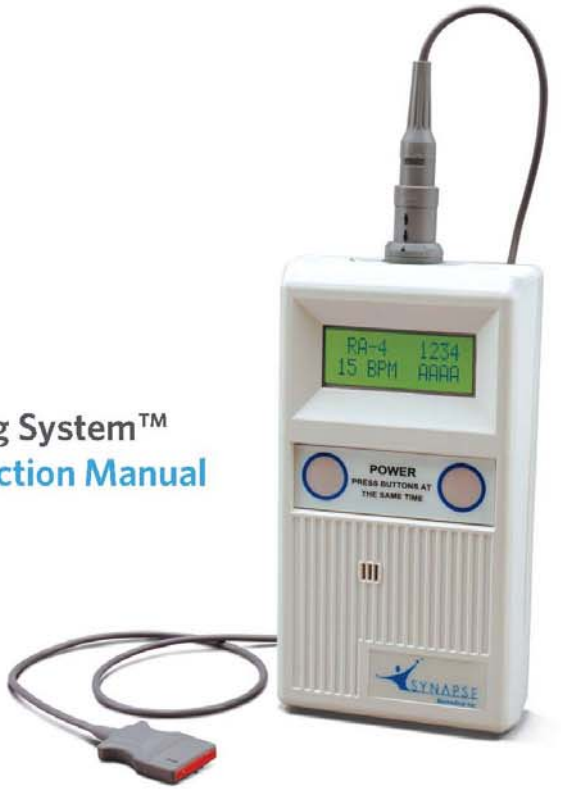
NeuRx Diaphragm Pacing System™
Patient/Caregiver Instruction Manual



Breathe deep... and live.

SYNAPSE
Biomedical Inc.

Key Contact Information

Doctor _____

Nurse _____

Contact Name _____

Center Name _____

Telephone _____

Fax # _____

Address _____

_____

Table of Contents

LABEL SYMBOLS

Below is an explanation of the symbols used on this product and its packaging. Refer to the appropriate product to see symbols that apply.

CONTROL SWITCH SYMBOLS

CAUTION

ON/OFF switch buttons. Must be pressed simultaneously to activate and deactivate the Stimulator.

SYMBOL EXPLANATIONS

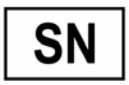
FOLLOW INSTRUCTIONS FOR USE

IEC 60601-1, Type BF Equipment

Conformite Europeene (European Conformity)
This symbol means that the device fully complies with Medical Device Directive 93/42/EEC.

IPX4 — The device is protected from splashing water.

Output voltages may approach 50 volt D.C. during operation.



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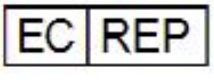

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France

WARNINGS AND CAUTIONS

Caution: Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician

Caution: The long-term effects of chronic electrical stimulation are unknown.

Caution: Safety has not been established for the use of the device during pregnancy.

Warning: This device is electrically powered and may produce tissue damage or electrical hazard if improperly used.

Warning: This device should be kept out of the reach of children.

Do NOT attempt to open the Stimulator case; the device has NO patient-accessible controls. Doing so can result in damage to the device.

Do NOT use in patients with an implanted electronic device (Insufficient clinical data is available, at this time, to establish safety with a cardiac pacemaker).

Do NOT connect the patient to high-frequency surgical equipment while connected to the external stimulator. Doing so can result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

Do NOT subject Patients implanted with the NeuRx Diaphragm Pacing System™ to Magnetic Resonance Imaging (MRI).

Do NOT use this device if skin in the electrode implant area is swollen, infected, or inflamed or if there are skin eruptions such as phlebitis, thrombophlebitis, or varicose veins.

Avoid operating this device in close proximity (for example 3 feet) to shortwave or microwave therapy equipment that may produce instability in the stimulator output.

Avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to ground (protective earth).

ELECTROMAGNETIC INTERFERENCE WARNING

Do follow the EMC information provided. The NeuRx™ RA/4 Stimulator needs special precautions regarding electromagnetic compatibility (EMC).

Use Caution around portable and mobile RF communications equipment as these can affect the NeuRx™ RA/4 Stimulator.

Do NOT use cables or accessories other than those specified. Doing so may result in increased emissions or decreased immunity of the NeuRx™ RA/4 Stimulator.

