



Patient Essentials

PATIENT'S MANUAL for Epilepsy

October 2014

Non-U.S. Version

This Patient's Manual is a supplement to the physician's manuals. It is not meant to take the place of advice from your doctor. For a complete discussion of indications for use, contraindications, precautions, warnings, and potential side effects, talk to your doctor.

Talk with your doctor about:

- How this device is used
- How it should not be used
- Safety measures
- Warnings
- Side effects

Your doctor's phone number: _____

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1. GLOSSARY _____

These terms are used in this manual.

adjunctive therapy

Additional, add-on; VNS is adjunctive therapy, which is added on to other antiepileptic treatments

adverse events

Complications and side effects

antiepileptic therapy

Any drug, operation, or device to help control seizures

clinical studies

Tests of the effectiveness and safety of a therapy on humans

Cyberonics®

Company that makes the VNS Therapy® System

electrodes

Part of the VNS Therapy lead that connects to the vagus nerve

epilepsy

Disorder with seizures

lead

VNS Therapy lead; small wire that connects the VNS Therapy pulse generator to the vagus nerve

MR

Magnetic resonance

MR Conditional

An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use

MR Unsafe

An item that poses hazards in all MRI environments

MRI

Magnetic resonance imaging

postictal

Recovery period after a seizure

programming wand

VNS Therapy instrument used to check or change VNS Therapy device and settings

pulse generator

VNS Therapy device implanted in the patient's chest; holds the battery and delivers stimulation to the vagus nerve through the VNS Therapy lead

reed switch

A mechanism that works like a gate. When the magnet closes it, the Normal signal (stimulation) cannot pass; the pulse generator is temporarily turned OFF

seizure

Convulsion; epileptic attack; a symptom of people with epilepsy

stimulate

Send electrical signal; with VNS Therapy, the pulse generator sends an electrical signal through the lead to the vagus nerve, which carries the signal to the brain

stimulation

The electrical signal that is sent from the pulse generator to the brain

vagus nerve

A nerve that extends from the brain through the neck to the major organs (e.g., heart, lungs, and stomach) in the torso

vagus nerve stimulation (VNS)

The electrical signal sent from the pulse generator to the vagus nerve

VNS Therapy[®]

Treatment received from vagus nerve stimulation

VNS Therapy System

All of the parts that provide VNS Therapy:
pulse generator, lead, programming wand,
programming computer, programming
software, and magnets

2. INTRODUCTION TO VNS THERAPY[®]

Many people have epilepsy. Through the years, doctors and scientists have learned much about seizures. They have developed drugs and other treatments. Despite these efforts, some people still have seizures. Your doctor has proposed the VNS Therapy System for you to reduce the frequency and duration of your seizures because drugs either have failed to control them adequately or have caused bad side effects.

The VNS Therapy System sends a mild electrical impulse to a nerve that goes to the brain. This nerve is called the vagus nerve. The treatment is vagus nerve stimulation (VNS) Therapy (VNS Therapy[®]).

With the AspireSR[™] (Model 106) generator, VNS Therapy also provides an Automatic Stimulation Mode that delivers stimulation at the onset of a seizure. This may stop the seizure, decrease the severity of the seizure, or improve the recovery time after the seizure.

3. THE VNS THERAPY SYSTEM

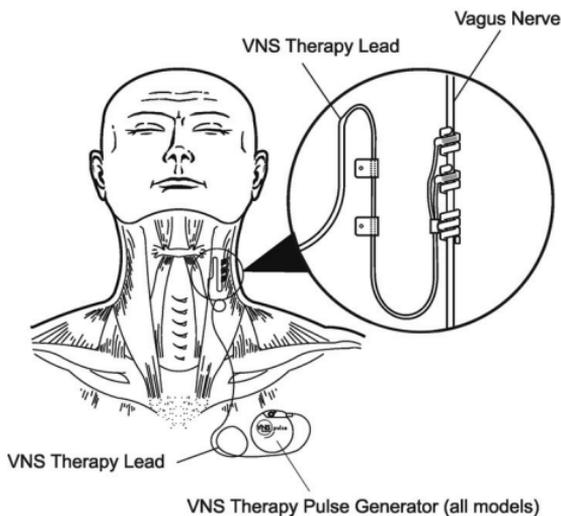
3.1. Parts of the VNS Therapy System

The VNS System has several implantable and nonimplantable parts (see Figure 1 and Figure 2).

3.1.1. *Implantable parts*

- VNS Therapy pulse generator
- VNS Therapy lead

Figure 1. Implantable Parts of the VNS Therapy System

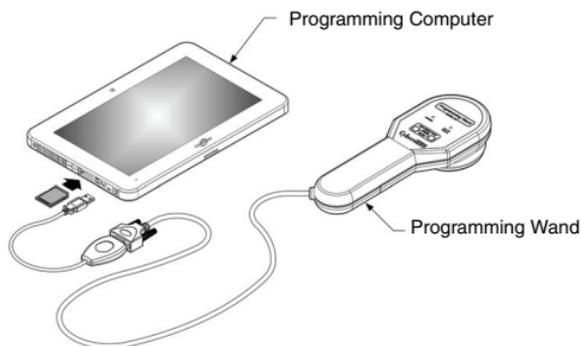


3.1.2. **Nonimplantable parts**

- VNS Therapy computer
- VNS Therapy software
- VNS Therapy programming wand
- Cyberonics magnets

i **Note:** The non-implantable parts may vary depending upon the system used by your physician.

Figure 2. Nonimplantable Parts of the VNS Therapy System



3.1.3. **Pulse generator**

The main part is the pulse generator, sometimes called a stimulator. Similar to cardiac pacemakers, which have been used since 1958 to control heart problems, the pulse generator is computer controlled and battery powered. It sends signals through the electrodes of the lead to the brain by way of the left vagus nerve. These signals help reduce the rate and duration of seizures.

3.1.4. Placement of the pulse generator and lead

The pulse generator is placed under the skin of the upper chest. The lead connects the pulse generator to the vagus nerve. It is surgically attached to the vagus nerve on the left side of the neck. A surgeon implants the pulse generator and lead during an operation that typically lasts about 1 to 2 hours. Later, your doctor sets the pulse generator to deliver periodic stimulation 24 hours a day (for example, 30 seconds ON and 5 minutes OFF). Additionally, if you have a Model 106, your doctor may also enable an automatic stimulation feature that responds to seizures. At the office, your doctor can read and change stimulation settings with the programming computer, programming software, and programming wand.

