


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

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| Manufacturer name and address | IGEA S.p.A. Via Parmenide, 10/a Carpi (MO) |
| Type | Single use sterile electrodes for IGEA electroporators |
| Series | EPSA Series |
| Models | H-30-ST, H-40-ST, H-40-IN, L-30-ST, L-40-ST, L-40-IN |
| Directive 93/42 EEC Classification and s.m.i. | Class IIA |
| Mark |  |
| Intended use | <p>Series EPSA electrode is a medical device for the passive transmission of electrical pulses to the tissues. The device is suitable for the electroporation-based treatment of surface/deep soft tissues and surface/deep tumour lesions.</p> <p>The treatment is carried out exclusively using IGEA compatible electroporators: Cliniporator mod. EPS02, Cliniporator VITAE mod. VGP02 (PRE-SET mode).</p> |
| Storage conditions | <p>The electrode must be stored in a dry and clean place, away from heat sources and in the following environmental conditions: Temperature: from 10°C to 40°C.</p> <p>Sterility is guaranteed until the expiration date indicated on the package, provided that the double wrapper remains intact.</p> |
| Disposal Conditions | <p>Dispose of the electrodes 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 electrodes have been applied to the patient they cannot be disposed of as municipal waste. Warning! Danger of infection for waste management personnel!</p> |

The electrode is a medical device, provided **STERILE**, single packaged in a double blister.

- Sterilization method: **Ethylene Oxide**.
- Validity period: the maximum period of use is 60 month (5 years).

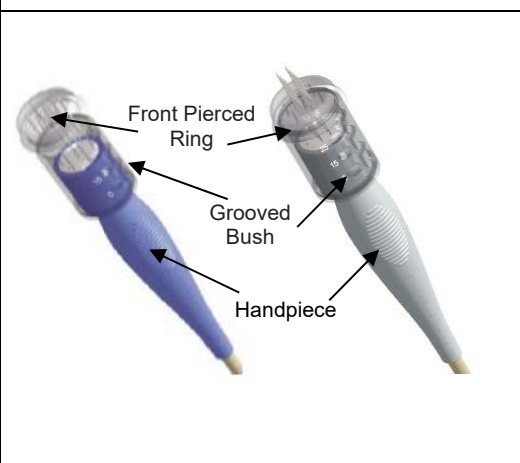
The electrode is **disposable** and must be used on one patient only, during a single treatment session, then disposed of.

Once the package is opened, the electrode must be used or disposed of, as **the device is not re-sterilizable**.

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

The EPSA series electrode consists of:

- An invasive part consisting of a series of needles with hexagonal or linear configuration, whose exposed part is adjustable in height thanks to mobile elements, which allow the selection of needles insertion depth and maintenance of the needles alignment during the penetration into the tissue. Depth selection can be selected by the front pierced ring and the grooved bush which allow the adjustment in steps of five millimeters. On some models, the needles are partially insulated by polymer sheaths.
- A shaped handpiece representing the area where the operator grasp the device.
- A connecting cable arranged in a "eight" conformation which ends with the connector for connection to compatible electroporator. The cable maintains the conformation thanks to a plastic tie which must be removed before treatment.



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Product Variants

There are several models that allow to optimise the treatment according to the location, type, depth and size of the lesion to be treated, whose characteristics are summarized in following the table:

| Ref. (ORDER CODE) | Model | Electrode Description |
|----------------------|---------|--|
| IG0E050 | H-30-ST | Adjustable electrode, hexagonal configuration (Hexagonal), 30 mm length (30), standard not insulated needles (ST andard) |
| IG0E040 | H-40-ST | Adjustable electrode, hexagonal configuration (Hexagonal), 40 mm length (40), standard not insulated needles (ST andard) |
| IG0E070 | L-30-ST | Adjustable electrode, linear configuration (Linear), 30 mm length (30), standard not insulated needles (ST andard) |
| IG0E090 | L-40-ST | Adjustable electrode, linear configuration (Linear), 40 mm length (40), standard not insulated needles (ST andard) |
| IG0E060 | H-40-IN | Adjustable electrode, hexagonal configuration (Hexagonal), 40 mm length (40), partially insulated needles (IN sulated) Length of the not insulated needles 20 mm |
| IG0E080 | L-40-IN | Adjustable electrode, linear configuration (Linear), 40 mm length (40), partially insulated needles (IN sulated) Length of the not insulated needles 20 mm |