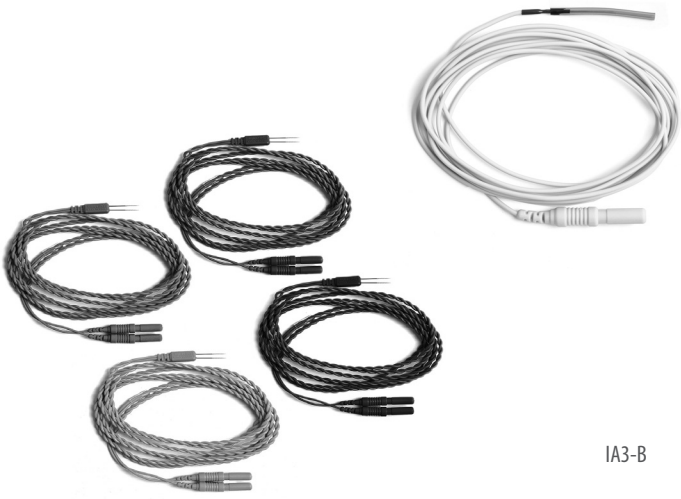
nerveäna® mastodon™

Needle Electrodes

Instructions For Use



IA3-B

-Symbols used in device labeling- *Check individual device label for applicable symbols*	
Symbol	**Description**
	Sterile
	Manufacturer
	Use by date
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Catalogue number
	Batch code
	BF applied part
	Prescription only
	Medical device
	Keep away from rain
	CE Mark
	Upper limit of temperature
	Keep away from sunlight
	Non-Sterile
	Authorized representative in the European Community
	Unique Device Identifier

THIS IFU IS USED WITH THE FOLLOWING PRODUCT CODES OR CODE PRE-FIXES:

- NVTKIT
- NVPTKIT
- LTE7003P
- SCKIT
- DCKIT
- EAKIT
- USE
- I-D
- PSS
- I-DK
- NVHS
- NVFKIT
- NPDC
- NPFC
- NVPFKIT
- NG15

INTENDED USE

Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG) and Evoked Nerve Potential (NP) signals. The electrodes are sterile and for single patient use only.

DESCRIPTION

Neurovision Medical Products, Inc. provides single-use, sterile, subdermal needle electrodes consisting of a stainless-steel fine tip for mild skin penetration and a safety touch proof connector on the opposite end of the lead wire. They are supplied in a variety of lengths, styles (single or paired), and colors to be suitable for any muscles and to support different procedure types.

WARNINGS

- The metal part of the needle electrode should not be visible after insertion. Make sure to completely insert the needle electrode into the patient.
- The subdermal needle electrode is for single patient use only.
- This single-use product is not designed for re-use. Attempts to clean and re-use this single-use device exposes patients and operators to risk of cross contamination.
- Do not re-sterilize.
- Not compatible with MRI.
- In case of subdermal needles or cork screws being used together with high voltage and frequency instruments (e.g. electrosurgery), a minimum distance of 20-30 cm between subdermal needles cables and stimulation instrument cables is required in order to avoid electrical interferences leading to skin burns.
- Maximum stimulation value: 60 mA.
- To avoid contamination of the device and therefore of the patient, the user must wear disposable gloves.

INSTRUCTIONS FOR USE

1. Do not use the selected needle if the pouch is damaged.
2. Open the pouch and remove needle from sterile pouch.
3. Connect the needle with the equipment.
4. Remove the needle sheath.
5. Introduce the needle into the area to be tested. Insert the needle up to hub.
   NOTE: Ensure the needle electrode is completely inserted into the patient.
6. After use, dispose of the needle according to standard protocols or alternatively put the needle in approved biohazard sharps containers.

RECOMMENDATIONS

- Communication between the surgeon and anesthesiologist is recommended to confirm expectations for pharmacological effects on neuromuscular activity.
- Clinicians should have experience with intraoperative neurophysiologic monitoring.
- Contact Customer Service, Sales or Clinical Support for any questions concerning the care or use of this product.

NEUROVISION
MEDICAL PRODUCTS

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