FDA approves NeuRx diaphragm pacing system for use in spinal cord- injured patients

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The U.S. Food and Drug Administration (FDA) has approved the NeuRx Diaphragm Pacing System (DPS) for spinal cord-injured patients who are dependent on ventilators for breathing. The light-weight, battery-powered electronic DPS allows patients to breathe and speak more naturally, while eliminating the need for a power source and concern over power outages.

The system was developed over the course of 20 years through a joint research effort of physicians and engineers, primarily at University Hospitals Case Medical Center, Case Western Reserve University and Louis Stokes Cleveland Veterans Affairs Medical Center, all located in Cleveland. NeuRx DPS is manufactured commercially by Synapse Biomedical, Inc., based in Oberlin, Ohio.

DPS gained national attention in 2003 when University Hospitals Case Medical Center (UHCMC) surgeon Raymond Onders, M.D., implanted the system in actor Christopher Reeve. Dr. Onders is the director of minimally invasive surgery at UHCMC.

"This is a major step in improving the quality of life for patients who have spinal cord injuries and cannot breathe without the help of a ventilator," said Dr. Onders. "Based on testimonials that I've received from patients who have been in the clinical trials, DPS provides patients with a freedom of mobility that they never imagined. They've sent

photographs or videos themselves parachuting from planes, sailing solo, or enjoying rides at amusement parks with their families; activities impossible to do with a ventilator."

NeuRx DPS is a technology providing electrical stimulation to muscle and nerves running through the diaphragm, the major muscle involved in breathing. When stimulated by NeuRx DPS, the diaphragm contracts, allowing patients to breathe more naturally than having air forced into their lungs as a mechanical ventilator does.

FDA approval is based on 50 patients implanted with the system at hospitals in the United States and Canada, including UHCMC; Shepherd Center in Atlanta; Methodist Neurological Institute in Houston; and Vancouver General Hospital. Dr. Onders, a founder and shareholder of Synapse, trained all of the implanting surgeons. Dr. Onders will continue to oversee initial surgeries as regional trauma centers are certified to offer the system.

According to information from Synapse, in the DPS clinical trial, more than 50 percent of spinal cord-injured patients were able to completely eliminate their need fro mechanical ventilation.

The system is implanted through minimally invasive laparoscopic surgery. Patients and caregivers who want to find a doctor who can evaluate their case for possible treatment should visit www.synapsebiomedical.com

A clinical trial also is underway testing DPS with patients who have Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease. This incurable and fatal neuromuscular disease is characterized by progressive muscle weakness. A pilot study demonstrated the feasibility of DPS to slow the decline of a ALS patients' respiratory function. UHCMC and several other sites in the United States are

involved in the study.

Source: University Hospitals of Cleveland