

An Introduction to VNS Therapy®

Fewer seizures. Shorter seizures. Better recovery.

SENTIVA®

To Learn More


call 1-888-867-7846

or visit VNSTherapy.com

Finn is a
patient with
VNS Therapy

Individual results may vary.

VNS
Therapy®

A close-up, profile view of a woman with long, dark brown hair, smiling and looking to the right. She is wearing a bright pink, sleeveless tank top. Behind her, a man with dark hair and a purple t-shirt is partially visible, looking in the same direction. The background is bright and out of focus, suggesting an outdoor setting like a beach or boardwalk under a clear blue sky. The lighting is bright and natural, highlighting the woman's features and the texture of her clothing.

Rosario
On VNS Therapy
since 2016

Still having seizures despite medications?

You are not alone. About 1 in 3 people with epilepsy have the type that is difficult to treat with medication.

VNS Therapy is designed specifically for people still living with seizures despite trying multiple medications. It is a proven long-term solution already being used by more than 100,000 people around the world, including more than 33,000 children.

Studies show after failing two medicines, there's only a 5% chance adding another will result in seizure freedom.

Many people experience long-lasting seizure control with VNS (Vagus Nerve Stimulation) Therapy. In fact, seizure control with VNS Therapy typically continues to improve over time.

VNS Therapy may improve your quality of life

Andres
On VNS Therapy
since 2014

VNS Therapy is a safe,
effective treatment with
benefits that usually
improve over time.

Visit VNSTherapy.com to view stories from
caregivers and people with VNS Therapy.



Benefits may include



Fewer Seizures



Shorter Seizures



Better Seizure
Recovery



Decreased Seizure
Severity



Less Medication



Improved Alertness,
Mood and Memory



Reduction in Status
Epilepticus



Improved Quality
of Life



Fewer Hospital and
ER visits

The overall quality of life has improved for many people with VNS Therapy.

VNS Therapy is the #1 prescribed device for seizures in children

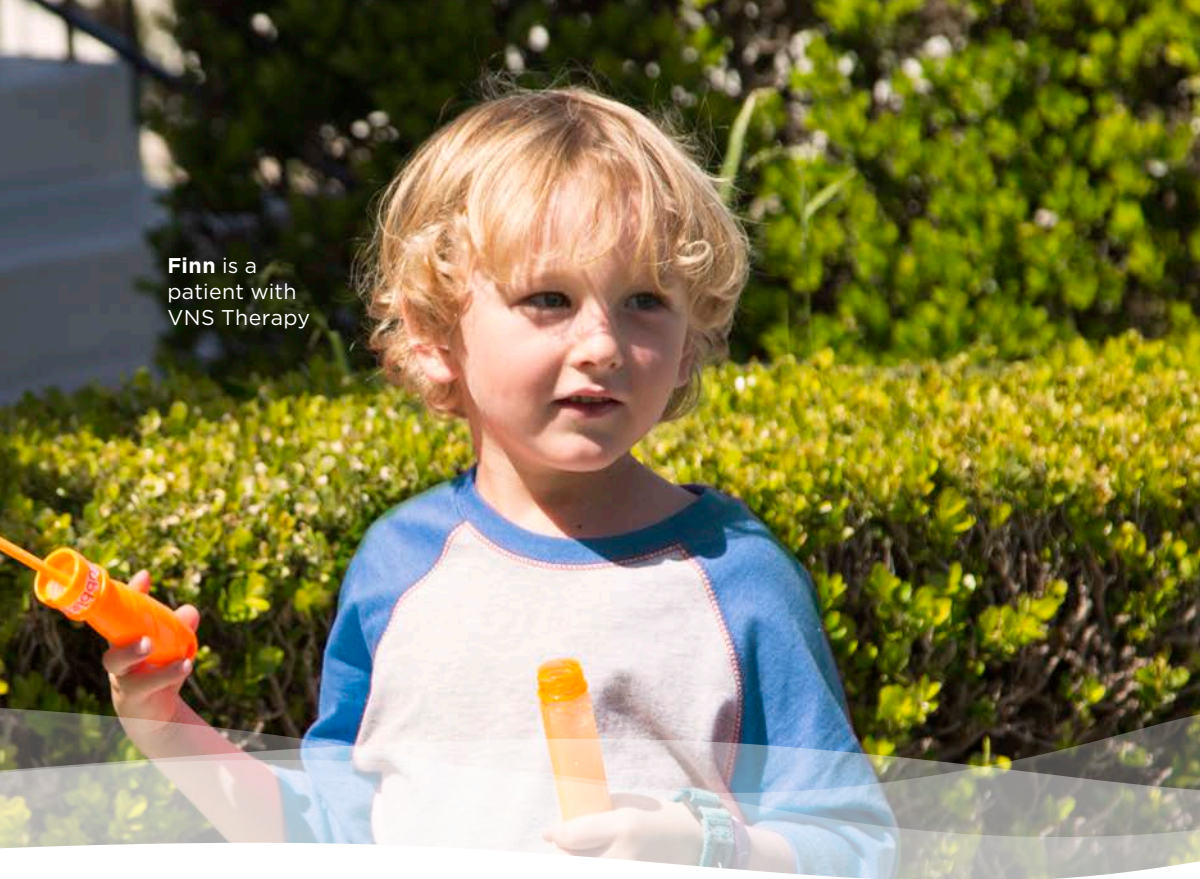
VNS Therapy is proven safe and effective for children.*

