



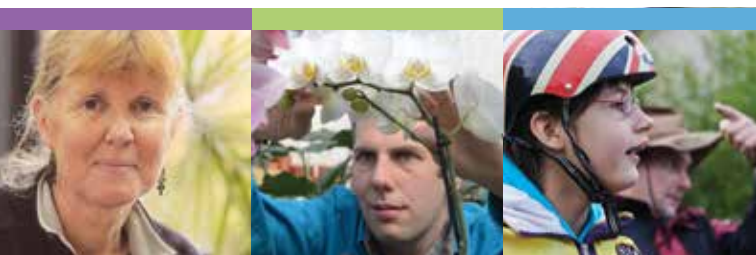
AspireSR[®]

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



Generator shown is actual size

*Individual results may vary

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 Mode¹

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 Mode²

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

2 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.

8 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.



AspireSR®

Safety Information for VNS Therapy

VNS Therapy 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. 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.

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. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. 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

AspireSR FAQ for patients

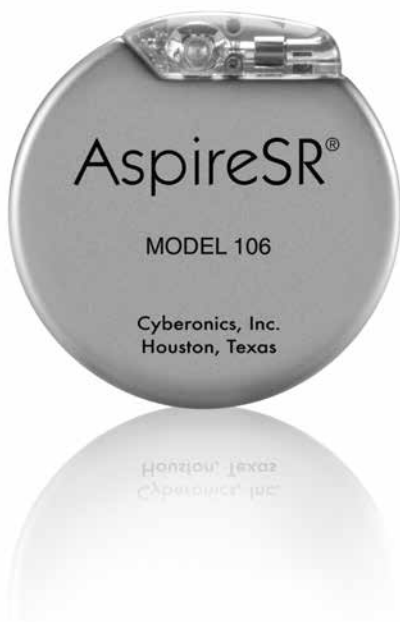
stimulation might worsen their condition. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias.

MRI can be safely performed; however, special equipment and procedures must be used.

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. The most commonly reported side effect from the implant procedure is infection.

*The information contained here represents partial excerpts of important prescribing information from the product labeling. Patients should discuss the risks and benefits of VNS Therapy with their healthcare provider. Visit www.VNSTherapy.com for more information.





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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