3.1.5. Cyberonics magnet

Cyberonics provides a magnet for you to stop or to activate stimulation when it is needed. The magnet (on-demand) stimulation is in addition to the Normal stimulation and Automatic Mode stimulation (applies to Model 106).



Note: See “The Cyberonics Magnets” on page 40.

3.1.6. Stimulation settings

The pulse generator has many settings for both Normal and Magnet stimulation. For the Model 106, there are also several settings related to Automatic Mode stimulation. Your doctor will choose the settings. He or she can change the periodic stimulation at any time with the programming wand,

programming software, and programming computer. Most of the time, changing the VNS Therapy System settings is a painless procedure, takes only a few minutes, and can be done in the doctor's office.

3.1.7. Pulse generator life

The battery in the pulse generator can last from 1 to 16 years.

The lifespan depends on these factors:

- Pulse generator model
- Settings your doctor chooses
- Interaction of the lead and vagus nerve over time

 **Note:** See “Battery depletion (running out)” on page 51.

When the battery in your pulse generator runs out, the pulse generator must be replaced in order for you to continue to receive VNS Therapy. This requires an additional surgical procedure. The operation involves anesthesia and generally takes less than an hour to complete.

3.1.8. Start or stop the stimulation

 **Note:** See “How to Use Your Cyberonics Magnets” on page 41.

At any time, you can start or stop the stimulation with a Cyberonics magnet.

4. PATIENT TIPS _____

These tips provide important information about the VNS Therapy System. They will be most useful after you have read the whole manual.

 **Note:** See “Frequently Asked Questions” on page 54.

When you see this symbol , pay special attention to the important information after it.

After you receive your VNS Therapy System, keep this important information in mind:

- **Check the pulse generator battery daily** by starting stimulation with the Cyberonics magnet.
- You should not receive a VNS Therapy System implant if your left vagus nerve has previously been cut.
- You CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy anywhere on your body if you have an implanted VNS Therapy System.
- **Use the Cyberonics magnet to stop the stimulation** if it becomes painful or irregular.
- **Call your doctor right away** if any of the following occur:
 - ◆ Your voice is constantly hoarse.
 - ◆ The stimulation becomes painful or irregular.

 **Note:** See “To check the pulse generator battery” on page 46.

 **Note:** See “How to Use Your Cyberonics Magnets” on page 41.

- ◆ The stimulation causes any choking, trouble with breathing, trouble with swallowing, or change in heart rate.
- ◆ You or someone else notices changes in your level of consciousness (e.g., you become constantly drowsy).
- ◆ You think that the pulse generator may not be stimulating properly or that the VNS Therapy System battery is depleted (stops stimulating).
- ◆ You notice anything new or unusual that you relate to the stimulation.
- ◆ The feeling that you usually have during stimulation becomes stronger or weaker.
- ◆ Your seizure rate, intensity, or duration (or any combination) increases.

 **Note:**
See
“Device
Complications” on
page 50 and “Side
Effects” on
page 26.

 **Note:** See
“MRI
Warnings”
on page 19

- Call your doctor before you have **any medical tests** that might affect, or be affected by, the VNS Therapy System, such as magnetic resonance imaging (MRI) scans.
- There are many types of MRI scans a patient cannot have, but MRI can be done under specific conditions. **Call your doctor before you have an MRI scan.**
- Consider registering with an emergency service such as MedicAlert[®] Foundation (www.medicalert.org) so information about the VNS Therapy System will be available to

hospital and emergency response personnel when needed. If you have questions about the MedicAlert Foundation, discuss it with your doctor.

- Call your doctor before you have **any other medical devices implanted**.
- Tell your doctor at your next visit if you no longer feel the routine stimulation. Your doctor may decide to change your settings.

Cyberonics *cannot provide* healthcare advice or services. Your source for health questions must always be your doctor.



Note: See “Medical Hazards” on page 22.

5. WHO USES VNS THERAPY? _____

Doctors prescribe VNS Therapy for people with certain types of seizures and medical backgrounds. It *is not right* for everyone who has epilepsy. Your doctor will decide if your seizures are the correct type to treat with VNS Therapy. Your doctor will also decide if you have any other medical conditions that might be affected by VNS Therapy.

5.1. Indications for Use

The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epilepsy 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 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.

5.2. Contraindications (When VNS Therapy Should Not Be Used)

- 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).
- 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”). **Diagnostic ultrasound is not included in this contraindication.**

Diathermy is a treatment to promote healing or relieve pain. It is provided by special medical equipment (diathermy equipment) in a doctor’s office, dentist’s office, or other healthcare setting.

Energy from diathermy therapy may cause heating of the VNS Therapy System. The heating of the VNS Therapy System resulting from diathermy can cause temporary or permanent nerve, tissue, or vascular damage. This damage may result in pain or discomfort,

loss of vocal cord function, or even possibly death if there is damage to blood vessels.

Diathermy may also damage parts of your VNS Therapy System. This damage can result in loss of therapy from your VNS Therapy System. More surgery may be required to remove or replace parts of your implanted device.

Injury or damage can occur during diathermy treatment whether your VNS Therapy System is turned “ON” or “OFF.”

- 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.

6. WARNINGS AND PRECAUTIONS _____

As with all types of treatment for epilepsy, VNS Therapy carries some risks. Talk to your physician about other risks not covered in this manual that you should know about. Also, be sure to ask any questions that you have about any of the following warnings, precautions, side effects, and possible hazards.

6.1. Warnings

With your doctor, review the warnings that follow, as well as any other issues that might be appropriate to discuss, such as status epilepticus and sudden unexplained death in epilepsy.

- **Avoid excessive vagus nerve stimulation**, which 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
 - ◆ Progressive neurological diseases other than epilepsy or depression

- ◆ Heart arrhythmias (irregular heart beats) or other heart abnormalities
 - ◆ History of dysautonomias
 - ◆ History of lung diseases or disorders, including shortness of breath and asthma
 - ◆ History of ulcers (gastric, duodenal, or other)
 - ◆ History of vasovagal syncope (fainting)
 - ◆ Only one vagus nerve
 - ◆ Other concurrent forms of brain stimulation
 - ◆ Pre-existing hoarseness
- **Swallowing difficulties**
Difficulty swallowing may occur with active stimulation, and aspiration may result from the increased swallowing difficulties.
 - **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).

