

NeuRx DPS[®] Fact Sheet

- THE DEVICE:** The NeuRx Diaphragm Pacing System (DPS)[®] was developed by physicians and engineers at several institutions with initial funding of \$1 million from the Department of Veterans Affairs. NeuRx DPS[™] allows patients with conditions affecting their respiratory muscles and nerves to breathe without using a mechanical ventilator. In 2009, NeuRx DPS[®] ranked third at the prestigious 6th annual Cleveland Clinic Medical Innovations Summit for the Top 10 Medical Innovations for 2009.
- HOW IT WORKS:** NeuRx DPS[®] consists 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. The pulse generator regulates movement of the diaphragm muscle, creating a vacuum-like effect in the chest cavity that draws air into the lungs. When this contraction eases, the air is expelled from the lungs. On average, this process is repeated 10-14 times per minute.
- THE PROCEDURE:** During minimally invasive laparoscopic surgery, a surgeon creates four dime-sized holes in the abdomen and inserts a laparoscope to see the diaphragm muscle. The surgeon then places small electrodes in areas near the phrenic nerves that control diaphragm contractions. The electrodes are attached through wires under the skin to a small battery-powered external pulse generator (EPG) that stimulates the muscle and phrenic nerves to cause the contraction of the diaphragm.
- The surgery is done with an overnight stay for observation. After surgery, the EPG is programmed for the volume of air taken in during diaphragm contractions. Patients with SCI perform daily physical therapy, called “conditioning,” to strengthen their diaphragms. Because the diaphragm of a Spinal Cord Injured (SCI) patient atrophies while on a ventilator, the patient begins using NeuRx[®] EPG to breathe for short periods of time. For SCI patients, NeuRx DPS[®] gradually extends the amount of time off the ventilator.
- For Amyotrophic Lateral Sclerosis (ALS) patients with chronic hypoventilation, the NeuRx DPS[®] conditioning delays the inevitable need for a ventilator.
- Both SCI and ALS patients can condition in the hospital, at a rehabilitation hospital or at home.
- ITS SUCCESS:** More than 400 SCI and ALS patients, including late actor Christopher Reeve, have been treated at leading centers around the world with the NeuRx DPS[®] technology. A list of spinal cord injury treatment centers can be found at www.synapsebiomedical.com/products/us_sci.shtml.

On September 2011, Synapse received FDA HDE approval to expand the indications for NeuRx DPS® to treat ALS patients with chronic hypoventilation. The approval was based on a demonstration that it's use with non-invasive ventilation (NIV) could significantly extend their lives and improve sleep quality when compared to NIV use alone. The findings are the result of a multicenter clinical trial that enrolled 144 patients with ALS of which 86 met the criteria for chronic hypoventilation.

Synapse continues work on expanding indications for use of the NeuRx® platform technology. Initial studies for use of NeuRx DPS® to wean intensive care patients off of mechanical ventilators have begun. This is as an alternate or assist for mechanical ventilation which is the #1 charged procedure in the U.S. and has an aggregate "national bill" to healthcare exceeding \$61 billion (2008, U.S. DHHS HCUP Nationwide Inpatient Sample statistics). In 2012, Synapse plans to begin discussion with FDA on our clinical trial design for the NeuRx® platform use in surgical intensive care.