Note before use

● Only licensed medical practitioners are allowed to use this product, or it shall be used under their guidance in person.

● Before use, operators should fully understand the product information and instructions.

● The company is not responsible for injury, infection or other damage caused by improper storage, preparation, use or disposal of electrodes.

1. Symbol Description

REF	Catalog number
LOT	Lot number
	Date of manufacture
	Manufacturer
Rx Only	Rx only
MD	Medical device
-10°C 50°C	Temperature limits
LATEX	Latex free
2	Do not re-use
CE 0197	CE mark
2 STERILIZE	Do not re-sterilize
	Caution
	Use by date
	Importer
	Consult instructions for use
	Do not use when package is broken
	Single sterile barrier system
STERILE EO	Sterilized using ethylene oxide
EC REP	Authorized Representative in the European
CE	CE mark

2. Disposable Subdermal Needle Electrodes

INTENDED PURPOSE

The connector of this device is connected to the electrophysiological monitoring and record system or intraoperative monitoring system.The other terminal is inserted subdermally into the patients relevant body parts. It is mainly used for transmitting the electrical stimulation signal from the system to the human body, or collecting the local electrical signal from the human body to the system.

WARNINGS

Read and understand the Warnings and Precautions associated with the use of subdermal needle electrodes in the User Manual for the specific Monitoring system you are using.

1. Only licensed medical practitioners are allowed to use this product, or it shall be used under their guidance in person.
2. Please check whether the package is within the validity period before use, otherwise it cannot be used. Visually check the sterilization mark on the package. It is not allowed to be used if the color is not completely changed from pink to brown, and it is strictly prohibited to be used if the package is damaged.

3. Electrode integrity should be checked 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.
4. Accurate positioning by color coding of electrode wires or hubs to avoid collection of electrical signals of wrong location.
5. Proper handling, insertion and placement of electrodes are critical for safe and accurate Monitoring.
6. 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.
7. False negative responses (failure to locate nerve) may result from neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
8. Reuse of single use electrodes increase the risk of infection and may cause degraded or ineffective monitoring.
9. Extreme care must be taken when handling instruments with sharp points or edges.
10. Electrode leads must be connected only to related recording/monitoring equipment. Electrical shock resulting in patient injury may result if the leads are connected to other types of equipment or connections.
11. To avoid alternate site patient burns or lesions: Do not activate electrosurgical instrument for prolonged periods while electrosurgical instruments is not in contact with tissue. Do not activate electrosurgical instrument near the recording or stimulating electrodes. Do not allow patient interface boxes or recording / stimulating electrodes sites to be flooded with saline. Do not allow excessive stray AC or DC leakage currents from patient connected equipment. Avoid creating an unintended grounding path through applied electrodes.
12. 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.
13. Keep the device away from the place with high electromagnetic disturbances intensity, such as the high frequency surgical equipment active in the hospital, heart failure surgery equipment, RF shielding room for magnetic resonance imaging systems, etc.
14. Stop using the device when the basic function is lost due to electromagnetic disturbances.
15. Do not use the device near other devices or in stacks because it could result in improper operation. If such use is inevitable, this device and other devices should be observed to ensure they are operating normally.
16. Cable Length is 50mm to 4000mm.
17. Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
18. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Disposable Subdermal Needle Electrodes, including cables specified by the manufacturer. Otherwise, the performance of the device may deteriorate.
19. The device itself does not produce any electromagnetic radiation.
20. Practitioner is responsible for the proper use of the device in accordance to the appropriate IEC60601-1, IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
21. See the system user manual of the equipments and systems connected to this device for more electrical safety and electromagnetic disturbances information.
22. Advice that a PATIENT with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.
23. Advice to avoid trans-thoracic stimulation.
24. Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to

protective earth.

25. The maximum operating ambient temperature is 35°C. Avoid patient harm due to excessive temperature at the electrode and electrode cable.