Children with difficult-to-control seizures who are treated with medicine alone may experience a decline in development.

- > Early use of VNS Therapy offers proven long-term outcomes for children at a critical time in their development
- > Improvements in alertness, concentration, and energy have been reported in clinical studies

*View important safety information on page 22. FDA-approved for people as young as four. Children (ages 4-11) may have a greater risk of infection than those 12 years of age and older and may be more likely to experience lead damage due to higher activity levels and the potential to manipulate the lead.

Finn is a patient with VNS Therapy



63% of children have **Fewer Seizures**
n=83



48% of children have **Shorter Seizures**
n=195



42% of children have **Less Severe Seizures**
n=195



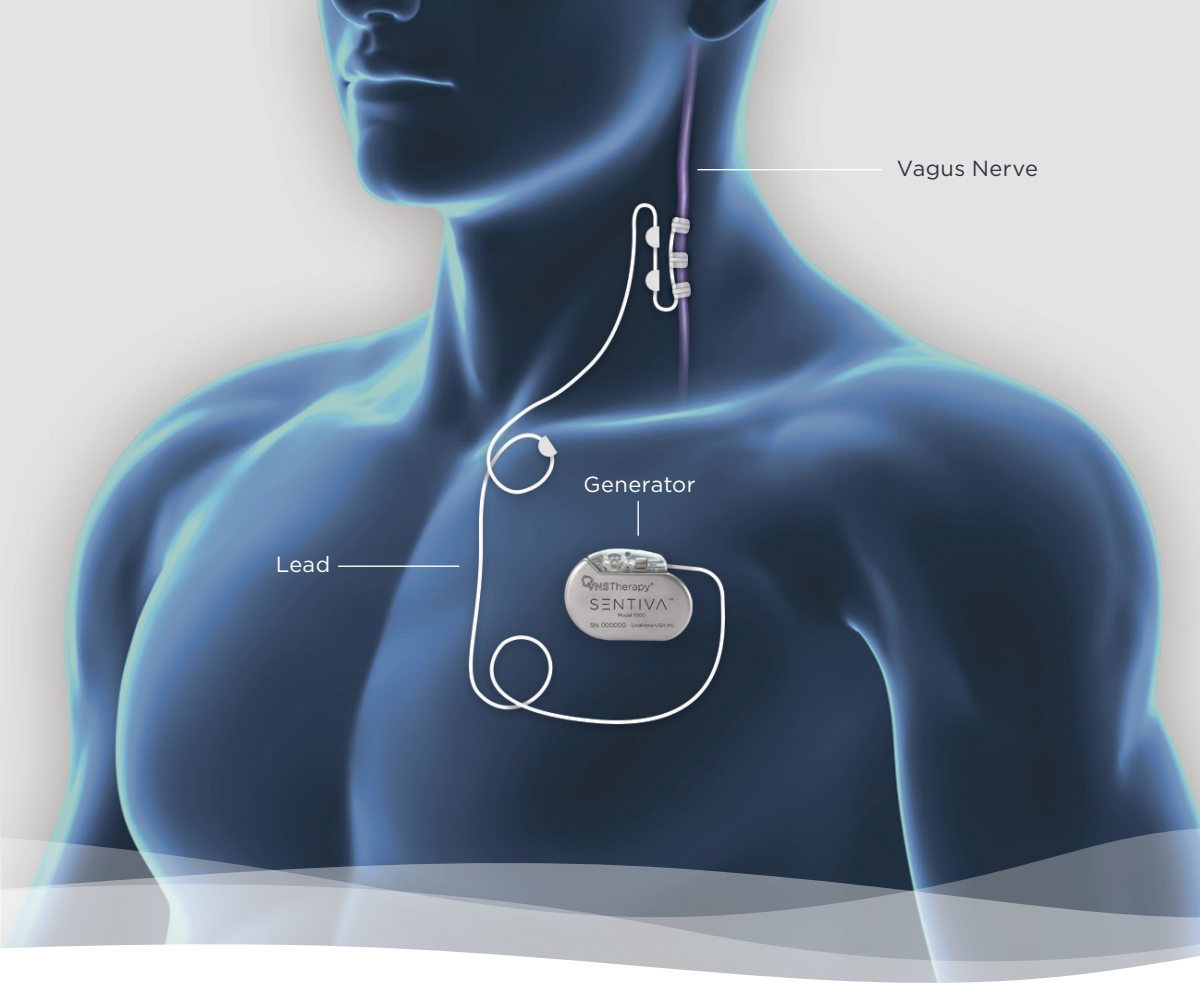
40% of children have **Better Recovery after Seizures**
n=195

