

VNS Therapy for Epilepsy

This pamphlet provides general information for the public. It is not intended to cover all possible uses, directions, precautions, interactions or adverse effects involving any product or device. It is not medical advice and should not be relied upon by consumers as such. All questions about vagus nerve stimulation, or any therapy for epilepsy, should be discussed with your treating physician.

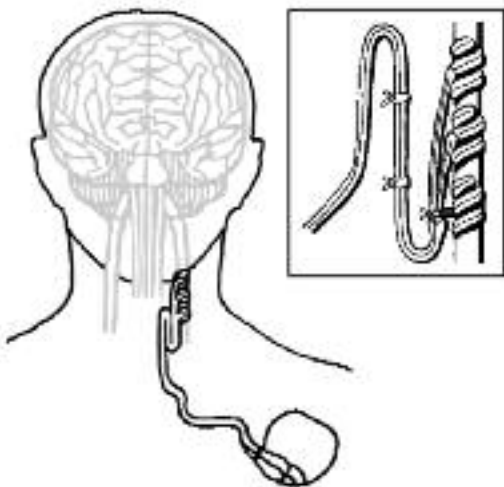
Understanding Vagus Nerve Stimulation (VNS) Therapy

VNS Therapy is a treatment approach that can improve seizure control, mood and quality of life over time. It may also provide an improved sense of control and independence to people with drug resistant epilepsy and allow patients to lead more normal lives.

VNS Therapy™ was approved by the U.S. Food and Drug Administration (FDA) in 1997 as an add-on treatment for certain kinds of hard-to-control epilepsy. An add-on treatment is one that is used in addition to another type of therapy—usually, treatment with medication.

In July 2005, the FDA also approved this therapy as a treatment for chronic or recurrent treatment-resistant depression for patients 18 years of age or older who experience major depressive episodes and have not had an adequate response to four or more adequate antidepressant treatments.

The therapy includes a pacemaker-like device about the size of a half dollar. It is placed in the chest and neck, just under the skin, involving two small incisions. The procedure, which takes about an hour, is usually done as standard outpatient surgery under general anesthesia. The device works continuously by sending small electrical impulses to the vagus nerve in the neck. These impulses then go to the brain to help prevent seizures where they start.



This diagram shows how the implanted pulse generator, lower right, is linked by electrodes to the left vagus nerve in the neck. The enlarged section of the diagram (upper right) shows how the ends of the flexible silicone leads are wound around the nerve.

Programming the Device

It is recommended that the device is turned on during the patient's check up visit, usually two weeks after the surgery.

Doctors program the device to deliver pulses of electrical stimulation automatically, 24 hours a day. A typical stimulation "dose" is about 30 seconds on and five minutes off, but settings may vary based on individual results. The device continues the cycle until the neurologist reprograms it or until the battery runs out—usually in 8 years. This will vary depending on how the device is programmed.

During office visits, the doctor checks the device to make sure it is working properly and that the treatment is not making the patient uncomfortable. VNS Therapy implants have low incidence, if any, of side effects such as depression, dizziness, confusion, weight gain, fatigue, insomnia, rash, facial hair and low energy. The most common side effects are temporary hoarseness/changes in voice tone, cough, tickling in the throat and shortness of breath which occur only during stimulation.

Sometimes people worry that the device may be rejected by the body. The device is made of titanium, a material that is widely used for pacemakers, and does not trigger an immune response. If it has to be removed, it is usually because it is not effective or because of infection from the surgery. Infection rates with the implant are considerably low, about 1 percent.

One of the most unique aspects of this type of therapy is the role that a special magnet plays in the treatment.

A special thin block magnet is attached to a strap that can either be worn on the wrist like a watch, or clipped to a belt like a pager.

The device delivers stimulation automatically, 24 hours a day, and the magnet can be used to deliver extra stimulation. This is done by the patient or a caregiver passing the magnet over the chest area where the device is implanted.

People use the magnet in this way when they sense a seizure is about to happen. For some, the extra stimulation stops the seizure, shortens it, makes it less severe, or reduces the time it takes to recover afterwards. Other people say using the magnet has little or no effect on their seizures.

How well will it work?

It's hard to know in advance how someone with drug resistant epilepsy will respond to VNS Therapy.

Many patients define success by the reduction in the number of seizures they experience and, sometimes, the reduction in how long their seizures last.

Studies show 4 out of 5 patients will experience some reduction in their seizures and that 40% of patients have less than half the seizures they were having as a result of VNS Therapy. A unique feature is that seizure control significantly improves over time and tends to maintain its effectiveness. Also, many patients experience less severe seizures, shorter seizures, improved recovery periods after seizures, fewer clusters and fewer visits to the emergency room.

With the device, most patients experience a better quality of life regardless of the reduction in their seizures. Many patients report improvement in alertness, mood, verbal skills and memory. In addition, 3 out of 4 patients have been able to decrease the number of their anticonvulsant drugs or dosages, potentially reducing side effects associated with those medications.

The sooner VNS Therapy is used, the more likely it is to improve long term seizure control and quality of life. It has been shown to be most effective when used early; within two years of diagnosis and after failure of only 2-3 adequate drug treatments.

