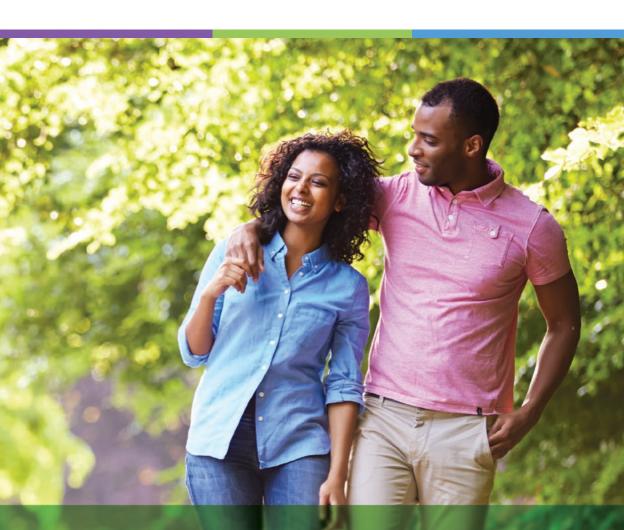


## An Introduction to VNS Therapy

Fewer seizures. Shorter seizures. Faster recovery. Why wait?\*



## **To Learn More**

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

# Are you struggling with uncontrolled seizures?

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 living with uncontrolled seizures and is a proven long-term solution already being used by more than 85,000 people around the world.

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

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

Why wait? Turn the page to learn more.



# VNS Therapy may improve your quality of life.

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



### **Benefits may include:**

- Fewer Seizures
- Shorter Seizures
- Faster Recovery
- **Decreased Seizure Severity**
- **Fewer Medications**
- Improved Alertness, Mood and Memory
- Improved Quality of Life

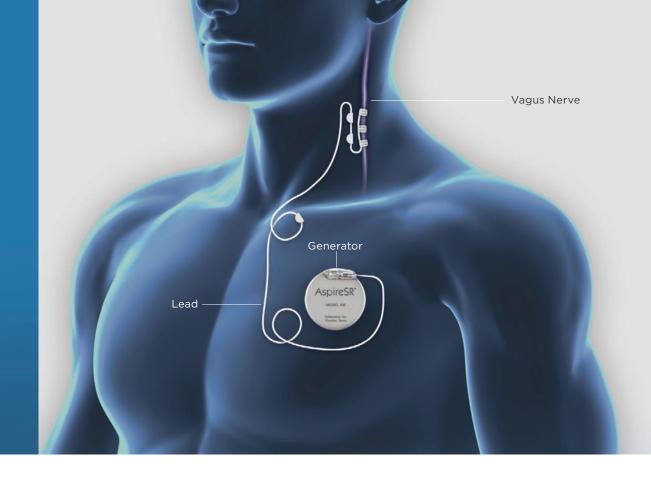
As you can imagine, VNS Therapy has improved the overall quality of life for many people living with drug resistant epilepsy.

In addition to these benefits, a small percentage (8%) of those with VNS Therapy report seizure freedom.

Visit VNSTherapy.com to view testimonials from caregivers and patients living with VNS Therapy.

# 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 to areas of the brain known to be associated with seizures.
- > It involves a short outpatient procedure which takes about an hour.
- > Most people go home the same day.



# Additional VNS Therapy features may provide even more control.

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 shorten your recovery time.



The VNS Therapy Magnet and NEW Detect & Respond features offer you ways to deliver an extra dose of therapy.

### The 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.

### The **Detect & Respond\*** Feature

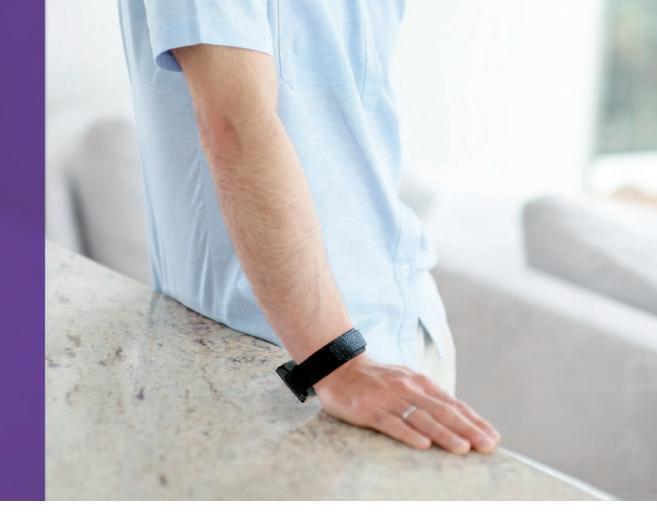
- > The latest advancement in VNS Therapy.
- > Detects a rapid rise in heart rate, which is often associated with a seizure.
- > Responds to this rapid increase in heart rate by automatically delivering an extra dose of therapy.





<sup>\*</sup> Also known as AutoStim Mode

VNS Therapy is not a drug. It does not have the same side effects nor does it interact with medications.



### The most common side effects of VNS Therapy include

- > hoarseness or changes in voice tone
- > prickling feeling in the skin
- > shortness of breath
- > sore throat
- > coughing

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

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.

# Why wait? Learn more about VNS Therapy today. On VNS Therapy since 2003

# To find out if VNS Therapy might be right for you:

- 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.

Calls take place the first Tuesday of every month, 7:00 PM Central Standard Time: 1-877-451-8943.

4. Visit www.VNSTherapy.com

## Safety Information for VNS Therapy

### **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.

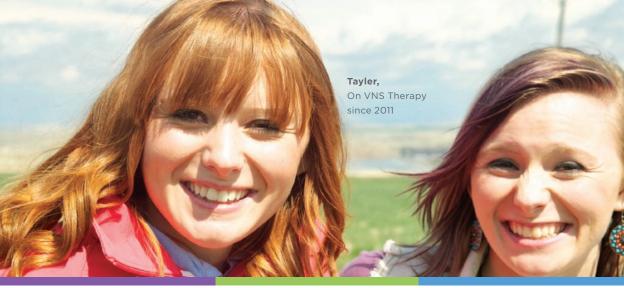
### **ADVERSE EVENTS**

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.







## To learn more about VNS Therapy:

- **Call toll-free:** 1-888-VNS-STIM (1-888-867-7846)
- Visit www.VNSTherapy.com
- Talk to Your Doctor
- Join us on Facebook

  www.facebook.com/VNSTherapyforEpilepsy

CYBERONICS, INC.
100 Cyberonics Boulevard
Houston, Texas 77058
Tel: +1.800.332.1375
Fax: +1.281.218.9332

CYBERONICS EUROPE BVBA
Vuurberg - Airport Plaza Building C Kyoto
Leonardo Da Vincilaan 19
1831 Diegem, Belgium
Tel: +32.2.720.95.93
Fax: +32.2.720.60.53

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