■ **Device malfunction**

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

■ **Device removal**

Device removal requires an additional surgical procedure. When removing a device, the surgeon may leave part of the lead behind. This may pose certain risks.

■ **Device manipulation**

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

- **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.



Note: You should see your physician if you exhibit any signs or symptoms of obstructive sleep apnea or worsening obstructive sleep apnea.



Note: See “Medical Hazards” on page 22.

i **Note:** For detailed MRI-related information, your doctor should refer to the *MRI with the VNS Therapy System* part of the physician's manual.

6.1.1. MRI Warnings

- **Before having Magnetic resonance imaging (MRI)**
You should contact your doctor before having any MRI performed so that it can be discussed with the MRI personnel. An MRI can be performed under certain conditions. *Before* undergoing an MRI scan, the VNS system diagnostic information needs to be collected and the current turned off. The current will need to be turned on again after the scan is completed.
- **Conditions where MRI should not be performed**
You should not have an MRI performed on your head, neck, or upper torso using a transmit RF body coil if you have the full VNS System implanted or if you have more than 2 cm of the lead remaining following removal of the VNS system. Heating of the lead caused by the transmit RF body coil during MRI may result in serious injury (e.g., burning of the vagus nerve and surrounding tissue). Also, there should be no exposure of the VNS System to any local RF coil.
- **If an MRI is needed**
 Additional surgery may be required to remove the VNS Therapy System if an MRI is needed.
- **MR Unsafe** 
 The VNS patient magnet, programming

computer, and programming wand are **MR Unsafe**. Do not carry these items into the MR scanner room. The magnet, programming computer and programming wand could become dangerous flying objects 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, if necessary.
- **MRI may change the pulse generator settings** (i.e., reset parameters) or turn on Magnet Mode stimulation (if “ON”). Stimulation has been shown to cause adverse events, as reported in the “Common side effects” on page 27 section of this manual.
- **Call your doctor** if you have questions about having an MRI scan.

6.2. Precautions

- **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 irritation.
- **Use during exercise (Model 106 only)**
Exercise or physical activity may trigger

Automatic Stimulation if the feature is ON due to heart rate changes detected by the device.

6.3. Environmental Hazards

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

6.3.1. Pacemaker Warning signs

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

6.3.2. Small appliances

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

6.3.3. Cellular phones

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

6.3.4. Transmitting devices

Properly operating electrical ignition systems and power transmission lines *should not affect* the pulse 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.

6.3.5. Antitheft devices, airport security systems, and other metal detectors

Antitheft devices and metal detectors should not affect the pulse 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.

6.3.6. Devices with strong electromagnetic fields

Electrical or electromechanical devices with a strong static or pulsing magnetic field can cause the pulse 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 pulse generator stops while you are in a strong electromagnetic field, move away from the source so the device may return to regular operation.

6.4. Medical Hazards

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

6.4.1. Routine diagnostic procedures

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

6.4.2. Mammography

Because the pulse 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.

6.4.3. Radiation treatment

Treatment with radiation, cobalt machines, and linear accelerators *may damage* the pulse generator. Note that 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.

6.4.4. Other procedures

External cardiac defibrillation and other procedures for heart problems, as well as extracorporeal shockwave lithotripsy, diathermy, and electrocautery, *may damage* the pulse generator. If you had any of these procedures and your doctor did not know about it, have the pulse generator checked.

While *diagnostic* ultrasound *should not affect* the VNS Therapy System, *therapeutic* ultrasound therapy *could damage* the pulse generator or inadvertently harm you.

6.5. Interference with Other Devices

While the pulse 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.

6.5.1. Radios and hearing aids

The pulse 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 pulse generator could affect them, but no effects have yet been reported. No detailed testing has been done, so the effects are unknown.

6.5.2. Implanted devices

The pulse 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 pulse generator.

6.5.3. Credit cards and computer disks

The Cyberonics magnets are very strong. They *can damage* televisions, computer disks, credit cards,

and other items that are affected by strong magnetic fields. Keep your magnet at least 25 centimeters (10 inches) away from any of these items. **Do not carry or store the magnets near them.**

7. CLINICAL STUDY PARTICIPANTS

Safety and effectiveness studies of VNS Therapy involved more than 450 people (both men and women). Most of these people had uncontrolled partial onset seizures. Most had more than six seizures a month, but all had at least one seizure a month in spite of taking drugs for epilepsy. The typical person in the study was about 33 years old (ages ranged from 3 to 63). He or she had epilepsy for more than 20 years before trying VNS Therapy.

Most took two drugs for seizures while they received VNS Therapy.

Some of them have now received VNS Therapy for more than 10 years. Worldwide, more than 40,000 people have had the VNS Therapy System implanted. If you would like to learn more about these research studies, talk to your doctor.

7.1. Side Effects

Some side effects are linked with the VNS Therapy System and stimulation. As a rule, they become less noticeable over time for most patients. Other problems, such as trouble breathing, can occur if device settings are set too high at first or are increased too rapidly, or if the device is started too soon after surgery. If this happens, your doctor can change the device settings.

The VNS Therapy System is not a drug. It does not cause drug-related toxic central nervous system side effects. Examples of such effects are memory loss, confusion, drowsiness (sedation), and difficulty concentrating.

7.1.1. Common side effects



Call your doctor any time hoarseness is painful, constant, or persists.

The most common side effect is hoarseness. Three other common side effects are sore throat, shortness of breath, and coughing. As a rule, these problems typically occur only during stimulation (the ON time of the cycle). Mostly, it lasts about 30 seconds every 5 minutes. Most people who have hoarseness, as well as the other three side effects, tolerate it well and notice it less as time goes on.



Testing magnet settings while you are in the doctor's office will help make sure you **can tolerate the settings**. Stimulation—or stopping it—can make seizures worse.

The following is a partial alphabetical list of the side effects possibly associated with the VNS Therapy System and reported during clinical trials of the VNS Therapy System. You may experience one or more of them. Talk to your doctor if any one of these items becomes too uncomfortable.