Even when people respond well, improvement usually takes time. It isn't likely to happen immediately after the doctor implants the device. Several months may go by before there's any change, followed by a slow but steady improvement. Because of this, patients are encouraged to commit to VNS Therapy for a least a 2 year period. If you or a family member are thinking of starting VNS Therapy, it may be helpful to talk to other people who are already living with the device.

Using the magnet

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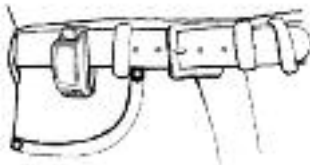
Although this therapy delivers stimulation automatically, 24 hours a day, the magnet can be used to deliver extra stimulation. This is done by the patient or a caregiver passing the magnet over the chest area where the device is implanted.

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Not everyone with an implant has a warning before a seizure begins. However, during a seizure, family members and caregivers can also be shown how to pass the magnet over the implant. This may help to shorten or stop the seizure completely.



This special VNS Therapy™ System magnet is worn on the wrist.



The magnet can also be clipped to a belt, like a pager.

The magnet offers many patients with drug resistant epilepsy and their families or caregivers an increased sense of control that may also help improve quality of life.

The magnet can also be used to give people a short break from the programmed stimulation.

By holding the special magnet in place over the device, someone with an implant can stop stimulation or turn off the pulse generator for a short time.

Reasons for wanting to stop the stimulation may include:

- Plans to sing or speak in public (to prevent changes in voice tone during stimulation)
- Eating (if people have a pre-existing condition that makes swallowing difficult)
- During exercise (if patients experience shortness of breath upon exertion during stimulation phase)
- Experiencing pain or other unusual discomfort during the stimulation phase.

Who Uses VNS Therapy?

VNS Therapy is approved for adults and adolescents over 12 years of age with partial onset seizures - seizures that begin in one part of the brain.

It is intended for people whose seizures do not respond to medications and who are either not good candidates for brain surgery, don't want to have brain surgery or those who may still experience seizures after brain surgery.

Currently, about 40,000 people have received VNS Therapy worldwide.

“When I got the VNS Therapy implant, it changed my life. I still take medicine, and I still have seizures, but I can honestly say my seizures have improved and I am able to function much better.”

Who Should Not Use VNS Therapy

VNS Therapy cannot be used in patients after a bilateral or left cervical vagotomy (removal of the left or both vagus nerves).

Cost

Once the neurologist recommends VNS Therapy as a possible treatment, there's the question of how much it costs and how to pay for it.

Most insurance companies, along with Medicare and most Medicaid carriers, cover the costs of VNS Therapy.

People who qualify for this treatment but do not have insurance or other funds to pay for the device may qualify for special assistance from Cyberonics, Inc., the manufacturer of the implant. The company has a range of support available to help patients interested in treatment.

Safety

For a complete listing of safety concerns please consult with your doctor or visit the manufacturer's website at www.VNSTherapy.com.

Frequently Asked Questions

1. Do small electrical appliances, cellular phones or metal detectors affect VNS Therapy?

According to the manufacturer, properly operating microwave ovens, toasters, hair dryers, and electrical appliances should not affect the pulse generator. Based on testing to date, cellular phones do not affect the pulse generator. Metal detectors at airports and other places should not affect the pulse generator.

2. What are the hazards, if any, of other kinds of medical treatment or tests when someone has a VNS Therapy implant?

Most routine procedures, such as having a routine ultrasound or an x-ray, should not affect your therapy, but anyone with the implant should always be sure to show their Cyberonics, Inc.-supplied identification card to all doctors, dentists, nurses, physical or sports therapists, rehabilitation providers, chiropractors, or any health professional providing treatment of any kind.

Patients with VNS Therapy should always let health professionals know that they have an implant and indicate where it is located on the body. Health professionals who have any questions are encouraged to visit, www.VNSTherapy.com.

If someone with VNS Therapy is going to have an MRI (magnetic resonance imaging) scan, special precautions should be taken. These should be discussed with the doctor in advance and the technicians giving the MRI should also be aware of the implant.



3. Does VNS Therapy cause sleep disturbances?

There have been reports that some people being treated with VNS Therapy have pauses in regular breathing (sleep apnea) and other sleep interruptions when the device turns on during sleep. If the patient or family members notice this effect, the doctor should be told.

4. If the special magnet doesn't prevent a seizure, does that mean that the device isn't working properly?

Possibly. Someone with an implant who has previously been able to prevent seizures by using the magnet should tell the doctor if it appears to have stopped working. On the other hand, it could mean that the settings may need to be adjusted by a doctor. In some cases, the magnet may not be effective at preventing or stopping a seizure.

5. Does the implant have to be replaced after a period of time?

According to the manufacturer, the battery can last 8 years, depending on the model and the stimulation settings used. It is important to schedule regular doctor appointments to monitor the battery life and to schedule a replacement before the battery runs out. Replacing the battery before it runs out will prevent symptoms from reappearing or worsening.

6. Where can I get more information about VNS Therapy?

Check with your doctor, or contact the Epilepsy Foundation* at 800-332-1000 or visit www.epilepsyfoundation.org. Information is also available on the manufacturer's website at www.VNSTherapy.com or via phone at 888-VNS-STIM.

**The Epilepsy Foundation provides information about treatments available for epilepsy. It does not endorse or promote use of any particular treatment or therapy, including VNS Therapy, and does specifically disclaim any liability for individual use of this product or drug therapy.*