FLAMMABILITY WARNING

Do NOT use the NeuRx™ RA/4 Stimulator in an oxygen enriched environment or near a flammable anesthetic mixture with air, oxygen or nitrous oxide. The NeuRx™ RA/4 Stimulator is not categorized as AP (anesthetic-proof) or APG (anesthetic-proof category G - gas) type of equipment.

PRECAUTIONS

Spinal Cord Injury (SCI) patients must have a mechanical ventilator available at all times. If you do not feel that you are receiving adequate ventilation or if any malfunction of the pacing device is suspected, you should be placed on mechanical ventilation immediately and the pacing system turned off. Caregiver availability and monitoring should be consistent with when a ventilator is used.

Do NOT expose the device to excessive moisture or severe mechanical shock. If display indicates system failure, pain is felt at the electrode site, or device is exposed to moisture or shock, disconnect the cable and contact Synapse Biomedical.

Do NOT conduct diathermy treatment or electro cauterization in the area of the implanted electrodes.

Do NOT have the stimulator connected during any type of electrical diagnostic treatment such as EMG or ECG.

Precautions should be observed when there is a tendency to hemorrhage following acute trauma or fracture, following recent surgical procedures when muscle contraction may disrupt the healing process, or where sensory nerve damage is present.

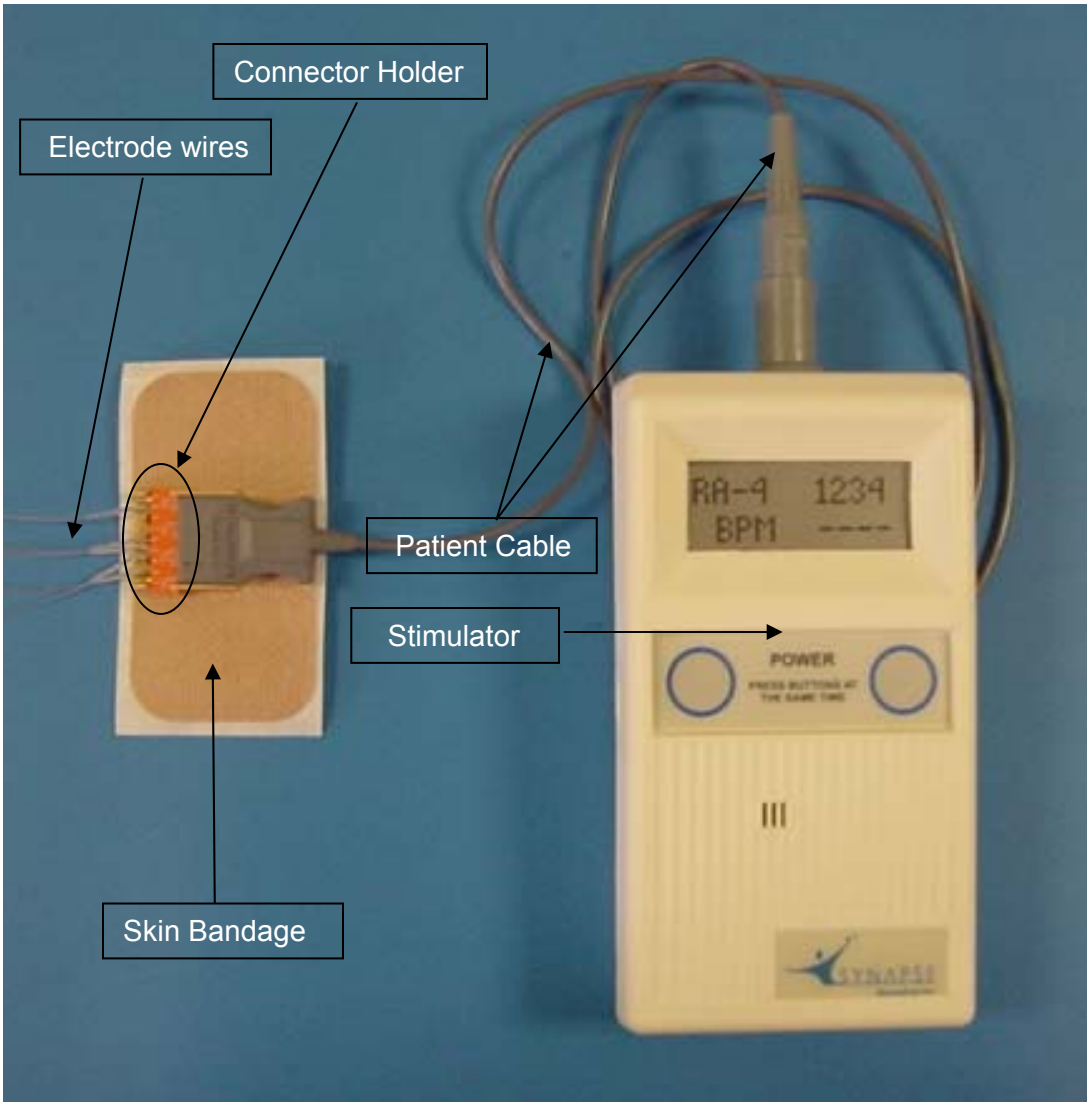
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation, the adhesive on the skin bandage, or the transparent dressing (Tegaderm™ and Op-Site™ are examples of transparent dressings) used over the gauze that covers the electrodes. Contact your physician or center if this occurs as irritation can usually be reduced by changing the stimulus parameters or removing the adhesive.

