scorpion®

EMG Stimulating Instruments
Reusable and Single Use

Instructions For Use

IS3-E

-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 CODE PRE-FIXES:

- I-ATF
- I-JRF
- I-D-MF
- I-MCF
- I-CSI
- I-D-SHEM
- I-MF
- I-D-ATF
- I-DK
- I-SHEM
- I-D-MCF

INTENDED USE

The Scorpion® EMG Stimulating Instrument is a manual surgical instrument intended for concurrent nerve stimulation and dissection of tissue. This device must be used in connection with the Nerveäna® or any approved IEC 60601-1, compatible EMG monitoring system with 42802 DIN compatible connectors.

DESCRIPTION

Scorpion® EMG Stimulating Instruments are surgical forceps that utilize triggered/evoked EMG nerve stimulation to test surgical tissue in intraoperative neuromonitoring (IONM). Reusable instruments are provided non-sterile. Prior to any use process instrument through cleaning and steam sterilization. Single-use instruments are provided sterile and require no processing before use.

CONTRAINDICATIONS

Non-reversible paralyzing agents, including anesthetic lubricants or topical sprays, may impair or reduce EMG responses rendering monitoring unreliable.

WARNINGS

- Avoid leaving stimulating tip in prolonged contact with motor nerve(s).
- Do not use cautery while stimulator is in contact with tissue and/or in surgical field to avoid patient burns.
- Connection of a patient to a high frequency (HF) surgical equipment and to an electro-myograph or evoked response equipment simultaneously may result in burns at the site of the electrodes and/or damage to the applied parts.

- Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the applied parts.
- A patient with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.
- Avoid trans-thoracic stimulation.
- Avoid accidental contact between connected but unapplied applied parts and other conductive parts including those connected to protective earth.
- Do not use needles that have been tampered with or attempt to straighten bent needles. They may become weak and cause injury to patient.
- Product is for use by a licensed physician only.
- **This device does not prevent damage to nerves. Surgeon must rely on anatomical knowledge and experience to safely use this device.**
- Do not use if sterile package has been opened or is damaged.
- Re-use or resterilization of single-use devices could result in patient morbidity and is an improper use of the device.

PRECAUTIONS

- Inspect device for defects prior to use and discard if any defects are found.
- Avoid injury by using extreme care when handling and cleaning reusable instruments with sharp points or edges.
- Do not connect electrode lead wires to any other types of equipment besides an IONM stimulator in order to avoid electrical shock to patient or user.
- False negative responses may arise from deep anesthesia, pre-existing neuropraxia, or fluid in surgical field. Poor electrode placement or dislodgment of electrode while moving patient can result in lack of contact between electrode and desired musculature and may also cause false negative responses.
- Ensure white STIM return needle is placed in subcutaneous tissue and not in muscle.
- Dispose of the single-use instrument and packaging in accordance with hospital waste standards and federal regulations.
- Avoid cauterization on dissecting stimulator. Bipolar cautery may be used between

tines.

- Remove instrument from contact with patient when not in use.
- Avoid use of electrosurgical coagulator, ultrasonic cutting device, or other high-temperature device near instrument as it may damage insulated coating.
- Metal brushes and scouring pads must not be used during manual cleaning of reusable instruments. These materials will damage the surface and finish of the instrument. Use only soft bristle nylon brushes with different shapes, lengths, and sizes to aid with manual cleaning.

INSTRUCTIONS FOR USE

Please read and follow all instructions.

CAUTION: Use of paralytics is a contraindication in EMG nerve monitoring.

Process reusable instrument through cleaning and steam sterilization prior to any use.

If using a reusable instrument

1. See CLEANING and STERILIZATION sections for details.
2. Place white STIM return needle subcutaneously and secure with tape (Figure 1).
3. Insert white STIM return connector into IONM system's corresponding STIM return port.
4. Locate sterile red stimulator lead wire. Attach blue connector to instrument's pin on finger loop.
5. Insert red connector into corresponding IONM system's STIM port (-). Refer to

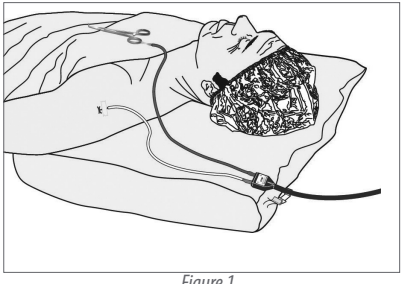

Figure 1

manufacturer's manual for detailed instructions.

6. Refer to the IONM system's operation manual for stimulation levels and proper settings. Stimulation range varies depending on surgical goals.
7. Within 30 minutes after use, remove excess bodily fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Bodily fluids and tissue should not be allowed to dry on instruments prior to cleaning.

If using a single-use instrument

1. Place white STIM return needle subcutaneously and secure with tape (Figure 1).
2. Insert white STIM return connector into IONM system's corresponding STIM return port.
3. Insert red connector into corresponding IONM system's STIM port (-). Refer to manufacturer's manual for detailed instructions.
4. Refer to the IONM system's operation manual for stimulation levels and proper settings. Simulation range varies depending on surgical goals.
5. Dispose of instrument in medical waste. Do not reuse.

CLEANING FOR REUSABLE INSTRUMENTS ONLY

1. Open instrument completely during cleaning process.
2. Prepare neutral pH enzymatic detergent as per detergent vendor's instructions. High alkaline detergents are not recommended for aluminum instruments.
3. Fully immerse device in the prepared detergent per detergent vendor's instructions.
4. Engage all movable parts during the soak time to allow complete penetration of detergent throughout the device.
5. Scrub the device using a soft bristled brush (may also use a syringe and pipe cleaner). Pay particular attention to movable parts, crevices, and other hard-to-reach areas until all visible soil has been removed.
6. Rinse all surfaces and crevices in reverse osmosis or deionized purified running water for a minimum of three minutes to remove any residual detergent or debris.
7. Dry the instrument with a clean, soft cloth.
8. Visually examine each instrument for cleanliness. If visible soil remains, repeat. cleaning procedure.

INSPECTION AND FUNCTION TESTING FOR REUSABLE INSTRUMENTS ONLY

1. Check for smooth movement of hinges throughout the intended range of motion. Locking mechanisms should be free of nicks. Check instruments with long slender features (particularly rotating instruments) for distortion. Instruments with broken, cracked, chipped, worn, or tarnished parts/surfaces should not be used. Return to Neurovision Medical Products, Inc. for inspection. Company will decide on the replacement or repair.
2. Lubricate the instrument before autoclaving with standard instrument lubricant or a steam permeable instrument lubricant.

STERILIZATION FOR REUSABLE INSTRUMENTS ONLY

1. Wrap clean instruments with sterilization wrap using a sequential wrapping technique or place in a self-sealing Tyvek pouch. If a wrapping method is used, make certain that the instruments are individually wrapped with two layers of the wrap. Other metal objects should never come in contact with the insulating material. Position all hinged instruments with latches open, tips spread, and all surfaces exposed.
2. Sterilize instruments using steam sterilization in an autoclave according to the following parameters:
    a. Prevacuum: 270°F (132°C)
    b. Sterilization time: 4 min
    c. Drying time: 30 min

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 Customer Service, Sales or Clinical Support for any questions concerning the care or use of this product.

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