

An Introduction to VNS Therapy™

Fewer seizures. Shorter seizures. Better recovery after seizures.



Breanna
VNS Therapy™ patient



To Learn More

call 1-888-867-7846
or visit [VNSTherapy.com](https://www.VNSTherapy.com)

Individual results may vary.

Living with Drug-Resistant Epilepsy

While some cases of epilepsy can be treated with medicine alone, drug-resistant epilepsy requires more than medicine to achieve seizure control.

What is drug-resistant epilepsy?

Drug-resistant epilepsy is defined as the failure of two anti-seizure medications to achieve long-term seizure freedom, as long as those medications were appropriately prescribed and properly used. In other words, seizures that continue after trying at least two antiseizure medications are considered drug-resistant epilepsy.

Drug-resistant epilepsy is also known as refractory epilepsy, hard-to-treat epilepsy and DRE.

Studies have shown that adding more medications is not likely to control this kind of epilepsy.

Goals When Treating Drug-Resistant Epilepsy

While drug-resistant epilepsy can't be treated by medicine alone, there is hope.

If you've tried multiple medications, yet continue to have seizures, it's time to question your seizure treatment.



1 in 3 
People with Epilepsy can't control seizures with medicine alone

 Talk to your doctor about other treatment options available.



John
VNS Therapy™ patient

Risks of Undertreated Epilepsy





Bella
VNS Therapy™ patient

Still having seizures despite medications?

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

VNS Therapy™ is a neuromodulation treatment designed for people with drug-resistant epilepsy 4 years of age and older with partial onset seizures. It can safely lead to fewer and shorter seizures and better recovery after seizures. It is a proven safe and effective solution already being used by more than 125,000 people around the world, including more than 35,000 children.

Studies have shown that adding more medications is not likely to control this kind of epilepsy.

Many people experience long-lasting seizure control with VNS Therapy™. In fact, seizure control with VNS Therapy™ typically continues to improve over time.

In a survey of 200 VNS Therapy™ patients and caregivers:*

94%

Reported they wish they had
known about VNS Therapy™ sooner



*Data on file. Survey Report. LivaNova USA, Inc. Houston, TX. October 2021.

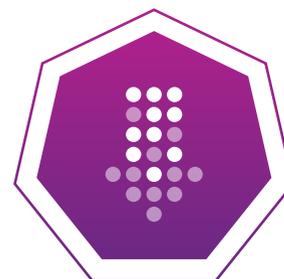
The overall quality of life has improved for many people with VNS Therapy™

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

Bennett
VNS Therapy™ patient

Visit VNSTherapy.com to view stories from caregivers and people with VNS Therapy™.

Benefits may include



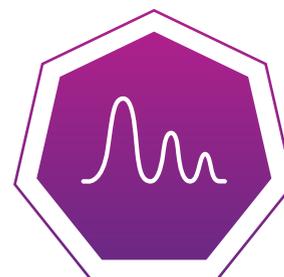
Fewer Seizures



Shorter Seizures



Better Recovery After Seizures



Less Severe Seizures



Less Medication



Improved Alertness, Mood and Memory



Reduced Seizure Worry



Improved Quality of Life



Fewer Hospital and ER visits

VNS Therapy™ is safe for children

VNS Therapy™ is safe and effective for treating drug-resistant epilepsy in children as young as 4 years old with partial onset seizures.*

Ethan
VNS Therapy™ patient

Bella
VNS Therapy™ patient

VNS Therapy™ has been shown to safely help children with drug-resistant epilepsy gain control over seizures. Use of VNS Therapy™ in children offers long-term outcomes for children at a critical time in their development.

- ▶ VNS Therapy™ has been used in more than 35,000 children worldwide.
- ▶ VNS Therapy™ is the #1 prescribed neuromodulation device for drug-resistant epilepsy in children.
- ▶ Children treated with VNS Therapy™ have been shown to have fewer seizures, shorter and less severe seizures, and better recovery after seizures.



*View important safety information on page 22. FDA-approved for people as young as four. Children (ages 4-11) may have a greater risk of infection than those 12 years of age and older and may be more likely to experience lead damage due to higher activity levels and the potential to manipulate the lead.