- Lack of coordination in the voluntary muscles (ataxia)
- Difficulty breathing, shortness of breath (dyspnea)
- Hoarseness (voice alteration)
- Impaired sense of touch (hypesthesia)
- Inability to sleep (insomnia)
- Increased coughing

- Indigestion (dyspepsia)
- Infection
- Inflammation of the throat (pharyngitis)
- Muscle movements or twitching generally associated with stimulation
- Nausea
- Pain
- Prickling of the skin (paresthesia)
- Throat, larynx spasms (laryngismus)
- Vomiting

These side effects could *potentially* occur:

- Aspiration (fluid in the lungs)
- Blood clotting
- Choking sensation
- Damage to nerves or blood vessels in the surgical area, including the carotid artery and jugular vein
- Device (pulse generator and/or lead) migration or extrusion
- Difficulty swallowing (dysphagia)
- Dizziness
- Duodenal ulcer, gastric ulcer
- Ear pain

- Facial flushing
- Facial paralysis, paresis
- Foreign body reaction to implants, including possible tumor formation
- Formation of fibrous tissue, pockets of fluid
- Heart rate and rhythm changes
- Hiccupping
- Incision site pain
- Irritability
- Left hemidiaphragm paralysis
- Left vocal cord injury or paralysis (affects voice)
- Low-grade fever
- Muscle pain
- Neck pain
- Nerve injury
- Painful or irregular stimulation
- Ringing in the ears (tinnitus)
- Skin, tissue reaction
- Sore, painful throat (laryngeal irritation)
- Stomach discomfort
- Tooth pain

- Unusual scarring at the incision site
- Urinary retention
- Vagus nerve paralysis
- Weight change
- Worsening of asthma and bronchitis
- Worsening of cardiac abnormalities, including heart rate and rhythm

7.1.2. *Surgical complications*

These surgical complications are sometimes linked with the VNS Therapy System. They may be short-term or long-term.

- Infection
- Pain at the incision site
- Tissue reactions, (responses of the skin) such as inflammation (redness) and skin irritation (soreness, itchiness)
- Blood clotting
- Pockets of fluid or fibrous tissue around the implanted devices
- Damage to or paralysis (loss of movement) of nearby nerves or muscles
- Hoarseness
- Changes or abnormalities in heart rate or function



Implantation of the lead may cause nerve constriction (squeezing of the nerve). **Call your doctor right away** if your voice is always hoarse a few days after surgery. (There could be other explanations for this symptom.)



If you undergo VNS generator replacement with a larger size device, you may initially experience increased discomfort or inflammation at the surgery site. Call your doctor if you experience symptoms that are concerning or do not improve.

7.1.3. Surgical scars

Scars from the surgery can be lessened. Talk to your surgeon if you have specific concerns.

7.2. Sudden Unexplained Death in Epilepsy (SUDEP)



Sudden unexplained death in epilepsy (SUDEP): Through August 1996, 10 sudden and unexplained deaths (definite, probable, and possible) were recorded among the 1,000 patients implanted and treated with the VNS Therapy device. During this period, these patients had accumulated 2,017 patient-years of exposure.

Some of these deaths could represent seizure-related deaths in which the seizure was not observed, at night, for example. This number represents an incidence of 5.0 definite, probable, and possible SUDEP deaths per 1,000 patient-years.

An update was performed with U.S. patient data through February 2005. This data includes 31,920 tracked VNS patients with 81,918 patient-years of implant experience. The total death count during this period was 733, indicating an all-cause mortality rate of 8.9 deaths per 1,000 patient-years. Of these 733 deaths, 387 were found to be “definitely not SUDEP”, 112 to be “possible SUDEP” and 234 to be unclassifiable for lack of information. If combined, these last two categories indicate the highest possible SUDEP rate to be 4.2 per 1,000 patient-years, which is marginally less than previously observed.

Although this rate exceeds that expected in a healthy (nonepileptic) population matched for age and sex, it is within the range of estimates for epilepsy patients not receiving vagus nerve stimulation, ranging from 1.3 SUDEP deaths for the general population of patients with epilepsy, to 3.5 (for definite and probable) for a recently studied antiepileptic drug

(AED) clinical trial population similar to the VNS Therapy System clinical cohort, to 9.3 for patients with medically intractable epilepsy who were epilepsy surgery candidates.

8. BENEFITS OF VNS THERAPY

8.1. Reduced Seizure Rate

Successful VNS Therapy most often decreases seizure rate. Some patients have reported a large decrease, others only a slight decrease, and still others no decrease. On the whole, the patients involved in the VNS Therapy clinical trials had a statistically significant (mathematically important) decrease in their seizure rates.

8.2. Other Benefits

Many patients and doctors have seen other changes as well. For some patients, VNS Therapy has resulted in:

- Less severe or shorter seizures
- Better recovery after seizures (postictal period)
- Improved feeling of well-being
- Better mood
- Improved alertness, memory, and thinking skills
- Fewer emergency room visits

Doctors have been able to reduce the dose of seizure drugs for some patients.

8.3. Gradual Improvement

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.

8.4. Not a Cure for Epilepsy

But remember, VNS Therapy is not a cure for epilepsy. It does not work for everyone.

Doctors who tested the VNS Therapy System cite the “Rule of Thirds” about long-term results. In the long-term VNS Therapy studies, one-third of the patients had a *dramatic* improvement in seizure control, one-third had a *good* improvement, and one-third had *little or no* improvement. At present, doctors have no way to predict which patients will respond to VNS Therapy.

9. TO HAVE THE DEVICE IMPLANTED _____

VNS Therapy requires surgical placement of the pulse generator and lead by a surgeon. At office visits, your doctor checks the settings and changes them as needed.

9.1. Surgery (Operation)

Surgery lasts from about 1 to 2 hours and typically involves general anesthesia, though local anesthesia is sometimes used. You may stay in the hospital overnight.

The surgeon makes a small incision on the left side of the neck and a second incision below the collarbone in the chest or armpit. The surgeon passes the lead under the skin between the two incisions. Next, the surgeon attaches the lead to the left vagus nerve in the neck. Then the surgeon attaches the other end of the lead to the pulse generator, which is subsequently placed in a “pocket” created at the site of the incision that was made below the collarbone. Finally, the surgeon closes the incisions. See Figure 1 on page 6.

