



The VNS Therapy[®] Magnet

A unique benefit of VNS Therapy



To Learn More

call **1-888-867-7846**
or visit **VNSTherapy.com**



What is the VNS Therapy[®] Magnet?

VNS Therapy is always working to control seizures. The magnet is an added benefit of VNS Therapy that serves two functions:

Starting an extra dose of therapy may...

- Stop the seizure
- Shorten the seizure
- Decrease the intensity of the seizure
- Shorten the recovery period following the seizure

Temporarily suspend therapy to manage side effects during activities such as singing, public speaking or exercising.



While the handheld magnet offers added control, VNS Therapy is always working to control seizures through the delivery of mild pulses to the vagus nerve.

How to use the VNS Therapy Magnet

Patients, family members, caregivers, teachers, and school nurses can use the magnet to initiate an extra dose of stimulation when the patient feels a seizure is about to start or during a seizure.



1 Respond

Always carry the magnet with you so you are ready to respond.



2 Pass (move)

Pass (move) the magnet over the generator for **less than** two seconds.

Two magnets are provided along with a wristband and a belt clip. When worn with the wristband, the magnet should be on the inside of your wrist.

The magnet can be used more than once during a seizure. Using the magnet more than once will not harm the patient or the generator.

When you want to control side effects by temporarily stopping stimulation, hold or tape the magnet over the generator. When the magnet is removed, stimulation will restart.

If patients experience troublesome or painful side effects from VNS Therapy for an extended period of time, they should contact their physician.

Tips on handling the VNS Therapy® Magnet

- The magnet should be kept at least 25cm (10 inches) away from credit cards, televisions, computers, microwave ovens, or other magnets
- Do not drop the magnet; it can break if it falls on a hard surface
- Patients should carry their magnet with them so that it is available for use as soon as a seizure occurs or to temporarily stop stimulation
- The magnet is the only magnet that should be used to either start or stop stimulation
- Contact your physician to get additional magnets

INTENDED USE / INDICATIONS—UNITED STATES

Epilepsy—VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures which are refractory to antiepileptic medications.

CONTRAINDICATIONS

VNS Therapy 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."

WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System Physician's Manual, 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 VNS Therapy 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. MRI can be safely performed; however, special equipment and procedures must be used.

Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. (AspireSR® only) Inform your doctor if you have an existing heart condition or are being actively treated for a heart condition (such as beta adrenergic blocker medications). Your doctor will determine if the AutoStim feature is right for you.

PRECAUTIONS

The safety and efficacy of VNS Therapy 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. (AspireSR® only) Use of the AutoStim Mode (also known as Detect & Respond Mode) will result in reduced battery life, which may require more frequent generator replacements.

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.

*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.

CYBERONICS, INC.
100 Cyberonics Boulevard
Houston, Texas 77058
Tel: +1.800.332.1375
Fax: +1.281.218.9332

CYBERONICS EUROPE BVBA
Vuurberg - Airport Plaza Building C Kyoto
Leonardo Da Vinciiaan 19
1831 Diegem, Belgium
Tel: +32.2.720.95.93
Fax: +32.2.720.60.53

©2016 Cyberonics, Inc, a wholly-owned subsidiary of LivaNova PLC. All rights reserved. Cyberonics®, AspireSR® and VNS Therapy® are registered trademarks of Cyberonics, Inc.

MagBro16U11

LivaNova
Health innovation that matters
www.VNSTherapy.com