

**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 stimulatory 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 four 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.

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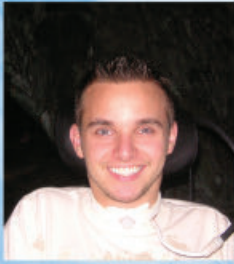
# NeuRx DPS™



Breathe deep... and live.

## Get Informed About Diaphragm Pacing





*"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

## Inspiration to live.

If you are ventilator-dependent as a result of a spinal cord injury, it's time you learn about the [NeuRx Diaphragm Pacing System™ \(DPS\)](#).

The NeuRx DPS™ is a groundbreaking neurostimulation technology designed to decrease your reliance on a ventilator, increase your independence and maximize your mobility. It uses minimally invasive technology to stimulate the diaphragm and increase ventilation to your lungs.

NeuRx DPS helps strengthen the diaphragm, allowing you to take deeper breaths for longer periods of time. This reduces your dependence on mechanical ventilation.

In the NeuRx DPS™ clinical trial of 50 high-level SCI patients:

- 100% of patients with intact phrenic nerve achieved tidal volume.
- 50% of patients achieved full-time (24/7) diaphragm pacing and eliminated the use of their ventilator.

With no moving parts, noiseless operation and at about the size of a TV remote, the state-of-the-art NeuRx DPS™ gives you freedom from the constraints of mechanical ventilation. A replaceable battery allows for 500 hours of continuous pacing.



NeuRx DPS can help a range of ventilator users, including:

- Those who are fully or nocturnally ventilator-dependent
- People who recently suffered spinal cord injury or have been vent-dependent for decades.

### Get the Facts

- It's TRUE that NeuRx DPS can transform lives. In a clinical trial, 100% of participants reported an increase in speech and independence.
- It's TRUE that NeuRx DPS™ users reported regaining their sense of smell and taste as well as eating more easily.
- It's TRUE that NeuRx DPS users reported expanded mobility and transportation options, so that travel was easier.
- However, it's FALSE that insurers will take away nursing support if you use NeuRx DPS.

[Learn more](#) about NeuRx DPS at [synapsebiomedical.com](http://synapsebiomedical.com)

[Download](#) an informative patient brochure at [synapsebiomedical.com/products/pdf/SCIBrochure.pdf](http://synapsebiomedical.com/products/pdf/SCIBrochure.pdf)

[Connect](#) with other NeuRx DPS users, who will answer your questions. Read their testimonials at [synapsebiomedical.com/news/success/](http://synapsebiomedical.com/news/success/).

[Contact](#) us directly at 440.774.2488 or [info@synapsebiomedical.com](mailto:info@synapsebiomedical.com)



*Synapse Biomedical and NSCIA proudly partner to provide education for patients, caregivers and professionals in the spinal cord community.*