

Have the **nerve** to expect more.  
Have the **nerve** to *reimagine what's possible.*

Discover how  
VNS Therapy® can  
help overcome  
the challenges of  
drug-resistant epilepsy



LivaNova  
Epilepsy

 VNS Therapy®



Have the **nerve** to explore another path forward

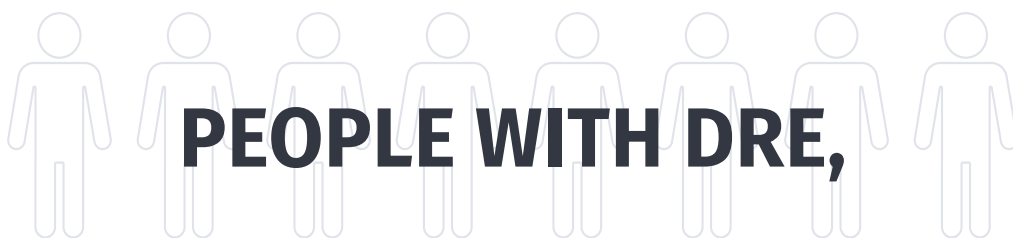
Whether it's you or your loved one who suffers from drug-resistant epilepsy (DRE), it's normal to feel stressed or powerless when a seizure occurs and you have no way to stop it. But the truth is that **you have options**.

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**VNS Therapy® has been used to treat**

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**MORE  
THAN 125,000**



**PEOPLE WITH DRE,**

including **35,000 children.**

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Could it make a difference  
in your situation?

**Discover VNS Therapy® for yourself and  
ask your doctor and healthcare team  
if it fits your treatment plan.**

LEARN MORE  
**INSIDE**



## Questions to ask your doctor and healthcare team

Before you make any decisions about VNS Therapy®, be sure to have a discussion with your doctor and healthcare team. Ask the following questions in your conversation:

What treatment options are available?

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At what point is surgery an option?

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Is VNS Therapy an appropriate option?

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How does VNS Therapy work?

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Will insurance cover VNS Therapy?

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Will I or my loved one require medicine after surgery?

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What are the side effects of VNS Therapy?

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“She went from struggling and barely passing 5th grade to being in the **top 5% of 6th graders.**”

– Shannon, mother of Bella, a real patient treated with VNS Therapy®\*



“I went from 23 seizures a day to **3 or 4 seizures a day.**”

– Johnny, a real patient treated with VNS Therapy®\*



“It’s important to shift our goals and talk about **options outside of medications.**”

– Dr. Kathryn Polovitz, a practicing physician who has treated real patients with VNS Therapy®\*

**SEE MORE STORIES  
OF REAL PATIENTS**  
by scanning the QR code†




\*These are the experiences of individuals who have been treated with VNS Therapy. Individual results may vary.

†For Android devices, use of a QR code reader application is required.


## Have the **nerve** to rethink your DRE treatment plan

You may be wondering what the difference is between epilepsy and drug-resistant epilepsy (DRE). After all, they have the same symptoms and can create many of the same challenges. Where they differ is in how they're treated. While epilepsy can be treated with medicine alone, **DRE requires more than medicine to achieve seizure control.**

### Quick facts about DRE

 EACH YEAR **40,000** ADULTS  
& **26,000** CHILDREN

are diagnosed with DRE

**1 in 3**   
**PEOPLE WITH EPILEPSY**  
 **CAN'T CONTROL SEIZURES WITH MEDICINE ALONE**

### The goals of treatment are to:

- ✓ gain seizure control
- ✓ reduce side effects
- ✓ improve quality of life

Even though DRE can't be treated by medicine alone, you still have options. It's important to talk with your doctor and healthcare team to understand all your available treatment options. Together, you can create a custom treatment plan that fits your needs.

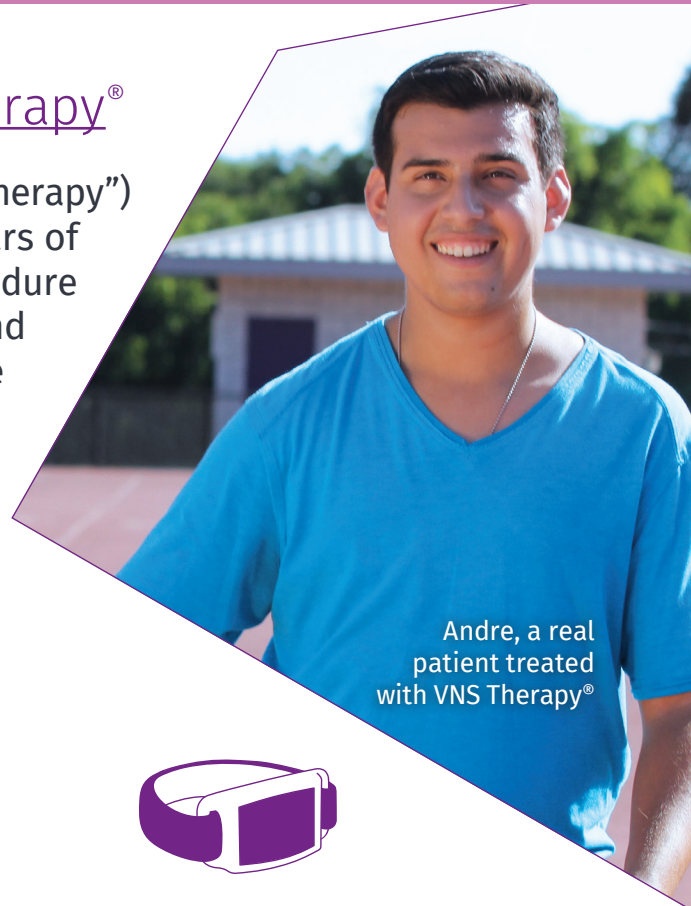


VNS Therapy® has helped more than 125,000 people with DRE, including 35,000 children

