



## An Introduction to **VNS Therapy**

Fewer seizures • Shorter seizures • Improved recovery



**Finn** is a real  
patient with  
VNS Therapy

**To Learn More**  
visit [VNSTherapy.co.uk](http://VNSTherapy.co.uk)

\*Individual results may vary

# Still having seizures despite medications?

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



VNS Therapy is designed specifically for people living with seizures and 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 if you haven't found seizure freedom with your first two medications, there is less than a 5% chance that another medication 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 continues to improve over time.**

# VNS Therapy may improve your quality of life

**VNS Therapy is a safe, effective treatment with benefits that have been shown to improve over time.**



**Olivia**  
on VNS Therapy

## Benefits may include:



Fewer Seizures



Shorter Seizures



Improved Seizure  
Recovery



Decreased Seizure  
Severity



Less Medications



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.

➤ Visit [www.VNSTherapy.co.uk](http://www.VNSTherapy.co.uk) to view testimonials from caregivers and patients whose lives have changed since having 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

**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  
**Improved Recovery after Seizures**  
n=195

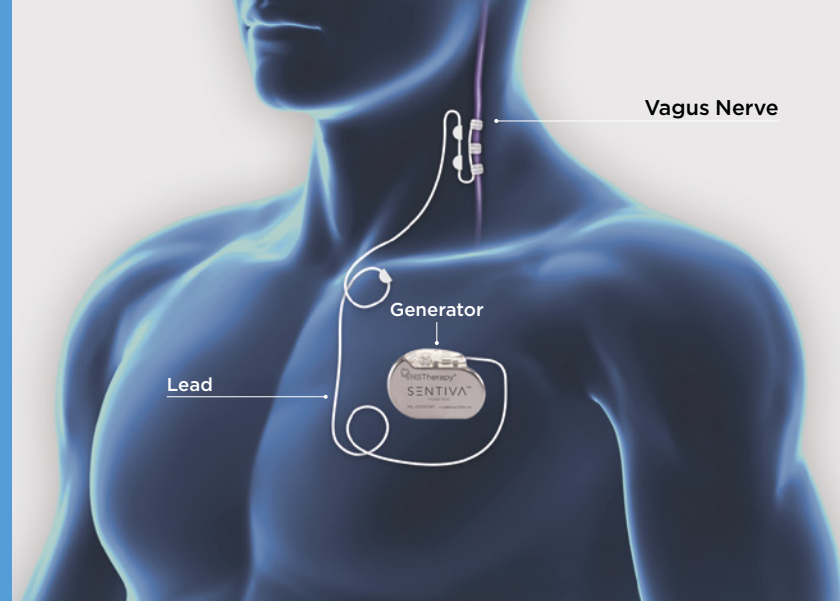
\* View important safety information on page 22.

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 usually takes about an hour
- › **VNS Therapy is not brain surgery**

# Latest Technology with VNS Therapy\*

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



Joshua  
on VNS Therapy



## Day & Night Programming

**Day & Night Programming is an optional feature available in the latest technology that allows for further personalisation of your treatment.**

- › Allows your doctor to customise 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

# The latest VNS Therapy technology provides you 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.**



## 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 & 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



## 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 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.**

- › The side effects generally only occur during stimulation and usually decrease over time
- › Most side effects are diminished 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.



# Frequently Asked Questions

## 1 Am I a candidate for VNS Therapy?

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

## 2 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.

## 3 Which results should I expect with VNS Therapy?

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

## 4 What is the procedure like?

VNS Therapy is not a 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.

## 5 Will the scars be noticeable?

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

## 6 How long will the battery last?

Depending on which device you receive and the settings, the battery life may range from 4.9 years to 10+ years. A short outpatient procedure, which usually takes less than an hour, is required to replace the device once the battery is depleted.

## 7 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.





# Safety Information for VNS Therapy

## INTENDED USE / INDICATIONS:

Epilepsy (Non-US)—The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications.

AspireSR® and SenTiva® feature an Automatic Stimulation Mode which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

## 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; pricking 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.

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This brochure is not intended to be a complete source of information on VNS Therapy. Please contact your healthcare professional or visit : <http://en.eu.livanova.cyberonics.com/safety-information>





**Visit** [www.VNSTherapy.co.uk](http://www.VNSTherapy.co.uk)



**Talk to your GP, epilepsy specialist nurse  
or neurologist.**



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