

## Lungpacer Medical Seeks to Fill Unique Niche in Diaphragm Pacing Market

by Jennifer French, senior editor

Lungpacer Medical, Inc., the Burnaby, BC manufacturer of diaphragm pacing systems, has its sights on filling an unmet medical need in intensive care. The FDA recently granted the company Expedited Access Pathway designation for its patented Lungpacer Intravenous Electrode Catheter. As such, the company is positioned to change the way invasive mechanical ventilation is performed for ICU patients around the world.

Founded in 2009, Lungpacer has been quickly meeting clinical milestones to bring the device to market. In October 2015, the company announced the initiation of a first in human feasibility study, the PACER study of 24 patients in Paraguay. Led by Steve Reynolds, the study results were presented earlier this year at the American Thoracic Society meeting, demonstrating the LIVE catheter can be easily positioned and effectively stimulate the diaphragm muscle.

Diaphragm pacing is nothing new in the neurotechnology market. Vendors such as Atrotech, Avery Labs, and Synapse Biomedical have commercialized diaphragm and phrenic nerve pacing for the treatment of chronic mechanical ventilation users. These devices were originally designed to be surgically implanted. Lungpacer brings a new twist to this well-established therapy while targeting a clinically unmet need.

Many ICU patients are too weak for an implanted breathing assistance system. Instead, they remain on invasive mechanical ventilation, resulting in diaphragm muscle atrophy, increased risk of pneumonia, and increased prevalence of lung injury or atelectasis. Currently half of the ICU IMV patients are 65 years or older, and the demographic is expected to grow by 65 percent in the next 15 years. There are approximately 2 million IMV patients worldwide each year running up daily hospital costs to nearly \$6,000 per day. Moreover, many have difficulty weaning off the ventilator because of disuse atrophy. For about 30 percent of those patients, it takes up to one week to wean off a ventilator and for another 10 percent it can take two to three weeks.

ICU IMV patients perform extensive exercises to strengthen the diaphragm to wean off prolonged use of mechanical ventilation but many are unable to wean at all and land themselves in long-term care facilities.

The Lungpacer technology seeks to change how IMV is used in the ICU and reduce the time to wean and the number of people unable to wean off the ventilator. The system consists of two components, a sensor connected to the ventilator endotracheal tube and the LIVE catheter. The catheter is a new form of the central venous line catheter traditionally used in the ICU to deliver fluids and extract blood. The clinical procedure remains the same but with added assisted technology. This catheter is lined with multiple electrodes. It is inserted through the skin and sutured in place while a cable sends sensing information to the control unit.

As the ventilator provides positive pressure, the sensors send signals to the electrodes pulsing the phrenic nerve to activate the diaphragm and fill the lungs in synchrony with the ventilator. Software helps the clinician place the electrode, identify the right and left phrenic nerve, and send pulses to the electrodes for optimum stimulation. This coupling with the IMV reduces the air pressure used from the ventilator by 20 to 30 percent, which was demonstrated in the PACER study. More importantly, it allows the patient to more effectively wean off the ventilator when the time arises. A study published in the *American Journal of Respiratory Critical Care Medicine* in August 2016 concluded that early transvenous phrenic nerve pacing may mitigate ventilator-induced diaphragm dysfunction.

The technology was the brainchild of Andy Hoffer of Simon Fraser University in Vancouver, BC. No stranger to the neuromodulation market, Hoffer previously founded Neurostream Technologies and Bionic Power. Inspired by the unfortunate experience of his mother, who could not wean off the ventilator after being admitted to the ICU with pneumonia, he developed the temporary pacing device in 2008 and founded

Lungpacer Medical in 2009. The current CEO, Doug Evans, is also a medical technology veteran. He is former COO of Kensey Nash which was sold to Royal DSM for \$360M and is inventor and developer of the Angio-Seal device for vascular closures, currently owned by St. Jude Medical. His passion also runs deep for this innovation as Evans' son, Cameron, was on a mechanical ventilator prior to his passing in 2012.

The expanding management team is gearing this company up for near-term commercialization. A former colleague and co-founder of Kensey Nash, John Nash, is the product development advisor. Mike Volker, formerly of Fraser's innovation office, has also joined the development team. Matt Gani is director of systems engineering and R&D, bringing his collective experience in stimulation, pacemaker, and defibrillator devices at Northstar Neuroscience, Biotronik, and St. Jude Medical.

In 2014, Hoffer and Evans raised \$5.5 million in private equity funding for proof of concept and completion of the preclinical studies. They raised another \$9.6 million in 2015 as convertible debt to improve upon the device prototype. To date, Lungpacer has raised \$20 million and hopes to bring in another \$25 million next year.

Lungpacer has pilot clinical trials planned for 2017 and is targeting CE Mark approval in 2018. The company is planning a North American multi-center pivotal trial of 200 patients in 2018. For the future, the company already has expansion products for pediatric and neonatal applications. "The Lungpacer diaphragm pacing therapy would be a first product of its kind," said Evans.

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