VNS Therapy™

An Introduction to VNS Therapy™

Fewer seizures • Shorter seizures • Improved recovery after seizures

Finn is a real patient with VNS Therapy

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Epilepsy

VNS Therapy™

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.

Olivia,
VNS Therapy patient

If seizures continue after two anti-seizure medications have been tried for an appropriate amount of time as determined by a doctor, it is considered to be **drug-resistant epilepsy**.

If you've tried multiple medications yet continue to have seizures, it may be time to consider alternative treatment options.

VNS Therapy™ is designed to reduce the frequency of seizures in people with drug-resistant epilepsy, and many people experience long-lasting seizure control with VNS Therapy.

VNS Therapy is used by more than 125,000 people including 35,000 children worldwide.

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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.

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

Tayler,
VNS Therapy patient

Benefits may include:

- Fewer Seizures
- Shorter Seizures
- Improved Seizure Recovery
- Less Severe Seizures
- Lower Dose of Current Medications
- Improved Alertness, Mood and Memory
- Improved Quality of Life
- Fewer Hospital and ER Visits

Visit www.VNSTherapy.ca to view testimonials from caregivers and patients whose lives have changed since having VNS Therapy.

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VNS Therapy™

VNS Therapy™ is proven as safe and effective for children, with 63% of children having fewer seizures*

Finn,
VNS Therapy patient

Many children with VNS Therapy also experience **shorter seizures**, **less severe seizures** and **improved recovery after seizures**.

*Based on a group of 83 patients following 24 months of VNS Therapy, with no anti-seizure medication changes.

Children with uncontrolled seizures who are treated with medicine alone may experience a decline in development.

In addition to reducing seizures, clinical studies reporting on the use of VNS Therapy in children have shown improvements in memory, mood, energy and alertness.

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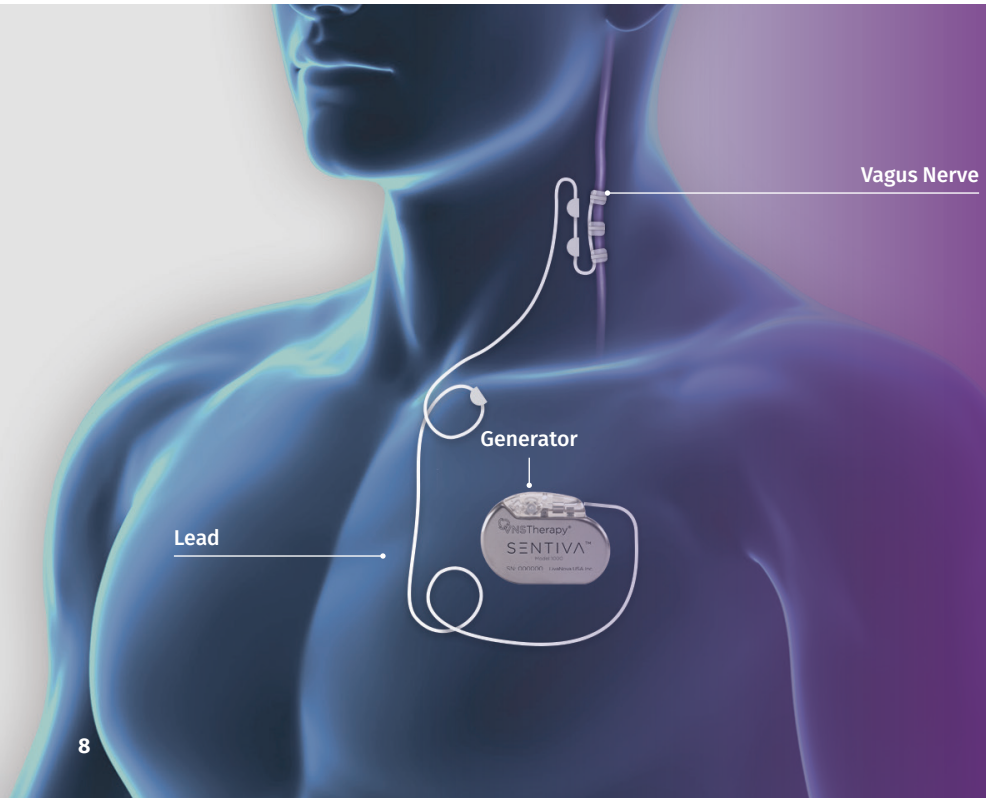
About VNS Therapy™

