

# VNS Therapy and Children

Fewer seizures. Shorter seizures. Better recovery.



**To Learn More**

call 1-888-867-7846

or visit [VNSTherapy.com](http://VNSTherapy.com)

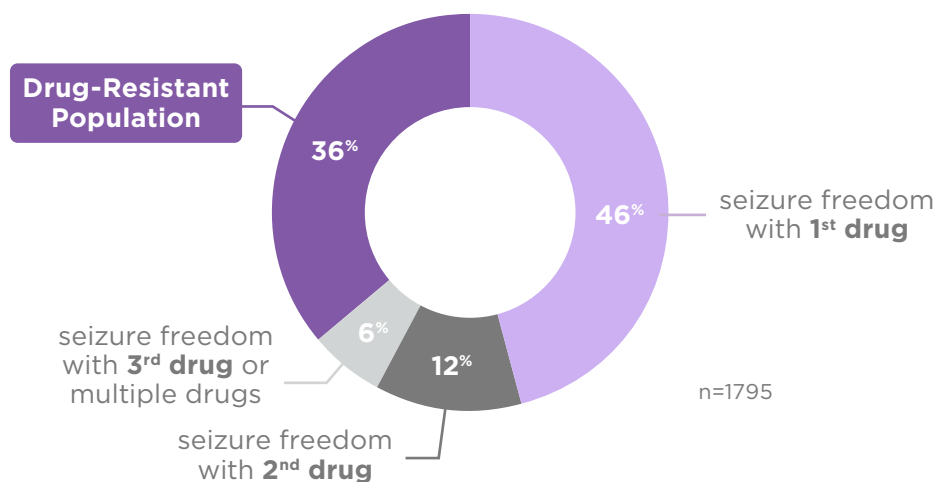


**David**  
On VNS Therapy  
since 2014

# Is your loved one still having seizures despite medications?

You are not alone. There are 3.4 million people living with epilepsy in the U.S., including 470,000 children. More than 45,000 children are diagnosed with epilepsy each year.

About 1 in 3 people with epilepsy have the type that is difficult to treat with medication. Studies show adding more medications is not likely to control this type of epilepsy.





# Recurring seizures and status epilepticus affect intellectual development in children.

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Uncontrolled seizures in children may cause problems with learning and memory during critical times of development. And, the earlier the onset of seizures in children, the greater the negative effects in cognition can be.

Worrying about your child's seizures can be stressful. We also know families with children with epilepsy often experience more challenges managing social relationships, employment, and their child's care.

When seizures continue despite trying multiple medications, it's important to consider other options.

# The consequences of not pursuing treatment of drug-resistant epilepsy are substantial.

Studies show undertreatment can increase the risks of:



Structural damage to the brain



Depression & anxiety



Sudden Unexpected Death in Epilepsy (SUDEP)



Learning & memory problems



Trouble sleeping



Social isolation



Missed school



Behavior issues



Verbal communication problems



Seizure-related injuries, ER and hospital visits



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

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VNS Therapy is a non-drug option 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 33,000 children.



## Early use in children results in better cognitive outcomes.

- > Studies show earlier use of VNS Therapy offers proven long-term outcomes for children at a critical time in their development
- > Children treated with VNS Therapy have shown to have fewer seizures, shorter seizures, and better recovery



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

- > Children with VNS Therapy have experienced an even better response than adults
- > VNS Therapy works well with the ketogenic diet. Many children have seen benefits quicker when combining the two treatments.

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

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Benefits may include:



