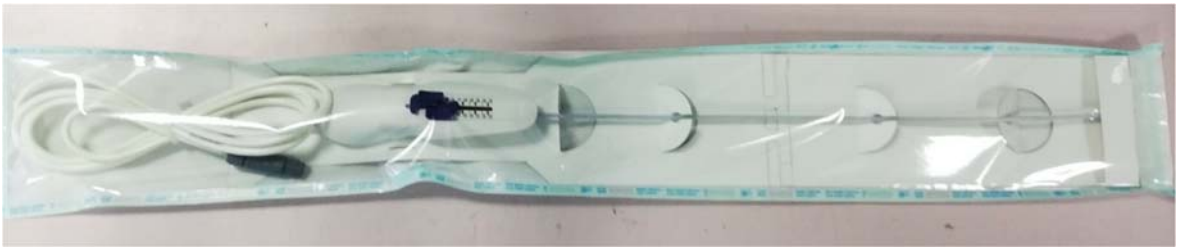
Single use sterile electrodes for electroporators IGEA, Series EGPS - DATA SHEET

Name and address of the manufacturer	IGEA S.p.A. Via Parmenide, 10/a Carpi (MO)
Device Type	***Single use sterile electrodes for electroporators IGEA, Series EGPS***
Series	*Series EGPS*
Models	E-L2-00-S4-2, E-L2-02-S2-2, E-X2-00-S4-2, E-X2-03-S2-2, E-L5-00-S4-2, E-L5-02-S2-2, E-L2-10-SA-B, E-L5-10-SA-B, E-X2-10-SB-B
Commercial Name	SLINGER
Directive 93/42 EEC classification	Class IIa
Mark	CE 0051
Intended use	The electrode Series EGPS is a medical device for the passive transmission of electrical pulses to the tissues. The device is indicated for the treatment by electroporation of soft tissues and both superficial and deep tumor lesions. The treatment is carried out exclusively using IGEA compatible electroporators: Cliniporator mod. EPS02, Cliniporator VITAE mod. VGP02 (PRE-SET mode). The device is compatible with other medical devices, including laparoscopic accesses and medical devices intended to guide and facilitate the positioning of the multi lumen.
Storage conditions	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. Sterility is guaranteed until the expiration date indicated on the package, provided that the double wrapper remains intact.
Disposal conditions	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!

The electrode is a medical device, supplied **STERILE,** disposable, individually packaged in a **double paper-laminated envelope**.



Sterilization method used: **Ethylene Oxide**.

Validity period: maximum period of use is 60 months (5 years).

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

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

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

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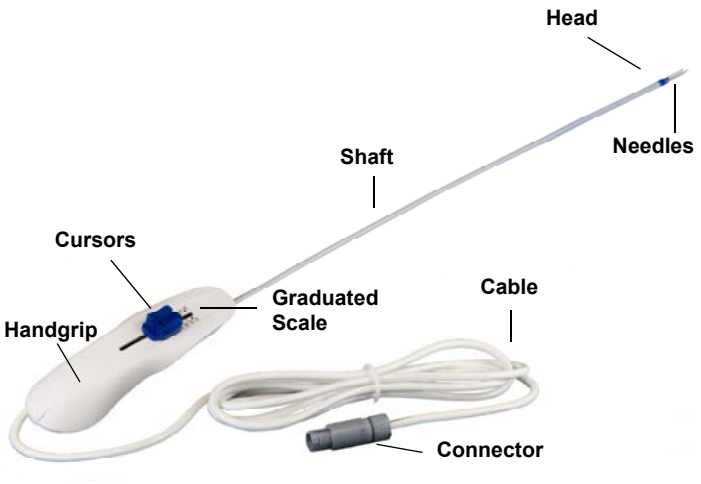
The electrode consists of a **handgrip** with a **graduated scale** and **cursors** for the movement of the **medical steel needles** with trocar tip, which constitute the active part and have the dual function of perforating the patient's tissues and conveying the electrical pulses in the treatment area .

The needles are placed in a square configuration around a central needle and slide inside the shapeable **shaft**, at the top of which there is a **head** which determines the divergence at 0°, 2°, 3° or 10°, depending on the model .

The needles, if provided, can have an insulating polymer sheath, which limits the exposed conductive part (active part).

The connection cable ends with the connector for connection to the electroporator.



Product variants: the different models differ in diameter and length of the Shaft, divergence, exposure and active part of the needles.

Order Code (REF)	Model (MODEL)	Shaft Diameter (mm)	Shaft Length (cm)	Divergence (gradi)	Max Needles Exposure (mm)	Active Part Length (mm)
IG0E801	E-L2-00-S4-2	L = 5	20	0	40	20
IG0E802	E-L2-02-S2-2	L = 5	20	2	20	20
IG0E803	E-X2-00-S4-2	X = 10	20	0	40	20
IG0E804	E-X2-03-S2-2	X = 10	20	3	20	20
IG0E805	E-L5-00-S4-2	L = 5	50	0	40	20
IG0E806	E-L5-02-S2-2	L = 5	50	2	20	20
IG0E821	E-L2-10-SA-B	L = 5	20	10	25	15
IG0E831	E-X2-10-SB-B	X = 10	20	10	15	15
IG0E841	E-L5-10-SA-B	L = 5	50	10	25	15