

Frequently Asked Questions (FAQs)

What is Synapse Biomedical Inc.?

Synapse Biomedical Inc. (SBI) was founded in September 2002 in Oberlin, Ohio. Synapse Biomedical is focused on the commercialization of the NeuRx DPS™, a life-transforming neurostimulation platform technology, to treat people with respiratory insufficiency. The NeuRx DPS™ was developed over the course of 20 years through a joint effort of physicians and engineers at several institutions, including Case Western Reserve University, University Hospitals Case Medical Center and the Veterans Administration Medical Center.

The NeuRx DPS™ was developed at Case Western Reserve University and the University Hospitals Case Medical Center. Funding was made possible in part by the Department of Veterans Affairs, who contributed more than \$1 million.

Synapse's Co-founder, CEO and President is Anthony Ignagni. The Chief Operating Officer is Moustapha Diop.

How can Synapse Biomedical help people with Spinal Cord Injury (SCI)?

CE Mark (CE Registration #518356) in November 2007, for treating patients with diaphragm dysfunction in the European Union. In June 2008 Synapse received FDA approval for the use of its NeuRx DPS™ for patients with spinal cord injury who can no longer breathe on their own.

How can Synapse Biomedical help people with Amyotrophic Lateral Sclerosis (ALS)?

In 2009, Synapse submitted to the FDA their 88 patient clinical trial data for treating chronic hypoventilation in ALS. Approximately 30,000 people in the US live with ALS. Of the estimated 5600 new cases diagnosed each year, 2400 have both chronic hypoventilation and intact phrenic nerves. It is this patient population that Synapse has applied for approval to treat with the NeuRx DPS™. For more information on the ALS study, please visit www.synapsebiomedical.com/clinicals/als.shtml

What is the NeuRx DPS™?

The NeuRx DPS™ is a diaphragm pacing system, meaning it provides electrical stimulation to diaphragm muscle and nerves. The NeuRx DPS™ is made up of four electrodes implanted in the diaphragm to stimulate the muscle, a fifth electrode under the skin to complete the electrical circuit, a connector holder, a cable and an external battery powered pulse generator.

How does the NeuRx DPS™ work?

As a diaphragm pacing system, the NeuRx DPS™ provides a more natural form of ventilation by electrically stimulating the muscle and nerves throughout the diaphragm. When stimulated by the NeuRx DPS™, the diaphragm contracts which mimics natural breathing and allows air to fill the upper and lower parts of the lungs rather than forcing air in like a mechanical ventilator.

Unlike a ventilator, the NeuRx DPS™ is silent. This silent operation does not draw attention when in public and may allow for a more restful sleep when the patient is able to use the NeuRx DPS™ for sleep periods. In addition to stimulating the diaphragm, the NeuRx DPS™ strengthens an SCI patient's diaphragm muscle. The ALS clinical study seeks to prove the NeuRx DPS™ stimulation delays the weakening of the ALS patient's diaphragm muscle.

How long does the battery last?

There are two batteries in the NeuRx DPS™. The first is a user replaceable disposable lithium battery with 500 hours of battery life. The NeuRx DPS™ also has a permanent backup rechargeable battery with approximately 8 hours of battery life that recharges every time a new disposable battery is inserted. The NeuRx DPS™ provides a tone every 10 seconds to alert the patient when the disposable battery needs to be replaced.

How is a person implanted with the NeuRx DPS™?

To insert the NeuRx DPS™ electrodes, surgeons create four holes smaller than a dime in the abdomen. In one hole, a laparoscope is inserted to see the diaphragm muscle and four electrodes are placed in areas near the phrenic nerves that control the diaphragm contractions. To find the best spot for each of the electrodes, the surgeon tests a number of areas on the under side of the diaphragm. The electrodes are attached through wires under the skin to a small battery powered external pulse generator (EPG) to cause the diaphragm to contract. The procedure takes approximately 60 minutes and the small holes are closed with surgical band aids.

Who performs the surgery?

