

**SINGLE USE STERILE ELECTRODES FOR IGEA ELECTROPORATORS, VGD SERIES**

Name and Address of the manufacturer	IGEA S.p.A. Via Parmenide, 10/a Carpi (MO), Italy
Type of device	✓ Single use sterile electrode for IGEA electroporators <small>vienkartinio naudojimo, suderinami su Igea prietaisų elektroterapijai</small>
Series	Series VGD ✓ <small>VGD serijos</small>
Directive 93/42 EEC Classification	Class IIa

Model	<small>Kodas</small> ✓ Order Code	<small>pastabos</small> ✓ Notes	Model	Order Code	Notes
VGD-1210T12	IG0E700	6 pcs set <small>6vnt/rinkinys</small>	VGD-0830C12	IG0E730	4 pcs set
VGD-1220T12	IG0E701	6 pcs set	VGD-0840C12	IG0E731	4 pcs set
VGD-1230T12	IG0E702	6 pcs set	VGD-0810C16	IG0E732	4 pcs set
VGD-1240T12	IG0E703	6 pcs set	VGD-0820C16	IG0E733	4 pcs set
VGD-1210T16	IG0E704	6 pcs set	VGD-0830C16	IG0E734	4 pcs set
VGD-1220T16	IG0E705	6 pcs set	VGD-0840C16	IG0E735	4 pcs set
VGD-1230T16	IG0E706	6 pcs set	VGD-0810C20	IG0E736	4 pcs set
VGD-1240T16	IG0E707	6 pcs set	VGD-0820C20	IG0E737	4 pcs set
VGD-1210T20	IG0E708	6 pcs set	VGD-0830C20	IG0E738	4 pcs set
VGD-1220T20	IG0E709	6 pcs set	VGD-0840C20	IG0E739	4 pcs set
VGD-1230T20	IG0E710	6 pcs set	VGD-0810C24	IG0E740	4 pcs set
VGD-1240T20	IG0E711	6 pcs set	VGD-0820C24	IG0E741	4 pcs set
VGD-1210T24	IG0E712	6 pcs set	VGD-0830C24	IG0E742	4 pcs set
VGD-1220T24	IG0E713	6 pcs set	VGD-0840C24	IG0E743	4 pcs set
VGD-1230T24	IG0E714	6 pcs set	VGD-0810C12	IG0E744	6 pcs set
VGD-1240T24	IG0E715	6 pcs set	VGD-0820C12	IG0E745	6 pcs set
VGD-1810T12	IG0E716	6 pcs set	VGD-0830C12	IG0E746	6 pcs set
VGD-1820T12	IG0E717	6 pcs set	VGD-0840C12	IG0E747	6 pcs set
VGD-1830T12	IG0E718	6 pcs set	VGD-0810C16	IG0E748	6 pcs set
VGD-1840T12	IG0E719	6 pcs set	VGD-0820C16	IG0E749	6 pcs set
VGD-1810T16	IG0E720	6 pcs set	VGD-0830C16	IG0E750	6 pcs set
VGD-1820T16	IG0E721	6 pcs set	VGD-0840C16	IG0E751	6 pcs set
VGD-1830T16	IG0E722	6 pcs set	VGD-0810C20	IG0E752	6 pcs set
VGD-1840T16	IG0E723	6 pcs set	VGD-0820C20	IG0E753	6 pcs set
VGD-1810T20	IG0E724	6 pcs set	VGD-0830C20	IG0E754	6 pcs set
VGD-1820T20	IG0E725	6 pcs set	VGD-0840C20	IG0E755	6 pcs set
VGD-1830T20	IG0E726	6 pcs set	VGD-0810C24	IG0E756	6 pcs set
VGD-1840T20	IG0E727	6 pcs set	VGD-0820C24	IG0E757	6 pcs set
VGD-0810C12	IG0E728	4 pcs set	VGD-0830C24	IG0E758	6 pcs set
VGD-0820C12	IG0E729	4 pcs set	VGD-0840C24	IG0E759	6 pcs set



Mark



Intended Use

VGD serijos vienkartiniai elektrodai yra medicinos priemonės, skirtos pasyviai elektrinių impulsų transmisijai į audinius. Tinkamas minkštųjų audinių, kaulų, vidaus organų ir didelių navikų elektroterapijai

The VGD Series single use electrode is a medical device designed for the passive transmission of electrical pulses to tissues. It is indicated for the treatment by electroporation of soft tissues, bone tissues and deep and / or large tumor lesions.

