## SYMBOLS AND DEFINITIONS:

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|---|---|
| | Manufacturer: Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC, and 98/79/EC. |
| EC REP | Authorized representatives in the European Community. This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol. |
| | Use by date: Indicates the date after which the medical device is not to be used. |
| LOT | Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| REF. | Catalog Number: Indicates the manufacturer's catalog number so that the medical device can be identified. |
| STERILE EO | Sterilized using ethylene oxide: Indicates a medical device that has been sterilized using ethylene oxide. |
| | Do not resterilize: Indicates a medical device that is not to be resterilized. |
| | Do not use if package is damaged: Indicates a medical device that should not be used if the package has been damaged or opened. |
| | Do not re-use: Indicatees a medical device that is intended for one use, or for use on a single patient during a single procedure. |
| | Consult instructions for use: Indicates the need for the user to consult instructions for use. |
| | Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
| MD | Medical Device Indicated |


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CE 0197

REV 02092022

INVOTEC INTERNATIONAL, INC.®

# INVOTEC SURFACE ELECTRODE

## INSTRUCTIONS FOR APPLICATION
to an Endotracheal Tube & Cranial Nerve Monitor/Stimulator

Reuse of this device may expose patient to infection or contamination risks. once the seal of the sterile packaging has been torn open its contents will not be taken back by the manufacturer.

Disposal
When disposing the product, take all steps necessary to avoid risk of injury or infection. Contaminated products must be disposed of as hazardous waste and handled to avoid contamination of third parties.

Any serious incident that has occurred in the relation to the device should be reported to Invotec International, Inc. MDSS GmbH, and the competent authority of the Member State in which the user and/or patient is established.

# INSTRUCTIONS FOR APPLICATION - ENGLISH

## INTRODUCTION

The single or dual channel surface electrodes, manufactured by Invotec International, Inc., are used during head and neck procedures to monitor EMG activity of the nerves supplying the laryngeal musculature when connected to an EMG monitor.

Laryngeal EMG signals are collected by the electrically conductive pads positioned against true vocal cords. This is accomplished by properly mounting the electrode onto the distal end of an appropriately sized endotracheal tube, prior to intubation. The electrode wire cables are fitted with universal "touch proof" connectors. These connectors are to be inserted into the appropriate nerve monitor pod or receptacle. Sub dermal needle electrodes with green and white hubs are available but not packaged with the electrode. This device is to be used only by a licensed and trained medical professional. The sole purpose of these instructions is to provide information on the proper placement and use of the electrode.

Note: Invotec International, Inc. warranties its electrode and limits its liability only to replacement for defect in materials or workmanship. To be used only by a licensed medical professional.

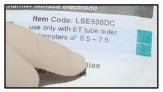
## INVOTEC SURFACE ELECTRODE INTENDED USE

The Invotec single and dual channel surface electrodes are designed to be positioned in contact with the true vocal cords, while being secured to an endotracheal tube, during surgical procedures of the head and neck.

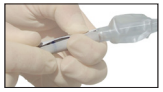
The Surface Electrode assists in EMG monitoring of the nerves supplying the laryngeal musculature during Thyroidectomy, Anterior Cervical Fusion, Carotid Endarterectomy and Skull base procedures.

## SECURING THE ELECTRODE TO THE ET TUBE

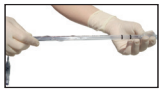
Step # 1 Verify the proper match and sizing of the Invotec Electrode and the ET Tube of choice by reviewing the labeling on both products. *Subdermal EMG ground needles are available, sold separately.*

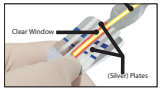
Step #2 Before removing the adhesive surface liner, test the size of the electrode by wrapping it around the tube. Be sure the electrode pad overlaps, but the silver plates do not touch or overlap.

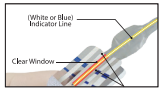



Step # 3 A. Straighten the ET tube in preparation of applying the electrode by flattening the tube with a stylet down the lumen.

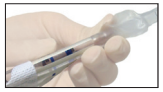



B. Expose the adhesive contact area on the back of the paddle electrode by pulling off the paper liner.






Step # 4 Place the distal end of the electrode paddle approximately ¾" (2cm) above the tube's cuff. Align the indicator line on the tube, with the clear window located between the silver metal plates.

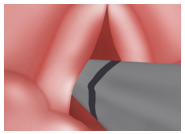



Step # 5 A. With the ET tube flat and its blue indicator line facing up, secure the electrode, adhesive side down. Secure one side of the electrode at a time by carefully rolling and padding. All electrode surfaces must be flat against the tube.


B. Check the mounted electrode for buckles and be sure its silver pads are not touching.
You are now ready to intubate.

## LARYNGEAL ELECTRODE INTUBATION INSTRUCTIONS

Reliable performance of Invotec surface electrodes requires proper positioning. Please follow these instructions carefully and avoid using long-acting paralytics.



Intubation # 1 Insert the ET tube under direct vision so that each true vocal cord is touching its respective pair of conductive silver pads. The electrode rests within the larynx between the two blue positioning stripes at final positioning.

Note the depth number on the ET tube against the maxillary central incisors before any further positioning of the patient.

Intubation # 2 After final positioning of the patient, align the middle of the pharynx behind the tongue. The posterior portion of the ET tube should be directly opposite the central maxillary incisor gap at the depth number noted after initial positioning.

Intubation # 3 Secure the ET Tube to the patient's face with two (2) pieces of tape.

## CONNECTING THE ELECTRODE TO THE MONITOR/STIMULATOR

These sterile devices are designed to be used with a broad range of multi-channel nerve monitor/stimulators. Please refer to the directions provided by the designated monitor's manufacturer for detailed instructions.

Securing #1 A. Complete securing the breathing circuits assuring the ET tube will not rotate or be pulled out of position.
B. Verify the final electrode positioning via direct Laryngoscopy.

Securing #2 Position the hardware according to the hardware manufacturer's instructions.
Please note: Nerve monitor/stimulators have interfaces (pods) into which stimulating instruments and electrodes are plugged. These pods and often hung from the side of the OR table.

Securing #3 For Single Channel: Plug the red touch proof connector into the Channel 1 positive receptacle (+) and plug the blue connector is inserted in to the negative (-) receptacle. Channel female plug spaces are denoted on the pods.
For Dual Channel: Follow the instructions provided by the monitor's manufacturer.

Securing #4 Secure a reference (ground) EMG sub dermal electrode in the shoulder or anterior chest wall and plug into the earth or ground receptacle, per monitor instructions.

**WARNINGS**

**Do not use paralytic anesthetic agents on the patient. These agents could dampen or eliminate EMG responses.**

**Avoid using ET tubes with high silicone content in conjunction with Invotec surface electrodes as this may cause the adhesive to slip.**

**Apply tube lubrication only after the electrode has been secured to the tube.**

**FOR SINGLE USE ONLY.**