Fewer Seizures



Shorter Seizures



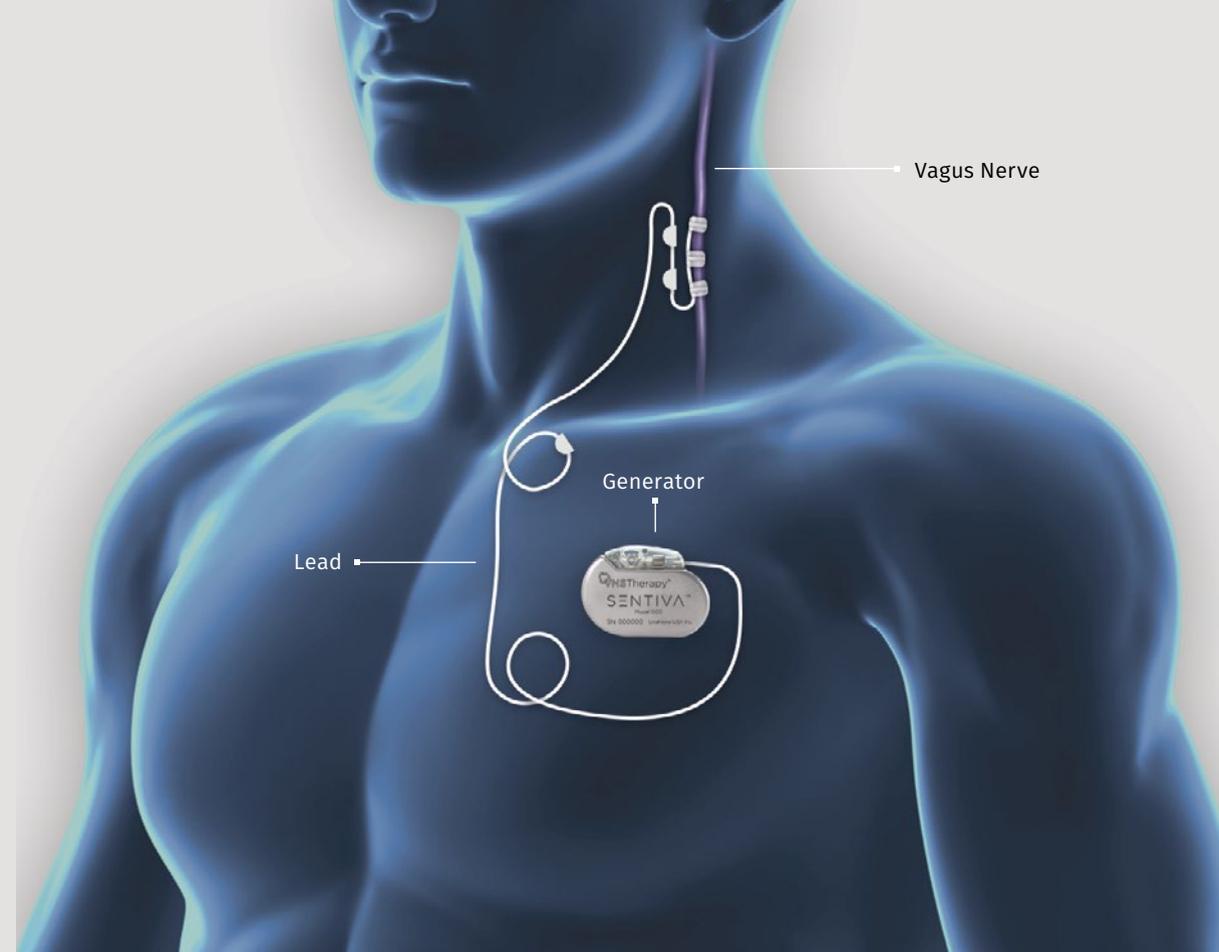
Less Severe Seizures



Better Recovery after Seizures

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.

