



An Introduction to VNS Therapy[®]

for people with epilepsy
and their families



Joshua
on VNS Therapy

LivaNova

You have options

Most people who have epilepsy take medications to control their seizures. However, it may be that even though you've taken your medicine and followed your doctor's advice, your seizures haven't eased up or stopped. Or your current treatment could be causing side effects that interfere with your daily activities. This is called drug-resistant epilepsy.



Drug-resistant epilepsy means your seizures have not been controlled even after trying multiple appropriate treatments. If this describes your situation, you are not alone. About one in three people with epilepsy (approximately 35%) experience this type of epilepsy that is difficult to treat with medication alone.

Years of medical research tells us that if two or three drugs have not given you seizure freedom, there's very little chance of gaining seizure freedom with any other drugs. It may be time to discuss different treatment options with your doctor.

Is VNS Therapy right for you?

VNS (Vagus Nerve Stimulation) Therapy is a unique treatment approach developed specifically for people with drug-resistant epilepsy.

More than 80,000 people worldwide have chosen VNS Therapy to help control their seizures without the side effects often associated with medications like depression, dizziness, confusion, weight changes, tiredness and trouble sleeping.

VNS Therapy is not another medication and it does not involve brain surgery. In addition, VNS Therapy has been proven to reduce the number and intensity of seizures for people with drug-resistant epilepsy. Many people using VNS Therapy have also reported improvements in mood, alertness and memory.

It is a safe, effective treatment that usually improves over time. Many people experience long-lasting seizure control with VNS Therapy.

How does it work?

- VNS Therapy is delivered by a device (generator) similar to a pacemaker and a thin, flexible wire (lead) that sends mild pulses to the left vagus nerve in the neck.
- The vagus nerve then sends these pulses to the brain to help control your seizures.
- Treatment is automatically delivered at regular intervals all day, every day so that you do not have to worry about missing a dose.

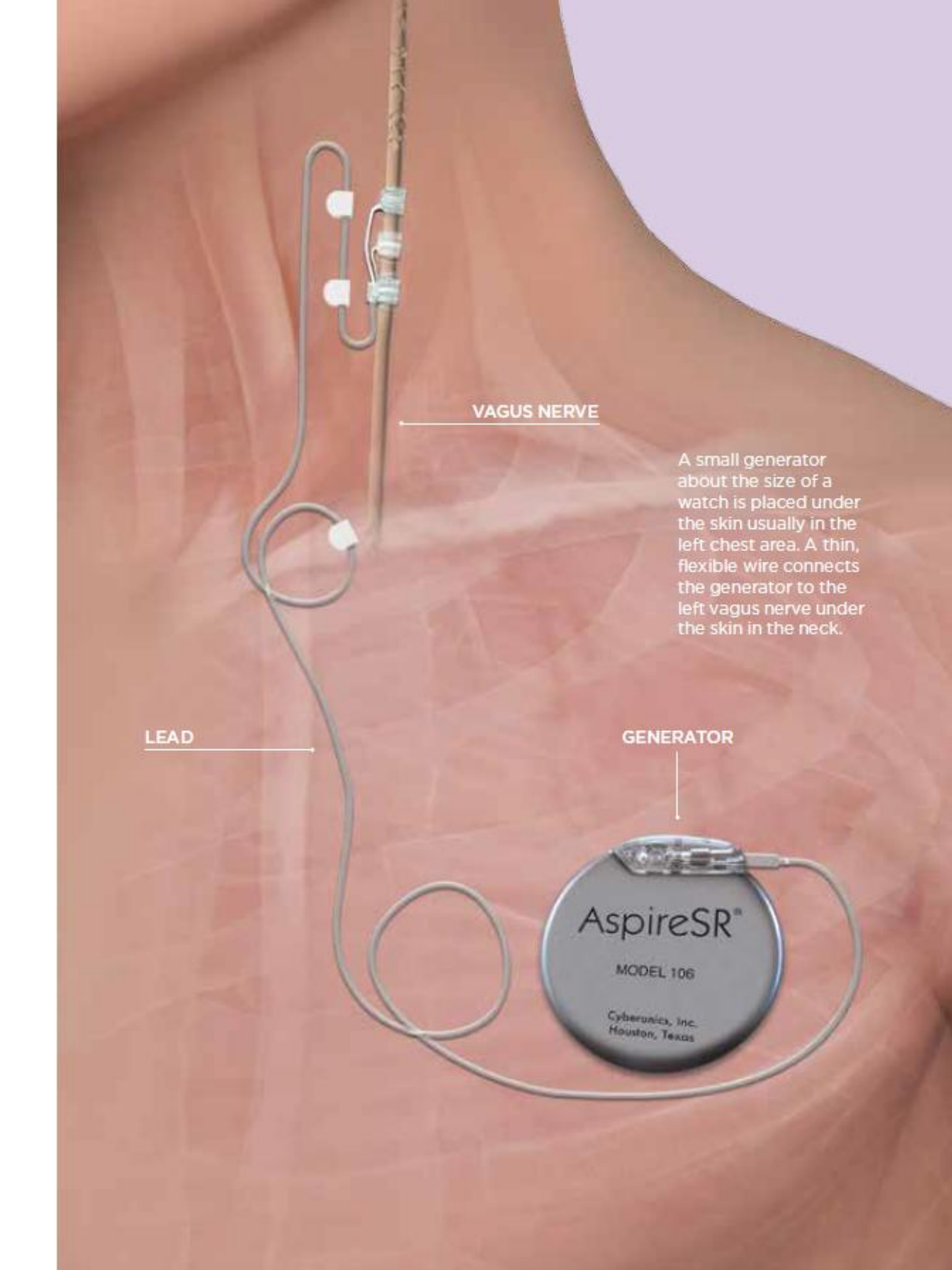
Are there potential side effects?