The VNS Therapy device sends mild pulses through the left vagus nerve to areas of the brain that are associated with seizures in an effort to control them.

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



- VNS Therapy consists of a small device (generator) that is implanted under the skin in the chest and connected to the left vagus nerve in the neck with a thin wire lead
- It involves a short outpatient procedure which usually takes 1-2 hours
- **VNS Therapy is not brain surgery**

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The latest VNS Therapy™ technology gives you more control

If you have a breakthrough seizure with VNS Therapy, an additional dose of stimulation may help stop or shorten your seizure, decrease its intensity and shorten your recovery time after a seizure.

Normal Mode

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

AutoStim Mode*

- Detects a rapid rise in heart rate, which may be associated with a seizure
- Responds to this rapid increase in heart rate by automatically delivering an extra dose of stimluation

* Only available in Models 106, 1000 and 1000-D

Magnet Mode

- An optional feature that may provide additional seizure control
- Provides you or a caregiver the ability to manually deliver an additional dose of stimulation on demand

If you need a replacement magnet, speak to your doctor

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Latest Technology with VNS Therapy™*

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

Josh,
VNS Therapy patient

Day & Night Programming

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

- Allows your doctor to customize 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 increase therapy settings at intervals they choose

This option can reduce the need for you to attend follow up appointments for programming, giving you time back to live your life.

*Only available in models 1000 and 1000-D

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VNS Therapy™

VNS Therapy™ Safety Information

Hauk,
VNS Therapy patient

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

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

Infection is the most common side effect of the procedure.

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.

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Frequently Asked Questions

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.

Will VNS Therapy® help me immediately?

The benefits of VNS Therapy are not always seen right away. In fact, seizure activity may improve slowly over the first 2 years of treatment. Long-term results from clinical studies suggest that the effects of VNS Therapy are significant and last over time.

Which results should I expect with VNS Therapy™?

The goals of VNS Therapy are fewer seizures, shorter seizures and improved recovery after seizures. VNS Therapy is an add on therapy, and 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.

If AutoStim gives me an extra stimulation, does that mean I'm about to have a seizure?

Not in all cases. The AutoStim Mode is designed to trigger based on rapid increases in your heart rate, which may signal the start of a seizure, however, not all seizures are accompanied by rapid heart rate increases. Depending on settings programmed by your doctor and your medical condition, an automatic stimulation may or may not be correlated with an actual seizure. It is important for you to tell your doctor if you think stimulation is coming on too much or too little so your doctor can adjust the settings appropriately.

What happens when I exercise if AutoStim is on?

The AutoStim Mode is designed to respond to rapid increases in heart rate. If you are exercising and your heart rate increases rapidly you may receive an extra dose of therapy, which is very similar to receiving an extra stimulation via the Magnet Mode.

What is the procedure like?

VNS Therapy is not a brain surgery. A small device (generator) is implanted under the skin in the chest and a thin wire (lead) connects the device to the left vagus nerve in the neck.

This occurs during a short, outpatient procedure typically performed under general anesthesia which usually lasts 1-2 hours and involves two small incisions.

Two weeks after the procedure, your doctor will begin to program the device to the most suitable settings for you.

Will the scars be noticeable?

Each person has different healing and scarring results. You should expect some scarring from the procedure. If scarring is a special concern for you, we recommend discussing this with your surgeon.

What are the side effects with VNS Therapy™?

