NEXT GENERATION VNS THERAPY

Treating patients with drug-resistant epilepsy just got easier — thanks to a new generation of VNS Therapy. Built on more than 20 years of proven experience, SenTiva provides responsive customizable technology that makes treating patients with drug-resistant epilepsy easier.

>100,000 patients treated
>30,000 children treated (<18y)

FDA-approved for children as young as 4
Advanced Technology

SenTiva employs the latest technology with an easy-to-use interface and more data and customization than ever before.

Responsive Stimulation: Detects and responds to heart rate increases that may be associated with seizures.

Confidently deliver VNS Therapy with one touch: Safe and easy pathway towards achieving targeted therapy levels. Follow an FDA-approved protocol or create custom protocols for specific patient profiles.

Safely titrate patients automatically without office visits: Program a titration schedule in one office visit. Titration changes will be applied while the patient lives their life.

Customized control for when your patients need it: Tailor programming for specific periods of the day. Select which parameters will change, what time the change will occur, and the duration of the change.

Quickly visualize patient trends: Quickly view long-term data at follow-up visits. Easily assess events of interest such as acute therapy activations, prone position, and low heart rate.

Access to high quality MRI: VNS Therapy is the only device for drug-resistant epilepsy with FDA-approval for 1.5T and 3T MRI.

Incidence of adverse events following stimulation (>5%) were voice alteration, increased coughing, pharyngitis, paresthesia, dyspnea, dyspepsia, and nausea.

Data on file. LivaNova USA. Houston, TX.

VNS Therapy System Physician’s Manual, LivaNova USA, Houston, TX.

Please see important safety information attached and at SenTiva.com/safety.


The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

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INTENDED USE / INDICATIONS

1. INTENDED USE / INDICATIONS

The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

2. CONTRAINDICATIONS

Vagotomy—The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy.

Difficulties—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.

3. 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/indication section of the physician's manuals.

The VNS Therapy System in patients with predisposed dysfunction of the cardiovascular system (e.g., pre-existent heart failure) have not been established. Post-implantation electrocardiograms and Holter monitoring are recommended if clinically indicated.

Postoperative bradycardia can occur among patients with certain underlying cardiac abnormalities. Hysterectomy can result in the implant being contraindicated. EMST test described in the implantation Procedure chapter of the physician's manuals. During the intraoperative EMST test, if the generator is left on, the maximum output for 1 minute would be 100 mA. In the event of asystole, severe bradycardia (heart rate <40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics (Lead Test), informing the physician that the system should be turned off. Care is required for patients with a history of obstructive sleep apnea, shortness of breath, coughing, swallowing difficulties, or aspiration

4. ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Generators with AutoStim only—The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

Generators with AutoStim only—The physical location of the device critically affects the feature's ability to properly sense heart beats. Care must be taken to follow the implant location selection process outlined in the implantation Procedure.

- Since the Scheduled Programming feature allows the generator to apply therapy increases at scheduled intervals, it may not be appropriate for use in patients who are nonverbal or are unable to use the patient magnet to stop undesired stimulation. Similarly, exercise caution for use of the feature in patients with a history of obstructive sleep apnea, shortness of breath, coughing, swallowing difficulties, or aspiration

- Magnetic resonance imaging (MRI) should not be performed using a transmit RF body coil for certain VNS Therapy System operation should always be checked by performing diagnostic activities after any of the procedures mentioned in the physician's manuals.

5. 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); hypotension (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (larynx spasms); nausea; pain; paraesthesia (prickling of the skin); pharyngitis (inflammation of the pharynx, throat); voice alteration (hoarseness); vomiting.

6. ADVERSE EVENTS — EPILEPSY

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 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.

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