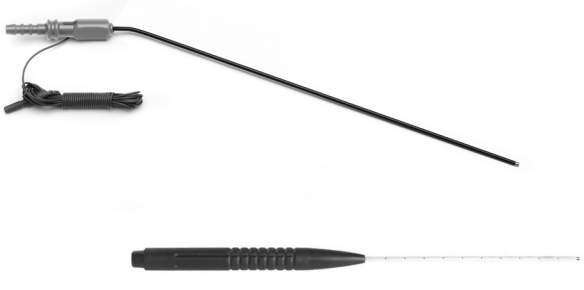
drytouch®

hummingbird®

Disposable Probe Stimulators

Instructions For Use



IS2-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:

- PSS
- I-D
- DNP
- BTP
- BMF
- FTP
- NVTKIT*
- NVFKIT*
- NVPTKIT*
- LTE7003P*
- SCKIT*
- DCKIT*
- EAKIT*

*Only included in product codes ending in D-5

INTENDED USE

IOM Stimulator Probes are used by the surgeon as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring, to identify nerves and spinal nerve roots and to assess nerve function. IOM Stimulator Probes disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral nerves for location and identification during surgery, including spinal nerve roots.

The Drytouch® Suction Stimulator Probe is a dedicated manual surgical instrument that allows the surgeon to clear secretions and test surgical tissue with nerve stimulation at the same time and with the same instrument. It is intended for use only by a licensed physician and in conjunction with the Neurovision Nerve locator Monitor System.

DESCRIPTION

Stimulator probes are single use, stainless steel probes which connect to a nerve stimulator for use in electromyography during surgery.

CONTRAINDICATIONS

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

WARNINGS

- This product is provided sterile and can be used for a single patient only. Attempts to clean and re-use this single-use device expose patients and operators to a risk of cross contamination.
- Do NOT leave IOM stimulation probe unattended in the surgical field.
- Do NOT use IOM Stimulator Probe as a dissecting tool or for any other purpose not specified in these Instructions for Use.
- Do not activate electrosurgical instruments while the stimulator probe is in contact with tissue, to avoid patient burns.

- Do not leave stimulating electrodes or probes in surgical field.
- Do not store stimulating electrodes or probes in electrosurgical instrument holder.
- Special operator attention may be required for stimulus currents exceeding 2 rnA RMS/cm2. The RMS value of current is generally lower than the stimulator current setting in mA. To calculate RMS current, waveform morphology, pulse width, repetition rate, and the stimulator current delivered must be considered. High stimulator current may cause involuntary patient movement resulting in patient injury.
- Direct stimulator contact may disrupt the operation of active implanted devices.
- The surgical practitioner must choose the appropriate size and locations of electrodes and probes based on the procedure to be performed and the stimulating current necessary for the application.
- Avoid trans-thoracic stimulation.

PRECAUTIONS

- Read and understand all the instructions for use before using any IOM stimulation probe device.
- Only to be used by trained and skilled personnel.
- After use, safely discard in accordance with established procedures for biohazardous waste.
- Maximum current intensity: 60 mA. Stimulation specific parameters to be determined by the supervising physician for the clinical application.
- Single use only.

GENERAL PROBE INSTRUCTIONS FOR USE

1. Do not use the selected probe stimulator if the pouch is damaged.
2. Remove the probe from two sterile pouches following normal Operating Room protocols.
3. Connect the stimulator probe connector to the equipment.
4. After its use dispose the probe stimulator in a hospital refuse container.

DRYTOUCH® INSTRUCTIONS FOR USE

1. Choose appropriately sized suction stimulator probe.
2. Place a white STIM return needle (reference electrode) close to or in surgical field and secure with sterile tape. Make sure it will not interfere with subsequent instruments used during surgery.
3. Connect white DIN (needle return wire) and blue DIN (probe lead wire) to corresponding EMG stimulation ports of IONM system in use.
4. Refer to the IONM system's operation manual for detailed set up instructions, stimulation levels and proper settings. Simulation range varies depending on surgical goals.
5. Attach standard suction tubing to ribbed connector of handle.
6. Start and stop suction by placing finger over keyhole opening located on top of DryTouch® handle. To increase or decrease intensity of suction, slide finger up and down slot of keyhole.
7. Clean DryTouch® of bone chips by gently wiping over suction apertures with dry gauze. Clear blocked suction by irrigating cannula with injection of sterile saline from suction tube connector exiting through the open lumen.
5. After its use dispose the probe stimulator in a hospital refuse container.

RECOMMENDATIONS

- Communication between 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

Stimulating Probes:
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