FRIENDSHIP MEDICAL

Disposable Pre-Gelled Surface Electrodes

Product Information and Instructions

DEVICE DESCRIPTION

The surface electrode consists of a biocompatible adhesive gel-backed electrode. The return electrode is a stainless steel subdermal needle electrode.

INTENDED USE

The surface electrodes are applied directly to the patient's skin. The return needle electrode is applied subdermally to the patient. The electrode set is intended to record physiological signals or to apply electrical stimulation with the Electroneurodiagnostic or other EMG monitor.

INDICATIONS

The electrodes are indicated for intraoperative motor nerve location.

CONTRAINDICATION

The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive neural stimulation. Whenever nerve paralysis is suspected, consult anesthesiologist.

WARNINGS

- While stimulating, it is recommended to use only approved EMG monitor(s) equipped with active audio and/or visual feedback systems to ensure delivery of current to intended tissues.
- Electrode integrity should be checked (by pressing electrodes check on the Electroneurodiagnostic System) after electrode insertion and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If electrode impedance is very high, discontinue use and replace.
- Reuse of single use electrodes and probes increase the risk of infection and may cause degraded or ineffective monitoring.
- False negative responses (failure to locate nerve) may result from neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
- Proper handling, insertion and placement of electrodes and probes are critical for safe and accurate EMG Monitoring.
- Improperly placed or bent needles increase the risk of the needle breaking off in the patient. Do not attempt to straighten bent needles, this can weaken the metal, causing the needle to break off in the patient.
- Extreme care must be taken when handling and cleaning instruments with sharp points or edges.
- To avoid patient burns: Do not activate the electrosurgical instruments while stimulator is in contact with tissue, Do not leave stimulating electrodes or probes in surgical field, Do not store stimulating electrodes or probes in electrosurgical instrument holder, Do not allow a second surgeon to use electrosurgical instrument while stimulator is in use.
- Electrode leads must be connected only to EMG recording/monitoring equipment. Electrical shock resulting in patient injury may result if the leads are connected to other types of equipment or connections.

Precaution

Contaminated single use electrodes and probes must be disposed of in an appropriate sharps biohazard container in accordance with hospital or other user facilities policy.

DIRECTIONS FOR USE

1. The skin at the site of electrode placement/insertion should be lightly abraded, and must be cleaned and dried to remove oils that may increase impedance.
2. Peel the liner from the surface electrodes, ensure that the two electrode pads are physically separated from each other, and apply firmly to the intended site. Choose the site carefully as the surface electrodes are not intended to be re-positioned.
3. Place the stimulus-return needle electrode subdermally.
4. Insert all electrode lead connectors into the Patient Interface (refer to the Electroneurodiagnostic System manual for detailed connection instructions.)

STERILITY

This device is intended for SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE THIS DEVICE.

XI'AN FRIENDSHIP MEDICAL ELECTRONICS CO., LTD. ASSUMES NO LIABILITY FOR DEVICES THAT HAVE BEEN RESTERILIZED BY HEALTH CARE FACILITIES.

Website:

www.xafdec.com

www.friendshipmedical.com.cn

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Note: When contacting Customer Service and Technical Support, please have the appropriate product number, date of purchase, and nature of inquiry available.

Xi'an Friendship Medical Electronics Co., Ltd.
No. 9 Gao Xin 1st Road, Hi-Tech Development Zone, Xian, Shaanxi, China, 710075.

EC REP
Friendship Europe ApS
Gl. Landevej 20
4000 Roskilde
DENMARK

[Symbol Description]

REF Catalog Number

LOT Lot Number

Consult Instructions for Use

Rx Only Rx Only

Use by date

Date of Manufacture

Manufacturer

EC REP Authorized Representative in the European Community

-10°C 50°C Temperature Limitation

Do not re-use

CE mark

Do not use when package is broken

Latex Free

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