Following 24 months of therapy.
References available upon request.

About VNS Therapy

The VNS Therapy device sends mild pulses through the vagus nerve to areas of the brain that are associated with seizures in an effort to control your seizures.

The goal of VNS Therapy is to prevent seizures before they start, and stop them if they do.



- > VNS Therapy is delivered through a device (generator and lead) that sends mild pulses through the vagus nerve
- > It involves a short outpatient procedure which takes about an hour
- > **VNS Therapy is not brain surgery**

Latest technology with SENTIVA®

VNS Therapy's latest technology includes features that offer treatment personalization and easier management.



Johnny
on VNS Therapy
since 2013



Day & Night Programming

Day & Night Programming is an optional feature available in SenTiva that allows for further personalization of your treatment.

- › Allows your doctor to customize VNS Therapy based on your lifestyle preferences or side effect management

Your doctor can program your device to different settings for any two periods of time during a 24 hour period.



Scheduled Programming

We know your time is valuable. Spending time in the doctor's office or traveling to and from may be inconvenient.


- › Scheduled Programming allows your doctor to pre-program your device to automatically change therapy settings at intervals he or she chooses to quickly reach your targeted dose

This option can reduce the need for you to attend follow up appointments for programming, giving you time back to live your best life.

*Only available in model 1000

SENTIVA®

provides you more control



Starr
on VNS Therapy
since 2003

If you have a breakthrough seizure with VNS Therapy, an additional dose of therapy may help stop or shorten your seizure, decrease its intensity and improve your recovery.



Detect & Respond*

- > Detects a rapid rise in heart rate, which is often associated with a seizure
- > Responds to this rapid increase in heart rate by automatically delivering an extra dose of therapy

*Also known as AutoStim Mode, only available in models 106 and 1000



VNS Therapy magnet

- > An optional feature that may provide additional seizure control
- > Provides you or a caregiver the ability to manually deliver an additional dose of therapy



VNS Therapy & MRI

- > With the latest technology, you can go to any center and safely have an MRI performed provided specific guidelines are followed
- > 100% access to brain MRI

Before scheduling any MRI, contact your doctor.

Explore your options for uncontrolled seizures

VNS Therapy, Responsive Neurostimulation System (RNS), and Deep Brain Stimulation (DBS) are add-on treatments for seizures that are not responsive to medications. Learn about the differences:

	VNS Therapy	RNS System	DBS
Number of People Treated	100,000+ including 33,000 children	Approximately 1,000	Not reported
Approval Ages	4+ years old	18+ years old	18+ years old
Seizure Type	Partial-onset	Partial-onset with frequent and disabling seizures (motor partial, complex, and/or secondary generalized)	Partial-onset (with and without generalized seizures)
Responsive Therapy	Yes [†]	Yes	No
Implant Procedure	Outpatient procedure, usually 1-2 hours	Invasive brain surgery, overnight hospital stay	Invasive brain surgery, overnight hospital stay
Estimated Battery Life	4.9-10+ years [‡]	5.1-9.4 years	3-5 years
Healthcare Cost Savings	Yes	Not reported	Not reported
MRI Compatibility	FDA-approved for MRI*	MRI unsafe	FDA-approved for MRI*
Rescue Therapy	Additional on-demand therapy as needed	Not available	Not available

*Provided specific guidelines followed

[†]Only available in models 106 and 1000

[‡]Specific to model 1000 depending on settings

Vivien
on VNS Therapy
since 2015



VNS Therapy is not a drug and does not have drug-related side effects

The most common side effects of VNS Therapy include:

- > hoarseness
- > shortness of breath
- > sore throat
- > coughing

Infection is the most common side effect of the procedure.