Fewer Seizures



Shorter Seizures



Better Seizure Recovery



Decreased Seizure Severity



Less Medication



Improved Alertness & Mood



Reduction in Status Epilepticus & SUDEP



Improved progress in school, memory & concentration



Fewer Hospital and ER visits



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

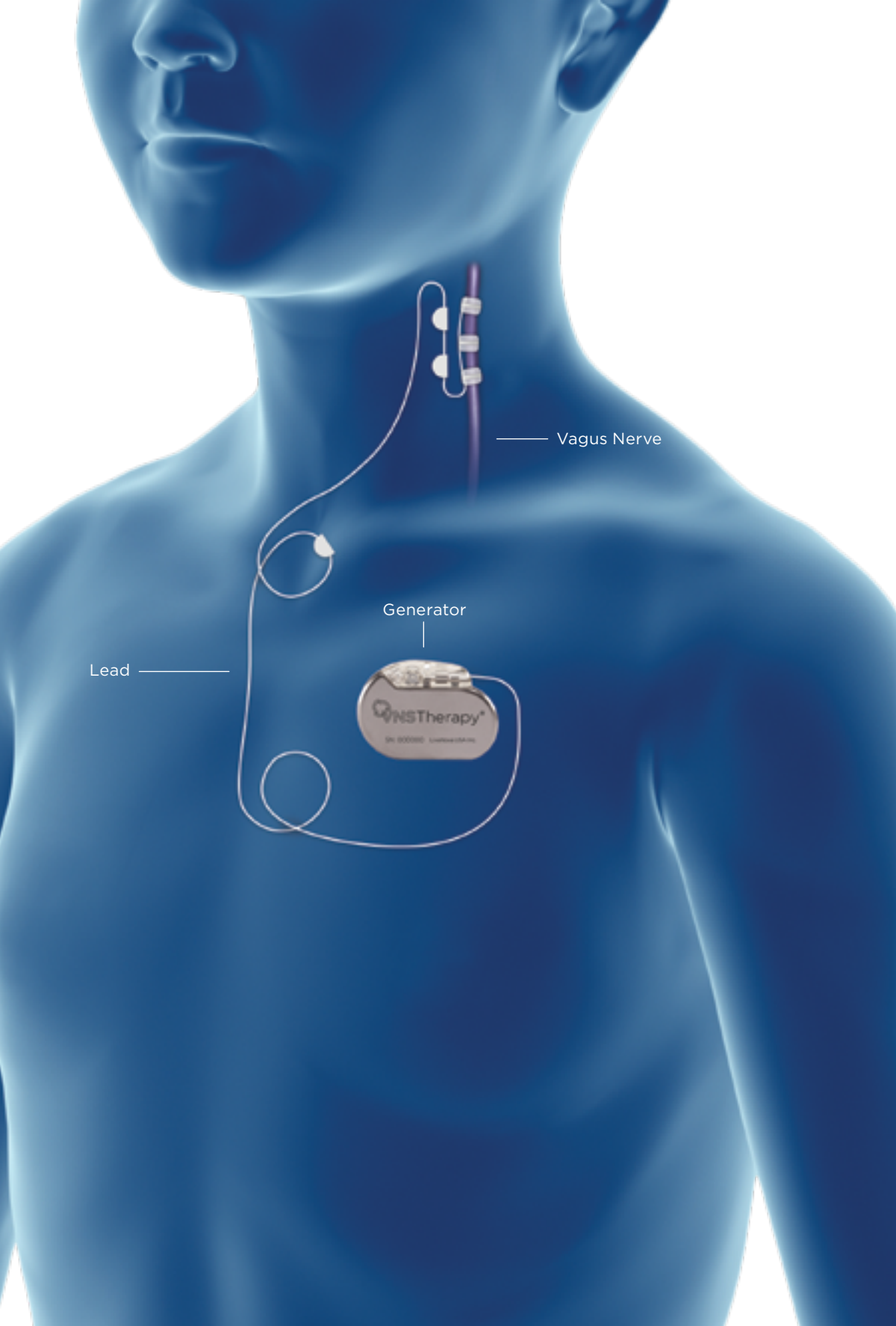


# The goal of VNS Therapy is to prevent seizures before they start, and stop them if they do.

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VNS Therapy is a smart device that sends mild pulses through the vagus nerve to areas of the brain associated with seizures.

- > It involves a short outpatient procedure which takes about an hour
- > VNS Therapy works all day, every day, even when your loved one is sleeping
- > **It is not brain surgery**



Vagus Nerve

Generator

Lead



# Your child can have an MRI safely performed at any center.\*

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We understand the importance of access to medical imaging in managing your child's health.