The surgery is accomplished at certified centers by a skilled Board Certified laparoscopic surgeon. Typically they will be trained in general, trauma or thoracic surgery. The surgeries will initially be proctored by a trained surgeon from an existing treatment center who has performed a minimum number of procedures. Additionally, initial support to the surgical team will be provided by a skilled service technician, typically a trained Respiratory Therapist or Registered Nurse.

Can any neurosurgeon perform this surgery?

No, although the procedure is performed to augment the phrenic nerve stimulation provided to the diaphragm, neurosurgeons are not typically trained to perform minimally invasive abdominal surgery.

Can my hospital be considered for performing this procedure?

Yes. Enter your contact information on www.synapsebiomedical.com/contact/inquiry.aspx or email Synapse Biomedical at info@synapsebiomedical.com

How can I be considered for this procedure?

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Can I have this procedure performed at any hospital?

No. The NeuRx DPS™ has been granted FDA approval as of June 2008. The device is available at select treatment centers that have been trained to perform the procedure and support the rehabilitation process for the reconditioning of a patient's diaphragm. For the latest list of approved treatment centers in the US go to www.synapsebiomedical.com/products/us_sci.shtml

How painful is the surgery?

The level of discomfort depends on the patients' level of sensation. Patients may feel tired or sore afterwards while their body heals from the surgery. Pain medications, if appropriate, can then be prescribed by your surgeon or physician.

What occurs after someone is implanted with the NeuRx DPS™?

The surgery is done with only an overnight stay for observation. After surgery, the EPG is programmed for the volume of air taken in during diaphragm contractions. This creates an effective yet comfortable breath. Because a patient diaphragm weakens while on a ventilator, at first they may only breathe using the NeuRx DPS™ for a short period of time. Patients use the device to strengthen their diaphragm, a process called conditioning, to extend the amount of time off of the ventilator. Conditioning usually occurs 3 – 5 times each day and initial sessions last between minutes or hours. Patients begin conditioning in the hospital, at a rehabilitation hospital or at home. They will receive specific conditioning instructions from their treatment center prior to discharge from the facility. Your treatment center may ask you to record each conditioning session in a conditioning diary.

Who was the first patient to use the NeuRx DPS™?

The first patient to be implanted was a 36-year old man from Ohio who was injured July 1998 in a swimming pool accident. In March 2000, 18 months after the incident, he underwent laparoscopic surgery, at University Hospitals in Cleveland, to implant the electrodes. After several months of diaphragm conditioning, he was weaned completely off his mechanical ventilator.

What is the longest use of the NeuRx DPS™ by an individual?

The NeuRx DPS™ has been implanted over 125 spinal cord injured individuals in the United States with high-level spinal cord injury. The longest term patient was implanted March 6, 2000 and has been using the DPS System as his means of respiratory support (24 hours per day) for over ten years.

You can access patient testimonials on the Synapse website at www.synapsebiomedical.com/news/success/.

Tell me about Christopher Reeve's experience with the NeuRx DPS™.

Christopher Reeve was the third patient to be implanted with the NeuRx DPS™. After a fluoroscopic examination of diaphragm movement and studies of his phrenic nerve activity, it was determined that his phrenic nerves were intact and he qualified for the procedure, still in clinical trials at the time. On February 28, 2003, he underwent a surgical procedure at University Hospitals Case Medical Center to implant the electrodes. Two days after his operation, he was back to work and gave a talk at Harvard University. On March 9, 2003, he returned to Cleveland to begin the reconditioning process of strengthening the diaphragm through intermittent stimulations. Unfortunately, Christopher Reeve did not achieve complete weaning but had successfully achieved durations of over 12 hours off the ventilator. Christopher Reeve elected to continue using the system throughout his course of treatment until his death.

What are the costs associated with this procedure? Is it covered by insurance?

Because the cost will vary based on the benefit plan, patients will need to work with their center to provide them with information on how reimbursement is obtained and can assist them in their insurance pre-approval process. Certain out-of-pocket costs related to the ventilator may decrease after being implanted with the NeuRx DPS™. For example, transportation, ventilator disposables and electricity costs will likely decrease.

