



For more information about the NeuRx Diaphragm Pacing System™, or to submit a patient inquiry, contact us at:

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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 who 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 who 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

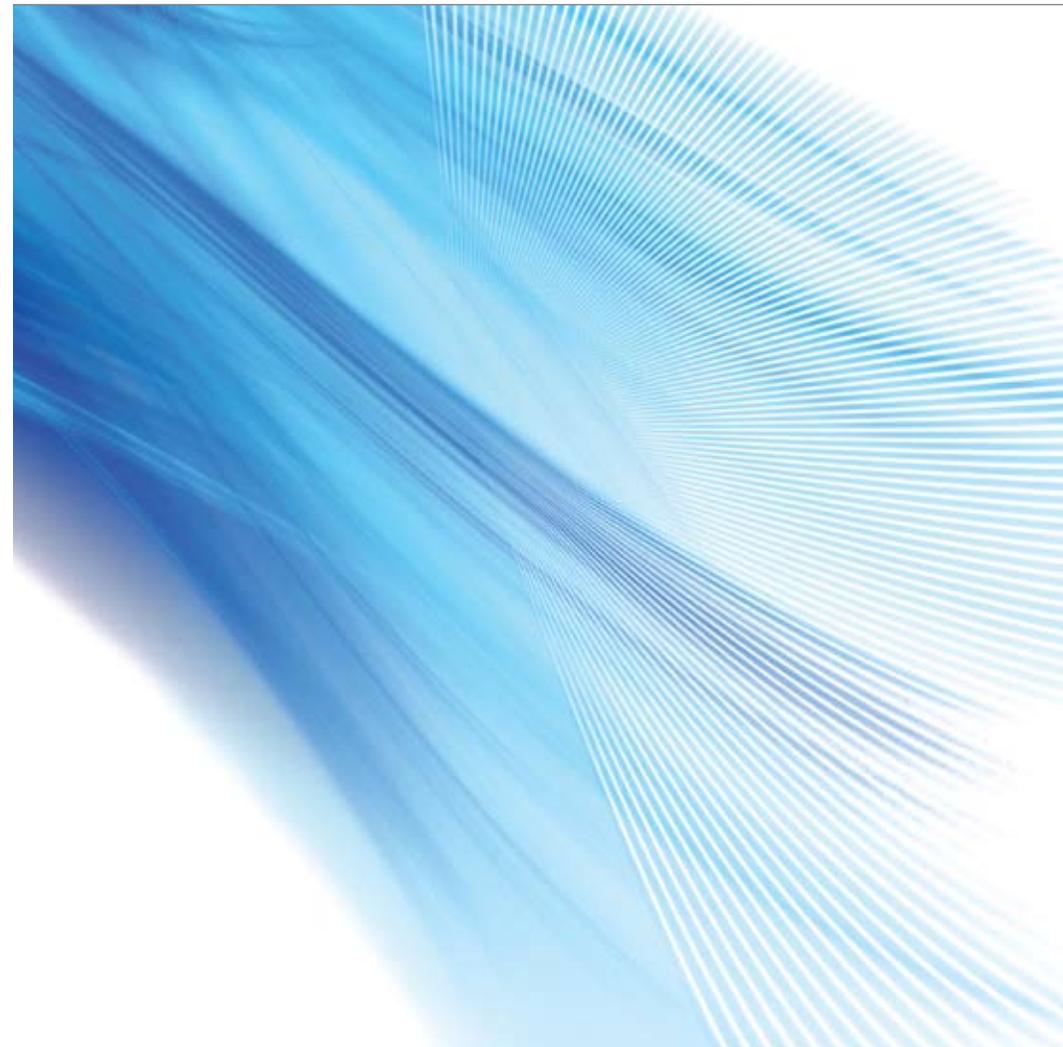
Authorized by Federal Law for use in the treatment of respiratory insufficiency for high-level spinal cord injured patients. The effectiveness of this device for this use has not been demonstrated.

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



Breathe deep... and live.