- > With the latest VNS Therapy technology, MRI is now more accessible than ever\*
- > 100% access to brain MRI
- > Before scheduling any MRI appointment, contact your child's doctor to discuss their upcoming MRI

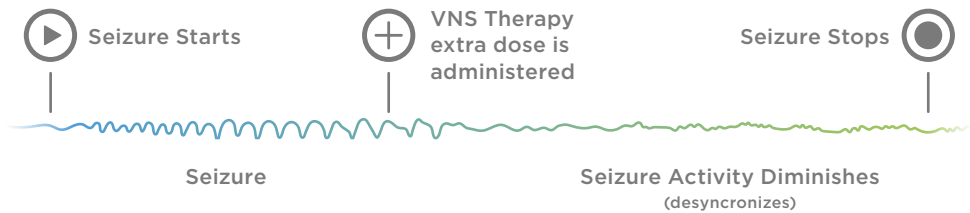
\*provided specific guidelines are followed





# The latest VNS Therapy technology provides you more control.

With responsive therapy, VNS Therapy detects a rapid rise in heart rate, which is often associated with a seizure and responds by automatically delivering a dose of therapy.\*



People with VNS Therapy had a significant reduction in seizures earlier with responsive therapy.\*

The VNS Therapy magnet is an optional feature that may provide on-demand seizure control.

- > Provides you or your loved one the ability to deliver an additional dose of therapy if needed
- > If your loved one has a breakthrough seizure with VNS Therapy, an additional dose of therapy may help stop or shorten the seizure

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









## Day & Night Programming

Day & Night Programming is an optional feature available that allows for further personalization of your loved one's treatment.

- › Allows for customized VNS Therapy based on lifestyle preferences or side effect management

Your loved one's doctor can program the device to different settings for any two periods of time during a 24 hour period.



## Scheduled Programming

We know your family's time is valuable. Spending time in the doctor's office may be inconvenient and require missing school days.

- › Allows your loved one's doctor to pre-program the device to automatically change therapy settings at intervals he or she chooses to quickly reach the targeted dose

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

\*Only available in model 1000

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

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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 reduced or eliminated by adjusting the device's settings.



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.



# VNS Therapy may be right for your loved one if they meet one or more of the following. Talk to your doctor if:

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- > Your loved one is still having seizures after trying two prescribed medications
- > You're ready to try other treatment methods to gain control of your child's seizures
- > The time it takes your loved one to recover from seizures is interfering with daily life
- > Side effects of the current treatment are having an impact on their life
- > You're worried about missing doses of your child's current seizure medication





# Frequently Asked Questions

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## **Is my loved one 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.

Talk to your child's doctor about VNS Therapy if medications have not provided acceptable seizure control or have side effects that are difficult to tolerate. Your child's doctor will decide if VNS Therapy is right for them.

## **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 we expect with VNS Therapy?**

The goals of VNS Therapy are fewer seizures, shorter seizures and better recovery. VNS Therapy is not a replacement for medications, nor does it prevent trying new ones. While some people are able to cut back on their medications with VNS Therapy, you and your child's doctor will determine the right treatment plan for you and your loved one. Individual results will vary.

## **How long will the battery last?**

The latest VNS Therapy technology 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 insurance?**

Many insurance companies cover the cost of VNS Therapy, including Medicare and Medicaid. One of our Case Managers can help verify insurance benefits for your loved one. 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. Your child 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 child's surgeon.

## **Will my loved one be able to go through airport security?**

At the airport, we recommend that you and your loved one provide TSA personnel with the VNS Therapy ID card, which explains your loved one has an implanted medical device. You can request a pat down check for them instead.

# Learn more about VNS Therapy today.

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## 1. Talk to your loved one's neurologist

about whether VNS Therapy is right for them.

## 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](http://VNSTherapy.com) for call details.

## 4. Visit [VNSTherapy.com](http://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.

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## To learn more about VNS Therapy:

 **Call toll-free:** 1-888-867-7846

 **Visit** [VNSTherapy.com](https://www.vnstherapy.com)

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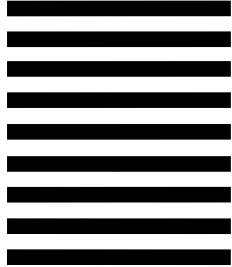
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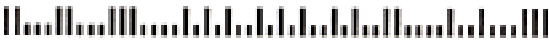
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Name \_\_\_\_\_ Patient  Caregiver

Address \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ ZIP \_\_\_\_\_

Telephone \_\_\_\_\_ E-mail \_\_\_\_\_

Signature \_\_\_\_\_  
(required)

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