Laryngeal Surface Electrodes

dragonfly®

Instructions For Use

IE3-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:

- NVTKIT-M*

**Excluding Product Codes containing NVTKIT-MSP and NVTKIT-600M*

- SCKIT
- LSE500
- DCKIT
- NVPTKIT-DC

INTENDED USE

The Laryngeal Surface Electrode is intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. 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

Dragonfly® Laryngeal Surface Electrodes are disposable, self-adhesive electrodes designed to attach to an endotracheal tube to record the activity of the vocal cord musculature when connected to an electromyographic (EMG) device. Each electrode is sterilized.

CONTRAINDICATIONS

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

WARNINGS

- Intubation beyond 8 hours is not recommended. Replace with a standard ET tube if ventilation is needed beyond this period.
- Do not use if recording electrode delivers electrode impedance levels higher than recommended by the EMG system in use.
- Be cautious that laser beams do not come in contact with the electrode during laser surgery.
- Do not use if sterile package has been opened or is damaged.
- Reuse or re-sterilization 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.
- This device does not prevent damage to nerves. Surgeon must rely on anatomical knowledge and experience to safely use this device.

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.
- Do not use if sterile package has been opened or is damaged.
- Avoid injury by disposing of devices in an appropriate FDA-approved sharps and/or biohazard container.
- Do not excessively bend EMG monitoring electrodes in order to maintain electrical integrity.
- Check electrode integrity after insertion.
- Do not subject a patient with an ET tube to Magnetic Resonance Imaging (MRI) or another electric stimulation unless a medical specialist has first been consulted.
- Proper placement of the electrode recording area is critical. Review instructions for use prior to intubation.
- Deflate cuff prior to repositioning tube
- False negative responses may arise from deep anesthesia, pre-existing neuropraxia, or fluid in surgical field. Poor electrode placement or dislodgement of electrode while moving patient can result in lack of contact between electrode and desired musculature and may also cause false negative responses.
- Any lubricant used on ET tube that occludes main lumen will impede functionality of device.

INSTRUCTIONS FOR USE

PLEASE READ AND FOLLOW ALL INSTRUCTIONS.
CAUTION: USE OF PARALYTICS IS A CONTRAINDICATION IN EMG NERVE MONITORING.

APPLICATION OF ELECTRODE

1. Choose appropriate, non-silicone, endotracheal (ET) tube and corresponding Dragonfly® electrode. See table below for guidance:

Dragonfly®	ET Tube ID Size	Item Code
1-Channel	6.0 – 7.0mm	LSE500MS
1-Channel	7.5 – 10.0mm	LSE500M
2-Channel	6.0 - 7.5mm	LSE500DCS
2-Channel	8.0 - 9.5mm	LSE500DCL

Before application, ET tube should be clean and free of any lubricants, finger oil, or other materials that may inhibit electrode adhesion.

2. Position ET tube to view posterior aspect and straighten using a stylet.
3. Remove paper backing of electrode to expose adhesive. Align electrode's mid-line with midline of the posterior portion (convex curvature) of tube, just above ET tube cuff. The wires should extend away from cuff (Figure 1).
4. Press electrode down, wrapping it toward the opposite (anterior) side of tube. Follow the proper wrapping technique for the Dragonfly in use:
   1-Channel: Wrap evenly to ensure electrode plates do not touch.
   2-Channel: Wrap the larger flap first. Next wrap the smaller flap so that it overlaps the large side of the electrode. ***Avoid rubbing surface as this may damage electrode.***
5. Press along entire surface and edge to ensure proper adhesion and to remove any kinks (Figure 2).

Figure 1

Figure 2

INTUBATION

1. A small amount of water-based lubricant may be applied to electrode. Do not use petroleum-based lubricants. Use of a stylet is recommended for proper placement.
2. Intubate using currently accepted medical techniques. Insert ET tube under direct vision or with a video laryngoscope. Avoid scraping electrode against sharp objects, such as patient's teeth or a laryngoscope blade.
3. Depth markings should be anterior with red wire(s) on the right and blue wire(s) on the left so that each vocal cord is touching its respective silver electrodes.
4. Note depth number on ET tube against maxillary central incisors before any further positioning of patient. Tape ET tube securely with 2 pieces of tape by wrapping each piece first around ET tube and then securing to upper lip. Do not remove tape once applied to tube. Apply additional tape if repositioning is needed.
5. Inflate cuff with minimum amount of air necessary to create an effective tracheal seal. Check pressure volume within cuff regularly to ensure seal is maintained.
6. After final positioning of patient, align ET tube in the middle of the pharynx behind the tongue. The posterior portion of ET tube should be directly opposite the central maxillary incisor gap at depth number noted after initial positioning.
7. Tightly secure ventilator circuit so that ET tube will not rotate or be displaced

and then verify final electrode position by laryngoscopy with a #3 Miller Blade or with a video laryngoscope.

8. Support ET tube to avoid kinking where it contacts teeth.

CONNECTING LEAD WIRES, GROUND & RETURN PLACEMENT *(included in kits only)*

**patient placement is suggested based on electrode type and EMG system*

1. Attach the red and blue electrode lead wires to the + and - terminals of the EMG recording device.
2. Nerveäna® system use: Apply green hydrogel to forehead and apply white STIM return electrode to deltoid (Figure 3).
3. Nerveana Plus and Alternative EMG system use: Apply white STIM return

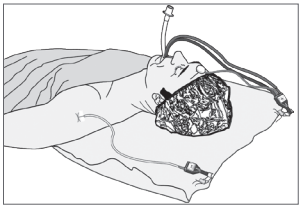

Figure 3

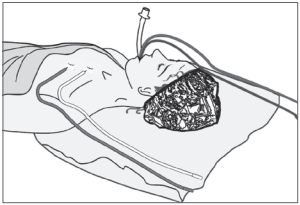

Figure 4

electrode to sternum and apply green EMG ground electrode just below that (Figure 4).

EXTUBATION

1. Extubate using currently accepted medical techniques.
2. Prior to extubation, deflate cuff completely with a Luer tip syringe.
3. Remove all tape. Pull out gently by ET tube; do not pull by harness.
4. Dispose of device and packaging in accordance with hospital waste standards and federal regulations.

RECOMMENDATIONS

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

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