The most common side effects reported for the VNS Therapy System are hoarseness, shortness of breath, sore throat and coughing. These side effects typically occur during stimulation and usually decrease over time. The most common side effect of the surgical procedure is infection. See "Side Effects" on page 23.

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Will the implanted device be visible to others?

The generator is small, not more than 2 inches (5 cm) in diameter depending on the model. If you have a small or thin frame, the shape of the device may be visible below the left collarbone. If this is a concern for you, we recommend discussing with your doctor.

How long will the battery last?

Depending on which device you receive and the settings, the battery life may range from 1-16 years. A short outpatient procedure, which usually takes less than an hour, is required to replace the device once the battery is depleted.

When going through security at the airport, will my VNS Therapy™ device be affected?

Antitheft devices, airport security systems and other metal detectors should not affect the generator or be affected by it. As a precaution, however, move through them at a steady pace; do not linger in the area and stay at least 40 centimeters (16 inches) away from such equipment.

Can I have an MRI with VNS Therapy™?

MRI can be safely performed with the VNS Therapy System provided specific guidelines are followed. Speak to your doctor about which areas of the body can be safely scanned. MRI scan requirements are different depending on your VNS Therapy device model and the implant location.

Notes

Safety Information for the VNS Therapy™ System

Brief Summary of Safety Information for Patients VNS Therapy™ System [Epilepsy Indication] (August 2020)

1. INDICATIONS

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.

If you have the AspireSR™ (Seizure Response) Model 106, SenTiva™ Model 1000 or SenTiva DUO™ Model 1000-D device, it has a feature called the Automatic Stimulation Mode. This feature is for patients who experience seizures that are associated with an increase in heart rate. The feature can also be turned off by your physician, allowing the device to operate the same way as other VNS Therapy System models

2. CONTRAINDICATIONS

Vagotomy— The VNS Therapy System should not be used (is contraindicated) in people who have had the left vagus nerve cut to treat another disorder (a left vagotomy).

Diathermy— Inform anyone treating you that you CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (hereafter referred to as "diathermy") anywhere on your body because you have an implanted VNS Therapy System (sometimes referred to as a "Vagus Nerve Stimulator" or "Vagus Nerve Stimulation"). Injury or damage can occur during diathermy treatment whether your VNS Therapy System is turned "ON" or "OFF." Diagnostic ultrasound is not included in this contraindication.

3. WARNINGS

Avoid excessive vagus nerve stimulation — Excessive stimulation of the vagus nerve can be produced by frequent magnet activation or more than 4 hours of continuous stimulation due to repeated magnet activations.

Unapproved uses — The safety and efficacy of the VNS Therapy System have not been established for uses outside its approved indications for use. The safety and efficacy of VNS Therapy have not been shown for people with these conditions: history of previous therapeutic brain surgery or brain injury, dysautonomias, lung diseases or disorders, including shortness of breath and asthma, ulcers (gastric, duodenal, or other), fainting (vasovagal syncope); irregular heartbeats (heart arrhythmias) or other heart abnormalities; other concurrent forms of brain stimulation; pre-existing hoarseness; progressive neurological diseases other than epilepsy or depression.

Swallowing difficulties — Difficulty swallowing may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Use of the magnet to temporarily stop stimulation while eating may mitigate the risk of aspiration.

Shortness of breath — Shortness of breath may occur with active VNS Therapy, especially if you have chronic obstructive pulmonary disease or asthma.

Obstructive sleep apnea — Use of the VNS Therapy device can cause or worsen pre- existing obstructive sleep apnea (episodes where breathing stops for short periods of time while sleeping). You should see your physician if you show any signs or symptoms of obstructive sleep apnea or worsening obstructive sleep apnea.

Device malfunction — Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage and other associated problems.

Device removal — Removal of the VNS Therapy System requires an additional surgical procedure. When a device is removed, the surgeon may leave part of the lead behind. This may pose certain risks.

Device manipulation — Do not manipulate the generator and lead through the skin, as this may damage or disconnect the lead from the generator and/or possibly cause damage to the vagus nerve.