DEVICE DESCRIPTION

The NeuRx DPS™ is a system designed to help patients breathe by stimulation of their diaphragm muscles.

It is implanted using standard laparoscopic surgical techniques in an outpatient procedure.

The implanted intramuscular diaphragm electrodes are connected to the NeuRx™ RA/4 (external) Stimulator through the Patient Cable and the Connector Holder site.



The stimulator provides repetitive electrical stimulation to the implanted electrodes to cause the patient's diaphragm to contract and cause the patient to draw breath in a manner similar to natural breathing.

A physician will program the Stimulator so that it produces the right stimulation patterns. If the stimulation is uncomfortable, tell the physician as he or she can adjust the Stimulator to reduce or eliminate the discomfort.

The user simply connects the device to the implanted electrodes and turns it on for use; no other controls are available or necessary for operation.

During use, the stimulator should be kept close to the patient's body to avoid pulling on the cable and electrodes.

The stimulator can be placed in a pocket of the patient's clothing, a fanny pack or simply placed on a table or other convenient location.

FUNCTIONAL FEATURES

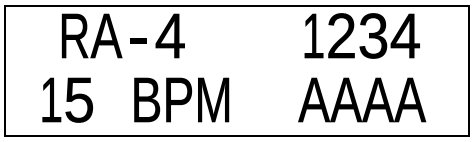
The cable should be securely inserted into the exit site connector and the top of the stimulator. The stimulator is programmed with parameter data that satisfies the patient's specific requirements.

To turn the stimulator ON: Depress the two buttons on the front of the stimulator simultaneously.

To turn the stimulator OFF: Depress the two buttons on the front of the stimulator simultaneously.

The buttons must be depressed simultaneously as a safety feature guarding against inadvertent activation.

The stimulator has a Liquid Crystal Display (LCD) that provides stimulator operational information.



The stimulator indicates the Breath-per-Minute (BPM) rate and when the individual electrodes are active.

During the inspiration phase, a letter 'A', 'B' or "C" is shown below each output number indicating that the stimulator is working well.

During the expiration phase, a '-' character is shown below each output number indicating that the stimulator is not active.

In the event that an 'X' appears below an output number, then a problem exists and your physician, center or Synapse Biomedical should be contacted.

The backup Stimulator may be carried with the patient as a spare Stimulator. It can be used at any time and may be helpful when diagnosing Stimulator or patient cable issues. The backup Stimulator should be cleaned and stored just like the Stimulator used daily. Your physician, center or Synapse Biomedical should be contacted when issues are discovered.

In the event that a '?' appears below an output number, it should be immediately followed by a letter. This can occur normally when the pulse modulation parameter is set at a high value or when the pulse width parameter is less than 50 µsec. Each stimulator is programmed with settings that were established during the conditioning session. This is considered a normal event.

SCI PATIENT INFORMATION

Patients with high-level spinal cord injuries typically experience chronic ventilatory insufficiency due to respiratory muscle paralysis. These patients historically have been supported predominantly through positive pressure mechanical ventilation. Alternatively, patients may be ventilated through activation of the nerves that cause the diaphragm to contract and create an inspiration. A device such as the NeuRx DPS™, that is surgically implanted in the diaphragm, does this and has given SCI patients the ventilatory support and freedom to experience a normal breathing pattern with the NeuRx DPS™ device as long as they have an intact phrenic nerve.

