TECHNICAL SHEET
SINGLE USE STERILE ELECTRODES FOR ELECTROPORATORS IGEA, SERIES EPSGUN

Manufacturer's name and address	IGEA S.p.A. Via Parmenide, 10/a Carpi (MO)
Type	Single use sterile electrodes for electroporators IGEA
Series	Serie EPSGun
Directive 93/42 EEC e s.m.i.	Class IIa
Mark	CE 0051
Intended use	Medical device for the passive transmission of electrical pulses to tissues. The device (hereinafter also called "electrode") is indicated for the treatment, by means of electroporation, of soft tissues and superficial cancer lesions. The device is indicated for the treatment of tissues no more than 3 cm deep from the surface of the skin surface or mucosa. Treatment is performed by using IGEA compatible electroporators, together with the **Handle**.
Storage conditions	The Electrode is supplied in a sterile pack. The Electrode must be stored in a dry and clean place, away from heat sources and in the following environmental conditions: Temperature: 10 °C – 40 °C. Sterility is guaranteed until the expiry date indicated on the package, provided that the double wrapping remains intact.
Disposal conditions	WARNING! Dispose of the device immediately after use, following the procedures provided for the disposal of sharp objects that have come into contact with blood or biological fluids. If the device has been applied to the patient it cannot be disposed of as household waste. **Risk of infection** for waste disposal personnel!

The device is supplied sterile and individually packaged in a double paper/coupled bag suitable for ethylene oxide sterilization (ETO).

- Sterilization method used: **Ethylene Oxide (ETO)**.
- Validity period: maximum period of use is 60 months (5 years)

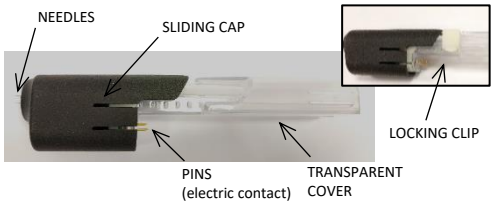
The electrode is **disposable** and must be used on one patient only, during a single treatment session, then disposed of.

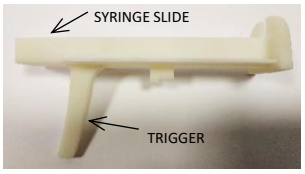
Once the package has been opened, the electrode must be used or disposed of, as the device **cannot be re-sterilized**.

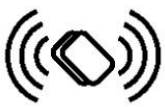
The electrode is produced and packaged with materials that **do not contain rubber latex**.

The EPSGun Series electrode consists of:

- An invasive part consisting of a series of **needles** (diameter of 0.45 mm) arranged in a linear geometric configuration. The needles are housed inside a **sliding cap**, protected by a **locking clip** that prevents any unwanted movements during transport and handling of the device. The locking clip must be removed before using the device. Through the appropriate **pins** it is possible to connect the device to the related accessory (Handle).
- A syringe slide that allows you to combine the Electrode with a compatible syringe (not included).
- A **Tag** placed on the outer envelope of the package, a radiofrequency identification device (RFIS) that allows you to recognize and activate the Electrode.







TAG

Product variants		There are several models that allow to optimize the treatment and must be chosen on the basis of the location, type, depth and size of the lesion to be treated.	
Model	**Order Code** Set of 5 electrodes	**Description of the electrode**	**Compatible Accessory / Order Code**
G-30-L2	IG0E202	EPSGun (**G**), Maximum length of the needles 30 mm (**30**). Linear configuration (**L**inear), consisting of two needles (**2**) 4mm distant from each other.	**Handle** IG0M920
G-30-L4	IG0E204	EPSGun (**G**), Maximum length of the needles 30 mm (**30**). Linear configuration (**L**inear), consisting of four needles (**4**) 4mm distant from each other.	