

Avery Breathing Pacemakers

provide a lower cost of care and a higher quality of life for ventilator dependent patients with quadriplegia, central sleep apnea, or diaphragm paralysis.

What is a Breathing Pacemaker?

An Avery Breathing Pacemaker is a phrenic nerve/diaphragm stimulator consisting of surgically implanted receivers and electrodes and an external transmitter with antennas worn directly over the implanted receivers.

The transmitter and antennas send radiofrequency energy to the implanted receivers just under the skin. The receivers then convert the radio waves into stimulating pulses.

These pulses are then sent down the electrodes to the phrenic nerves, causing the diaphragms to contract. This contraction causes inhalation of air. When the pulses stop, the diaphragms relax and exhalation occurs. Repetition of these pulse trains produces a normal breathing pattern.

Avery Breathing Pacemakers are the only diaphragm pacing system to have full premarket approval by the US FDA for adult and pediatric use, and to also have CE marking privileges under the European Active Implantable Medical Device Directive.

They are approved by the Center for Medicare & Medicaid Services for Medicare reimbursement and by most private and government insurance plans throughout the world.

Who are candidates for pacing?

Avery Breathing Pacemakers are indicated for adult and pediatric patients with chronic respiratory insufficiency who would otherwise be dependent on ventilatory support.

Functioning phrenic nerves and intact diaphragms are necessary for the device to work appropriately. Typical diagnoses include:

- high spinal cord (C1 - C3) or brainstem injuries.
- congenital or acquired central hypoventilation syndromes.
- diaphragm paralysis of various etiologies.

What are the advantages of Avery Breathing Pacemakers over Positive Pressure Ventilation (PPV)?

Pacing is superior to mechanical ventilation since the inhaled air is drawn into the lungs by the diaphragm under negative pressure, rather than being forced into the chest under positive pressure. This is physiologically more accurate and comfortable for the patient.

Pacing reduces hospital readmissions as the patient is at a much lower risk of upper airway infections including ventilator-associated pneumonia (VAP).

Most patients strongly prefer pacing over mechanical ventilation because it:

- allows for normal breathing and speech patterns.
- eases eating and drinking.
- improves sense of smell.
- is small (about 1 lb) and does not require the bulky batteries and awkward tubing of a mechanical ventilator, greatly enhancing their mobility.
- operates silently which improves their ability to actively participate in social and educational activities.

A 2008 study published in the journal *Spinal Cord*¹ found that maintaining a patient with diaphragm pacing costs about 90% less than the comparable costs for keeping a patient on a positive-pressure ventilator. The study concluded that, when compared to mechanical ventilation, pacing:

- noticeably improves the quality of life.
- significantly reduces upper airway infections.
- reduces costs for disposable equipment.
- improves the quality of speech.
- reduces mortality and prolongs life.
- provides a positive Return on Investment (ROI) typically in the first year following implantation.

While the startup cost for a breathing pacemaker system may be high, ongoing operating costs are very low and a pacing patient can easily save up to \$20,000 per year in ventilator related expenses.

What are the advantages of Avery Breathing Pacemakers over similar devices?

Avery Breathing Pacemakers are the only device approved for both adult and pediatric patients. The youngest patient ever implanted was 56 days old, and the oldest was 84 years of age.

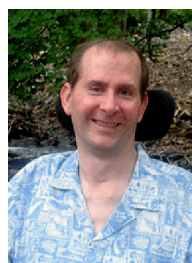
Through use of fully implanted receivers and external antennas, Avery Breathing Pacemakers do not have a percutaneous connector which can result in a chronic infection risk and ongoing wound management issues for caregivers. Since the patient's skin is left intact, they are able to participate in water therapy, swimming, etc.



Kathleen, pacing since 1971



Monique, pacing since 1978



Brodie, pacing since 1980



Chuck, pacing since 1982



Tatjana, pacing since 1993

By placing electrodes on the phrenic nerve rather than the diaphragm itself, Avery electrodes are not subject to the mechanical stresses and premature lead wire failure that can be caused by repetitive muscle movement.

Avery Breathing Pacemakers are powered by readily available alkaline batteries, not expensive proprietary batteries that require frequent replacement.

