as stated.
- The electro-cauteries are not suitable to cauterize heavy haemorrhages.

## 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.

## WARNINGS PRINTED ON CAUTERY

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

## 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

Attention: This product contains batteries.

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