VNS Therapy is not a drug and, therefore, does not have the same side effects and does not interact with other medications.

The most common side effects of VNS Therapy include:

- A feeling of hoarseness or changes in voice tone
- Coughing
- A tickling sensation in the throat
- A feeling of shortness of breath

These side effects generally occur only when the generator is on and usually decrease over time. You will be given a handheld magnet that can be used to temporarily control these side effects during activities such as public speaking, singing, or exercising if needed.



VAGUS NERVE

A small generator about the size of a watch is placed under the skin usually in the left chest area. A thin, flexible wire connects the generator to the left vagus nerve under the skin in the neck.

LEAD

GENERATOR

AspireSR®

MODEL 106

Cyberonics, Inc.
Houston, Texas



What does VNS Therapy involve?

Step 1: Implanting the generator and lead

- VNS Therapy involves a minimally invasive procedure, which is performed by a surgeon typically under general anaesthesia.
- The procedure takes about an hour and most people go home the same day.
- In most cases two small incisions are made – one in a natural crease on the left side of the neck and one on the left chest area, below the collarbone.
- A small generator about the size of a watch is placed under the skin usually in the left chest area.
- A thin, flexible wire connects the generator to the left vagus nerve under the skin in the neck.
- A short procedure is required to replace the generator once the battery is depleted, usually after 3-8 years depending on the settings.

Step 2: Adjusting the parameters

- Programming is a simple, non-invasive procedure. Your doctor will gradually adjust the parameters to find a dose that is effective and comfortable for you. The goal of dose adjustment is to provide the most seizure relief with the fewest side effects.
- The dose adjustment is typically a painless procedure. If the stimulation is uncomfortable, you will know about it immediately, and your doctor can adjust the dose to a comfortable setting before you leave the office.
- Your doctor programs the generator to automatically deliver the appropriate dose of stimulation for you. A common dose is 30 seconds of stimulation every 5 minutes.
- Once the dose is adjusted, stimulation is regular and automatic.
- The VNS Therapy generator is usually turned on 2 weeks after the implant procedure.
- At first, you may be required to see your doctor or nurse once every 2 weeks until they determine the best settings for you. Later, you may just need to visit your doctor every few months.