9.2. Follow Up After Surgery

The pulse generator is usually turned on 2 weeks after it is implanted. (Your doctor will program the pulse generator to the proper settings for you.) At that office visit and at subsequent visits, your doctor will check the VNS Therapy System. Your doctor



The operation can be reversed if you and your doctor ever decide to have the VNS Therapy System removed. Removal of the pulse generator and/or lead requires another surgical procedure. Sometimes when a surgeon removes a VNS Therapy System, the surgeon will decide to leave a portion of the lead behind in order not to risk damaging the vagus nerve. This may pose certain risks (see “Medical Hazards” on page 22).

will make sure that it is working well and that the treatment is not uncomfortable for you.



Cyberonics recommends that you see your doctor at least once every 6 months. Your doctor will check the VNS Therapy System for safe and effective operation.

You will continue to take your regular antiepileptic medications for at least 3 months after surgery before any medication change is attempted. For many patients, the medications will not be changed.

You will be given an Implant and Warranty Registration Card. It has information about your pulse generator and lead.



Carry the Patient Emergency Information Card at all times.

You will also receive a Patient Emergency Information Card. It has phone numbers to call in case of a device-related emergency.



Your doctor is your first source for health-related questions and information. Cyberonics *cannot* provide healthcare advice or services.

9.3. Antiepileptic Medications (Drugs for Seizures)

You will continue to take your drugs for epilepsy for at least 3 months after the operation. Your doctor may try to change your drugs after that time. For many patients, the medications will not be changed. Always follow your doctor's instructions about your medications.

9.4. Programming Modes

Your pulse generator is set for two types (modes) of stimulation: Normal and Magnet. A third mode (Automatic Stimulation) is available for you if you have the Model 106. Each mode is independent of the other. *Usually (but not always)*, the settings are different for the modes. Your doctor chooses and

sets the cycle time and the amount of current for each mode.

9.4.1. **Normal Mode**

Normal Mode stimulation has an automatic ON and OFF cycle—for example, 30 seconds ON and 5 minutes OFF. Your pulse generator operates in this mode most of the time.

9.4.2. **Magnet Mode**

Magnet Mode gives a single, on-demand stimulation. *On-demand* means that *you* control when it starts by using the magnet. Your doctor may set Magnet Mode stimulation longer than Normal Mode stimulation. The current may be a little higher so that you know when it starts. Magnet Mode can be used to start a single stimulation cycle and to check the battery.

If you feel no stimulation when you pass the magnet over the pulse generator, ask your doctor about increasing the magnet stimulation.



Note: If Magnet Mode has not helped you in the past, your doctor may have turned the Magnet Mode feature OFF. If it is OFF, you will not be able to use the magnet to start stimulation or to check the battery. **You will always be able to stop any stimulation (to turn your pulse generator OFF) with the magnet.**

9.4.3. Automatic Stimulation Mode (Model 106 pulse generator only)

 **Note:** AutoStim may not work for everyone, so you and your doctor may decide to turn this feature off. You will always be able to stop Normal, AutoStim, or Magnet Mode stimulation with the magnet.

AutoStim Mode is a feature that detects when a seizure is beginning or has begun by monitoring your heart rate. The stimulation is very similar to the stimulation of the Magnet Mode but does not require the use of the magnet. The current setting may be set equal to or a little higher than Normal Mode.

10. THE CYBERONICS MAGNETS _____

10.1. How to Handle the Cyberonics Magnets

After your operation, your doctor will give you two magnets. You should carry one of the magnets with you at all times in your pocket, in your purse away from credit cards, or in another convenient place. If you prefer, you can wear them like a watch or a pager (see Figure 3).

Both styles of Cyberonics magnets contain a high-power magnet that is surrounded by a plastic casing in the shape of a watch. These magnets should be operated and stored at temperatures ranging from -20°C (-4°F) to $+55^{\circ}\text{C}$ ($+131^{\circ}\text{F}$). With normal use, they should remain powerful for approximately 3 years.

The watch-style magnet attaches to your wrist with a wristband. The magnet should be on the inside of your wrist so that the label can be placed over the pulse generator to start or stop stimulation.

The pager-style magnet has a belt clip so that the magnet and clip can be removed without coming apart. To use the pager-style magnet, remove the belt clip and magnet from your belt. Place the label against the pulse generator (see Figure 3).



In case of a seizure —

The most common use for the magnet is to try to stop a seizure. If you feel an aura or a seizure beginning, start stimulation right away by passing the magnet over the pulse generator for 1-2 seconds. (See details in the sections that follow.)



Never put or store the magnets

near credit cards, televisions, computers, computer disks, microwave ovens, watches, or other magnets. Keep them at least 25 centimeters (10 inches) away.



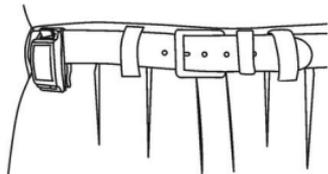
Do not drop the magnets.

They can break if dropped on a hard surface.

Figure 3. The Cyberonics Magnets



Cyberonics Magnet
(watch-style)



Cyberonics Magnet
(pager-style)



Carry a magnet with you at all times.

Show your family members or caregivers how to use the magnet in case they see you having a seizure.

10.2. How to Use Your Cyberonics Magnets

Each person has different results from using the magnet. Some people say that the magnet *stops* all or most seizures, *shortens* them, or *lessens* their intensity or their recovery period. For other people, the magnet has little or no effect. Even if the magnet has little effect for you, keep one with you at all times. You may need to turn OFF the pulse generator.

The magnet can be used in three ways:

1. **To start stimulation** (if the Magnet Mode feature was activated by your doctor)
 - When you are having an aura
 - When a seizure begins
 - During a seizure

2. **To stop stimulation temporarily or turn OFF the pulse generator**
 - When you plan to sing or speak in public (if stimulation bothers you when you do this)
 - When you are eating (if you have swallowing problems)
 - If stimulation becomes uncomfortable or painful
3. **To check daily that the pulse generator battery is working** (if the Magnet Mode feature was activated by your doctor)

10.2.1. To start stimulation

Pass (move) either magnet over the pulse generator for 1-2 seconds. *Stimulation will start right away after the magnet passes over the pulse generator. If difficulty is encountered with a single pass of the magnet, a cross-pattern swipe technique may also be used to activate the stimulation (see Figure 4 on page 43).*

There are three reasons why the magnet may not start stimulation:

1. The pulse generator is not working. For example, the battery has expired.
2. Your doctor has not activated the Magnet Mode feature.
3. You or your caregiver did not correctly apply the magnet to start stimulation.

