



IMPORTANT FACTS ABOUT VNS (VAGUS NERVE STIMULATION) THERAPY™

What is VNS Therapy?

- VNS Therapy consists of an implanted pacemaker-like device that delivers mild, intermittently pulsed signals to the patient's left vagus nerve, which then activates various areas of the brain.
- Roughly the size of a small pocket watch and weighing less than one ounce, the pulse generator is implanted in the patient's left chest area. A thin thread-like wire, attached to the generator, runs under the skin to the left vagus nerve in the neck.
- The implant procedure typically takes approximately one to two hours.
- Although the VNS Therapy surgical procedure does not involve the brain, stimulation to the left vagus nerve has been shown to induce widespread bilateral effects in areas of the brain implicated in seizures and mood disorders and responsible for modulation of key neurotransmitters such as serotonin and norepinephrine.¹
- Using an external dose adjustment system, physicians can adjust the stimulation duration, frequency and intensity.

Indications for VNS Therapy

- VNS Therapy was approved in the U.S. in 1997 as an adjunctive therapy for reducing the frequency of seizures in adults and adolescents over 12 years of age with partial-onset seizures which are refractory to antiepileptic medications.
- VNS Therapy was approved in the U.S. in 2005 as an adjunctive, long-term treatment for chronic or recurrent depression for patients 18 year of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.
- VNS Therapy is currently approved for sale as a treatment for epilepsy in all the member countries of the European Union, Canada, Australia and other markets. The VNS Therapy System also is approved for sale in the European Union (March 2001) and in Canada (April 2001) as a treatment for depression in patients with treatment-resistant or treatment intolerant major depressive episodes including unipolar depression and bipolar disorder (manic depression).
- VNS Therapy is at various levels of investigational clinical studies as a potential treatment for other chronic disorders.

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VNS Therapy Experience in Epilepsy

- To date, more than 40,000 patients worldwide have been treated with VNS Therapy.
- The implant procedure does not involve the brain and is a short outpatient procedure. There is a very low incidence rate of surgical complications.
- VNS Therapy has been proven to effectively decrease seizures.² Many physicians and patients report that the quality of life is improved by the reduction in frequency and severity of seizures.³
- VNS Therapy provides seizure reduction and quality-of-life benefits that improve over time.²

Common Side Effects with VNS Therapy

- The most common side effects associated with VNS Therapy include hoarseness, sore throat, shortness of breath and coughing.¹
- Side effects typically occur only during stimulation and typically diminish over time.¹
- An animal study failed to show evidence of impaired fertility or harm to the fetus due to VNS Therapy.³
- Because VNS Therapy is not a drug, it produces no drug interactions with concurrent medications.

More Information

- For more information about VNS Therapy, its indications, contraindications, warnings and precautions, please call Cyberonics at **1-888-VNS-STIM** or visit the web site at www.VNSTherapy.com.

¹ Henry TR. "Therapeutic mechanisms of vagus nerve stimulation." *Neurology* 2002;59:S3-14.

² Morris G, Mueller W. "Long-term treatment with vagus nerve stimulation in patients with refractory epilepsy." *Neurology* 1999;53:1731-35.

³ Tatum WO, Johnson KD, Goff S. "Vagus nerve stimulation and drug reduction." *Neurology* 2001;56:561-3.

³ "Physician's Manual: VNS Therapy Pulse Model 102 Generator and Pulse Duo Model 102R Generator." Houston, TX: Cyberonics, Inc.