Generators Actual Size



VNS Therapy can provide more control

The VNS Therapy magnet is included in the essentials kit given to everyone who receives VNS Therapy. The magnet may provide additional benefits for some people, but it is not necessary to use it in order to receive benefit from VNS Therapy.





By briefly placing the magnet over the generator if you feel a seizure coming on or during a seizure, you or your caregiver may be able to:

- Stop your seizure
- Shorten your seizure
- Decrease the intensity of your seizure
- Reduce the recovery period after your seizure.

You can also fix or hold the magnet over your VNS Therapy generator to temporarily stop stimulation during certain situations or activities when even mild side effects are inconvenient, such as:

- Public speaking
- Singing
- Exercising or other strenuous activity

If you experience troublesome side effects for an extended period of time, contact your doctor.

How do you feel about your current therapy?

It is important to evaluate your current epilepsy treatment and the way it affects your life. If you can answer “yes” to any of these questions, it may be time to talk to your doctor about treatment options beyond medication.

1. Are you taking multiple medications for seizure control and still having seizures?
2. Are you experiencing side effects from your current treatments that interfere with your daily activities?
3. Have you repeatedly been to the emergency room or admitted to the hospital because of your seizures or seizure-related injuries?
4. Does the time it takes you to recover from your seizures stop you from continuing with your daily activities?

We understand that treatment is not just about seizure control. The goal of your treatment should be to help you improve seizure control with the fewest side effects so you can have the best possible quality of life.

Frequently Asked Questions

Q. Am I a good candidate for VNS Therapy?

A. People who continue to have seizures despite treatment with two or more medications and have side effects that are difficult to tolerate may benefit from adding VNS Therapy to their treatment plan. If multiple medications have not given you acceptable, ongoing seizure relief, it may be time to consider a different treatment option like VNS Therapy.

Q. How many people have had VNS Therapy?

A. VNS Therapy is approved worldwide for the treatment of difficult-to-treat epilepsy. To date, more than 80,000 people with epilepsy have used VNS Therapy.

Q. If I have VNS Therapy, will I still need to take medications?

A. VNS Therapy is an added treatment to your current medications. It is not a replacement for them. And VNS Therapy does not stop you from trying additional medications. You and your doctor will determine your treatment plan. It is important to always follow your doctor's recommendations about your medications.

Q. Are there risks linked with the implant procedure?

A. Even a minimally invasive outpatient procedure has some level of risk. It is important that you discuss this question with your surgeon. However, VNS Therapy has a very long and well-understood safety profile.

Q. Will my neurologist perform the procedure?

A. No. Surgeons who are specially trained will perform the VNS Therapy procedure. They may be ear, nose, and throat specialists; neurosurgeons; or general surgeons. But you will continue to see your neurologist afterwards for medication management and VNS Therapy dose adjustments.

Frequently Asked Questions Continued

Q. Does the device work immediately?

A. Response to treatment varies for each person. Typically, there is a 2-week period before stimulation is turned on. Then your neurologist will adjust your dose settings during routine office visits over time. Studies have shown that the benefits of VNS Therapy continue to improve over time, so VNS Therapy should be given time to work as well as it can. It may take anywhere from a few months to one or two years to see the full benefits of VNS Therapy.

Q. Will electrical and electronic equipment affect the VNS Therapy device?

A. Generally household appliances, such as microwave ovens, toasters, hair dryers, and cell phones will not affect the device. A full list of warnings and precautions is included in the Patient's Manual in the Patient Essentials Kit you will receive after the procedure. Magnets contained in some tablet computers and covers, such as Apple® iPad® products, may be strong enough to cause accidental activation of VNS Therapy stimulation under certain conditions. Patients with VNS Therapy should use reasonable caution around devices that generate a strong electric or magnetic field and keep these types of devices at least 15 cm away from the body area where the generator is implanted. If you have additional questions please contact your physician.