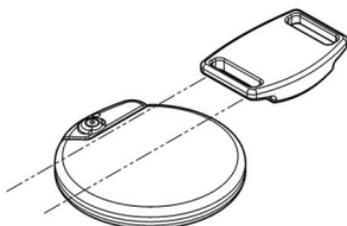


The correct position for the magnet may vary from patient to patient. The position depends on how the pulse generator is implanted. Find the position that works best for you.

i **Note:** To show the correct position of the magnet with the pulse generator, the magnet has been drawn without the belt clip or wristband. The belt clip and wristband use the same magnet.

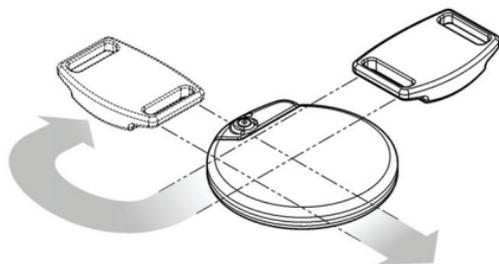
Figure 4. Start Stimulation

Standard Magnet Activation



! For Model 103, 104, 105, and 106 generators, the cross-pattern magnet activation technique may cause duplicate magnet activations to be shown in your doctor's records. Your doctor is aware of this and the duplicate magnet activation records are not considered a device malfunction.

Optional Cross-pattern Magnet Activation

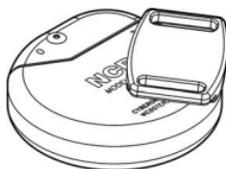


! Avoid over stimulation. More than 4 hours of *constant* stimulation (from magnet use) may hurt your left vagus nerve.

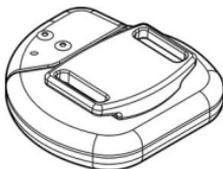
10.2.2. To stop stimulation

1. Put the magnet over the pulse generator (see Figure 5 on page 44). If the stimulation stays on, move the magnet around until it stops.

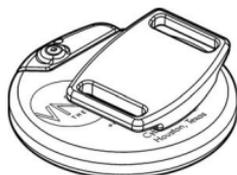
Figure 5. Stop Stimulation



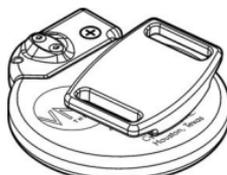
Model 100



Model 101



Model 102



Model 102R



Model 103



Model 104



Model 105



Model 106

2. Leave the magnet over the pulse generator. If needed, tape it to your chest or use an elastic, wrap-around bandage.

3. If you stopped the stimulation because it was painful or felt unusual, call your doctor right away.

The pulse generator will not stimulate while the magnet is in place, but it will start when the magnet is removed.

10.2.3. Things to remember about the magnets

10.2.3.1. Start stimulation

Pass the magnet over the pulse generator for 1-2 seconds to start the single Magnet Mode stimulation. If difficulty is encountered with a single pass of the magnet, a cross-pattern swipe, as shown in Figure 4 on page 43, may also be used to activate the Magnet Mode.

10.2.3.2. Stop stimulation

Place the magnet over the pulse generator. Hold it there for as long as you want the stimulation stopped.

10.2.3.3. Hold magnet less than 65 seconds (less than 3 seconds for Model 106)

If you hold the magnet in place **for less than 65 seconds (or 3 seconds for Model 106)** and then remove it, you will feel one Magnet Mode stimulation. Then your Normal stimulation cycle will start again.

10.2.3.4. Hold magnet more than 65 seconds (more than 3 seconds for Model 106)

If you hold the magnet in place **for longer than 65 seconds (or more than 3 seconds for Model 106)** and then remove it, you will not get a Magnet Mode stimulation. Instead, your Normal cycle will start again.



Note: The period for which you hold the magnet in place *does not count* as part of the set OFF time.

10.2.4. To check the pulse generator battery

Check the battery the same way that you start stimulation.

Pass (move) the magnet over the pulse generator for 1-2 seconds (see Figure 4 on page 43).

Stimulation will start after the magnet is removed.



Use the magnet each day to check that the pulse generator is working.



Note: The Magnet Mode feature is optional. For a few patients, it may not be used. Your doctor will decide whether to use it or turn it OFF. If it is OFF, you will not be able to use the magnet to start stimulation or to check the battery. **You will always be able to stop stimulation (to turn the pulse generator OFF) with the magnet.** If you feel nothing when you pass the magnet over the pulse generator, ask your doctor about increasing the magnet stimulation to a level that you can feel.

10.3. How the Magnets Work

The VNS Therapy System senses a magnetic field. When you pass or hold a magnet over the pulse generator, a **reed switch** inside the pulse generator closes. This switch works like a gate. When the magnet closes it, the Normal signal (stimulation) cannot pass. The pulse generator is temporarily turned OFF.

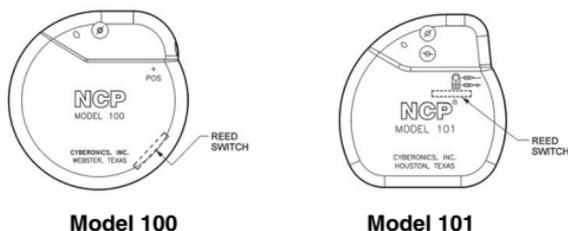
When the magnet is removed, the switch (gate) opens right away. The VNS Therapy System is turned back ON and can stimulate again.

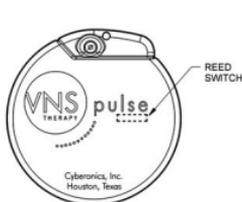
10.3.1. Find the reed switch

You may need to move the magnet around to find the reed switch and start stimulation (Figure 4 on page 43) or stop stimulation (Figure 5 on page 44).

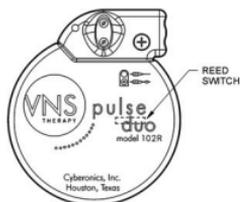
The label side of the magnet should face the reed switch. Figure 6 shows the position of the switch.