The SCI patient's guide to increasing independence with the NeuRx Diaphragm Pacing System™



PACING THE DIAPHRAGM:

The NeuRx DPS™ Program for People with Spinal Cord Injury (SCI) and Ventilator Dependency



Q What happens when I breath?

When you breathe, oxygen is brought into the lungs and absorbed into your veins. The veins carry the oxygen to your heart, which pumps it through your arteries so that it can nourish your organs and tissues. At the same time, carbon dioxide is taken out of your veins by the lungs and removed from your body when you exhale.

Q How can the NeuRx Diaphragm Pacing System™ improve my quality of life?

As someone who has experienced a spinal cord injury, or who cares for someone living with SCI, you are intimately familiar with the mental, physical and emotional challenges that each new second brings to the life you have come to know since the injury occurred.

Now, it's possible that your life can change again for the better.

Introducing the NeuRx Diaphragm Pacing System™, a groundbreaking, life-transforming neurostimulation technology designed to:

- Decrease your reliance on a ventilator.
- Increase your day-to-day independence.
- Maximize your freedom.

With no moving parts, noiseless operation and small size, the NeuRx DPS™ enhances your mobility and transportation options, and returns your sense of taste and smell.

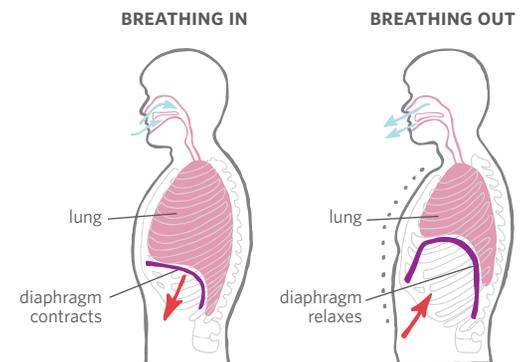
The state-of-the-art NeuRx DPS™ is engineered to help you to breathe deeply ... and live more fully.

Q What is the diaphragm and how does it work in creating respiration?

The diaphragm is the body's most important breathing muscle. It is a sheet that separates your abdomen from your chest. When you breathe in, the phrenic nerves cause the diaphragm to push down into your abdomen. This creates more space for your lungs to expand as air rushes in. At the same time, the muscles between your ribs cause your ribcage to expand and move upward.

Patients with high-level spinal cord injuries typically experience chronic breathing problems primarily due to diaphragm muscle paralysis. Because of this, SCI patients have typically been supported through positive pressure mechanical ventilation.

When the diaphragm contracts, the chest cavity enlarges, reducing the pressure inside. To equalize the pressure, air rushes into the lungs. When the diaphragm relaxes, the elasticity of the lungs and chest wall pushes air out of the lungs.



LASZLO NAGY



"The NeuRx DPS™ System allows me to travel and to leave my home virtually worry free. It has made my life much easier."

Q

What is the NeuRx Diaphragm Pacing System™ and how does it improve the way an SCI patient breathes?

Unlike a mechanical ventilator, the NeuRx DPS™ provides a gentle, rhythmic, electrical stimulation to your diaphragm, causing it to contract. Initially in an SCI patient, this stimulation works to exercise and strengthen your diaphragm muscle, which had weakened while you were on a ventilator. You will begin taking deeper breaths for longer periods of time. With the assistance of the NeuRx DPS™, the breaths you take are similar to a natural, comfortable breathing pattern. This enables many SCI patients to regain their sense of smell and taste. The system can achieve long-term replacement of positive pressure mechanical ventilation for SCI patients with intact phrenic nerves.

The NeuRx DPS™ consists of:

- Four electrodes implanted in the diaphragm
- A fifth electrode to complete the electrical circuit
- A connector holder
- A cable
- A small, external, battery-powered pulse generator

Your caregiver controls the NeuRx DPS™ and can turn the device on and off when you choose. When it is off for extended periods, you will likely need to return to positive pressure ventilation support. The settings are defined by a trained clinician or your physician and can only be adjusted by them. The easily-concealed pulse generator provides stimulus timing and control in order to regulate movement of your diaphragm and optimize respiration.

Q

What does NeuRx DPS™ stimulation feel like?

