



# A small change can make a big difference

Patient DVD and Frequently Asked Questions

Cyberonics®

# Introduction

Epilepsy is a common condition that affects up to six million people in Europe. Its treatment varies from person to person, but there are some general patterns. Most people with epilepsy can be controlled with an antiepileptic drug, or a combination of drugs. However, a third of the patients with epilepsy cannot be seizure free with drugs alone and are referred to by doctors as having 'difficult-to-treat' epilepsy.

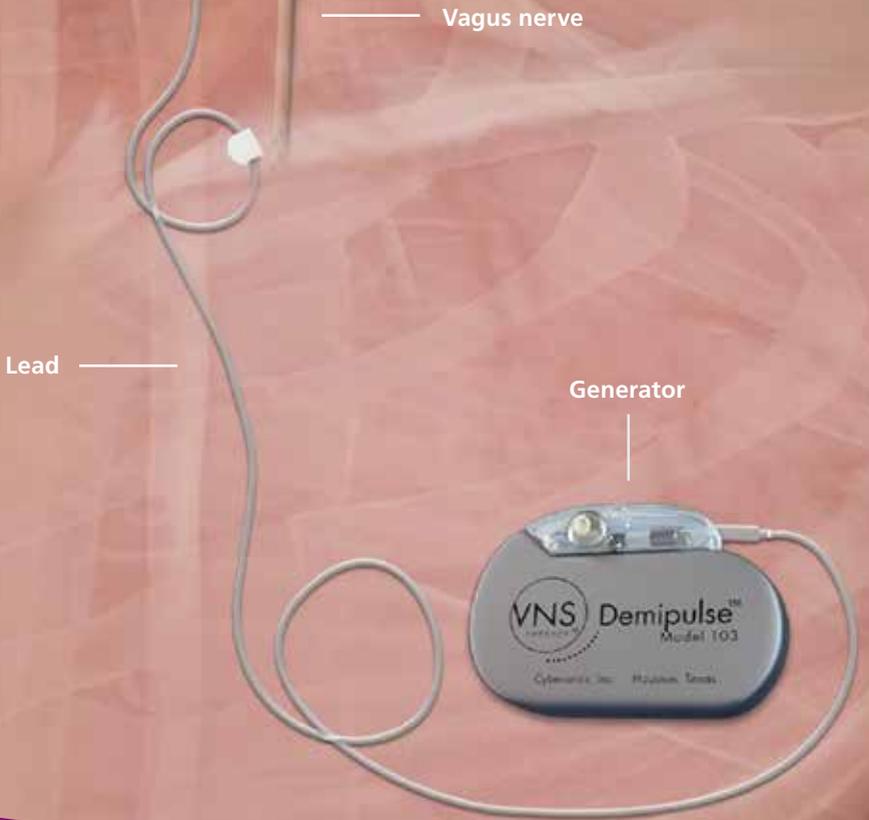
Having 'difficult-to-treat' epilepsy is not the end of the story. Indeed, other treatment options might be proposed to those patients. One option is Vagus Nerve Stimulation or VNS Therapy.

It is the recommendation of your doctor that you consider VNS Therapy because your seizures are not satisfactorily controlled by the medication you are taking, or perhaps you are not happy with your current treatment.

This booklet will help answer some questions you may have after watching the DVD. If you need further information, please ask your doctor or nurse.



A small generator about the size of a watch is placed under the skin usually in the left chest area. A thin, flexible wire connects the generator to the left vagus nerve under the skin in the neck.



# VNS Therapy basics

## **Q** What is VNS Therapy?

**A** VNS Therapy stands for Vagus Nerve Stimulation Therapy. VNS Therapy uses a small medical device to send electrical impulses to the left vagus nerve in the neck. Those electrical impulses are then sent from the vagus nerve to the brain and help to prevent the electrical irregularities that cause the seizures.

## **Q** What is the vagus nerve?

**A** The vagus nerve is a major communications link between the body and the brain. It sends sensory and motor information from the body to the brain and from the brain to the body. There is one nerve on each side of the body. For the purpose of VNS Therapy, the left vagus nerve is stimulated.

## **Q** What does the VNS Therapy device look like?

**A** VNS Therapy uses a small pacemaker-like medical device (the pulse generator) that sends small electrical pulses to the left vagus nerve in the neck via a lead and electrodes.

## **Q** How often does the device send electrical impulses?

**A** VNS Therapy helps prevent the electrical irregularities that cause seizures. Depending on each individual, the electrical pulses are sent approximately every three to five minutes to the brain for 30 seconds or so. The output current will also be adapted to your particular needs. Once the VNS Therapy generator has been set by your doctor or nurse, it will continuously cycle as programmed, 24 hours a day, every day for many years without you having to think about it.