Device trauma — Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted could possibly cause damage to the lead.

Not a cure — The VNS Therapy System does not stop all seizures. Continue to avoid activities that can be hazardous to you and others, such as driving and swimming alone.

Before having any MRI performed — Call your doctor, so your VNS Therapy System can be discussed with the MRI personnel. In many cases, an MRI can be performed safely under certain conditions. However, for a few other cases, surgery may be required to remove the VNS Therapy System prior to an MRI. Before undergoing an MRI scan with your VNS Therapy System, the VNS system diagnostic information will be collected and the current turned off. The current will be turned on again after the scan is completed. Your doctor has access to detailed MRI-related information in the physician's manual.

Patient Magnet is MR Unsafe — Do not carry the patient magnet into the MR scanner room. The magnet could become a dangerous flying object if attracted by the strong magnetic field of the MRI scanner.

Pain or other sensation during MRI scan — If, during an MRI scan, you have any pain, discomfort, heating, or other unusual sensations, notify the MRI operator, so the MR procedure can be stopped.

Cardiac Arrhythmia (Model 106 or 1000/1000-D only) — If you have a cardiac arrhythmia, the Automatic Stimulation feature of the Model 106 is not suitable for you. This includes heart conditions or treatments that do not allow necessary changes in your heart rate, such as atrial fibrillation, pacemaker dependency, implantable defibrillator, or cardiac medications such as beta blockers.

4. PRECAUTIONS — IMPLANTABLE DEVICE: GENERAL

Use during pregnancy — The safety and effectiveness of the VNS Therapy System have not been established for use during pregnancy.

Laryngeal irritation may result from stimulation — Patients who smoke may have an increased risk of laryngeal (commonly called the "voice box") irritation.

AutoStim Devices (Model 106 and 1000/1000-D)

Use during exercise — Exercise or physical activity may trigger Automatic Stimulation if the feature is ON due to heart rate changes detected by the device.

Heart Rate Changes Not Associated with Seizures — Situations, including but not limited to exercise or physical activity, that cause rapid increases in heart rate may trigger Automatic Stimulation if the feature is ON. If this is a concern, talk to your doctor about ways to stop stimulation during these situations. This could include using your magnet or having your doctor turn the AutoStim feature OFF.

Battery Drain — If your doctor has turned on the AutoStim feature, there will be a greater impact on battery life than if the feature is turned off, which may require more frequent generator replacements.

AutoStim follow-up visits — Use of the AutoStim feature will reduce battery life. Once the AutoStim feature has been activated, your doctor will work with you to determine a treatment plan to get to the most benefit.

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Time-based Features (Models 1000/ 1000-D only) — Optional time-based features (e.g., Day-Night Programming, Scheduled Programming) do not automatically adjust for Day Light Savings Time or time zone changes. If you are using one of these features, you will need to go back to your doctor for reprogramming of the generator for any time changes.

5. PRECAUTIONS — IMPLANTABLE DEVICE: ENVIRONMENTAL & MEDICAL HAZARDS

Being close to certain types of equipment can affect the generator. Move away from or avoid equipment such as transmitting antennas.

Pacemaker Warning signs — Talk to your doctor before going into places with Pacemaker Warning signs.

Small appliances — Properly operating microwave ovens and other small electrical appliances, such as toasters, hair dryers, and electric shavers, should not affect the generator.

Cellular phones — Cellular phones can affect some implanted cardiac defibrillators and pacemakers, but tests to date show that they do not affect the generator.

Transmitting devices — Properly operating electrical ignition systems and power transmission lines should not affect the generator. Sources with high energy levels, such as transmitting antennas, may interfere with the device. Move at least 1.8 meters (6 feet) away from any equipment that interferes with your device.

Antitheft devices, airport security systems, and other metal detectors — Antitheft devices and metal detectors should not affect the generator or be affected by it. As a precaution, however, move through them at a steady pace; do not linger in the area and stay at least 40 centimeters (16 inches) away from such equipment.

