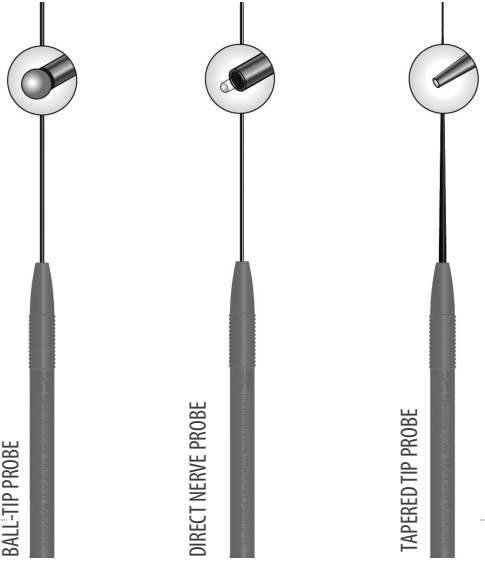
hummingbird®

Single-Use EMG Stimulator Probes

Instructions For Use



IS1-F

-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:

- LTE7003P*
- NVFKIT*
- NVTKIT*
- NVPFKIT*
- NVPTKIT*
- SCKIT*
- EAKIT*
- DNP
- TTP
- BTP
- I-D

* *when ending with T-5 or D-5*

INTENDED USE

The Hummingbird single-use EMG stimulator probe is a dedicated manual surgical instrument that allows the surgeon to test surgical tissue for nerve stimulation using evoked/trigger EMG. The stimulation probe is intended for intraoperative neuromonitoring by a licensed physician with any appropriate/compatible neuromonitoring machine.

DESCRIPTION

Hummingbird single-use EMG stimulator probe is designed to be used in intraoperative neuromonitoring (IONM). Hummingbird probes are surgical instruments that utilize triggered/evoked EMG nerve stimulation to test surgical tissue. Hummingbird probes attach to female DIN 42802 connections on compatible IEC 60601-1 neuromonitoring systems. Each probe is sterilized* to ISO standards.

**see product packaging for method of sterilization*

CONTRAINDICATIONS

- Non-reversible paralyzing agents, including anesthetic lubricants or topical sprays, may impair or reduce EMG responses rendering monitoring unreliable.
- Single-use EMG stimulator probe is not designed to manipulate tissue. Do not insert intramuscularly.

WARNINGS

- Avoid leaving the stimulator probe in prolonged contact with a motor nerve(s).
- Application of RF cautery surgical equipment used near the stimulation probe or white STIM return electrode may result in burns at or near the STIM return needle

site and/or damage the stimulator probe.

- Do not use cautery while stimulator is in contact with tissue and/or in surgical field to avoid patient burns.
- A patient with an implanted electronic device such as a pacemaker or defibrillator should not be subjected to stimulation unless specialist medical opinion has been obtained first.
- Connect single-use EMG stimulator probes to the neuromonitoring output connections only. Do not connect them to any other equipment. Improper connection of probes may result in a potentially hazardous condition.
- Do not use needles that have been tampered with or attempt to straighten bent needles. They may become weak and cause injury to the patient.
- 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.
- Product is for use by a licensed physician only.

PRECAUTIONS

- Inspect the device for defects prior to use and discard if any defects are found.
- Do not use product if the device expiration date on the label has passed.
- Ensure STIM return needle (reference electrode) is placed in the subcutaneous tissue and not in the muscle.
- Dispose of the device and packaging in accordance with hospital waste standards and federal regulations.
- Avoid injury by disposing of sharps in an appropriate biohazard container.
- False negative responses may arise from deep anesthesia, pre-existing neuropraxia, or fluid in the 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.
- Remove the stimulator tip from contact with the patient when not in use.

INSTRUCTIONS FOR USE

1. Based on surgical procedure, choose the appropriate stimulator probe. (*see Figure 1*)
2. Connect white STIM return and follow the instructions based on probe type:

Figure 1: Probe tip options

Monopolar Probe:

a. Place a white STIM return needle (reference electrode) close to or in the surgical field, secure with sterile tape. Make sure it will not interfere with subsequent instruments used during the surgery.
b. Connect the white return wire DIN (needle) and the blue lead wire DIN (probe) to the corresponding EMG stimulation ports of the IONM system in use. Refer to the manufacturer's manual for detailed instructions.

Bipolar Probe:

a. Connect the white return wire DIN (probe) to the corresponding EMG stimulation port of the IONM system in use.
b. Connect the black lead wire DIN (probe) to the corresponding EMG stimulation port of the IONM system in use. Refer to the manufacturer's manual for detailed instructions.

3. To check stimulus flow, set current to 0.5 mA, touch the tip of probe to a damp cloth. The IONM system's current indicator should be activated. If a signal is not

received, see operation manual.

4. Stimulation range varies depending on surgical goals. For stimulation levels and proper settings refer to the opertion manual of the IONM system in use.

The working length of the probe (shaft) is flexible and may be adjusted slightly. Excessive, acute, and repetitive bending is not recommended as the probe may be damaged or break. *(See Figure 2 below)*

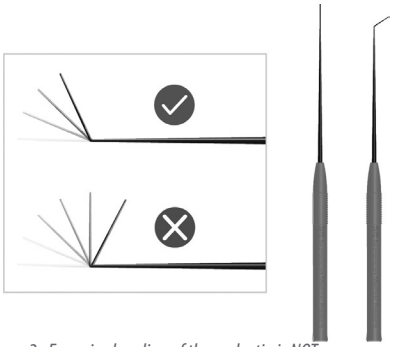


Figure 2: Excessive bending of the probe tip is NOT recommended.

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

Distributed by:
Neurovision Medical Products, Inc.
353 Sanjon Road
Ventura, CA 93001 USA
tel: 866-815-6999
fax: 877-330-1727
neurovisionmedical.com

Kirwan Surgical Products
180 Enterprise Drive
Marshfield, MA 02050 USA
tel: 781-834-9500
fax: 781-834-0022
ksp.com