**Will you or your loved one be next?**

## Have the **nerve** to discover VNS Therapy®

VNS Therapy® (short for “vagus nerve stimulation therapy”) is a treatment **designed for people with DRE** 4 years of age and older. It involves a short outpatient procedure in which a small device is implanted in the chest and a thin wire connects the device to the vagus nerve in the neck. VNS Therapy delivers mild pulses to the vagus nerve to help prevent seizures before they start and help stop them if they do.



Andre, a real patient treated with VNS Therapy®

## VNS Therapy® delivers stimulation in 3 ways



### Normal Mode

*Helps Prevent Seizures*

Stimulation is delivered at regular intervals all day, every day, to help prevent seizures



### AutoStim Mode

*Responds to increases in heart rate that may be the sign of a seizure\**

An extra dose of therapy is automatically delivered at the sign of a rapid increase in heart rate, which is typical of many seizures



### Magnet Mode

*Delivers On-Demand Treatment*

Stimulation is manually delivered by swiping the included VNS Therapy Magnet over the generator to help stop or shorten a seizure once it starts



VNS Therapy can be customized to address your unique treatment needs

**Has your doctor talked to you about VNS Therapy®?**

\*Only available in models 106 and 1000.



## Have the **nerve** to redefine seizure control

VNS Therapy® has been proven to not only help reduce the number of seizures your child may experience—it may also shorten the length of seizures that do occur, improve post-seizure recovery, and reduce the risk of hospitalization. Plus, early use of VNS Therapy has been shown to offer better long-term outcomes related to mental and physical development, which is critical at younger ages.

## VNS Therapy® has been shown to reduce the impact of seizures

In a study that compared the before/after effects of being treated with VNS Therapy for 2 years:



**63% of children**  
had fewer  
seizures



**48% of children**  
had shorter  
seizures



**42% of children**  
had less severe  
seizures



**40% of children**  
had improved post-  
seizure recovery

## VNS Therapy has shown to reduce the risk of hospitalization

**FEWER** EMERGENCY ROOM VISITS  
HOSPITALIZATIONS  
DAYS IN THE HOSPITAL



VNS Therapy has been shown to help children with DRE gain control over seizures

**Could VNS Therapy® help your child achieve better seizure control?**

Have the **nerve** to advance your child's potential

In addition to its seizure-reducing benefits, VNS Therapy® may offer your child **meaningful quality-of-life improvements**. This is especially important, as his or her brain and body are still developing.

VNS Therapy® can offer powerful quality-of-life benefits

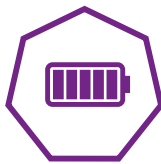
VNS Therapy has shown to offer significant improvements related to:



**Alertness**



**Concentration**



**Energy**



**Mood**



**Verbal  
communication**



Bella, a real  
patient treated  
with VNS Therapy®



VNS Therapy has been shown to have a meaningful impact on quality of life

**Could VNS Therapy® help your child live a more active life?**



## Have the **nerve** to minimize medicine-related side effects

As powerful as VNS Therapy® is at treating seizures, rest assured that it's safe to use. VNS Therapy has been studied for more than 25 years and has shown to be well tolerated, with none of the side effects typical of anti-seizure medications. While there are some side effects, the most common can be reduced or completely eliminated by adjusting the device settings with your doctor.

## VNS Therapy® is well tolerated and has side effects that usually decrease over time

The most common side effects include:

- Hoarseness or change of voice
- Sore throat
- Shortness of breath
- Coughing



**NO MEDICINE-RELATED  
SIDE EFFECTS**

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**SAFE TO USE  
WITH OTHER MEDICINES**

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VNS Therapy has proven to be a safe and effective way of treating DRE

**Could VNS Therapy® help reduce the number of medications needed?**

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## LEGACY

Have the **nerve** to trust the only device treatment for DRE with 25 years of experience

With more than 25 years of real-world treatment experience, VNS Therapy® has a legacy you can count on. With **technology that's designed with patients in mind**, VNS Therapy can meet the unique challenges of your situation and help you or your loved one overcome the burdens of DRE.



Starr, a real patient treated with VNS Therapy®

VNS Therapy® has a proven track record you can count on

MORE THAN **125,000**

 **PEOPLE TREATED WORLDWIDE**  
including **35,000 children**.

**75%**  of all VNS Therapy patients



HAVE CHOSEN TO  
**REPLACE THEIR DEVICE**  
AT THE END OF SERVICE

**#1**

VNS Therapy is the #1 prescribed device for DRE  
**Could VNS Therapy® be right for you?**

Visit **ReimagineSeizureControl.com** for more information on VNS Therapy.  
See full Safety Information on reverse side.

 **VNS Therapy®**

# 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) and/or additional features such as prone position detection and low heart rate detection 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.