AspireSR®
Essential information about your new device
FAQs for Patients

Your doctor recommends that you receive the latest VNS Therapy device. This brochure will give you more information on the differences between this new device and previous generations of VNS Therapy.

For more information please contact your healthcare professional.
AspireSR®
All the benefits* of previous generations of VNS Therapy

Plus the NEW Detect & Respond Mode

MODEL 106
Cyberonics, Inc.
Houston, Texas

Generator shown is actual size
*Individual results may vary
What is AspireSR?

AspireSR is the first and only VNS Therapy that provides responsive stimulation. The AspireSR generator contains 3 modes: Standard Mode, Magnet Mode and now Detect & Respond Mode.

Standard Mode
Ongoing delivery of mild pulses to the vagus nerve. Treatment is delivered at regular intervals all day, every day so you do not have to worry about missing a dose.

Magnet Mode
Manual delivery of an extra dose of therapy as needed. Magnet Mode may be used during Standard Mode and Detect & Respond Mode.

NEW! Detect & Respond Mode
Responsive automatic delivery of an extra dose of therapy when a rapid increase in heart rate is detected that may be associated with seizures.

How does Detect and Respond mode work?

8 in 10 people living with seizures experience a rapid increase in heart rate before or during a seizure. AspireSR can detect this increase and responds by delivering an extra automatic stimulation. This new feature may help you better manage your seizures.

1. Also known as Normal Mode
2. Also known as AutoStim Mode
**3 Will it feel different from my previous device?**

Your healthcare professional will programme the settings for the automatic stimulation the same way as he/she is doing for the Standard Stimulation and Magnet Mode.

If you think stimulation is coming on too much or too little, or if you feel discomfort, your healthcare professional can adjust the settings appropriately.

**4 Will this replace my magnet?**

With AspireSR you can still use the magnet to receive extra stimulation or to stop your stimulation to manage side effects as with previous generators of VNS Therapy.
5. What happens when I exercise?

The detection system of AspireSR is designed to respond to rapid increases in heart rate. If you are exercising and your heart rate increases rapidly you may receive an extra dose of therapy, but this will not harm you in any way as it is very similar to receiving an extra stimulation via the Magnet Mode.

6. What if I don’t like the automatic stimulation?

The new Detect and Respond function can be switched off so you only receive standard VNS Therapy.

7. Is there a risk of receiving too much stimulation?

The detection system in the device has built in safety mechanisms that will make sure that you will not get too much stimulation.
When automatic stimulation is activated, does that mean I’m about to have a seizure?

OR

When automatic stimulation was activated and I did not have a seizure, does this mean my seizure was prevented?

Not in all cases. AspireSR is designed to detect and respond to rapid increases in heart rate, which may be associated with a seizure.

Depending on your medical condition and the settings programmed by your healthcare professional, an automatic stimulation may or may not be associated with an actual seizure.

Your healthcare professional will be able to give you more details during follow up visits.
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 AspireIR™ (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 possible for patients to feel the pulses from the implantable pulse generator and/or the lead. In the Implantation Procedure chapter of the physician’s manual. Device 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 increased incidence of 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. Physicians 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 excessive 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 unexpected 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 System. 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 of exposure. 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 told to have the device replaced as soon as possible. Infection control procedures should be followed. If the device is exposed to any potential infectious agent, it should be replaced. Infections should be treated as soon as possible.

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. Untimelimited 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 circuitry. 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. Other therapeutic radiation sources include Extracorporeal Shock Wave Therapy (ESWT), and radiofrequency (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 System. 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 duration of therapy. Do not program the pulse generator to the output 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); hypesthesia (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; paresthesia (prickling of the skin); pharyngitis (inflammation of the pharynx, throat); voice alteration (hoarseness); vomiting. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

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.
This brochure is not intended to be a complete source of information on VNS Therapy. Please contact your health care professional or visit www.VNSTherapy.com for more information.

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