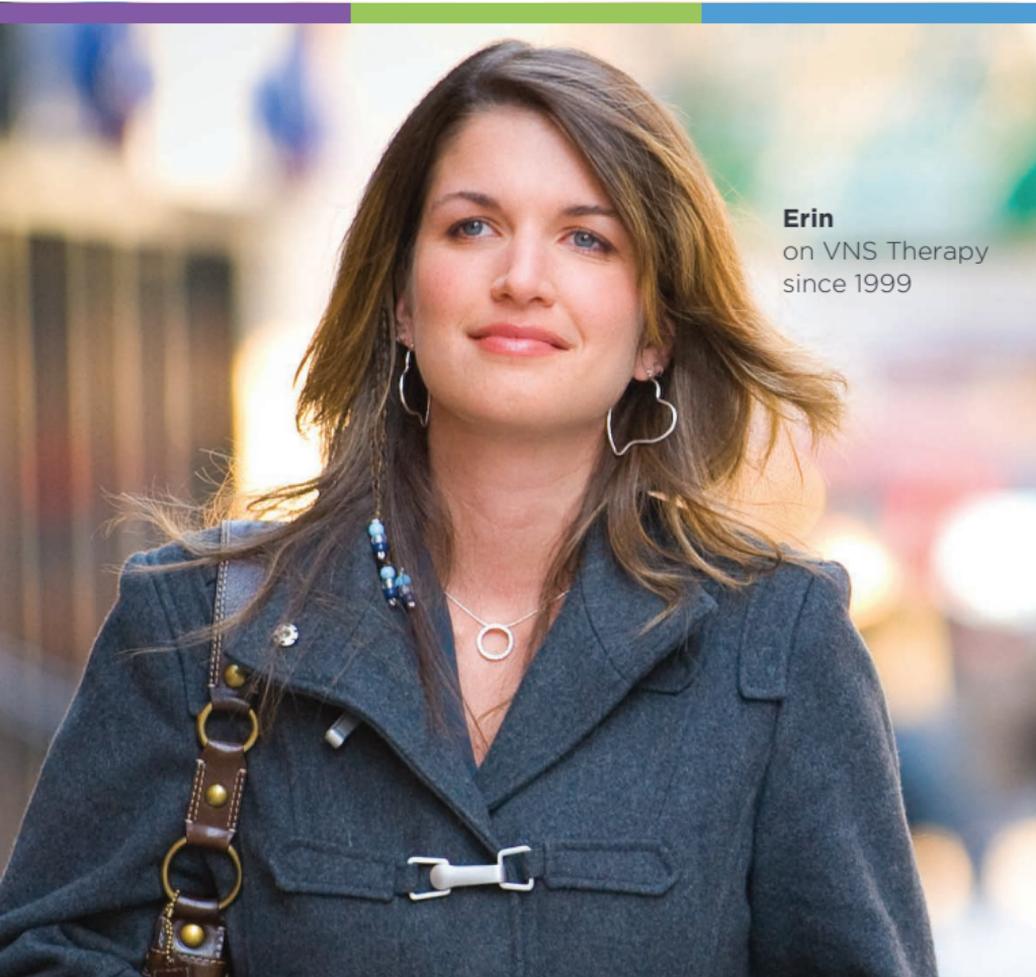


Understanding More About VNS Therapy[®]

Answers to Frequently Asked Questions



Erin
on VNS Therapy
since 1999

To Learn More

call **1-888-867-7846**
or visit **VNSTherapy.com**

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VNS Therapy

Understanding more about VNS Therapy

VNS (Vagus Nerve Stimulation) Therapy has improved the overall quality of life for many people living with drug-resistant epilepsy.

Benefits of **VNS Therapy** may include:

- ✓ Fewer seizures
- ✓ Shorter seizures
- ✓ Faster recovery
- ✓ Decreased seizure severity
- ✓ Improvements in alertness, memory and mood

VNS Therapy is not another medication and it does not involve brain surgery. It is a safe, effective treatment that has provided many people with long-lasting seizure control.



1 Am I a good candidate for VNS Therapy?

If you have tried multiple medications and are still having seizures, VNS Therapy might be right for you. You should ask your doctor about VNS Therapy if multiple medications have not given you acceptable seizure relief or have side effects that are difficult to tolerate.

2 How many people have VNS Therapy?

To date, more than 85,000 people worldwide have used VNS Therapy, a proven long-term solution for people with uncontrolled seizures.

