The VNS Therapy® Magnet
A unique benefit of VNS Therapy®

For patients with epilepsy treated with VNS Therapy
What is the Patient Magnet?

Use of the magnet is not necessary to receive VNS Therapy. The magnet is an added benefit of VNS Therapy that serves two functions:

1. **Starting an extra dose of stimulation may**
   - Stop the seizure
   - Shorten the seizure
   - Decrease the intensity of the seizure
   - Shorten the recovery period following the seizure

2. **Stopping stimulation to temporarily control side effects during certain activities such as public speaking, singing, or exercising**

VNS Therapy works to control seizures by intermittently stimulating the vagus nerve automatically, 24 hours a day, regardless of whether a patient chooses to use the magnet.
Patients, family members, caregivers, teachers, and school nurses can use the magnet to initiate an extra dose of stimulation when a seizure happens.

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.

How to use the Patient Magnet

When you feel a seizure is about to start or during a seizure, you or a caregiver can place the magnet over the chest area where the generator is implanted.

Swipe the magnet over the generator for less than 3 seconds.
Tips on handling the Patient 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 Patient Magnet is the only magnet that should be used to either start or stop stimulation
• Contact your physician to get additional magnets
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Safety Information for VNS Therapy

Brief Summary* of Safety Information for the VNS Therapy® System [Epilepsy Indication] (July 2017)

INTENDED USE / INDICATIONS:
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. 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:
Vagotomy—The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy.

Diathermy—Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

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 — GENERAL:
Physicians should inform patients about all potential risks and adverse events discussed in the physician’s manuals. This document is not intended to serve as a substitute for the complete physician’s manuals. The safety and efficacy of the VNS Therapy System have not been established for uses outside the “Intended Use/Indications” chapter of the physician’s manuals. The safety and effectiveness of the VNS Therapy System in patients with predisposed dysfunction of cardiac conduction systems (re-entry pathway) have not been established. Post-implant electrocardiograms and Holter monitoring are recommended if clinically indicated. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. It is important to follow recommended implantation procedures and intraoperative product testing described in the Implantation Procedure chapter of the physician’s manual. During the intraoperative System Diagnostics (Lead Test), infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics (Lead Test) or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS). Difficulty swallowing (dysphagia) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties are at greater risk for aspiration. Dyspnea (shortness of breath) may occur with active VNS Therapy. Any patient with underlying pulmonary disease or insufficiency such as chronic obstructive pulmonary disease or asthma may be at increased risk for dyspnea. Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Lowering stimulus frequency or prolonging “OFF” time may prevent exacerbation of OSA. Vagus nerve stimulation may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage. Patients should be instructed to use the magnet to stop stimulation if they suspect a malfunction, and then to contact their physician immediately for further evaluation. Patients with the VNS Therapy System or any part of the VNS Therapy System implanted should have MRI procedures performed only as described in the MRI with the VNS Therapy System instructions for use. In some cases, surgery will be required to remove the VNS Therapy System if a scan using a transmit RF body coil is needed. Excessive stimulation at an excess duty cycle (i.e., one that occurs when “ON” time is greater than “OFF” time) and high frequency stimulation (i.e., stimulation at ≥50Hz) has resulted in degenerative nerve damage in laboratory animals. Patients who manipulate the pulse generator and lead through the skin (Twiddler’s Syndrome) may damage or disconnect the lead from the pulse generator and/or possibly cause damage to the vagus nerve.

WARNINGS — EPILEPSY:
The VNS Therapy System should only be prescribed and monitored by physicians who have specific training and expertise in the management of seizures and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device. The VNS Therapy System is not curative. Physicians should warn patients that the VNS Therapy System is not a cure for epilepsy and that since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, and in strenuous sports that could harm them or others. 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. 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.