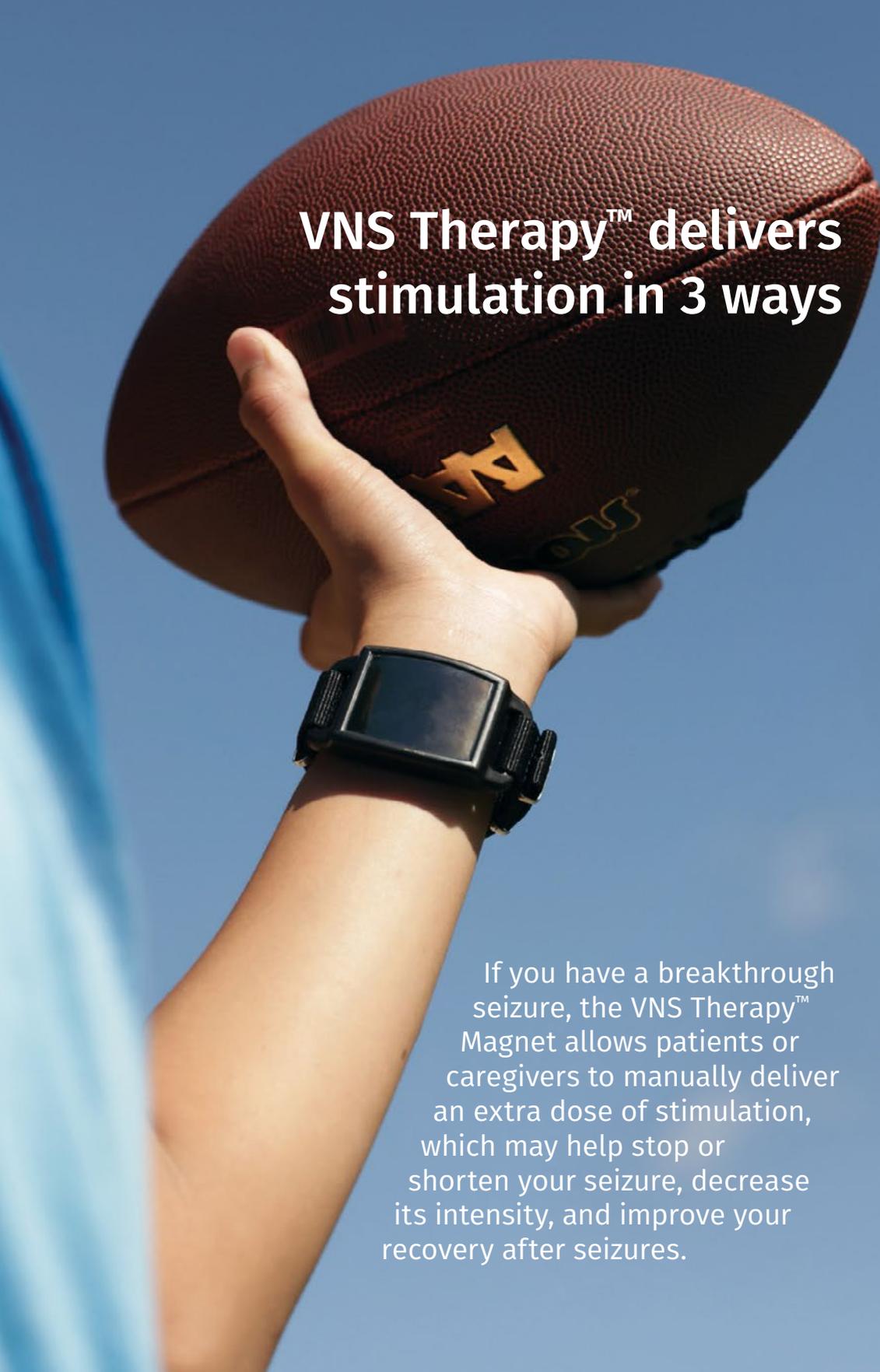


The goal of VNS Therapy™ is to prevent seizures before they start, and stop them if they do.

- ▶ VNS Therapy™ is a small device (generator and lead) that is implanted under the skin in the chest and connected to the left vagus nerve in the neck.
- ▶ It involves a short outpatient procedure which takes about one to two hours.
- ▶ VNS Therapy™ is delivered through a device (generator and lead) that sends mild pulses through the left vagus nerve.



VNS Therapy™ is not brain surgery



VNS Therapy™ delivers stimulation in 3 ways

If you have a breakthrough seizure, the VNS Therapy™ Magnet allows patients or caregivers to manually deliver an extra dose of stimulation, which may help stop or shorten your seizure, decrease its intensity, and improve your recovery after seizures.



