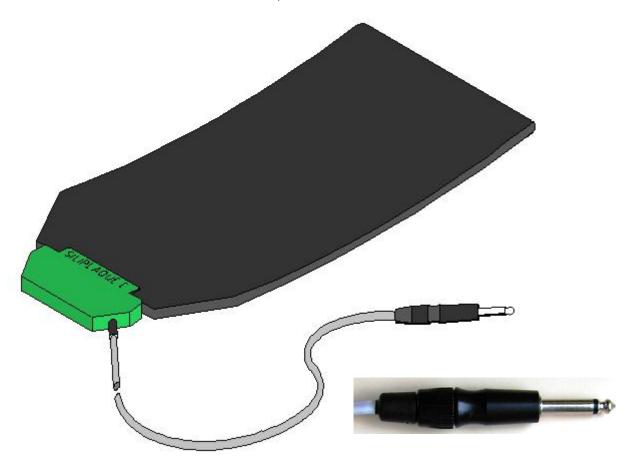


FICHE TECHNIQUE / DATASHEET

Electrode neutre / Neutral electrode SILIPLAQUE C, REF. V11IS1C



1.	Dispositif Médical Medical Device	SILIPLAQUE C
	GMDN code	42551: A non-active conductor that is used in an electrosurgical generator system providing an electrical connection and route for the emitted energy that is used to deliver an electrosurgical effect to create lesions at a desired site on the patient. It is fastened to the patient's body, typically where full area contact is best achieved for a particular intervention. It may or may not be designed with permanently attached cables and is reusable.
	Description	Dispositif réutilisable / reusable device Plaque souple, simple surface, 437 cm² (147 x 297 mm), avec câble de longueur 5m et fiche mâle Ø 2.35mm Flexible plate, single surface, 437 cm (147 x 297 mm), with cable length of 5m and plug Ø 2.35mm
	Reference code	V11IS1C
	Usage revendiqué Intended use	Electrode neutre d'électrochirurgie en mode monopolaire Neutral electrode for electrosurgery in monopolar mode

Rédaction : R. LAGOU	SILIPLAQUE C_ FT-0914_Rev1 Rev. 1	Date : 02/09/2014





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2	Classification (MDD	Classe IIb suivant l'annexe IX, règle N°9
	93/42/EEC annex IX)	Class IIb following annex IX, rule N°9
		IEC / EN 60601-2-2 : 2009 ; IEC / EN 60601-1 : 2007 ;
3	Normes appliquées Applied standard	EN ISO 10993-1: 2009; EN 980: 2008; EN ISO 14971: 2012
4	Tension assignée Rated voltage	HF: 416 Vp
4		50/60Hz : 1100 Vp
5	Matériaux Materials	- Plaque en Silicone chargé carbone / Silicone plate loaded carbon
		- Coque en POM C chargé fibre de verre 30% / POM-C shell with fiberglass 30%
		- Câble PVC (Câble Silicone sur demande)/ PVC cable (Silicon cable on request)
6	Produits toxiques ou allergènes Toxicity, Allergy	- Sans latex, sans DEHP / latex free, DEHP free
		- Conformité RoHS / RoHS compliance
7	Traitements / processing	- Nettoyage manuel avec détergeant doux / Manual cleaning with mild detergent
		- Désinfection de surface (lingettes Cidalkan; Wip-Anios; Surf-Anios) / Surface disinfection wipes (wipes Cidalkan; Wip-Anios; Surf-Anios)
		- Rinçage à l'eau claire / rinse with clear water
		- Stérilisation à l'autoclave à 134°C/20min avec câble Silicone / Steam sterilization at 134°C / 20 min with Silicon cable
8	Conditionnement / Packing	À l'unité, emballage non stérile / Single, non sterile packaging
9	Origine / Origin	Fabriqué en France par LAMIDEY NOURY Medical Made in France by LAMIDEY NOURY Medical



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