The first step in using the NeuRx DPS™ device is the process of increasing diaphragm muscle strength. Patients who have long standing and significant respiratory paralysis will require conditioning of the diaphragm muscle in order to sustain ventilation. The more the diaphragm is conditioned, the stronger the diaphragm will become.

Conditioning can happen every hour. In the beginning, the recommended stimulator usage for SCI patients is 15 to 30 minutes each session. As the diaphragm gets stronger, the length of sessions should increase and the number of daily sessions should decrease. Allow 45-60 minutes between sessions to allow the diaphragm to fully recover. Always consult your physician before making any changes to daily pacing sessions.

CONDITIONING SESSIONS

The following describes the process of one conditioning session:

- Secretions should be cleared prior to conditioning and managed throughout the conditioning session.
- Connect patient cable to orange connector block and to the stimulator.
- Place pulse oximeter on patient and continuously monitor throughout conditioning session.
- Turn stimulator on and remove from ventilator.
- Allow patient to get comfortable on stimulator (2 – 3 minutes) and measure tidal (breath) volumes with Respirometer. Make note of tidal volume, pulse oximeter reading and any comments, complaints, or discomforts.
- At the midway point of a conditioning session, measure tidal (breath) volumes with Respirometer. Compare to initial readings and, using the BORG scale below, determine the effort to breathe. Make note of tidal volume, pulse oximeter reading and any comments, complaints, or discomforts. If the effort to breathe on the BORG scale is 4 or greater, discontinue the session and return to the mechanical ventilator. If the pulse oximeter reads below 90%, discontinue the session and return to the mechanical ventilator.
- Prior to ending a conditioning session, measure tidal (breath) volumes with Respirometer. Make note of tidal volume measurements, pulse oximeter reading, breathing effort, and any comments, complaints, or discomforts.
- When conditioning session is over, place back on the ventilator and turn the stimulator off.
- Allow approximately 45-60 minute rest period between sessions.
- Conditioning notes should be reviewed with the physician to determine increases in conditioning time.

BORG Scale (breathing effort):

0 = No Breathlessness at all
1 = Very Slight Breathlessness
2 = Slight Breathlessness
3 = Moderate Breathlessness
4 = Somewhat Severe Breathlessness
5 = Severe Breathlessness
7 = Very Severe Breathlessness
10 = Maximum Breathlessness

CONDITIONING WARNINGS

STOP conditioning session and be placed back on the ventilator:

- If you notice any change in heart rate or feeling of chest discomfort
- If signs of shortness of breath or any discomfort persists or worsens.
- If oxygen level drops below 90%.
- If management of secretions becomes difficult.
- Your Borg scale is 4 or greater.

CAUTION: Always wear a Passy-Muir™ valve while sleeping to help prevent obstructive sleep apnea. Contact your physician if you do not already have one.

CAUTION: Use caution when eating and drinking while conditioning. A Passy-Muir™ valve should be worn during these conditioning sessions to reduce the risk of aspiration.

USE an abdominal binder when you are in your chair as this may improve your tidal (breathing) volumes.

WARNING: External electrical stimulation should not be done in the chest area.

ALARMS

The stimulator initiates an audible alarm if it detects any of the following problems:

- If the connection from the cable to the box or the cable to the electrode wires becomes loose or disconnects a beep lasting the duration of an inhaled breath will sound. The alarm will repeat at each programmed inhalation until the cable is reconnected.
- A 10 second long beep, audible alarm will sound when the stimulator switches to the internal backup battery. The 10 second alarm repeats once every hour.
- A 20 second long beep, audible alarm will sound when the internal backup battery is low. The 20 second alarm repeats once every minute.

CARE OF CABLE

- The cable connects the exit site connector (wires) to the stimulator.
- Do not cut, kink or pull the cable
- Do not manipulate the metal pins in the end pieces of the cable
- Do not immerse in water
- Keep extra cables in a dry secure location
- When in use, the cable should fit securely into the exit site connector and the stimulator
- The length of the cable should be long enough to provide comfort and allow range of motion without pulling on the exit site connector
- Notify your physician or center if the cable gets cut, kinked, falls in water, or has a loose connection to the exit site connector or stimulator

CARE OF LEADS

- Do not pull on the wires coming through the skin
- Do not cut the wires
- Use extreme caution when shaving skin area around wire site