The sensation varies from patient to patient. Some feel nothing, while some describe a slight quivering feeling. Most patients are aware that their diaphragm is moving, but they become less conscious of the movement as conditioning becomes part of their daily routine.

Q

How long does the device's battery power last?

The NeuRx DPS™ operates on two batteries: a disposable lithium battery with 500 hours of life, and a permanent, rechargeable backup battery that lasts eight to 24 hours. The device will sound a tone when the disposable battery needs replacing.



DANIEL LEBLANC

"I feel more social. I can talk clearly and louder, which sure helps when you're in a crowd. The sense of freedom that it's given me has made me do things that I wouldn't have."

Q

How is the NeuRx DPS™ implanted?

A simple, minimally invasive outpatient procedure is used to implant the device's four biocompatible electrodes, two in each side of your diaphragm. To find the best locations, your surgeon will test a number of areas on the underside of your diaphragm. This is accomplished with a special mapping instrument that stimulates the diaphragm's surface. The fifth electrode is placed just below the skin near the exit site of the other electrodes. Only a few stitches are needed to close the small incisions. The entire procedure lasts approximately 90 minutes.

Q

Is the implantation surgery painful?

You may feel sore after your surgery, as your body heals. Your doctors can prescribe pain medications, if appropriate.

Q

What is the downside to the implantation surgery other than the usual risks?

The clinical study has demonstrated the NeuRx DPS™ treatment and use is safe when used according to directions. The most commonly reported adverse event related to CO₂ migration called capnothorax was easily managed operatively.

Q

Do you need to wrap or cut the phrenic nerve? I'm concerned about permanent damage if a cure is found.

Unlike with other technologies, the wires are placed directly in the diaphragm muscle. If you wish to discontinue use, talk to your doctor. Your doctor may decide to remove the wires or cut the wires at the skin. Do NOT attempt to have your caregiver do this.

Q

If I take blood thinners, can I be treated?

Patients that take blood thinner medication can receive treatment. As for any surgical procedure, your physician will recommend when to stop and how long you will need to remain off your medication.

HEATHER JOHNSON



"It's true that the diaphragm pacer doesn't change the fact that I'm paralyzed, but it really has enhanced my life."

Q

What happens after surgery?

After implantation, a clinician will work with you to determine comfortable stimulation settings that will maximize your diaphragm's performance. The device's settings can only be adjusted by a trained clinician.

Prior to discharge, you will receive specific conditioning instructions from your care team. You may be instructed by your physician not to use the NeuRx DPS™ right away to allow your body time to heal from surgery.

The initial conditioning sessions last as long as you can tolerate being off the ventilator, which depends on how weak your diaphragm is. During a conditioning session, your caregiver will turn on the NeuRx DPS™ and then remove you from the ventilator. Your caregiver will measure your oxygen level with a finger clip on a pulse oximeter or may measure the amount of air you are breathing with a handheld device called a Wright Respirometer. A pulse oximeter and Wright Respirometer are not essential to conditioning and may not be available in your payer plans. You should check with your insurance provider.

Your care team will instruct you on the number and duration of your conditioning sessions. To maximize your progress, record the time you remain on the pacing system at each session.



Q Who is eligible to use the NeuRx DPS™?

Since FDA approval in June 2008, twenty-five leading medical centers have been approved to offer the NeuRx DPS™ for treatment in the US. You can view a growing list of approved treatment centers in the United States at www.synapsebiomedical.com/products/us_sci.shtml and in Europe at www.synapsebiomedical.com/products/european_centers.shtml; or contact us toll-free: 888-767-3770.

Q How do I know the NeuRx DPS™ will work for me?

Your clinician can help you decide if the device is appropriate for you. The typical indication is for those spinal cord injured patients dependent on mechanical ventilation for all or part of the day. Even though the electrodes are placed in the diaphragm, patients must have an intact phrenic nerve from the spinal cord to the diaphragm. Your clinician will use your history and possibly an electromyogram (EMG) along with a radiology study to determine if the nerves that run from your neck to your diaphragm are still functioning. At times the only way to know if the system will work is during the mapping part of the laparoscopic procedure. The diaphragm has to move with stimulation for the NeuRx DPS™ to be effective.

