

Breathe deep... and live.

The ALS patient's guide to maximizing your quality of life with the NeuRx Diaphragm Pacing System™



Your ALS Center staff can help answer questions and offer guidance regarding treatment options available to you. For more information about the NeuRx Diaphragm Pacing System™, or to submit a patient inquiry, contact us at:

Synapse Biomedical, Inc.

300 Artino Street
Oberlin, Ohio 44074
toll-free: 888.767.3770
Fax: 440.774.2572

Synapse Biomedical Europe S.A.R.L

156 Place des Aubépines
95680 Montlignon
France
Tel: +33 (0)9.60.12.44.98
Fax: +33 (0)1.74.18.08.19
mdiop@synapsebiomedical.com

info@synapsebiomedical.com
www.synapsebiomedical.com

PACING THE DIAPHRAGM:

The NeuRx DPS™ Program for people with Amyotrophic Lateral Sclerosis (ALS)



Q How do the lungs work?

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?

Life is about savoring moments. Being with your children, and supporting them as they grow. Seeing your grandchildren graduate and begin their adult life's journey. Traveling to incredible places you never thought you'd visit. Moments and memories... to share, enjoy and cherish.

Now, as someone living with ALS, you have a new resource that can empower you to stay involved. You can experience and savor your own memorable moments in ways you thought were no longer possible.

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

- Delay your reliance on a ventilator.
- Increase your day-to-day independence.
- Maximize your quality of life.

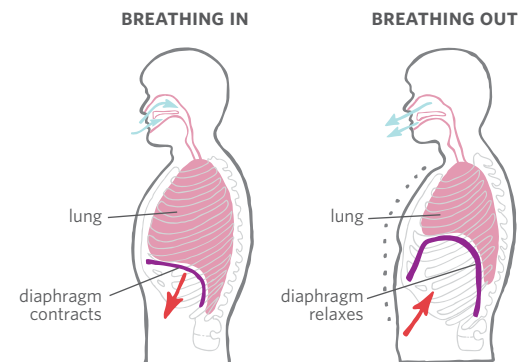
With no moving parts, noiseless operation and its small size, the state-of-the-art NeuRx DPS™ is engineered to help you to breathe deeply... and live more fully.



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 a negative pressure in your lungs, which expand as air rushes in.

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.





Q How is the diaphragm affected by ALS?

With ALS, the diaphragm can weaken like any other muscle. This happens because the phrenic nerves are gradually damaged, just like the nerves that go to your arms and legs.

Your ALS doctor will measure your breathing ability on a regular basis and may suggest simple exercises to help you expand your lungs when you are no longer able to take a deep breath. Your doctor may also suggest using a non-invasive positive pressure ventilation machine that will help you take bigger breaths when your nighttime breathing is too shallow. (BiPAP® is one brand name on the market.)



Q

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

The NeuRx DPS™ provides a gentle, rhythmic, electrical stimulation to your diaphragm. This stimulation conditions and exercises that muscle, helping you to take deeper breaths. With the assistance of the NeuRx DPS™, the breaths you take are similar to those that follow a natural, comfortable breathing pattern.

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

You control the NeuRx DPS™, turning the device on and off when you choose. The easily concealed pulse generator provides stimulus timing and control to regulate movement of your diaphragm and to optimize respiration.

The system is currently undergoing a controlled clinical trial for ALS in the United States. Our study is determining if diaphragmatic pacing effectively slows the decline in a patient's forced vital capacity (FVC) and delays the onset of respiratory failure. Data from our NeuRx DPS™ pilot study showed the average rate of decline in unassisted breathing function was 2.4 percent per month while, at nine months, breathing function in ALS patients using the NeuRx DPS™ declined by only 1 percent per month.

CE
008G

INVESTIGATIONAL DEVICE: Limited by
Federal Law to Investigational Use in the U.S.

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 every ten seconds when the disposable battery needs replacing.

Q How is the NeuRx DPS™ implanted?

The device's four biocompatible electrodes are implanted during a minimally invasive procedure. Using a mapping instrument, your surgeon will test a number of areas on the underside of your diaphragm to find the best locations for implant. 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 typically lasts 60 to 90 minutes. 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 results of the NeuRx DPS™ pilot study have not raised any safety concerns related to the implantation, stimulation effects, or events associated with the device. The most commonly reported adverse event has been a broken electrode at the external connection, which is easily managed with a non-surgical repair conducted during a routine clinical visit.

Q What happens after surgery?

