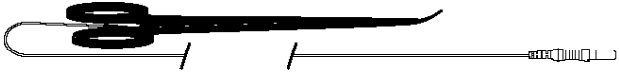
scorpion®

Single-Use EMG Stimulating Instrument

Instructions For Use



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01-25-2023

MEDICAL DEVICE ICON TABLE	
Symbol	Symbol Title
	Manufacturer
	Consult Instructions For Use
	MR Unsafe
	Catalogue Number
	Lot Number
	Do not use if product packaging is damaged
	Product has an expiration or use-by date
	Product is sterilized
	Do not reuse
	keep away from direct sunlight
	Caution
	Humidity Limit

MEDICAL DEVICE ICON TABLE CONTINUED	
Symbol	Symbol Title
	Prescription Only
	Temperature Limit
	Unique Identifier
	Country of Manufacturer

THIS DEVICE USED WITH BELOW PRODUCTS:

- I-D-WSF512
- I-DK-WSF512

INTENDED USE:

The **Scorpion®** Single-Use EMG Stimulating Instrument is indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification purposes during surgery, including spinal nerve roots. This instrument is used in electromyography (EMG), nerve conduction studies (NCS), intraoperative neurophysiological monitoring (IONM) and Evoked Nerve Potential (NP) monitoring.

INDICATIONS FOR USE:

This instrument is applied during intraoperative neurophysiological monitoring in surgical procedures to locate and identify peripheral, cranial and spinal nerve roots that are at risk of damage.

INTENDED USERS:

The intended users are healthcare professionals specifically trained and certified in electrophysiology techniques.

COMPATIBILITY WITH ACCOMPANYING DEVICES:

This device must be used in connection with any approved IEC 60601-1, compatible EMG monitoring system with 42802 DIN compatible connectors.

PATIENT TARGET GROUPS:

The patient target groups are any patients identified by the above medical experts to benefit from the diagnostic procedures as described above.

CONTRAINDICATIONS:

The Scorpion® Single-Use EMG Stimulating Instruments are not indicated for any patients that have not been identified by the above-mentioned medical experts to benefit from the procedures as described above.

DESCRIPTION:

The Scorpion® Single-Use EMG Stimulating Instruments are surgical forceps that utilize triggered/evoked EMG nerve stimulation to test surgical tissue in intraoperative neuromonitoring (IONM). Each instrument is provided **STERILE**.

WARNINGS:

- Careless use of any element in electrosurgical systems may cause serious burns.
- The use of the device with safely functioning and compatible electrosurgical generators and accessories is the user's responsibility.
- Read and understand all warnings, precautions, cautions and instructions before attempting to use any electrosurgical system.
- When stimulating nerves, an appropriate voltage / current should be applied according to the stimulator manufacturer's operating instructions.

PRECAUTIONS:

- USA Federal Law restricts this device to sale by or on the order of a physician.
- Do not use the device if the sterile packaging is opened or damaged or if the use-before-date has passed.
- Inspect the device after opening in a sterile field. Discard if damaged.
- For single-patient use only. Do not reuse or re-sterilize. Cleaning and re-sterilizing the device can affect its safety, performance, and effectiveness and expose patients and users to unnecessary risks such as infection and transmissible diseases.
- Sterility is guaranteed up to expiration date unless package is opened or damaged.
- The device has been sterilized using ethylene oxide gas. Some patients may be allergic to residuals of this gas.

- Do not use the device in strong electrical fields, as any induced electrical field may influence the stimulation output on the connected equipment (if applicable), may make the readings on the connected equipment unreliable and may result in localized tissue heating.
- To avoid damage to the nerve or tissue, the device must be kept separate from active electrosurgical devices and the patient when not in use. A separate holder is recommended.
- Keep voltage / current settings at the lowest possible level to achieve the desired effects.
- Do not stimulate for a prolonged period of time to prevent nerve fatigue.

USE OF PRODUCT:

Remove and discard the protection sheath from the device shaft / tip before use, when applicable.
The stimulating dissector is a monopolar probe that requires a separate single needle electrode to act as the return.
This single needle electrode is supplied in the carton (depending on the variant).
Both tips of the dissector are active.
To use the dissector as a probe, close the tips and touch the nerve.
If the nerve monitor responds when the tips are apart during dissection, either of the tips may be close to the nerve.

RECOMMENDATIONS:

- Communication between surgeon and anesthesiologist is recommended to confirm expectations for pharmacological effects on neuromuscular activity.
- Clinicians using Scorpion® Instruments should have experience with intraoperative neurophysiologic monitoring.
- Contact Neurovision Medical Products, Inc. for any questions concerning proper use of this product.

MRI SAFETY INFORMATION:

Do not use in an MR scanning environment. The device has not been evaluated for safety in an MR environment. It has not been tested for heating or unwanted movement in an MR environment. Product safety in the MR environment is unknown. Performing an MR exam on a person who has this medical device inserted or positioned on them may result in injury and/or device malfunction.

STORAGE, TRANSPORT, AND HANDLING:

Keep away from extreme temperatures, humidity and direct sunlight.

PRODUCT DISPOSAL:

Always discard used devices in a properly marked medical biohazard container.

CUSTOMER SERVICE:

For further information regarding the use of this product or to report any issues, please contact Neurovision Medical Products, Inc. at www.neurovisionmedical.com or 866-815-6999.

NOTE: All serious incidents associated with the use of this product should be reported to Technomed Europe at quality@technomed.nl and to a competent authority of the country where the user is established.

NEUROVISION
MEDICAL PRODUCTS

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