What is diaphragm pacing?
Who should be considered, how it works, what methods are available

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Introduction

Diaphragm Pacemakers have been around for over 50 years, and have allowed patients with high spinal cord injury (SCI) liberation from chronic mechanical ventilation

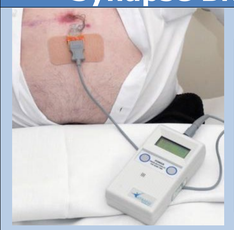
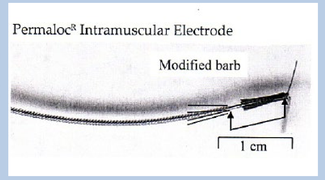
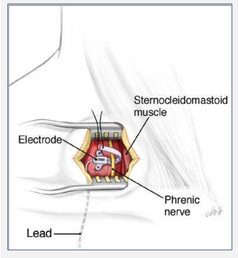
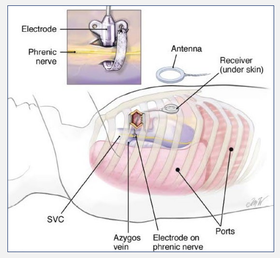
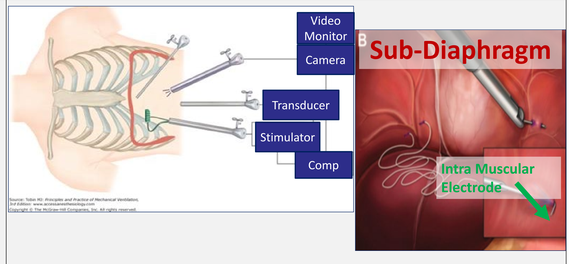
- *Patients with high SCI at or above C3 often have an interruption of the upper and lower motor neurons of the phrenic nerve. This causes paralysis of the diaphragm and those afflicted are frequently reliant upon mechanical ventilatory support*

What is a Diaphragm Pacemaker?

A Diaphragm Pacemaker is a phrenic nerve stimulator (PNS). Electrodes are surgically placed near the phrenic nerves in the neck, chest, or underneath the diaphragm.

- Stimulating pulses are sent to the nerves causing the hemi-diaphragm muscles to contract in unison producing inhalation.
  - *When the pulses stop, the diaphragm relaxes, causing exhalation. This cycle of on-and-off stimulation of the nerve is repeated in a pattern that mimics natural breathing*
- There are two commercially available diaphragm pacemakers in the United States, The Avery Biomedical Spirit and the Synapse Biomedical NeuRx System.

Diaphragm Pacemaker System Parameters

Criteria	Avery Biomedical – Spirit	Synapse Biomedical – NeuRx
Equipment	 External Transmitter and Receiver/Electrode Implants	  External Controller and Intramuscular Electrode
Approvals and Indications	**FDA:** PMA# P860026 **CE Mark** **Pediatric and Adult:** Upper motor neuron respiratory muscle paralysis and central alveolar hypoventilation syndrome	**FDA:** PMA# P200018 **CE Mark** **Adults 18+:** Spinal Cord Injury **Adults 21+:** ALS
Settings Adjustment	Amplitude and Respiratory Rate set by user. Pulse Width, Pulse Interval, Inspiratory Period, and Amplitude Slope are set by clinician/technician.	All parameters set by clinician/technician
Surgical Approach	  Electrodes can be placed on the phrenic nerve in the neck or the chest. The receiver is placed in a subcutaneous pocket on the patient's torso.	 Four electrodes are placed under the diaphragm muscle near branches of the phrenic nerve.
Stimulation Parameters	Pulse Width: 100µs to 999µs Pulse Interval: 40ms to 130ms Amplitude: 0mA to 10mA Respiratory Rate: 6 BPM to 30 BMP Inspiratory Period: 0.5 to 1.6s	Pulse Width: 10µs to 200µs Pulse Interval:50ms to 200ms Amplitude: 5mA to 25mA Respiratory Rate: 8 BPM to 18 BMP Inspiratory Period: 0.8s to 1.5s
System Redundancy	Two separate circuits (Left and Right) operate independently with a synchronized rate. Two-point redundancy	Both sides controlled by common circuit through single wire. Single reference anode used.
Adverse Events	0 MAUDE Reports found in FDA database	22 MAUDE Reports found in FDA database

Comparison to Traditional MV

Benefits *(References available upon request)*	Diaphragm Pacing	Mech. Vent
Natural breathing and speech patterns[1]	√	X
Safe and effective long-term use[2]	√	X
Reduced upper airway infections and secretions[3]	√	X
Improved venous return, better cardiac output and better oxygen[4]	√	X
Reduced mechanical and physiological complications[5]	√	X
Reduced hospital readmissions[6]	√	X
Increased freedom due to increased mobility[7]	√	X
Reduced need of care and assistance[8]	√	X
Able to close tracheostomy	√	X

Conclusions

It has been previously demonstrated that patients who undergo diaphragm pacer placement have used them daily for 20–30 years, with select patients able to pace for 24 hours a day.

There remains a significant number of mechanical ventilator dependent high SCI patients who are unaware of the benefits offered by pacing devices including cost savings and reduced risk of respiratory infections