These side effects generally only occur during stimulation and usually decrease over time.

Most side effects may be diminished or eliminated by adjusting the device's settings.



Jaime
on VNS Therapy
since 1999

The VNS Therapy magnet is available to temporarily suspend therapy as needed to manage side effects during activities such as singing, public speaking or exercising

Frequently Asked Questions

Am I a candidate for VNS Therapy?

VNS Therapy is for people as young as four years old who have tried at least two antiseizure medications and are still having seizures. You should ask your doctor about VNS Therapy if medications have not given you acceptable seizure control or have side effects that are difficult to tolerate. Your doctor will decide if VNS Therapy is right for you.

Does the device work immediately?

Response to treatment varies for each person. It may take from a few months or longer to see benefits. Studies show the benefits of VNS Therapy continue to improve over time.

What results should I expect with VNS Therapy?

The goals of VNS Therapy are fewer seizures, shorter seizures and better recovery. 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 with VNS Therapy, you and your doctor will determine the right treatment plan for you. Individual results will vary.

How long will the battery last?

SenTiva has a battery life of 4.9-10+ years depending on settings. A short, outpatient procedure is required to replace the device once the battery is depleted.

Will VNS Therapy be covered by my insurance?

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

What is the procedure like?

VNS Therapy is not brain surgery. A small device (generator) is implanted in the chest and a thin wire (lead) connects the device to the vagus nerve in the neck. This occurs during a short, outpatient procedure which involves two small incisions and is typically performed under general anesthesia.

Will the scars be noticeable?

Each person has different healing and scarring results. You should expect some scarring from the procedure. Most people do not think scarring is a major concern. If this is a special concern for you, we recommend you discuss it with your surgeon.

Will I be able to go through airport security?

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

Brittany
On VNS Therapy
since 2004



Learn more about VNS Therapy today

1. Talk to your neurologist

about whether VNS Therapy is right for you.

2. Call a VNS Therapy 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.

3. Join our Community Chat at 1-877-451-8943

and hear from VNS Therapy patients, caregivers and other people thinking about getting VNS Therapy. On this call, you can get first hand 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.

Visit VNSTherapy.com for call details.

4. Visit VNSTherapy.com

Safety Information for VNS Therapy

INTENDED USE / INDICATIONS --UNITED STATES

Epilepsy -- The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

CONTRAINDICATIONS

The VNS Therapy System should not be used in people who have had the left vagus nerve cut (a left vagotomy). Anyone implanted with the VNS Therapy system CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy. Injury or damage can occur during diathermy treatment whether the VNS Therapy system is turned “ON” or “OFF.”

Note: Diagnostic ultrasound is not included in this contraindication.

WARNINGS

VNS Therapy carries some risks. Physicians should inform patients about the warnings, precautions, side effects, and hazards associated with VNS Therapy, 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 provided specific guidelines are followed. Patients should contact their physician before scheduling an MRI. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias.

(AspireSR® and SenTiva® only) Physicians should be informed of any existing heart condition or active treatment for a heart condition (such as beta adrenergic blocker medications). The physician will determine if the Automatic Stimulation feature (also known as AutoStim and Detect & Respond) is appropriate for each patient.

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® and SenTiva® only) Situations, including but not limited to exercise or physical activity, that cause rapid increases in heart rate may trigger AutoStim if the feature is ON. If this is a concern, patients can talk to their physician about ways to stop stimulation during these situations. Use of the AutoStim Mode (Detect & Respond feature) will result in reduced battery life, which may require more frequent generator replacements.

(SenTiva® only) Optional time-based features do not automatically adjust for Daylight Savings Time or differing time zones.

ADVERSE EVENTS

The most commonly reported side effects are hoarseness, sore throat, shortness of breath, and coughing. Other adverse events reported during clinical studies as statistically significant are ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); hypoesthesia (impaired sense of touch); insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; prickling of the skin (paresthesia); 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.



To learn more about VNS Therapy:  **Call toll-free:** 1-888-867-7846
 **Visit** VNSTherapy.com

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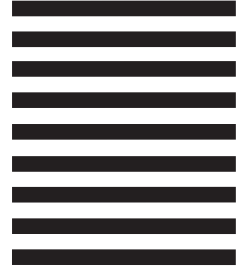
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Talk to your doctor



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www.facebook.com/VNSTherapyforEpilepsy

To receive additional educational materials, please complete the information below and mail it to us.

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Please print:

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Signature _____
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