Storage conditions

The VGD Series electrode is supplied in a sterile package; it must be kept in a dry and clean place, away from heat sources and in normal conditions of temperature and relative humidity. The sterility of the device is guaranteed until the expiration date indicated on the package, provided that the wrapping remains intact.

Disposal Conditions

WARNING! Dispose of all the elements of which the electrode is composed immediately after use, following the procedures for the disposal of sharp objects that have come into contact with blood or biological liquids for the needle. If the electrodes have been applied to the patient, they cannot be disposed of as municipal waste. Danger of infection for waste personnel!



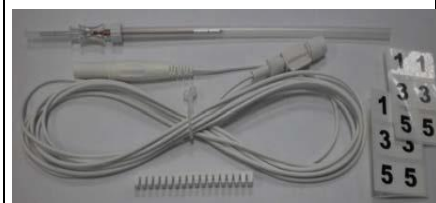
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- ✓ The device is supplied **sterile** and individually packaged in a PETG blister sealed with Tyvek[®]. *Priemonės yra sterilios, supakuotos individualiai*
- Sterilization method used: Ethylene Oxide;
 - Period of validity: the maximum period of validity 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, since **the device cannot be re-sterilized**.
- The electrode is produced and packaged with materials that do not contain rubber latex.



The device mainly consists of:

- **Needle:** Consisting of an AISI 304 steel bar marked with a centimetre scale, a handgrip, a stopper and is partially covered with an insulating polymeric material (sheath). The distal part of the uncoated needle is the active area of the device (active part). The handgrip has the dual function of facilitating the grip during use and allowing the mechanical and electrical connection with the cable. The stopper allows, if necessary, to limit the insertion depth of the needle.
- **Cable:** About 3 meters long, it ends on one side with a plug connector, for connection to the electroporator, on the other with the element that allows mechanical fixing and electrical connection to the needle.
- **Spacer:** In each package there is a notched element, which can be used by the operator to optimize the positioning of the needle.



Product Variants	There are different needle models that allow to optimize the treatment and must be chosen based on the location, type, depth and size of the lesion to be treated.			
Description of various models Mod.: VGD-aaxxZyy	aa: is the diameter of the needle in mm: 0.8mm (Gauge 21), 1.2mm (Gauge 18), 1.8mm (Gauge 15); xx: is the length of the active part in mm (10/20/30/40 mm); Z: is the type of the tip : "T" Trocar, "C" Chiba; yy: is the total length of the needle in cm (12/16/20/24* cm) <i>*24 cm only for models VGD-08xxCyy e VGD-12xxTyy</i>			
Set of 4 VGD needle electrodes Needle diameter 0.8 mm (21 G) (SOFT TISSUE)	CHARACTERISTICS AND ORDER CODE			
	NEEDLE TOTAL LENGTH	ACTIVE PART LENGTH		
		20 mm	30 mm	40 mm
		12 cm	-	-
		16 cm	-	-
Set of 6 VGD needle electrodes Needle diameter 0.8 mm (21 G) (SOFT TISSUE)	CHARACTERISTICS AND ORDER CODE			
	✓ <i>Bendras adatos ilgis</i> NEEDLE TOTAL LENGTH	✓ ACTIVE PART LENGTH <i>aktyvios dalies ilgis</i>		
		20 mm	30 mm	40 mm
		12 cm	-	-
		16 cm	-	-
Set of 6 VGD needle electrodes Needle diameter 1.2 mm (17 G) (SOFT TISSUE)	CHARACTERISTICS AND ORDER CODE			
	✓ <i>Bendras adatos ilgis</i> NEEDLE TOTAL LENGTH	✓ ACTIVE PART LENGTH <i>aktyvios dalies ilgis</i>		
		20 mm	30 mm	40 mm
		12 cm	Code IG0E701	Code IG0E702
		16 cm	-	Code IG0E706
Set of 6 VGD needle electrodes Needle diameter 1.8 mm (15 G) (BONE)	CHARACTERISTICS AND ORDER CODE			
	✓ <i>Bendras adatos ilgis</i> NEEDLE TOTAL LENGTH	✓ ACTIVE PART LENGTH <i>aktyvios dalies ilgis</i>		
		20 mm	30 mm	40 mm
		12 cm	Code IG0E717	Code IG0E718
		16 cm	Code IG0E721	Code IG0E722