Usually, you can return home the day after surgery. (ALS patients with low breathing test scores will stay in the hospital an extra day or two.) Within four days of your procedure, a clinician will work with you to determine NeuRx DPS™ settings that provide the optimum stimulation to your diaphragm while maintaining your complete comfort.

You'll receive specific conditioning instructions, but it is suggested that you begin your diaphragm conditioning sessions four to seven days after surgery, once you are rested and free of pain. These 30-minute sessions should take place at least four times per day. Use of the NeuRx DPS™ beyond your sessions should be approved by your physician.

You'll also return for evaluations at your ALS clinic every two to three months after your surgery. These follow-up evaluations include diagnostic testing and review of your device's settings along with help in managing any other issues involved with your diagnosis of ALS.



Q Can the NeuRx DPS™ device be used during exercise?

Except during hydrotherapy, your stimulator device can be used while exercising without restriction. Patients have commented that use of the device during or after exercise helps them recover faster and feel less short of breath. However, results vary from patient to patient.

Every patient receives two NeuRx DPS™ stimulators. You can elect to have one programmed at your normal rate for breaths per minute (BPM) and the second at a higher BPM rate, when exercising or to take larger breaths. If you wish to keep one stimulator as a backup, a third device may be purchased from Synapse BioMedical, Inc.

Q Can I use BiPAP™ with diaphragmatic pacing?

Non-invasive positive pressure ventilation (BiPAP) has been proven to help patients with ALS. BiPAP and NeuRx DPS™ can be used simultaneously. BiPAP helps rest the accessory muscles of respiration while NeuRx DPS™ maintains diaphragm strength and consistent movement.

NeuRx DPS™ helps strengthen the diaphragm and convert it to the better slow twitch muscle fibers, allowing some patients to decrease their use of BiPAP. Since BiPAP and NeuRx DPS™ are working in different ways, we recommend both to patients to optimize their respiratory function.

Q Who is eligible to use the NeuRx DPS™?

For ALS, the NeuRx DPS™ is currently available at certified centers in the United States and Europe which can be viewed at www.synapsebiomedical.com. Specific criteria must be met in order to be considered for the procedure. You must be able to tolerate a surgical procedure and your ALS physician has to document that your diaphragm is capable of being stimulated.

Your center can provide a complete list of requirements and qualifications.

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

While everyone's progression of ALS and symptoms are different, the NeuRx DPS™ is intended for people experiencing problems with respiration but not dependant on mechanical ventilation. If there are intact nerve pathways through the diaphragm then stimulation can be used. Two methods may be used to determine if these pathways are intact: observation under fluoroscopy (a full-motion x-ray) or a phrenic nerve conduction EMG study. If either of these methods shows positive results, then the NeuRx DPS™ has had good success in stimulating the diaphragm for contraction and conditioning.

After these test your physician can further explain the potential risks and benefits of the application of the NeuRx DPS™ and help you decide if surgery it is right for you.

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

Costs related to the NeuRx DPS™ program will depend upon your specific benefits plan. You'll need to coordinate with your healthcare provider and your insurance company regarding pre-approval and reimbursement processes.

Synapse Biomedical has established Medicare, Medicaid and private insurance reimbursement consultation to assist certified centers in obtaining pre-approved patient coverage in certain cases. Additionally, we are providing our centers with resources to address Medicare support for ALS patients in order to supplement their existing coverage. Visit www.synapsebiomedical.com for more information.

You may also find that certain out-of-pocket costs will decrease after obtaining diaphragm pacing with the NeuRx DPS™ program. Examples of these diminished costs may include any of the expenses associated with ventilators.

Q 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. This innovative research 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 for a person with spinal cord injury in March 2000. As of January 2008, that patient continues to use the system's diaphragmatic pacing successfully.

Q 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 January 2008 the NeuRx DPS™ was approved for sale in Europe (CE Registration #CE 518356).

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

You should learn as much you can so that you can be comfortable making a decision.

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

You may also contact ALS patients using the NeuRx DPS™ through www.patientslikeme.com

"As a caregiver to my husband Pat, anything that helps make living with ALS easier is huge. The diaphragm pacer has allowed Pat to sleep in his bed, instead of the recliner chair. During the day, when Pat "paces", he feels like it rejuvenates him, helps him to get a deeper breath, and gives him more daytime energy. Since Pat has had his pacer implanted, I feel like we have been given a major boost to Pat's quality of life."



PAT AND JENNY DWYER