CARE OF EXIT SITES & CONNECTOR

- Keep the skin at the exit sites clean and dry
- Do not scratch skin at exit sites
- Clean the exit sites with alcohol wipe, allow alcohol to dry, place gauze dressing over the exit site. Be sure to cover all the wire with the gauze. Place a transparent dressing over the gauze. (Tegaderm™ and Op-Site™ are examples of transparent dressings)
- Change the dressings every 3 days or more often if the dressing becomes wet or otherwise soiled
- If the area becomes red, swollen, painful or drainage appears: notify your physician.
- Do not manipulate the metal pins in the connector
- The exit site connector should lie flat against the surface of the skin
- Observe that the electrode leads are properly positioned within the connector
- This connector will snap into a skin bandage (provided by the research team)
- Notify your physician if there is a change in the appearance of the connector
- You should change the skin bandage weekly or if it becomes soiled

CLEANING OF COMPONENTS

- The surfaces of the Stimulator may be cleaned and disinfected with a solution of ¼ teaspoon of household bleach (3-6% bleach) to 1 pint of water. Rubbing alcohol (isopropanol) may be used in place of the bleach. Typical cleaners such as glass or multi-surface spray cleaners are adequate. Do NOT use these cleaners on parts that will contact the skin (for example, electrodes at the exit sites).
- The surfaces of the Patient Cables may be cleaned with a mild anti-bacterial hand soap solution.

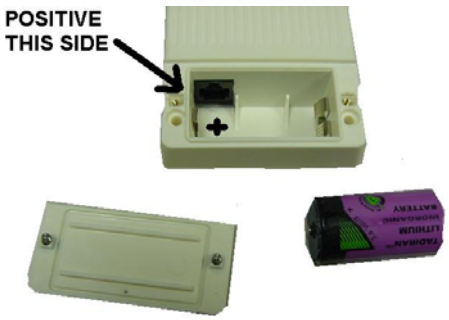
BATTERY INSTALLATION

WARNINGS

- If the stimulator displays “LOW BATTERY” then replace the battery immediately!
- Ensure that the Stimulator is turned OFF prior to battery replacement.
- The device contains a permanently installed back-up lithium-ion battery and is not replaceable.
- The device contains a replaceable lithium-ion battery and replacement by inadequately trained personnel could result in an explosion. Follow the following procedure:

BATTERY REPLACEMENT

- ✓ Use only SPECIAL size “C” Lithium batteries. Do not use a standard alkaline battery in the Stimulator. The size “C” Lithium batteries can be obtained from Synapse Biomedical.
- ✓ It is very important to install battery in the correct orientation
- ✓ It should be replaced every 500 hrs (3 weeks of full time pacing)
- ✓ The stimulator will initially display “REPLACE BATT” when your battery needs replaced.
- ✓ To change the battery, use the provided flat blade screwdriver to remove the battery cover located on the back bottom of the stimulator. Remove old battery and replace with new.
- ✓ Replace the battery cover and secure with mounting screws.
- ✓ Dispose of depleted batteries according to local regulations.



TROUBLESHOOTING

The following guide can be helpful in determining the source of problems with the DPS system:

Problem	Action
Pacing of the diaphragm stops	1. Check the connections of the electrode leads to the Connector Holder 2. Check the connection of the Patient Cable to the Connector Holder 3. Check the connection of the Patient Cable to the Stimulator
Patient is not receiving adequate ventilation	Disconnect the Stimulator and return the patient to a ventilator
Patient Discomfort during pacing	Contact your physician. The Stimulator program may need adjustment
Bleeding, bruising, or infection of the electrode implantation site(s)	Contact your physician.
Patient feels pain at the electrode site	Disconnect the Stimulator first, then contact your physician
Skin irritation or hypersensitivity to stimulation	Contact your physician
Multiple "**X**"s appear on the Stimulator display	Disconnect the Patient Cable from the Stimulator and insert Test Plug. If problem persists then contact Synapse Biomedical
The Stimulator is exposed to substantial amount of water or fluid	Disconnect the Stimulator first, then contact Synapse Biomedical
A continuous audio alarm during the Inspiration Interval.	1. Check the connections of the electrode leads to the Connector Holder 2. Check the connection of the Patient Cable to the Connector Holder 3. Check the connection of the Patient Cable to the Stimulator
The Stimulator beeps every hour	The Stimulator is running on its internal battery. Replace the main battery as described in this manual.
The Stimulator beeps every minute	The Stimulator is running on its internal battery and the internal battery is getting low. **Replace the main battery immediately** as described in this manual.