Q I have been on a ventilator 20 years. Can I still get the NeuRx DPS™ treatment?

Treatment success is not dependent on time on a ventilator. It is dependent on whether you have an intact phrenic nerve to stimulate the diaphragm. One of our patients was on a ventilator 28 years before treatment. Typically injuries at cervical spine levels 1 through 3, and possibly level 4, are treatable.

Q Can I trigger my own breath like I can on my ventilator?

No, unlike a ventilator the NeuRx DPS™ is set by your physician to stimulate a comfortable level of breaths per minute. However, some patients can supplement with Glossopharyngeal breathing (frog breathing).

Q Can the NeuRx DPS™ match the number of breaths I receive from my ventilator?

The NeuRx DPS™ can be set to between 8 and 18 breaths per minute. You are provided two systems so one can be set at a higher setting if desired.

Q Is my speech changed using the NeuRx DPS™?

If you have been on a ventilator your diaphragm has gotten weak and will need to be strengthened, so your initial speech will be softer. Over time, as your diaphragm gets stronger, your breathing capacity (Tidal Volume) will typically increase giving you natural-sounding speech. You may be able to supplement your breath, which could allow you to raise your voice when speaking.

"This definitely gives me more confidence. It also reduces my risk of getting the upper respiratory problems that come along with the vent, since the pacer is more natural."

ADAM BOOKER



Q Does the NeuRx DPS™ work with Functional Electrical Stimulation (FES) bike?

You are provided two NeuRx DPS™ pulse generators. One can be set at a higher level for FES use.

Q I don't like being suctioned. Does the NeuRx DPS™ replace suctioning?

The NeuRx DPS™ does not replace suctioning. When traveling you will all the same equipment that is used on a weekly basis.

However, clinical patients noted a marked decrease in the need for suctioning. This is possibly a result of expanding the lower lobes of the lungs and reducing the time exposed to or eliminating ventilator humidification.

Q Can I use a Respiration CoughAssist® with the NeuRx DPS™?

Yes. Many of the existing NeuRx DPS™ users also use CoughAssist® to control secretion buildup.

Q Can I use the NeuRx DPS™ pacing system only at night?

Yes, if you have nocturnal-only needs, you may benefit from the NeuRx DPS™. You will need to check with your physician.

Q How do I eat with the NeuRx DPS™ pacer?

Just as you first had to learn to eat while being ventilated, you adjust to eating with diaphragm pacing, and it will feel natural again. Fortunately, your epiglottis will help sense the need for swallowing and close to allow swallowing. Initially, the use of a Passy-Muir valve can help prevent aspiration of food.

Q Can I use the NeuRx DPS™ if I cannot swallow?

You do not need to be able to swallow to use the NeuRx DPS™. Some SCI patients that cannot swallow have been successfully implanted. Some SCI patients rely on a feeding tube for nutrition and use the system. A patient with a cuffed tracheostomy tube can use the device.

Q How does this impact my caregiver's life?

Caregivers' comments include how dressing, bathing and transfers are easier when the ventilator tubing is no longer necessary. Concerns of a power outage are minimized because the NeuRx DPS™ operates on extended-life lithium batteries so the charging and storage of extra large batteries is minimized, making traveling simpler. In addition, eliminating the risk that a tube would pop off at night allows a more restful sleep.



Are the costs of the NeuRx DPS™ and the implantation procedure covered by my health insurance?

Your costs related to the NeuRx DPS™ program will depend upon your specific benefits plan. You'll need to coordinate information regarding pre-approval and reimbursement processes with your healthcare provider and your insurance company. Synapse Biomedical, Inc. has provided treatment centers with Medicare, Medicaid and private insurance reimbursement information to assist you in obtaining coverage.

You may find that certain out-of-pocket costs will decrease after obtaining diaphragm pacing with the NeuRx DPS™ program. Examples include decreased costs of disposables associated with mechanical ventilation and transportation.