**Q What sort of procedure is involved with implanting the device?**

**A** VNS Therapy is not brain surgery. Implanting the device involves a simple surgical procedure that requires only two small incisions (in the neck and in the left chest area). It is a short procedure usually done under general anaesthesia and entails only a short stay in the hospital.

**Q Does the implantation hurt?**

**A** After the surgery, you may feel some pain where the incisions have been made. This will only last for a few days and your doctor or nurse may recommend painkillers for this short period of time.

**Q Will I see the device after it is implanted?**

**A** Apart from tiny scars, which fade with time and blend in with the natural fold of your neck, and a slight bulge in your chest, the device is hardly noticeable.

**Q What sort of scars will I have with VNS Therapy?**

**A** There are usually two scars, one below the left collarbone or close to the armpit to place the pulse generator and the other in the neck, on the left side, to position the electrodes. They are not large scars and may even be obscured by the folds in the skin.

**Q When does the device need to be replaced and what happens then?**

**A** There is a tiny battery in the device that generates the electrical pulses. Usually, this battery lasts between five to ten years. The battery life depends on the current and other settings that are used. During your follow-up visits, the doctor or nurse will check the battery life. When the battery is running low, they will arrange for a new one to be implanted. This involves an even smaller operation as only the generator has to be replaced. The operation takes less than one hour and can be done under general or local anaesthesia.

# After the implantation

## **Q** What happens straight after implantation?

**A** Shortly after implantation, you will be asked to return to the hospital to see your doctor or nurse, initially every two weeks or so. This is to monitor your progress and adjust the settings of the VNS Therapy device. Later, visits may be every few months.

## **Q** How do I adjust the settings?

**A** During scheduled visits, your doctor or nurse will adjust the settings as appropriate for you. Once the VNS Therapy device is programmed, it will cycle continuously without you having to think about it.



## **Q** How does the doctor or nurse adjust the settings?

**A** During scheduled follow-up visits, the VNS Therapy device may be adjusted by your doctor or nurse, according to your response to date. This is done through a wand and a handheld computer. The wand is placed over the device and through the handheld computer your doctor or nurse can read and adjust the stimulation settings. This is painless and can even be done through your clothes.



Generators Actual Size

# The results of VNS Therapy

## **Q** What is the 'success rate'?

**A** 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, patients involved in VNS Therapy clinical trials had a significant decrease in their seizure rates.

## **Q** How soon can I see results?

**A** The benefits of VNS Therapy are not always noticeable immediately. The effects may take from a few months up to one or two years to reach their optimum level. These positive effects do not typically wear off; in fact, they may even improve over time.

## **Q** How will my everyday life change?

**A** In addition to experiencing fewer and less severe seizures, many VNS Therapy patients report an improvement in mood, alertness and memory. It has also been reported that these patients make fewer unplanned visits to the hospital.

## **Q** Will I still need my medication?

**A** This depends on the results from VNS Therapy. Some doctors prefer to keep the medication unchanged for several months. Indeed, it may be necessary to continue with antiepileptic medication in addition to VNS Therapy, but many patients and their doctors report a reduction in the number and/or doses of medications over time. Your doctor or nurse will advise you at each visit.

# The magnet

**Q** What is this magnet for?

**A** The magnet immediately activates the VNS Therapy device.

**Q** When do I use the magnet?

**A** The VNS Therapy magnet can be used when you feel a seizure coming on, or during a seizure.

**Q** What does it do and how do I use it?

**A** Swiping the VNS Therapy magnet over the device activates an extra stimulation, which may either potentially stop the seizure, shorten the seizure or decrease the intensity of the seizure. It may also improve the recovery period following the seizure.



**Q** What happens if I hold the magnet to the device, rather than swiping?

**A** Fixing and holding the VNS Therapy magnet over the device temporarily stops stimulation. This is useful during times or activities when even mild side effects could be inconvenient.



# Other concerns

## **Q** How safe is VNS Therapy?

**A** VNS Therapy has been clinically proven to provide a safe therapy. Over 70,000 people with epilepsy worldwide have been treated with VNS Therapy.

## **Q** Will the side effects be the same as my medication?

**A** VNS Therapy is not a drug. It does not cause drug-related toxic central nervous side effects, such as memory loss, confusion, drowsiness (sedation) and difficulty concentrating.

## **Q** So what are side effects of VNS Therapy?

**A** The most common side effects of VNS Therapy may include temporary hoarseness or changes in voice tone, coughing, tickling in the throat and shortness of breath. These side effects generally occur during the stimulation periods and typically decrease over time.