Figure 6. Reed Switch Position

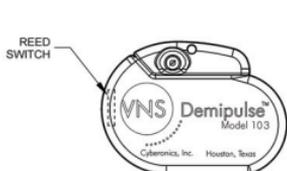




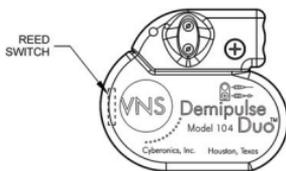
Model 102



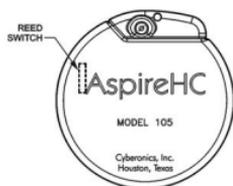
Model 102R



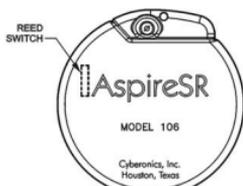
Model 103



Model 104



Model 105



Model 106

10.3.2. Know your magnets

These tips are also given elsewhere in these instructions. Be sure that you understand them.

- **Use the magnet *as often as you like, but not longer than 4 hours in a row.*** Continuous or frequent magnet use will deplete (use up) the pulse generator battery and could hurt your left vagus nerve. If you need to use the magnet a lot, you may want to have your Normal

stimulation settings changed. Discuss this change with your doctor during your next visit.

- **With your doctor's permission, it is okay to leave the magnet in place** for a short while, for example, to sing a song. The pulse generator will not stimulate while the magnet is in place. The Normal Mode cycle begins again when the magnet is removed.
- **If stimulation hurts**, hold the magnet over the pulse generator and keep it there. The stimulation will stop as long as the magnet is there. If necessary, tape the magnet in place. Contact your doctor right away.
- **Always carry the magnet with you.** Show your family members or care givers how to use it in case they see you having a seizure.
- Keep the magnets away from credit cards, computer disks, watches, and other items affected by strong magnetic fields.
- **If you lose one of your magnets and need a replacement**, contact your doctor.
- **And remember—if you are not sure how to use the magnets, ask your doctor to show you how.**

10.4. How to Replace the Cyberonics Magnets

To order a new magnet, contact your doctor. You may also request a copy of this Patient's Manual.

11. OTHER IMPORTANT INFORMATION ABOUT YOUR VNS THERAPY SYSTEM

11.1. Device Complications

Complications linked to the VNS Therapy System can result from:

- Surgery
- Pulse generator malfunction (not working)
- Battery depletion (running out)
- Touching or moving the device through the skin

11.1.1. Surgery

Like a heart pacemaker, the VNS Therapy device is implanted during surgery. One incision is made in the neck to attach the lead to the vagus nerve, and a second incision is made in the chest for the pulse generator. All types of surgery carry some risks. In addition to the risks described in the earlier section of this manual that summarized the experience from clinical studies, there are potential mechanical complications related to the surgical implantation of the device. The pulse generator and/or lead can—but rarely do—move or come through the skin. Also, the lead can break or become disconnected from the pulse generator.

11.1.2. **Pulse generator malfunction (device not working right)**

The pulse generator can malfunction, though this is rare. The stimulation from a pulse generator that is not working right can cause intense neck pain, hoarseness, choking, or trouble breathing.



Stimulation from a pulse generator that is not working right could damage the vagus nerve and lead to permanent hoarseness or other complications. Malfunction of the pulse generator could cause the battery to run out sooner than expected. **If you have any of these symptoms**, or if stimulation becomes painful, irregular, or nonstop, place the magnet over the pulse generator. Hold it there to stop stimulation (see “How to Use Your Cyberonics Magnets” on page 41), then **call your doctor right away**.

11.1.3. **Battery depletion (running out)**



Note: See “To check the pulse generator battery” on page 46 for how to tell if the device is stimulating.

The battery in your pulse generator will normally last between 1 to 16 years, depending on the settings. The pulse generator battery will slowly lose its power. When it starts to run out, it will begin to stimulate differently. You may sense this change as irregular stimulation. At the end of battery life, the stimulation will stop completely.

The dose settings impact how long the battery in the pulse generator will last. For example, the battery may last for 3 years at a higher setting, compared with 8 years at a lower setting. For the full range of settings in relationship to battery life, ask your doctor.

When the battery in your pulse generator runs out, the pulse generator must be replaced in order for you to continue to receive VNS Therapy. This requires an additional surgical procedure. The operation involves anesthesia and generally takes less than an hour to complete.

Replacement or removal of the lead is a different procedure. It is not required for routine replacement of the pulse generator.



After stimulation stops (when the pulse generator battery runs out), seizure rate, intensity, or duration may increase. If Normal stimulation stops, your seizures may become worse than before stimulation started. If you think the pulse generator might not be working right, call your doctor.

11.1.4. Manipulation of the pulse generator and lead

The pulse generator is secured into place during surgery, but the device can move slightly. It may be possible to feel the lead under the skin after surgery. This feeling is normal. It should become less apparent over time (several weeks). Manipulation of the lead should be prevented at all times.



Never move or twist the pulse generator or manipulate the lead. Doing so could damage the lead or your vagus nerve. It could require that the pulse generator and lead be replaced.

12. CYBERONICS' PATIENT WARRANTY AND SAFETY LISTING



Please send
Cyberonics
**a change of
address notice** if
you move.

Government agencies require makers of implantable devices to contact people in case of emergencies related to the device. Cyberonics has a list of people who have had the pulse generator and lead implanted. The information is kept in confidential files. It is a permanent record of the implantation surgery. In some cases, the file has information on seizures. Cyberonics will release a file only if required by law.

13. FREQUENTLY ASKED QUESTIONS _____

Patients and their family members often ask these questions.

How do most people respond to VNS Therapy?

When the device was tested in the clinical trials, the seizure rate decreased for most patients. Some patients had no change or had an increase in seizure rate. Some patients do not have a clear decrease in seizure rate until after they have had many months of VNS Therapy.

Can I know if I will be helped before I am implanted with the pulse generator and lead?

At this time, there is no way to predict what your response will be.

What are the results of the VNS Therapy clinical trials?

This manual provides a summary of important safety and effectiveness results from the clinical studies. Your doctor can give you information about the clinical (research) studies.

What is the implantation surgery like?

You will be given a general or local anesthetic. The operation usually takes 1 to 2 hours. You will probably stay in the hospital overnight. Ask your surgeon to tell you more about the

anesthetic, the operation, and the hospital stay so that you will know what to expect.

Are there risks linked with the surgery?

Any surgery has some type of risk. It is important that you discuss this question with your surgeon.

Will the scars be noticeable?

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

Will people be able to see the implanted device through my skin?