SERVICE

The RA/4 External Stimulator has no user serviceable parts and it is recommended that if the unit becomes inoperable it is returned to Synapse Biomedical, Inc. for service.

REPLACEMENT PARTS

The following standard replacement parts may be ordered directly from Synapse Biomedical, Inc. as required.

ITEM	PART NUMBER	ORDER QUANTITY
Lithium Battery	29-0007	6
Patient Cable	22-0011	1
Connector Holder	22-0004	15

ACCESSORY

The following accessory may be ordered directly from Synapse Biomedical, Inc.

ITEM	PART NUMBER	ORDER QUANTITY
Screwdriver	29-0018	1

SPECIFICATION

Power Source	3.6-volt lithium battery
Battery Life	500 hours
Operating Temperature	+41 to +104 F
Storage Temperature	+20 to +140 F
Relative Humidity	10% to 85%
Pulse Waveform-type	Regulated-current biphasic
Pulse Amplitude	5mA to 25mA
Pulse Width	10use to 200usec
Pulse Period	20msec to 250msec
Inspiration Interval	0.8sec to 1.5sec
Inspiration Rate	8 to 18 Breaths per Minute

GLOSSARY

The following definitions are helpful in understanding the procedure and components of NeuRx Diaphragm Pacing System™.

Alcohol Wipe – individually packaged pad saturated with 70% Isopropyl Alcohol used to cleanse the skin's surface. For single use only.

Connector Holder – a bandage with a special plastic "shell" attached that is used to end of the Patient Cable

Covering Bandage – an adhesive bandage that covers the electrodes that exit the skin

Diathermy – treatment procedure that uses high frequency energy waves to generate a deep heat of body tissues. Can be used as a treatment for pain relief

Electrode (or Percutaneous Electrode) – specially made thin wire, which is placed through the skin into the diaphragm and used to deliver electrical stimulation.

Electrode Connector – a plastic strip that the doctor connects one end of the Electrodes to, after implanting the other ends of the electrodes into the diaphragm

EMG – Electromyography is a method for measuring muscle activity via the electrical signals produced by muscles when they are stimulated.

ECG – Electrocardiogram is a recording of the electrical activity of the heart.

IEC – International Electrotechnical Commission (IEC) is an international standards organization dealing with electrical, electronic and related technologies.

Patient Cable – the covered wire that connects the Stimulator to the electrodes at the connector holder

Programming – the process of entering personalized parameter data that satisfies the patient's specific requirements into the stimulator

Spasm – sudden involuntary or uncontrolled muscle tightening

Stimulator – a battery-operated controller that is programmed to generate a controlled amount of electrical stimulation

NOTES

77-0017 Rev D

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NeuRx™ RA/4 Diaphragm Pacing System: Product technical manual must be reviewed prior to use for detailed disclosure.

INTENDED USE

The NeuRx™ RA/4 is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. For use only in patients 18 years of age or older.

CONTRAINDICATIONS

The NeuRx™ RA/4 is contraindicated in patients whom the physician determines are not candidates for surgical procedures due to physical or mental conditions.

WARNINGS/PRECAUTIONS/ADVERSE EVENTS

This device should be kept out of the reach of children. Safety has not been established for pregnancy, patients under the age of 18, patients with suspected or real heart problems, or patients who have implanted electrical devices or epilepsy. The long-term effects of electrical stimulation of the diaphragm are unknown. This device is electrically powered and may produce tissue damage or electrical hazard if improperly used. The system may be affected by excessive moisture, severe mechanical shock, diathermy, electro cauterization, and radiation therapy. Implanted patients should not be connected to high-frequency surgical equipment or subjected to magnetic resonance imaging (MRI). Care should be taken to avoid operation of this device in close proximity to shortwave or microwave therapy equipment. Discontinue use of this device if skin in the implant area becomes swollen, infected, or inflamed or if there are skin eruptions such as phlebitis, thrombophlebitis, or varicose veins. Adverse events related to the system include capnothorax, equipment failure leading to loss of breathing, infection, airway compromise, spasms, pain or discomfort with stimulation, and difficulty eating. Patients must have a mechanical ventilator available at all times.

HUMANITARIAN USE DEVICE

Authorized by Federal Law for use in the treatment of respiratory insufficiency for high-level spinal cord injured patients. The effectiveness of this device for this use has not been demonstrated.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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