3. Disposable Corkscrew Needle Electrodes

INTENDED PURPOSE

The connector of this device is connected to the electrophysiological monitoring and record system or intraoperative monitoring system.The other terminal is inserted subdermally into the patients relevant body parts. It is mainly used for transmitting the electrical stimulation signal from the system to the human body, or collecting the local electrical signal from the human body to the system.

WARNINGS

Read and understand the Warnings and Precautions associated with the use of corkscrew needle electrodes in the User Manual for the specific Monitoring system you are using.

1. Only licensed medical practitioners are allowed to use this product, or it shall be used under their guidance in person.
2. Please check whether the package is within the validity period before use, otherwise it cannot be used. Visually check the sterilization mark on the package. It is not allowed to be used if the color is not completely changed from pink to brown, and it is strictly prohibited to be used if the package is damaged.
3. Electrode integrity should be checked 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.
4. The Electroneurodiagnostic System does not prevent the surgical severing of nerves. If these devices are compromised, the surgical practitioner must rely on alternate methods, or surgical skill, experience, and anatomical knowledge to prevent damage to nerves.
5. High stimulator current and/or transcranial motor stimulation may cause involuntary patient movement resulting in patient injury.
6. High stimulator current and/or transcranial motor stimulation activating of the fifth cranial nerve or mastication muscles may cause tongue lacerations.
7. The surgical practitioner must choose the appropriate placement of electrodes, based on the procedure to be performed, and the stimulating voltage necessary for the application.
8. Proper handling, insertion and placement of electrodes are critical for safe and accurate monitoring.
9. Improperly placed or bent needles increase the risk of needle breaking off in the patient.
10. Extreme care must be taken when handling instruments with sharp points or edges.
11. Avoid trans-thoracic stimulation. Maintain anode and cathode stimulating sites in close proximity.
12. Avoid accidental contact between connected but unapplied electrodes of other conductive parts.
13. Reuse of single use electrodes increases the risk of infection and may cause degraded or ineffective monitoring.
14. The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, responses to direct or passive neural stimulation. Whenever nerve paralysis is suspected, consult anesthesiologist.
15. Keep the device away from the place with high electromagnetic disturbances intensity, such as the high frequency surgical equipment active in the hospital, heart failure surgery equipment, RF shielding room for magnetic resonance imaging systems, etc.
16. Stop using the device when the basic function is lost due to electromagnetic disturbances.
17. Do not use the device near other devices or in stacks because it could result in improper operation. If such use is inevitable, this device and other devices should be observed to ensure they are operating normally.
18. Cable Length is 50mm to 4000mm.
19. Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

20. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Disposable Corkscrew Needle Electrodes, including cables specified by the manufacturer. Otherwise, the performance of the device may deteriorate.
21. The device itself does not produce any electromagnetic radiation.
22. Practitioner is responsible for the proper use of the device in accordance to the appropriate IEC60601-1, IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
23. See the system user manual of the equipments and systems connected to this device for more electrical safety and electromagnetic disturbances information.
24. Advice that a PATIENT with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.
25. Advice to avoid trans-thoracic stimulation.
26. Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
27. The maximum operating ambient temperature is 35 ° C. Avoid patient harm due to excessive temperature at the electrode and electrode cable.

4. Disposable EMG Needle Electrodes

INTENDED PURPOSE

The connector of this device is connected to the EMG monitors. The other terminal is inserted subdermally into the patients' relevant body parts. It is mainly used for transmitting the electrical stimulation signal from the system to the human body, or collecting the local electrical signal from the human body to the system.

WARNINGS

Read and understand the Warnings and Precautions associated with the use of EMG needle electrodes in the User Manual for the specific Monitoring system you are using.

