Studying Faster Ventilator Independence

Participating in this study may help you and others breathe independently

Without a strong diaphragm it is impossible to breathe independently[1]

Artificial breathing support from a ventilator may weaken the diaphragm muscle more than 50% in less than one day[2] making it difficult to regain independent breathing.

Lungpacer® is designed as a personal trainer for the diaphragm muscle

Lungpacer's AeroPace™ system is designed to stimulate the nerves that activate the diaphragm with repetitive exercises for 10-20 minutes twice per day to rebuild diaphragm strength and empower natural, independent breathing.[3]

> ***Lungpacer therapy provides an exciting potential solution to help mechanically ventilated patients return to natural breathing more quickly.***
>
> Dr. Joseph Shrager - Stanford University School of Medicine

Outcomes from a previous clinical study showed

Lungpacer strengthened the diaphragm and improved lung function

246%
Stronger Diaphragm[3]
(MIP)

128%
Improved Lung Function[4,5]
(RSBI)

Positive trending clinical outcomes

7.4%
Increase in Ventilator Weaning[3]

7.9%
Greater Survival[3]

1.4 Days
Less on a Ventilator[3]

These results from a randomized, controlled trial compared patients treated with Lungpacer therapy to patients treated with the standard of care. The rate of serious adverse events was the same between both groups.

CAUTION: Investigational Device. Limited by Federal law (United States) to investigational use.
Used exclusively for clinical investigations.

Lungpacer®

Your Participation Matters

Participating in this study will help evaluate the safety and efficacy of this device to seek FDA approval

Possible benefits of participating

- Help other patients by taking part in medical research.
- Potential access to Lungpacer therapy at no cost.
- Receive more detailed follow-up care which may improve health.[6]
- May receive compensation up to $2,500.

Important considerations

- Treatment may be more effective, less effective, or the same as compared to standard treatment.
- Mild or serious adverse effects may occur.
- More attention to your medical care may be required.

Get Started

1 Qualify

Patients on a ventilator at least 4 days should discuss qualification criteria with your doctor.

2 Consent

Review and complete the Informed Consent Form with your doctor.

3 Participate

Participants will be randomly placed in either a “Control Group” or a “Treatment Group.”

Control Group patients receive:

- Standard care provided to ventilator patients.
- May receive a typical catheter to deliver fluids and medications.
- Additional tests to measure progress towards weaning off the ventilator.

Treatment Group patients receive:

- Everything in Control Group.
- Multi-function AeroPace™ catheter to deliver fluids, medications, and diaphragm stimulations.
- Twice daily therapy sessions intended to strengthen the diaphragm.

You can leave the study at any time without any impact on your care.

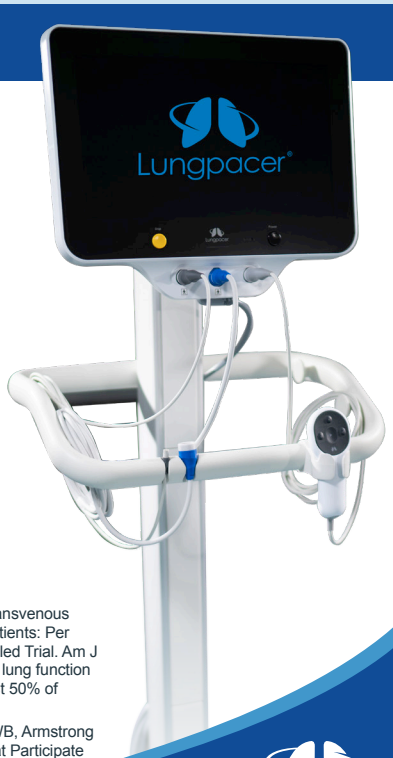
For more details go to **Rescue3Study.com**

Lungpacer’s AeroPace System

AeroPace stimulates the nerves that activate the diaphragm muscle, the source of natural breathing. For patients unable to breathe on their own, the AeroPace therapy provides repetitive exercises intended to rebuild diaphragm muscle strength critical to healthy breathing. Lungpacer is an FDA Breakthrough Device.

AeroPace Catheter

The multi-function AeroPace catheter can be used to provide fluids and medications and is similar in size and shape to a typical catheter. The AeroPace catheter additionally delivers small energy stimulations to targeted nerves in the upper body to activate and exercise the diaphragm.



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1. Jubran A, Tobin MJ. Pathophysiologic basis of acute respiratory distress in patients who fail a trial of weaning from mechanical ventilation. Am J Respir Crit Care Med. 1997;155:906–15.

2. Levine S, et al. Rapid Disuse Atrophy of Diaphragm Fibers in Mechanically Ventilated Humans. N Engl J Med. 2008 27 Mar; 358(13): 1327-35.

3. Dres, M., et al. Temporary transvenous diaphragm neurostimulation in difficult-to-wean mechanically ventilated patients – results of the RESCUE 2 randomized controlled trial. Eur Resp J 2020; 56(64): 4352: 246% stronger diaphragm (MIP)/P=0.0010; +7.4% increased ventilator independence/P=0.586; 7.9% greater survival /P=0.216; 1.4 days less dependent on a ventilator/P=0.498. Modified Intent to Treat Subset (mITT).

4. Lungpacer Data on File: 128% improved lung function (RSBI)/P=0.102, not significant. Modified Intent To Treat Subset (mITT).

5. Dres M, Gama De Abreu M, Similowski T. Temporary Transvenous Diaphragm Neurostimulation in Mechanically Ventilated Patients: Per Protocol Results from the RESCUE-2 Randomized Controlled Trial. Am J of Respir Crit Care Med 2021;203: A4668: 167% improved lung function (RSBI)/P=0.0487. Per Protocol (PP) group received at least 50% of Lungpacer therapy sessions.

6. Majumdar SR, Roe MT, Peterson ED, Chen AY, Gibler WB, Armstrong PW. Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials. Arch Intern Med. 2008;168(6):657–662.

Lungpacer®