

AspireSR[®]

The Newest Advancement
in VNS Therapy[®]



To Learn More

call **1-888-867-7846**

or visit **VNSTherapy.com**

 **VNSTherapy[®]**

AspireSR

The newest advancement in VNS Therapy

All the benefits of previous generations of VNS Therapy...*

- ✓ Fewer seizures
- ✓ Shorter seizures
- ✓ Faster recovery
- ✓ Decreased seizure severity
- ✓ Improvements in alertness, memory and mood

+ Plus the NEW
Detect & Respond Mode.

Generator shown is actual size



* Individual results may vary

Houston, Texas
Cyberonics, Inc.



Erin
on VNS Therapy
since 1999

AspireSR FAQs

1 **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 a seizure.

* Also known as AutoStim Mode

AspireSR FAQs

2 How does Detect & 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 dose of therapy. This new feature may help you better manage your seizures.

3 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.

4 What if I don't like the new feature?

The new Detect & Respond feature can be switched off by your healthcare professional. Switching off the feature will not impact your ability to receive Standard Mode and Magnet Mode Therapy.



5 Is there a risk of receiving too much stimulation?

No. AspireSR has built-in safety protocols.

6 When I receive responsive stimulation does that mean I am about to have a seizure?

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 extra dose of therapy may not be associated with a seizure. If you feel stimulation is too frequent, not frequent enough or if you feel any discomfort, talk to your healthcare professional about adjusting the settings.

AspireSR FAQs

7 Will all of my seizures be detected with AspireSR?

AspireSR is designed to detect and respond to rapid increases in heart rate, which may be associated with the onset of a seizure. Some seizures may not have a large enough increase to be detected. In these cases, Magnet Mode is available to you to receive an extra dose of therapy.



The VNS Therapy Magnet

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.

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





To Learn More About VNS Therapy:



Call toll-free:

1-888-VNS-STIM (1-888-867-7846)



Visit:

www.VNSTherapy.com



Talk to your doctor



Join us on Facebook:

www.facebook.com/VNSTherapyforEpilepsy

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 Vincilaan 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.

www.VNSTherapy.com

ASRPtFAQ16U11

LivaNova

Health Innovation that Matters