## **Q** Does VNS Therapy interact with my medication?

**A** No. There are no interactions with medication.

## **Q** What about using household electronic equipment?

**A** There is no effect whatsoever generated by household appliances, such as microwave ovens and mobile telephones, on the VNS Therapy device. Nor does the device affect the normal operation of these household devices.

## **Q** What about travelling, especially metal detectors?

**A** Again, there is no specific reason to be concerned about. The VNS Therapy device should not be affected by, nor does it affect, security systems such as metal detectors. As a precaution, move through them at a steady pace and do not linger in the area.



### **Q** What about other medical procedures?

**A** There are no specific precautions you need to take, with two exceptions: **Therapeutic Diathermy** (a treatment to promote healing or relieve pain): Patients with VNS Therapy should not be exposed to short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy. You should inform your healthcare professional about this.

**Magnetic Resonance Imaging (MRI):** Special precautions must be taken. You should always consult your doctor before having an MRI.

### **Q** Is VNS Therapy safe for pregnant women?

**A** In some experimental animal studies, no impairment of fertility or harm to the foetus has been shown due to VNS Therapy. In case you want to become pregnant or you are pregnant, contact your doctor.

### **Q** Can I have a shower with the VNS Therapy device?

**A** Yes, you can have a shower or wash yourself without any problem. The device is not affected by water.

### **Q** Are some sports not allowed for patients implanted with a VNS

#### **A** Therapy generator?

You should always consult your doctor or nurse before engaging in unsupervised activities, such as driving and swimming, and in strenuous sports that could harm you or others.

### **Q** What will happen if VNS Therapy doesn't work for me?

**A** If VNS Therapy has not helped you after one or two years, or you and your doctor consider VNS Therapy as ineffective in any way, there are several options. The device can simply be turned off and remain in your chest for an indefinite period of time. The generator may also be removed if you prefer or your doctor recommends it. This will involve a minor surgical procedure. Importantly, if you have VNS Therapy, you are still a candidate for any new treatment that could emerge in the future, for instance, new surgical procedures or new drugs.

# Information

- 1 More information can be found on [www.VNSTherapy.com](http://www.VNSTherapy.com)
- 2 Extensive information on VNS Therapy can be found in the [Patient's Manual](#).
- 3 If you still have questions about VNS Therapy, please contact your [doctor or nurse](#).

## References:

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- DeGiorgio C. et al. Vagus nerve stimulation for epilepsy: Randomized comparison of three stimulation paradigms. *Neurology* 2005;65:317-319.
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- Physician's Manual: VNS Therapy™ Pulse Model 102 Generator. Cyberonics, Inc. Houston, Tex; July 2007.
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# Safety Information for VNS Therapy

## Brief Summary\* of Safety Information for the VNS Therapy® System

[Epilepsy Indication] (February 2014)

**Epilepsy (Non-US)**—The VNS Therapy system is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications. The Model 106 AspireSR™ (Seizure Response) features the Automatic Stimulation Mode, which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

### CONTRAINDICATIONS

The VNS Therapy system cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy system.

Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether the VNS Therapy system is turned “ON” or “OFF.”

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

### WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, or in strenuous sports that could harm them or others. The safety and efficacy of the VNS Therapy system has not been established for uses outside of its approved indications. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. Patients should use the magnet to stop stimulation if they suspect a malfunction, and contact their physician immediately for further evaluation. Removal or replacement of the VNS Therapy system requires an additional surgical procedure.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. VNS Therapy may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

## **PRECAUTIONS**

The safety and efficacy of The VNS Therapy System has not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation. There is a risk of infection with the implantation surgery that may require the use of antibiotics to treat or removal of the device. The VNS Therapy System may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable devices, careful programming of each system may be necessary to optimize the patient's benefit from each device. With the Model 106 only, because the device senses changes in heart rate, false positive detection unrelated to seizure activity (e.g., exercise) may cause unintended stimulation. The Model 106 also may not detect all seizures.

## **ADVERSE EVENTS**

The most commonly reported side effects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. Other adverse events reported during clinical studies as statistically significant are ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); hypesthesia (impaired sense of touch); insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; pharyngitis (inflammation of the pharynx, throat); and vomiting. These typically occur only during stimulation, are well tolerated and noticed less as time goes on. The most commonly reported side effect from the implant procedure is infection. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

\*The information contained in this summary represents partial excerpts of important prescribing information taken from the product labeling. The information is not intended to serve as a substitute for a complete and thorough understanding of the vns therapy system nor does this information represent full disclosure of all pertinent information concerning the use of this product. Patients should discuss the risks and benefits of VNS Therapy with their healthcare provider. Prescription only - device restricted to use by or on the order of a physician.

PatBS14-11-2000-OUS





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