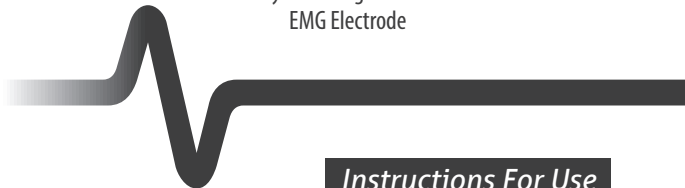


Laryngeal Surface Electrodes

dragonfly[®]























EasyAim[®] Single Channel
EMG Electrode



Instructions For Use



IE4-D

-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:**

• LSE600

• NVTKIT-600

• NVTKIT-MSP

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 (ET) tube to record the activity of the vocal cord musculature when connected to an electromyographic (EMG) device. Each electrode is sterilized.

EasyAim Single Channel Kits include a unique single channel Dragonfly[®] electrode with a single recording plate that wraps 360° around any ET tube.

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. EasyAim Single Channel Laryngeal Electrodes come in 2 sizes for use with ET Tubes with I.D. of 2.0-5.5 and 6-10.
2. Before application, ET tube should be clean and free of any lubricants, finger oil,

or other materials that may inhibit electrode adhesion.

3. Position ET tube to view posterior aspect and straighten using a stylet.
4. Application and wrapping of electrode around ET tube.

For MSP Electrode

Locate the numbered guideline on the electrode that matches the tube's inner diameter number (2.0 – 5.5). Remove paper backing and align the corresponding numbered guideline with the middle of the posterior portion of the tube, just above the ET tube cuff (Figure 1). The blue lead wire should extend away from the tube cuff. Press electrode down, first wrapping the shorter side toward the top (anterior) surface of the ET tube. Next wrap the larger side in the opposite direction until it overlaps the other side of the electrode (Figure 2).

For 600M Electrode

Remove paper backing on electrode and align border of the silver plate with the middle of the posterior portion of the tube, 1mm above the edge of the ET tube cuff (Figure 1). The blue lead wire should extend away from the tube cuff. Press electrode down, first wrapping the shorter side toward the top (anterior) surface of the ET tube. Next wrap the larger, silver side in the opposite direction until it overlaps the other side of the electrode (Figure 2). Make sure the shorter side is not wrapped over the silver surface.

VERIFYING APPLICATION



Figure 1



Figure 2

Press down along the entire surface and edge to set adhesive. Avoid rubbing as this may damage the electrode surface.

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.

*Support ET tube to avoid kinking where it contacts teeth. *Caution: Intubation with Dragonfly® electrodes for longer than 8 hours is not recommended.*

APPLYING THE SURFACE ELECTRODE

1. Place the reference electrode over the Mastoid Process or back of the Trapezes. Apply a stimulator return electrode to the Sternum. Then, insert the ground electrode just below the stim return electrode on the shoulder (Figure 3a) and sternum (Figure 3b).

FINAL SETUP AND TESTING

1. Insert the blue Dragonfly® electrode lead wire into an (+) EMG terminal, plug the reference lead into an (-) EMG terminal and plug the ground lead wire into the ground terminal.
2. Test impedance. All should be around .5 (k Ω) and no higher than 1.0 (k Ω)a

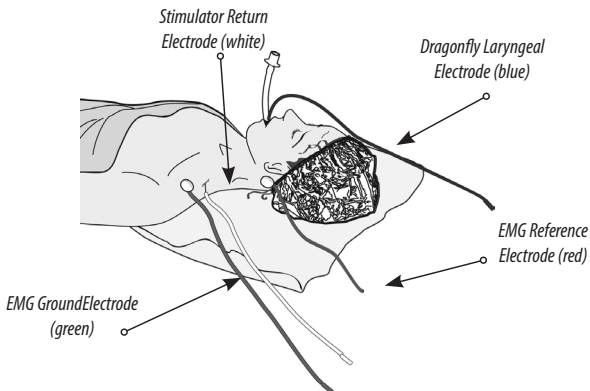


Figure 3a: Electrode Set-up for Nerveäna® System

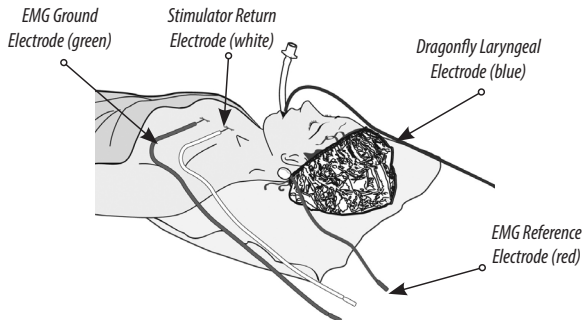


Figure 3b: Electrode Set-up for alternative nerve monitoring system

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.



Neurovision Medical Products, Inc.

353 Sanjon Road

Ventura, CA 93001 USA

Tel: 866-815-6999

Fax: 877-330-1727

neurovisionmedical.com

Australian Sponsor:

Emergo Australia

201 Sussex Street

Darling Park, Tower II, Level 20

Sydney, NSW 2000

Australia