VNS Therapy FAQs

3 What does drug-resistant epilepsy mean?

About one in three people with epilepsy will experience a type of seizure that is difficult to treat with medication, often referred to as drug-resistant epilepsy. Research shows that if you haven't found seizure freedom with your first two drugs, there is a 95% chance that no drug or combination of drugs will result in seizure freedom.

4 What type of benefits can I expect with VNS Therapy?

Many people report fewer seizures, shorter seizures, less severe seizures, fewer medications and faster recovery times following seizures. People with VNS Therapy also often report improvements in alertness, mood and memory, and an overall improved quality of life. Individual results may vary.



5 What are the potential side effects?

The most common side effects with VNS Therapy are hoarseness or changes in voice tone, a prickling feeling in the skin, shortness of breath, sore throat and coughing. These side effects generally only occur during stimulation and usually decrease over time.

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

VNS Therapy is not a replacement for your medications, nor does it stop you from trying new ones. While some people are able to cut back on their medications while on VNS Therapy, you and your doctor will determine the right treatment plan for you. It is important to always follow your doctor's recommendations about your medications.

VNS Therapy FAQs

7 Does the device work immediately?

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

8 Will I be seizure-free with VNS Therapy?

The goals of VNS Therapy are fewer seizures, shorter seizures and faster recovery times following seizures. A small percentage of people (8%) report seizure-freedom with VNS Therapy. Individual results will vary.



9 Is VNS Therapy covered by my insurance?

Many insurance companies cover the cost of VNS Therapy, including Medicare and Medicaid. One of our Nurse Case Managers can help you verify your insurance benefits. Call 1-888-867-7846 to speak with a Nurse Case Manager.

10 What is the procedure like?

A small device (generator and lead) is implanted during a short, outpatient procedure that is performed under general anesthesia. The procedure involves two small incisions and usually takes about an hour.

11 How long does the procedure take?

The actual procedure takes about an hour. Most people go home the same day.

VNS Therapy FAQs

12 **What will happen when the battery in my VNS Therapy device goes out?**

A short procedure, which usually takes less than an hour, is required to replace the device once the battery is depleted.

Typically, a generator will last three to eight years depending on your settings.

13 **When going through security at the airport, will my VNS Therapy device be affected?**

At the airport, we recommend that you provide security officers with your VNS Therapy ID card, which explains you have an implanted medical device. You can request a pat down check instead.



14

Am I able to have a MRI with my VNS Therapy device?

MRIs are approved under specific conditions for patients with VNS Therapy. Please speak with your physician regarding any medical concerns.

VNS Therapy FAQs

15 How can I learn more about VNS Therapy?

- 1. Talk to your neurologist** about whether VNS Therapy is right for you.
- 2. Call a VNS Therapy Nurse Case Manager toll-free at 1-888-867-7846.** He or she can answer questions about VNS Therapy and also help you with insurance and payment questions. VNS Therapy is covered by many insurance plans, including Medicare and Medicaid.
- 3. Join our monthly Phone Facts conference call at 1-877-451-8943** and talk with VNS Therapy patients and other people thinking about getting VNS Therapy. On this call, you can get firsthand information about the procedure and learn what it feels like to have VNS Therapy. An epilepsy specialist is available for every session. You do not have to provide your name, even if you wish to ask questions. All calls are free and confidential.

The Phone Facts Call takes place the first Tuesday of every month, 7:00 PM Central Time: 1-877-451-8943.

- 4. Visit www.VNSTherapy.com**

INTENDED USE / INDICATIONS—UNITED STATES

Epilepsy—VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures which are refractory to antiepileptic medications.

CONTRAINDICATIONS

VNS Therapy 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."

WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System Physician's Manual, 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 VNS Therapy 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. MRI can be safely performed; however, special equipment and procedures must be used.

Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. (AspireSR® only) Inform your doctor if you have an existing heart condition or are being actively treated for a heart condition (such as beta adrenergic blocker medications). Your doctor will determine if the AutoStim feature is right for you.

PRECAUTIONS

The safety and efficacy of VNS Therapy 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. (AspireSR® only) Use of the AutoStim Mode (also known as Detect & Respond Mode) will result in reduced battery life, which may require more frequent generator replacements.

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.

*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.

This brochure is not intended to be a complete source of information on VNS Therapy. Please contact your healthcare professional or visit www.VNSTherapy.com for more information.





To Learn More About VNS Therapy:



Call toll-free:

1-888-VNS-STIM (1-888-867-7846)



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Talk to your doctor



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