The pulse generator is shaped like a disk. The Model 100 is about 5.5 centimeters (2.2 inches) across and 1.32 centimeters (0.5 inch) thick. It is about the size of a thick pocket watch and weighs about 55 grams (1.94 ounces). The Model 101 is slightly smaller—5.4 centimeters (2.1 inches) across and 1 centimeter (0.4 inch) thick; it weighs about 38 grams (1.34 ounces). The Model 102 is even smaller overall—5.2 centimeters (2.0 inches) across and 0.7 centimeter (0.27 inch) thick; it weighs about 25 grams (0.88 ounce). The Model 102R is 5.2 centimeters (2.0 inches) by 5.8 centimeters (2.3 inches) and 0.7 centimeter (0.27 inch) thick; it weighs about 27 grams (0.95 ounce). The

Model 103 is 4.6 centimeters (1.8 inches) by 3.3 centimeters (1.3 inches); it weighs about 16 grams (0.56 ounce). The Model 104 is 4.6 centimeters (1.8 inches) by 4.1 centimeters (1.6 inches); it weighs about 18 grams (0.63 ounce). The Model 105 and 106 are 5.2 centimeters (2.0 inches) across and 0.7 centimeter (0.27 inch) thick; it weighs about 25 grams (0.88 ounce). If you have a small frame or are very thin, the device may be visible below your left collarbone.

What happens after the surgery?

Your doctor will set your treatment settings into your device. If the stimulation feels uncomfortable, your doctor can change it to make you more comfortable. The doctor will use the programming wand to check and fine-tune your stimulation settings at each visit.

Your pulse generator will work automatically. But you can use the magnet to start or stop stimulation at any time. Your doctor will show you how and when to use it.

Will I be able to tell when the stimulator is on?

Many people note a tingling feeling or a change in their voice (hoarseness) during stimulation. This effect usually becomes less noticeable over time.

i **Note:** See “Side Effects” on page 26 for information about less common side effects.

What are the side effects of VNS Therapy?

The most common side effects reported for the VNS Therapy System are a tingling sensation in the neck and mild hoarseness in the voice, both of which occur only during stimulation.

What does the magnet do?

The magnet can both start and stop stimulation. Your doctor must activate the Magnet Mode before you can start stimulation with the magnet. To receive extra stimulation, put the magnet over the pulse generator and then move it away. The device will deliver extra stimulation apart from your treatment schedule.

You can easily use the magnet yourself. Your family, companions, or caregivers can use it for you if you are having a seizure. To turn OFF the stimulation, hold the magnet over the pulse generator. Remove the magnet to restart the Normal stimulation cycle.

Can I stop all my seizures with the magnet?

Results from magnet stimulation differ for each person.

Some people report that the magnet stops all or most of their seizures, lessens the intensity, or shortens the duration. For others, the magnet has limited or no effect.

When should I use the magnet?

Use the magnet in these three circumstances:

1. To start stimulation
 - a. When you are having an aura that comes before a seizure
 - b. When you believe you are beginning a seizure
 - c. Any time during a seizure
2. To stop stimulation
3. To test that the device is operating properly

Do I have to use the magnet to try and stop a seizure?

No. Whether you use the magnet or not is completely up to you and whoever is with you. It may also depend somewhat on whether the magnet has helped before. Remember, Cyberonics recommends using the magnet daily to test that the device is working right.

How does the magnet work?

The pulse generator has a sensor (the reed switch) that recognizes the magnet and starts extra stimulation.

Can any magnet be used?

Only the Cyberonics magnet should be used with your VNS Therapy System. If you lose your magnet or require extra magnets, contact your doctor. In an emergency, you may try

other strong magnets. The use of other, non-Cyberonics magnets will not harm the VNS Therapy System, but there is no way to know whether a magnet other than the Cyberonics magnet will work.

Will the magnet affect my normal treatment schedule?

The magnet overrides your normal treatment schedule, whether or not the device is “ON” at that time. Once the magnet-activated stimulation ends, the device will return to the treatment schedule set by your doctor.

How often can I use the magnet?

Use the magnet as often as you like, but for no more than 4 hours (1 stimulation right after another). Constant or frequent use of the magnet will use up the battery in the pulse generator and could hurt the nerve. If you use the magnet often, your normal device settings may need to be changed. Discuss this fact with your doctor during your next visit.

Depending on the settings, the magnet starts the device for 7 to 60 seconds each time you use it. Using it again during the same period has no effect on output amplitude, but will restart the magnet ON time. Wait until the stimulation ends before trying it again.

What if the magnet is accidentally kept in place over the pulse generator for an extended period?

No stimulation will be delivered while the magnet is kept over the device. Normal and magnet-started stimulations will resume only after the magnet is removed.

Is it possible to stop all stimulation using the magnet?

Yes. To stop stimulation, hold the magnet over the pulse generator and keep it there. Use this method if you have unusual or painful stimulation. Then call your doctor right away. The magnet will stop all stimulation while it is held in place. You may need to secure the magnet by taping it over the device.

Who should carry the magnet?

You should carry the magnet so that it is always with you. You may also want your family members or caregivers to have access to a Cyberonics magnet. They can apply it if they see you having a seizure.

Is the magnet an environmental hazard?

The Cyberonics magnet can damage computer disks, credit cards, watches, and other items affected by strong magnetic fields. Keep your magnet at least 25 centimeters (10 inches) away from any of these items. Do not store magnets near such items.

Will dropping my magnet affect its strength?

Dropping your magnet should not affect the magnet's strength. This is a problem that afflicts low-power magnets. The Cyberonics magnet is a high-power magnet and should not lose its strength when dropped or if the casing cracks.

How long will my magnet last (does it have an expiration date)?

Based on normal use, the Cyberonics magnet should have an approximate service life of 3 years.

Will all of my seizures be detected if I have the Model 106 generator?

It depends. Several factors determine how accurately the Model 106 device can detect seizures, and results can vary from patient to patient. Since your doctor is most knowledgeable about your medical condition and history, you should contact him or her if you have questions regarding the seizure detection feature of the Model 106.

If I have the Model 106 generator and Automatic Stimulation is activated, does that mean I'm about to have a seizure?

Not in all cases. The Automatic Stimulation is designed to trigger based on changes in your heart rate, which may signal the start of a seizure. 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.

Other questions?

If you have other questions about the VNS Therapy System, any of its parts, or VNS Therapy in general, talk to your doctor.

14. CONTACT INFORMATION _



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REP

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