1. Electrode integrity should be checked 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.
2. False negative responses (failure to locate nerve) may result from neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
3. Accurate positioning by color coding of hubs to avoid collection of electrical signals of wrong location.
4. 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.
5. Only licensed medical practitioners are allowed to use this product, or it shall be used under their guidance in person.
6. Please check whether the package is within the validity period before use, otherwise it cannot be used. Visually check the sterilization mark on the package. It is not allowed to be used if the color is not completely changed from pink to brown, and it is strictly prohibited to be used if the package is damaged.
7. 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.
8. Reuse of single use electrodes increase the risk of infection and may cause degraded or ineffective monitoring.
9. Extreme care must be taken when handling instruments with sharp points or edges.
10. Keep the device away from the place with high electromagnetic disturbances intensity, such as the high frequency surgical equipment active in the hospital, heart failure surgery equipment, RF shielding room for magnetic resonance imaging systems, etc.
11. Stop using the device when the basic function is lost due to electromagnetic disturbances.
12. Do not use the device near other devices or in

stacks because it could result in improper operation. If such use is inevitable, this device and other devices should be observed to ensure they are operating normally.

13. Cable Length is 1000mm to 3000mm， The selection of wire length shall be determined by professional doctors.
14. Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
15. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Disposable EMG Needle Electrodes, including cables specified by the manufacturer. Otherwise, the performance of the device may deteriorate.
16. The device itself does not produce any electromagnetic radiation.
17. Practitioner is responsible for the proper use of the device in accordance to the appropriate IEC60601-1, IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
18. Practitioner is responsible for proper use, periodic safety certification of devices and equipments connected to the device, and AC power grounding in accordance to the appropriate IEC60601-1 , IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
19. See the system user manual of the equipments and systems connected to this device for more electrical safety and electromagnetic disturbances information.
20. Advice that a PATIENT with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.
21. Advice to avoid trans-thoracic stimulation.
22. Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
23. The maximum operating ambient temperature is 35°C. Avoid patient harm due to excessive temperature at the electrode and electrode cable.

5. Disposable Nerve Locating Probes

A.INTENDED PURPOSE

This product is intended to transmit the electric signal of human body parts during operation.

The Disposable Nerve Locating Probes is a single use, ETO-sterilization Medical device, which is designed for using with the nerve integrity monitor to transfer the electroneurodiagnostic signal and stimulate the nerve during surgical operation.This device is intended for use to locate, identify and stimulate peripheral motor nerves during surgery to assist the surgeon in locating and mapping motor nerves. Through the use of evoked potentials and electromyographic (EMG) signals. This helps reduce the risk of nerve damage during surgery.

B.WARNINGS

Read and understand the Warnings and Precautions associated with the use of Probes in the User Manual for the specific Monitoring system you are using.

1. Only licensed medical practitioners are allowed to use this product, or it shall be used under their guidance in person.
2. Please check whether the package is within the validity period before use, otherwise it cannot be used. Visually check the sterilization mark on the package. It is not allowed to be used if the color is not completely changed from pink to brown, and it is strictly prohibited to be used if the package is damaged.
3. Electrode integrity should be checked 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.
4. 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 an anesthesiologist.
5. The Electroneurodiagnostic System does not prevent the surgical severing of nerves. If these

devices are compromised, the surgical practitioner must rely on alternate methods, or surgical skill, experience, and anatomical knowledge to prevent damage to nerves.

6. To avoid patient burns:

• Do not activate electrosurgical instruments while the stimulator probe is in contact with tissue.

• Do not allow a second surgeon to use an electrosurgical instrument while the stimulator is in use.

• Do not leave stimulating electrodes or probes in surgical field.

• Do not store stimulating electrodes or probes in electrosurgical instrument holder.

7. False negative responses may result from:

• Shorted EMG electrode or cabling (conductive parts of applied electrodes or cables contacting each other).

• Inadequate stimulus current. Verify stimulator current setting is high enough and verify stimulus delivery by observing measured patient current.

• Inadequate current for stimulation of nerve through hardware, such as stimulus dissection instruments, may vary based on the physical size, shape characteristics, and design of the hardware and proximity to the nerve.

• Neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.

• Inadvertent simultaneous current delivery from two stimulator (Patient Interface Module) probe outputs. This may result in current division between the stimulator probes or electrode.

• Incorrect test settings.

8. High stimulator current may cause involuntary patient movement resulting in patient injury.

9. Direct stimulator contact may disrupt the operation of active implanted devices.

10. 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.

11. Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.

12. Improperly placed or bent probes increase the risk of the probe breaking off in the patient. Do not attempt to re-straighten or re-bend the probe. This can weaken the metal, causing the probe to break off in the patient.

13. Extreme care must be taken when handling instruments with sharp points or edges.

14. Inadequate stimulus current flow may be caused by non-flush contact between the stimulating electrode or probe and the nerve, inadequate stimulator probe electrical contact surface area, or high impedance.

15. Inability to deliver stimulus current flow may be caused by:

• Stimulator return electrode not connected, or other incomplete electrical connection between the Electroneurodiagnostic System, monitoring electrode and stimulator probe.

• Stimulus set to 0.00 mA.

• Defective stimulating electrode or probe.

16. Avoid accidental contact between connected but unapplied electrodes and other conductive parts.

17. Re-use of single use probes increases the risk of infection and may cause degraded or ineffective monitoring.

18. Keep the device away from the place with high electromagnetic disturbances intensity, such as the high frequency surgical equipment active in the hospital, heart failure surgery equipment, RF shielding room for magnetic resonance imaging systems, etc.

19. Stop using the device when the basic function is lost due to electromagnetic disturbances.

20. Do not use the device near other devices or in stacks because it could result in improper operation. If such use is inevitable, this device and other devices should be observed to ensure they are operating normally.

21. Cable Length is 50mm to 4000mm.

22. Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

23. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the probe, including cables specified by the manufacturer.

Otherwise, the performance of the device may deteriorate.

24. The device itself does not produce any electromagnetic radiation.
25. Practitioner is responsible for the proper use of the device in accordance to the appropriate IEC60601-1, IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
26. Practitioner is responsible for proper use, periodic safety certification of devices and equipments connected to the device, and AC power grounding in accordance to the appropriate IEC60601-1 , IEC60601-1-1 medical safety standard and IEC60601-1-2 electromagnetic disturbances requirements.
27. See the system user manual of the equipments and systems connected to this device for more electrical safety and electromagnetic disturbances information.
28. Advice that a PATIENT with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.
29. Advice to avoid trans-thoracic stimulation.
30. Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
31. The maximum operating ambient temperature is 35°C. Avoid patient harm due to excessive temperature at the electrode and electrode cable.

6. Disposable Pre-Gelled Surface Electrodes

A.INTENDED PURPOSE

The disposable pre-gelled surface electrodes are applied directly to the patient's skin. The electrode set is intended to record physiological signals or to conduct electrical stimulation with the Electroneurodiagno.

B.WARNINGS

Read and understand the Warnings and Precautions associated with the use of Pre-Gelled surface electrodes in the User Manual for the specific Monitoring system you are using.

1. When collecting bioelectric signal from human body and using it for stimulation (that is, the system sends a signal), only use common wires, and the system interface (socket) should have a ground loop.
2. Only licensed medical practitioners are allowed to use this product，or it shall be used under their guidance in person.
3. Please check whether the package is within the validity period before use, otherwise it cannot be used. It is strictly prohibited to be used if the package is damaged.
4. Pay attention to the position of each color code, and do not collect electrical signals in a wrong position.
5. Electrode integrity should be checked after electrode placement and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If electrode impedance is not suitable, discontinue use and replace.
6. Reuse of single use electrodes increases the risk of infection and may cause degraded or ineffective monitoring.
7. False negative responses (failure to locate nerve) may result from neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
8. Proper handling, placement of electrodes are critical for safe and accurate EMG Monitoring.
9. To avoid patient burns: Do not activate the electrosurgical instruments while stimulator is in contact with tissue. Do not leave stimulating electrodes in surgical field. Do not store stimulating electrodes in electrosurgical instrument holder. Do not allow a second surgeon to use electrosurgical instrument while stimulator is in use.
10. Electrode leads must be connected only to relevant recording/monitoring equipment. Electrical shock resulting in patient injury may result if the leads are connected to other types of equipment or connections.
11. 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.