Normal Mode

Helps prevent seizures

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



AutoStim Mode*

Responds to rapid increases in heart rate

An extra dose of therapy is automatically delivered at the sign of a rapid increase in heart rate, which may be associated with seizures.



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



VNS Therapy™ Magnet

Delivers On-Demand Treatment

Provides you or a caregiver the ability to manually deliver an additional dose of stimulation by swiping the VNS Therapy™ Magnet to help stop or shorten a seizure once it starts.

Latest technology with VNS Therapy*

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

Johnny
VNS Therapy™ patient



Day & Night Programming

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

- ▶ Allows your doctor to customize VNS Therapy™ based on your lifestyle preferences or side effect management.



*Only available in models 1000 and 1000-D

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 he or she chooses in advance until you reach your targeted dose.



*Only available in models 1000 and 1000-D

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



VNS Therapy & MRI

With the latest technology, MRI is now more accessible than ever.

- ▶ MRI is safe with VNS Therapy™ provided specific guidelines are followed.

Before scheduling any MRI, contact your doctor.

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.

- ▶ These side effects generally only occur during stimulation and become less noticeable over time for most patients.
- ▶ Most side effects may be diminished by adjusting the device's settings.



VNS Therapy™ is not a drug and does not have drug-related side effects

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

Isla
VNS Therapy™ patient



Frequently Asked Questions

Am I a candidate for VNS Therapy™?

VNS Therapy™ is an add-on neuromodulation treatment designed for people with drug-resistant epilepsy 4 years of age and older with partial onset seizures. Talk to your doctor about VNS Therapy™ if medications have not given you acceptable seizure control. You and your doctor will decide if VNS Therapy™ is right for you.

Does the device work 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.

Will I be able to stop taking anti-seizure medications with VNS Therapy™?

VNS Therapy™ is an add-on treatment, not a replacement for your medications, nor does it prevent you from trying new ones. While some people are able to reduce their dose of medications with VNS Therapy™, you and your doctor will determine the right treatment plan for you. Individual results will vary.

How long will the battery last?

The latest VNS Therapy™ technology has a battery life of 2–10 years depending on settings. A short, outpatient procedure is required to replace the device once the battery is depleted.

Will VNS Therapy™ be covered by my insurance?

Many insurance companies cover the cost of VNS Therapy™, including Medicare and Medicaid. One of our Care Coordinators can help you verify your insurance benefits. Call 1-888-867-7846 to speak with a Care Coordinator.

What is the procedure like?

With VNS Therapy™ a small device (generator) is implanted in the chest and a thin wire, known as the lead, connects the device to the left vagus nerve in the neck. This outpatient procedure usually takes 1 to 2 hours. It involves two small incisions and is typically performed under general anesthesia.

Will the scars be noticeable?

Each person has different healing and scarring results. Some scarring should be expected from the procedure. If scarring is a special concern, we recommend discussing this with the surgeon.

Will I be able to go through airport security?

Just as someone might carry an identification card if they had a pacemaker, the same is true of the VNS Therapy™ device. While a metal detector or screening booth will not cause harm or damage the VNS Therapy device, it may be advisable to request a wand examination to avoid setting off any alarms. A pat-down check may also be requested instead of walking through metal detectors.

Vivien
VNS Therapy™ patient





Brittany
VNS Therapy™ patient

Learn more about VNS Therapy™ today

1. Talk to your neurologist

about whether VNS Therapy™ is right for you.

2. Call a VNS Therapy™ Care Coordinator 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.

3. Join our Community Chat Webinar at VNSTherapy.com

and hear from VNS Therapy™ patients, caregivers and other people thinking about getting VNS Therapy™. On this webinar, you can get first hand information about the procedure and learn what it feels like to have VNS Therapy™. An epilepsy specialist is available for every session. All webinars are free and confidential.

Visit VNSTherapy.com for call details.

4. Visit VNSTherapy.com

1. INDICATIONS

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.

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; under 4 years of age; progressive neurological diseases other than epilepsy.

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)

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.

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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Talk to your doctor



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