



An Introduction to **VNS Therapy**

Fewer seizures • Shorter seizures
Faster recovery • **Why wait?***



To Learn More
visit VNSTherapy.co.uk

*Individual results may vary

Are you struggling with uncontrolled seizures?

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 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.

**So what are you waiting for?
Turn the page to learn more.**

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.**

Benefits may include:

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



Joshua
on VNS Therapy

VNS Therapy has improved the overall quality of life for many people living with drug resistant epilepsy.

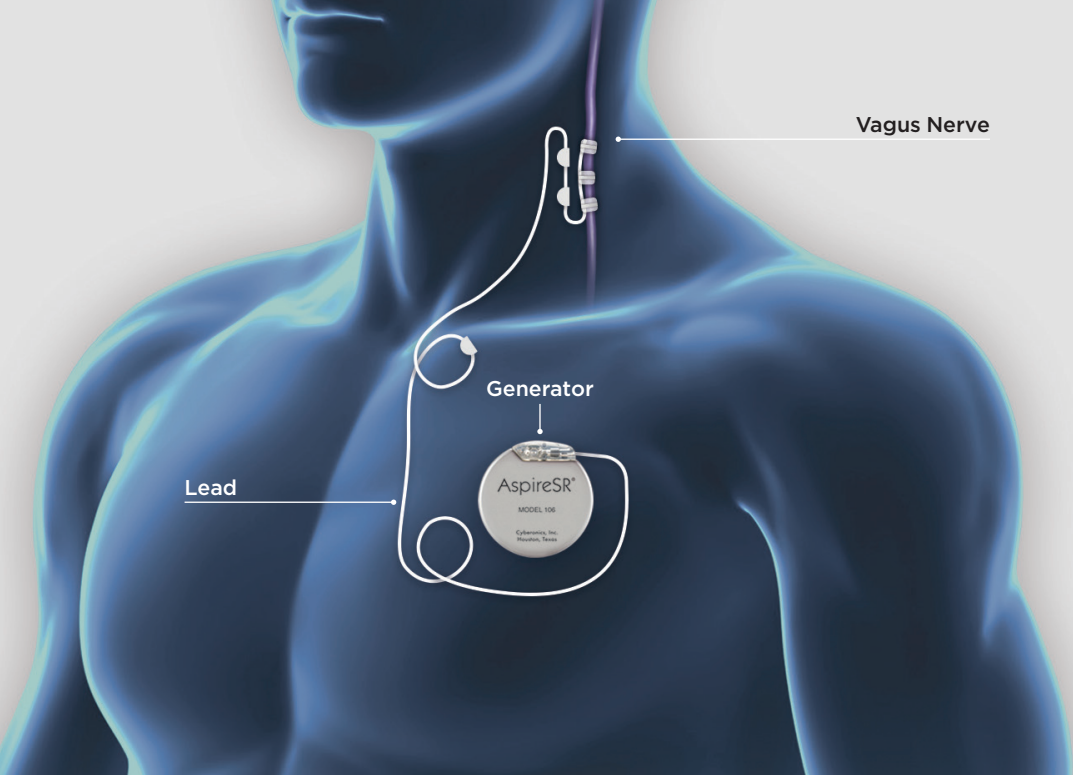
In addition to these benefits, a percentage (8%) of those with VNS Therapy report seizure freedom.

➤ **Visit www.VNSTherapy.co.uk to view testimonials from caregivers and patients whose lives have changed since having VNS Therapy.**

About VNS Therapy

The **VNS Therapy** device sends a mild pulse 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.
- › Clever technology that 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

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.



If side effects occur, 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.

How do you feel about your current therapy?

- 1** Are you taking multiple medications for seizure control and still having seizures?
- 2** Are you experiencing side effects from your medications with your daily activities?
- 3** Have you repeatedly been to the emergency room or admitted to the hospital because of your seizures or seizure-related injuries?
- 4** Does the time it takes to recover from your seizures restrict from continuing with your daily activities?

If you answer YES to any of these questions, VNS Therapy may be the right option for you.

It's time to talk to your GP, epilepsy specialist nurse or neurologist.

Frequently Asked Questions

1 Am I a good candidate for VNS Therapy?

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

2 How many people have VNS Therapy?

To date, more than 85,000 people worldwide have used VNS Therapy, a proven long-term solution for people with uncontrolled seizures.

3 What does drug-resistant epilepsy mean?

About one in three people with epilepsy will experience a type of seizure that is difficult to treat with medication, often referred to as drug-resistant epilepsy. Research shows that if you haven't found seizure freedom with your first two drugs, there is a 95% chance that no drug or combination of drugs will result in seizure freedom.

4 What type of benefits can I expect with VNS Therapy?

Many people report fewer seizures, shorter seizures, less severe seizures, fewer medications and faster recovery times following seizures. People with VNS Therapy also often report improvements in alertness, mood and memory, and an overall improved quality of life. Individual results may vary.

Frequently Asked Questions

Continued

5 What are the potential side effects?

The most common side effects with VNS Therapy are hoarseness or changes in voice tone, a prickling feeling in the skin, shortness of breath, sore throat and coughing. These side effects generally only occur during stimulation and usually decrease over time.

6 If I have VNS Therapy, will I still need to take medications?

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. It is important to always follow your doctor's recommendations about your medications.

7 Does the device work immediately?

Response to treatment varies for each person. Typically, there is a two-week period before stimulation is turned on. Then your neurologist will adjust your dose settings during routine office visits. Studies show that the benefits of VNS Therapy continue to improve over time, so it may take anywhere from a few months to one or two years to see the full benefits.

8 Will I be seizure-free with VNS Therapy?

The goals of VNS Therapy are fewer seizures, shorter seizures and faster recovery times following seizures. A small percentage of people (8%) report seizure-freedom with VNS Therapy. Individual results will vary.

9 What is the procedure like?

A small device (generator and lead) is implanted during a short, outpatient procedure that is performed under general anesthesia. The procedure involves two small incisions and usually takes about an hour.

10 How long does the procedure take?

The actual procedure takes about an hour. Most people go home the same day.

11 What will happen when the battery in my VNS Therapy device goes out?

A short procedure, which usually takes less than an hour, is required to replace the device once the battery is depleted. Typically, a generator will last three to eight years depending on your settings.

12 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.

13 Am I able to have a MRI with my VNS Therapy device?

MRIs are approved under specific conditions for patients with VNS Therapy. Please speak with your physician regarding any medical concerns.

Safety Information for VNS Therapy

Brief Summary* of Safety Information for the VNS Therapy® System [Epilepsy Indication] (February 2014)

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. The Model 106 AspireSR™ (Seizure Response) features the 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 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.”

Cardiac arrhythmia (Model 106 only)—The AutoStim Mode feature should not be used in patients with clinically meaningful arrhythmias or who are using treatments that interfere with normal intrinsic heart rate responses (e.g., pacemaker dependency, implantable defibrillator, beta adrenergic blocker medications).

WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, 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 the VNS Therapy system 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. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

PRECAUTIONS

The safety and efficacy of The VNS Therapy System 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. With the Model 106 only, because the device senses changes in heart rate, false positive detection unrelated to seizure activity (e.g., exercise) may cause unintended stimulation. The Model 106 also may not detect all seizures.

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. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

* 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 : www.vnstherapy.co.uk



Visit www.VNSTherapy.co.uk



Talk to your GP, epilepsy specialist nurse or neurologist.



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