


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 prietaisu elektroporacijai</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	IGOE700	6 pcs set <small>6vnt/rinkinys</small>	VGD-0830C12	IGOE730	4 pcs set
VGD-1220T12	IGOE701	6 pcs set	VGD-0840C12	IGOE731	4 pcs set
VGD-1230T12	IGOE702	6 pcs set	VGD-0810C16	IGOE732	4 pcs set
VGD-1240T12	IGOE703	6 pcs set	VGD-0820C16	IGOE733	4 pcs set
VGD-1210T16	IGOE704	6 pcs set	VGD-0830C16	IGOE734	4 pcs set
VGD-1220T16	IGOE705	6 pcs set	VGD-0840C16	IGOE735	4 pcs set
VGD-1230T16	IGOE706	6 pcs set	VGD-0810C20	IGOE736	4 pcs set
VGD-1240T16	IGOE707	6 pcs set	VGD-0820C20	IGOE737	4 pcs set
VGD-1210T20	IGOE708	6 pcs set	VGD-0830C20	IGOE738	4 pcs set
VGD-1220T20	IGOE709	6 pcs set	VGD-0840C20	IGOE739	4 pcs set
VGD-1230T20	IGOE710	6 pcs set	VGD-0810C24	IGOE740	4 pcs set
VGD-1240T20	IGOE711	6 pcs set	VGD-0820C24	IGOE741	4 pcs set
VGD-1210T24	IGOE712	6 pcs set	VGD-0830C24	IGOE742	4 pcs set
VGD-1220T24	IGOE713	6 pcs set	VGD-0840C24	IGOE743	4 pcs set
VGD-1230T24	IGOE714	6 pcs set	VGD-0810C12	IGOE744	6 pcs set
VGD-1240T24	IGOE715	6 pcs set	VGD-0820C12	IGOE745	6 pcs set
VGD-1810T12	IGOE716	6 pcs set	VGD-0830C12	IGOE746	6 pcs set
VGD-1820T12	IGOE717	6 pcs set	VGD-0840C12	IGOE747	6 pcs set
VGD-1830T12	IGOE718	6 pcs set	VGD-0810C16	IGOE748	6 pcs set
VGD-1840T12	IGOE719	6 pcs set	VGD-0820C16	IGOE749	6 pcs set
VGD-1810T16	IGOE720	6 pcs set	VGD-0830C16	IGOE750	6 pcs set
VGD-1820T16	IGOE721	6 pcs set	VGD-0840C16	IGOE751	6 pcs set
VGD-1830T16	IGOE722	6 pcs set	VGD-0810C20	IGOE752	6 pcs set
VGD-1840T16	IGOE723	6 pcs set	VGD-0820C20	IGOE753	6 pcs set
VGD-1810T20	IGOE724	6 pcs set	VGD-0830C20	IGOE754	6 pcs set
VGD-1820T20	IGOE725	6 pcs set	VGD-0840C20	IGOE755	6 pcs set
VGD-1830T20	IGOE726	6 pcs set	VGD-0810C24	IGOE756	6 pcs set
VGD-1840T20	IGOE727	6 pcs set	VGD-0820C24	IGOE757	6 pcs set
VGD-0810C12	IGOE728	4 pcs set	VGD-0830C24	IGOE758	6 pcs set
VGD-0820C12	IGOE729	4 pcs set	VGD-0840C24	IGOE759	6 pcs set

✓ Mark	
✓ Intended Use	<p><small>VGD serijos vienkartiniai elektrodai yra medicinos priemonės, skirtos pasyviai elektrinių impulsų transmisijai į audinius. Tinkamas minkštųjų audinių, kaulų, vidaus organų ir didelių navikų elektroporacijai</small></p> <p>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.</p>
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.

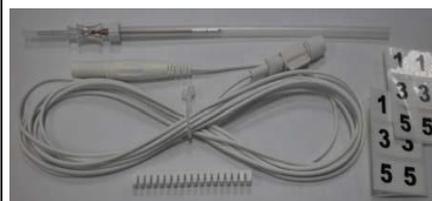
Once the package has been opened, the electrode must be used or disposed of, since **the device cannot be re-sterilized**.

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)
 *24 cm only for models VGD-08xxCyy e VGD-12xxTyy

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	-	-	-	
20 cm	Code IG0E737	Code IG0E738	-	
24 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	-	-	-	
20 cm	Code IG0E753	Code IG0E754	-	
24 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	Code IG0E707	
20 cm	-	Code IG0E710	Code IG0E711	
24 cm	-	Code IG0E714	-	

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	Code IG0E719	
16 cm	Code IG0E721	Code IG0E722	Code IG0E723	
20 cm	-	Code IG0E726	Code IG0E727	