Avery electrodes use 99.99% pure platinum for nerve contacts, which is superior to stainless steel as it eliminates the possibility of ionic exchange at the neural interface.

Avery Breathing Pacemakers have a dual redundant design that ensures a single-point failure does not result in a complete loss of life support:

- each implanted side is independent of the other.
- each transmitter side is independent of the other.
- each transmitter side runs off its own battery.
- the common respiratory rate control has an internal backup.

Avery Breathing Pacemakers have user-adjustable controls for amplitude and respiratory rate which allow patients and caregivers to optimize settings for the patient's needs.

Systems include a transtelephonic monitor which allows the patient to send diagnostic data to ABD from anywhere in the world. Reports are sent to the patient's physician free of charge.

Avery Breathing Pacemakers are not contraindicated for patients who have, or may require, another implanted medical device such as a cardiac pacemaker, infusion pump, or vagal nerve stimulator.

Surgical Considerations

Implantation of Avery Breathing Pacemakers:

- can be performed either cervically or thoracically using minimally-invasive techniques such as video-assisted (VATS) or thoracoscopic approaches.
- have been successful when used in conjunction with phrenic nerve grafts to restore nerve viability in patients who would not otherwise be a candidate for pacing.
- does not require approval from a hospital Investigational Review Board (IRB).
- does not require the purchase of any specialized instrumentation or capital equipment.

Surgeons:

- do not require any specialized training.
- do not require the assistance of a company-employed physician.
- are provided onsite technical support at each surgical case at no additional cost.

Avery representatives are available to inservice clinicians and other caregivers on the operation of the system.

Safety and Efficacy

Avery Biomedical Devices operates:

- an FDA registered and inspected manufacturing facility of Class III medical devices since 1980.
- a quality management system which complies with the requirements of ISO 13485.
- its own certified clean room to ensure the absence of impurities in its implantable devices.

Avery Breathing Pacemakers have:

- been in commercial distribution since the 1970's, with some patients pacing for over thirty years.
- been implanted in over 2,000 patients in over 40 countries, establishing an unsurpassed record of safety and reliability.
- had premarket approval from the FDA since the inception of the requirement in 1986.
- had CE marking privileges for distribution within the European Union since 1995.

Avery Breathing Pacemakers use:

- a proprietary radiofrequency circuit design which rejects interference caused by other electronic devices.
- components that prevent direct current from being delivered to the nerve, which eliminates the possibility of nerve damage from stimulation.
- military-grade and other high-quality components and materials to ensure the highest reliability and excellent durability.
- a custom carrying case which not only protects the transmitter from fluid and dirt, but provides convenient storage for spare antennas, spare batteries and the patient's identification card.

A 2002 study published in the journal *Pacing and Clinical Electrophysiology*² demonstrated that there is "no apparent deterioration in pacing parameters or respiratory measurements from continuous pacing in excess of 10-15 years" and "pathologic studies demonstrate phrenic nerve integrity and preserved diaphragm histology despite 10 years of continuous pacing."

If you know someone whose life could be changed by an Avery Breathing Pacemaker, please contact us today.

Avery Biomedical Devices, Inc.

61 Mall Drive

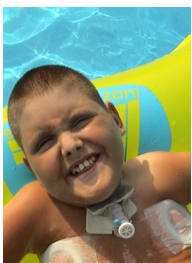
Commack, NY 11725-5725

www.averybiomedical.com

Phone: 631-864-1600, Fax: 631-864-1610

¹ "Mechanical Ventilation or Phrenic Nerve Stimulation for Treatment of Spinal Cord Injury-Induced Respiratory Insufficiency" *Spinal Cord*. May 2008, Vol. 46, No. 11, pp. 738-742.

² "Long Term Follow-up of Pacing of the Conditioned Diaphragm in Quadriplegia." *Journal of Pacing and Clinical Electrophysiology*. June 2002, Vol.25, No.6, pp.897-906.



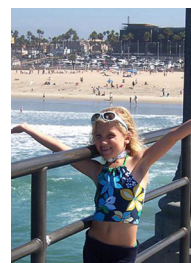
Nicolas, pacing since 1994



Taylor, pacing since 2006



Ed, pacing since 2009



Olivia, pacing since 2010



Kevin, pacing since 2012