Electronic Article Surveillance (EAS) System tag deactivators — The tag deactivators found in many retail stores can interfere with VNS Therapy when it is used near the generator. It can cause accidental activations or stop pulses. Stay at least 60 centimeters (2 feet) away from tag deactivators to avoid potential interference.

Devices with strong electromagnetic fields — Electrical or electromechanical devices with a strong static or pulsing magnetic field can cause the generator to start suddenly. Such devices may include strong magnets, tablet computers and their covers, hair clippers, vibrators, antitheft tag deactivators, and loudspeakers. Keep this type of equipment at least 20 centimeters (8 inches) away from your chest. If your generator stops while you are in a strong electromagnetic field, move away from the source so the device may return to regular operation.

Medical equipment, procedures, and surgery using certain electrical instruments can affect the VNS Therapy System's operation and sometimes damage the generator or lead.

Make sure that medical personnel know you have a device implanted in your chest.

Always call your doctor before you have any medical tests that may affect, or be affected by, the VNS Therapy System as described in this section. Precautions may be needed.

Routine diagnostic procedures — Most routine diagnostic procedures, such as diagnostic ultrasound and radiography (x-rays), should not affect the VNS Therapy System.

Mammography — Because the generator is in your chest, you may need to be specially positioned for a mammogram. Otherwise, the device may be seen as a shadow on the mammogram. It could make a lesion or lump in that area hard or even impossible to detect. Make sure that your doctor and the mammography technician are aware of the implanted device.

Radiation treatment — Treatment with radiation, cobalt machines, and linear accelerators may damage the generator. No testing has been done to date. The effect of radiation on the device is not known. Talk with your doctor if you plan to have radiation treatment.

Other procedures — External cardiac defibrillation and other procedures for heart problems, as well as extracorporeal shockwave lithotripsy, diathermy, and electrocautery, may damage the generator. If you had any of these procedures and your doctor did not know about it, have the generator checked. While diagnostic ultrasound should not affect the VNS Therapy System, therapeutic ultrasound therapy could damage the generator or inadvertently harm you.

While the generator is stimulating or being set or tested, it may briefly interfere with nearby equipment. If this happens, move at least 1.8 meters (6 feet) away from such equipment.

Radios and hearing aids — The generator can interfere with devices that operate in the 30 kHz to 100 kHz range. Hearing aids and transistor radios operate in this range. In theory, the generator could affect them, but no effects have yet been reported. No detailed testing has been done, so the effects are unknown.

Other Implanted devices — The generator may affect other implanted medical devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems. These could lead to inappropriate responses from the generator.

6. PRECAUTIONS — MAGNETS

After your operation, your doctor will give you two magnets and accessories. The magnets contain a high-power magnet that is surrounded by a plastic casing in the shape of a watch. With normal use, they should remain powerful for approximately 3 years

Keep magnet with you — Always carry the magnet with you. Show your family members or caregivers how to use it.

Other implanted devices — Do not place the magnet over a pacemaker since it may affect pacemaker function and could change the pacing rate. Do not place the magnet over a defibrillator (sometimes called ICD) since it could turn the device OFF

Damage from magnet — Never put or store the magnets near credit cards, televisions, computers, computer disks, microwave ovens, watches, other magnets or items affected by strong magnetic fields. Keep them at least 25 centimeters (10 inches) away.

If you are not sure how to use the magnet or have questions, ask your doctor to show you how.

7. SIDE EFFECTS

Adverse events reported during clinical studies as statistically significant are listed below in alphabetical order: ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); dyspnea (difficulty breathing, shortness of breath); hypoesthesia (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; paresthesia (prickling of the skin); pharyngitis (inflammation of the pharynx, throat); voice alteration (hoarseness); vomiting. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

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Visit www.VNSTherapy.ca

Talk to your GP, epilepsy specialist nurse or neurologist.

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