Q. Will metal detectors (such as airport security) affect the VNS Therapy device?

A. Antitheft devices and metal detectors should not affect the VNS Therapy device or be affected by it. As a precaution, however, move through a metal detector at a steady pace; do not linger in the area.

Q. What will happen when the battery in my VNS Therapy device goes out?

A. Another procedure is required to replace the generator once the battery is depleted. This minor procedure requires only one incision and usually takes less than an hour.

Q. Is VNS Therapy safe for pregnant women?

A. Although the safety and effectiveness of VNS Therapy have not been specifically studied in pregnant women, healthy, full-term births have been reported with VNS Therapy. In addition, studies have not shown any harm to the foetus. If you want to become pregnant or you are pregnant, please contact your doctor.

Q. What will happen if VNS Therapy doesn't work for me?

A. If VNS Therapy has not helped you after one or two years, or you and your doctor consider VNS Therapy ineffective in any way, there are several options. The device can be turned off and remain implanted for an indefinite period of time. It may also be removed if you prefer or your doctor recommends it. Removal of the generator will involve a minor procedure and the lead will most likely remain in place. Talk to your doctor if you have questions about having the device removed. It is important to know that if you have VNS Therapy, you are still a candidate for any new treatment that could emerge in the future, for example, new surgical procedures or new drugs.

Safety Information for VNS Therapy

Brief Summary* of Safety Information for the VNS Therapy® System [Epilepsy Indication] (February 2014)

Epilepsy (Non-US)—The VNS Therapy system is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications. The Model 106 AspireSR™ (Seizure Response) features the Automatic Stimulation Mode, which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

CONTRAINDICATIONS

The VNS Therapy system cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy system.

Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether the VNS Therapy system is turned "ON" or "OFF."

Cardiac arrhythmia (Model 106 only)—The AutoStim Mode feature should not be used in patients with clinically meaningful arrhythmias or who are using treatments that interfere with normal intrinsic heart rate responses (e.g., pacemaker dependency, implantable defibrillator, beta adrenergic blocker medications).

WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, or in strenuous sports that could harm them or others. The safety and efficacy of the VNS Therapy system has not been established for uses outside of its approved indications. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. Patients should use the magnet to stop stimulation if they suspect a malfunction, and contact their physician immediately for further evaluation. Removal or replacement of the VNS Therapy system requires an additional surgical procedure.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition.

VNS Therapy may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

PRECAUTIONS

The safety and efficacy of The VNS Therapy System has not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation. There is a risk of infection with the implantation surgery that may require the use of antibiotics to treat or removal of the device. The VNS Therapy System may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable devices, careful programming of each system may be necessary to optimize the patient's benefit from each device. With the Model 106 only, because the device senses changes in heart rate, false positive detection unrelated to seizure activity (e.g., exercise) may cause unintended stimulation. The Model 106 also may not detect all seizures.

ADVERSE EVENTS

The most commonly reported side effects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. Other adverse events reported during clinical studies as statistically significant are ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); hypesthesia (impaired sense of touch); insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; pharyngitis (inflammation of the pharynx, throat); and vomiting. These typically occur only during stimulation, are well tolerated and noticed less as time goes on. The most commonly reported side effect from the implant procedure is infection. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

- * The information contained in this summary represents partial excerpts of important prescribing information taken from the product labeling. The information is not intended to serve as a substitute for a complete and thorough understanding of the vns therapy system nor does this information represent full disclosure of all pertinent information concerning the use of this product. Patients should discuss the risks and benefits of vns therapy with their healthcare provider. Prescription only - device restricted to use by or on the order of a physician.

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This brochure is not intended to be a complete source of information on VNS Therapy. Please contact your healthcare professional or visit : www.vnstherapy.co.uk



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