PRECAUTIONS — GENERAL:
Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy physician’s manuals. Prescribing physicians should be experienced in the diagnosis and treatment of depression or epilepsy and should be familiar with the programming and use of the VNS Therapy System. Physicians who implant the VNS
Therapy System should be experienced performing surgery in the carotid sheath and should be trained in the surgical technique relating to implantation of the VNS Therapy System. The safety and effectiveness of the VNS Therapy System have not been established for use during pregnancy. VNS should be used during pregnancy only if clearly needed. The VNS Therapy System is indicated for use only in stimulating the left vagus nerve in the neck area inside the carotid sheath. The VNS Therapy System is indicated for use only in stimulating the left vagus nerve below where the superior and inferior cervical cardiac branches separate from the vagus nerve. It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics preoperatively. The surgeon should ensure that all instruments are sterile prior to the procedure. 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 pacemaker, defibrillator therapy or other types of stimulators, careful programming of each system may be necessary to optimize the patient’s benefit from each device. Reversal of lead polarity has been associated with an increased chance of bradycardia in animal studies. It is important that the electrodes are attached to the left vagus nerve in the correct orientation. It is also important to make sure that leads with dual connector pins are correctly inserted (white marker band to + connection) into the pulse generator’s lead receptacles. The patient can use a neck brace for the first week to help ensure proper lead stabilization. Do not program the VNS Therapy System to an “ON” or periodic stimulation treatment for at least 14 days after the initial or replacement implantation. For Models 100, 101, 102 and 102R do not use frequencies of 5 Hz or below for long-term stimulation. Resetting the pulse generator turns the device OFF (output current = 0 mA). For Model 100, 101, 102 and 102R resetting the pulse generator will result in device history loss. Patients who smoke may have an increased risk of laryngeal irritation. Unintended Stimulation (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. Device Placement (Model 106 only)—For the Automatic Stimulation Mode of the Model 106 generator, the physical location of the device critically affects this feature’s ability to properly sense heart beats. Therefore, care must be taken to follow the implant location selection process outlined in the Implantation Procedure. Note that this implant location selection procedure may be performed preoperatively as part of the patient’s surgical work-up.

ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS:

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a pulse generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation. VNS Therapy System operation should always be checked by performing device diagnostics after any of the procedures mentioned in the physician’s manuals. For clear imaging, patients may need to be specially positioned for mammography procedures, because of the location of the pulse generator in the chest. Therapeutic radiation may damage the pulse generator’s circuity. Sources of such radiation include therapeutic radiation, cobalt machines, and linear accelerators. The radiation effect is cumulative, with the total dosage determining the extent of damage. The effects of exposure to such radiation can range from a temporary disturbance to permanent damage, and may not be depictable immediately. External defibrillation may damage the pulse generator. Use of electro-surgery [electrocautery or radio frequency (RF) ablation devices] may damage the pulse generator. Magnetic resonance imaging (MRI) should not be performed using a transmit RF body coil for certain VNS Therapy device configurations or under certain specific conditions. In some cases, heating of the lead caused by the transmit RF body coil during MRI may result in serious injury. Static, gradient, and radio frequency (RF) electromagnetic fields associated with MRI may change the generator settings (i.e., reset parameters) or activate the VNS device if the Magnet Mode output remains “ON”. Note that certain magnetic resonance (MR) system head coils operate in receive-only mode and require use of the transmit RF body coil. Other MR systems use a transmit/receive RF head coil. Local or surface coils may also be receive-only RF coils that require the transmit RF body coil for MRI. The use of a receive RF coil does not alter hazards of the transmit RF body coil. Exposure of the VNS Therapy System to any transmit RF coil must be avoided. Do not perform MRI scans using any transmit RF coil in the defined exclusion zones. See the MRI with the VNS Therapy System instructions for use for details or further instructions for special cases such as lead breaks or partially explanted VNS Therapy systems. Extracorporeal shockwave lithotripsy may damage the pulse generator. If therapeutic ultrasound therapy is required, avoid positioning the area of the body where the pulse generator is implanted in the water bath or in any other position that would expose it to ultrasound therapy. If that positioning cannot be avoided, program the pulse generator output to 0 mA for the treatment, and then after therapy, reprogram the pulse generator to the original parameters. If the patient receives medical treatment for which electric current is passed through the body (such as from a TENS unit), either the pulse generator should be set to 0 mA or function of the pulse generator should be monitored during initial stages of treatment. Routine therapeutic ultrasound could damage the pulse generator and may be inadvertently concentrated by the device, causing harm to the patient. For complete information related to home occupational environments, cellular phones, other environmental hazards, other devices, and ECG monitors, refer to the physician’s manuals.

ADVERSE EVENTS — EPILEPSY

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); hyperventilation (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; paresthesia (pricking 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.

*The information contained in this Brief Summary for Physicians represents partial excerpts of important prescribing information taken from the physician’s manuals. (Copies of VNS Therapy physician’s and patient’s manuals are posted at www.livanova.com) The information is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the physician’s manuals for the VNS Therapy System and its component parts nor does this information represent full disclosure of all pertinent information concerning the use of this product, potential safety complications, or efficacy outcomes.

26-0009-0100/3 (Non-U.S.) — 1