Also, the National Spinal Cord Injury Association (NSCIA) has kindly provided the following guidance should an issue arise:

- a. Aggressively follow the appeals process for each individual insurance company. Be sure that the doctor writes very thorough documentation in support of the need for continued care coverage. This will be dictated by the level of injury and most certainly, anyone above C4, who would be the likely candidates for this system, will need intense care coverage for other reasons than ventilation. i.e. There may be multiple reasons for intense care coverage at C4 and above.
- b. See the NSCIA page for 'appeals': <http://spinalcord.org/news.php?dep=32&page=163> As noted, it is important to provide statements/expert opinions/articles that support the need.
- c. Contact the Insurance Commissioner http://www.naic.org/state_web_map.htm for each particular state if an appeal is denied. Inquire if the state has a Health Insurance Ombudsman who could be helpful with the particulars of an appeals process. Insurance companies should have a medical review committee that can be asked to review a request for coverage.
- d. For state specific as well as universal resources on obtaining health insurance services: <http://spinalcord.org/resources/index.php?link=I&list=119>
- e. Patient advocacy: www.patientadvocate.org
- f. Consumer guides for each state on getting and keeping health insurance: <http://www.healthinsuranceinfo.net/>



Is my caregiver skilled nursing support lost when I go off a ventilator?

You should inquire with your insurance provider regarding the level of support and whether this could be an issue. Some insurers restrict your need for support to your condition of quadriplegia with tracheostomy and need for suction. Also see the answer to the previous question on your rights regarding insurance and coverage.



How long has the NeuRx DPS™ been in development?

The NeuRx DPS™ has been developed over a 20-year period at University Hospitals and Case Western Reserve University in Cleveland, Ohio. The innovative research performed at these institutions has led to significant advances in state-of-the-art electrical stimulation for the treatment of chronic respiratory insufficiency, enabling patients to enhance their independence and quality of life.

The first clinical implant of the NeuRx DPS™ was performed in March 2000. This patient has used it continuously for eight years as of June 2008 without any use of a ventilator.



The bottom line: What is the NeuRx Diaphragm Pacing System's™ proof of performance?

Each SCI patient's success with the NeuRx DPS™ varies. Yours will depend upon your physical condition, your motivation to reduce your reliance on positive pressure ventilation, and the support of your caregivers.

In our clinical trial of 50 high-level spinal cord injury patients implanted with the NeuRx DPS™:

- One out of two patients achieved full-time diaphragm pacing and were able to eliminate the use of their ventilator.
- Two out of three patients now pace more than 12 hours per day and have significantly reduced the amount of time spent on their ventilator.
- Nineteen out of twenty patients are able to pace for more than four continuous hours, and many continue to work to condition and strengthen their diaphragm.



How long has Synapse Biomedical been in business?

Synapse Biomedical, Inc., headquartered in Oberlin, Ohio, was founded in 2002 to develop and advance the NeuRx DPS™ and make it commercially available and affordable for all those who suffer from respiratory insufficiency. In November 2007 the NeuRx DPS™ was approved for sale in Europe (CE Registration #CE 518356).



Where can I learn about people who have used the NeuRx DPS™?

You can access patient testimonials on the Synapse Biomedical website: www.synapsebiomedical.com

Here is one example of a NeuRx DPS™ success story:



SAMANTHA RODZWICZ
PENSACOLA, FLORIDA
C1 QUADRIPLEGIC

"... my miracles are increases in quality of life. ...I only use the NeuRx DPS™ for about 16 hours a day. However, by my standards, the technology has been a miracle. The pacer immediately eliminated the need for ambu bagging during transfers, suctioning and ventilator malfunctions, enabling me to be cared for by one person instead of the previous necessity of two sets of hands. I primarily use the DPS™ while in bed. With the reprieve from the hum of the ventilator and tubes pulling at my throat, I am now able to sleep throughout the night. Finally, since I began using the NeuRx DPS™ I have not had any cases of pneumonia. The pacer plays a vital role in my respiratory health... The NeuRx DPS™ has done more than change the way I breathe, it has changed my life."