Synapse Biomedical, Inc. has established Medicare, Medicaid and private insurance reimbursement information and guidance to support treatment centers efforts to obtain pre-approved patients coverage.

Does this surgery allow patients to be off a ventilator forever?

For spinal cord injury patients, the results have varied from patient-to-patient. It depends on the patient's motivation to reduce his or her reliance on positive pressure ventilation and the support of the caregivers. In clinical trials, of 49 patients implanted over 6 months:

- 1 out of 2 patients achieved full-time pacing and were able to eliminate their use of positive pressure ventilation.
- 2 out of 3 study participants pace over 12 hours per day and significantly reduced their time on positive pressure ventilation
- 9 out of 10 able to pace for >4 continuous hrs and many continue to work to condition and strengthen their diaphragm.

What is Spinal Cord Injury?

SCI is damage to the spinal cord that can result in loss of function, such as mobility or feeling.

Who has spinal cord injury and what is it caused by?

As of January 2008, the National Spinal Cord Injury Database estimates 227,000 – 300,000 individuals in the United States live with SCI and about 12,000 new cases of SCI occur each year. It is estimated that approximately 500 new cases of mechanical ventilator dependency occur each year that would be eligible for diaphragm pacing.

The leading causes of SCI injuries are vehicle crashes (47%), falls (22%) and violence (~14%). Other causes are trauma, sports injuries or disease, such as polio or spinal bifida.

Are all SCI patients the same?

No. SCI can be divided into three groups depending on the location of the injury. High tetraplegia injuries are cervical spine injuries between vertebra C1-C4. Low tetraplegia injuries are cervical spine injuries between vertebra C5-C8 and paraplegia are typically vertebra injuries of thoracic, lumbar vertebra or sacrum. All of these injuries result in impairment of sensory and motor functions to a varying degree.

What are the effects of SCI?

The higher the site of the injury, the greater number of nerves affected, which can result in partial or complete paraplegia (legs). Tetra injuries can affect the arms and legs and in some instances cause ventilator dependency. A 20 year old tetraplegic patient with ventilator dependency has a decreased life expectancy of more than 14 years compared to a tetraplegic patient not on a ventilator.

The leading causes of death for spinal cord injury patients are pneumonia, pulmonary emboli and septicemia.

Is there a cure for SCI?

No, at this time there is no cure for spinal cord injury. New research and studies are constantly taking place, in efforts to one day find a remedy.

How can Synapse help people with SCI?

Synapse is currently marketing the NeuRx DPS™ that can allow some SCI patients, depending on the level of injury, to breathe again without a ventilator. Some spinal cord injuries result in damaged phrenic nerves; therefore, these patients cannot benefit from the implant.

What is Amyotrophic Lateral Sclerosis (ALS)?

ALS is a rapidly progressing, incurable and fatal neuromuscular disease that attacks the nerve cells responsible for controlling voluntary muscles. It is characterized by progressive weakness that results in paralysis. ALS is also known as Lou Gehrig's Disease and Motor Neuron Disease.

Who has ALS?

There are about 30,000 individuals living with ALS in the United States and about 5,600 people are diagnosed each year. People of all races and ethnic backgrounds are affected, but it is most often diagnosed in men ages 45-65.

What causes ALS?

For about 90-95% of patients, there is no clear cause of ALS. In about 5-10% of ALS cases, the disease is inherited.

What are the symptoms of ALS?

The earliest symptoms of ALS are cramping, stiffness, weakening or twitching of muscles. This can manifest itself in slurred or nasal speech, difficulty chewing or swallowing, and difficulty walking or running. ALS does not affect a patient's ability to see, smell, taste, hear or touch. It also does not usually affect the patient's mind or intelligence.

How can I get more information about Synapse or its NeuRx DPS™?

For more information, please visit <http://www.synapsebiomedical.com> or contact: Steven Annunziato SVP Marketing & Sales, 440-787-0187 or sannunziato@synapsebiomedical.com