Over a period of 30 years, despite the addition of more than 12 new AEDs (some with novel MOAs), seizure freedom rates in newly diagnosed epilepsy have not improved.
VNS Therapy is the most proven device therapy for drug-resistant epilepsy

Responsive VNS Therapy may be associated with an earlier onset of effect

Mean follow-up 13 months

- 59% reported ≥ 50% reduction in seizures
- 41% reported ≥ 80% reduction in seizures

Responsive VNS Therapy (Hamilton) n=51

Conventional VNS Therapy (Elliott) n=400

Patients having seizures for less than 10 years responded better to VNS Therapy

Earlier use of VNS Therapy may enhance seizure control

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

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. Please see important safety information attached and at https://us.livanova.cyberonics.com/safety-information.

1. INTENDED USE / INDICATIONS

Generators with AutoStim only

adrenergic blocker medications). Patients also should not have a history of chronotropic incompetence (i.e., deficient normal intrinsic heart rate responses (e.g., pacemaker dependency, implantable defibrillator, beta

RF body coil is needed. Physicians who implant the VNS Therapy System should be experienced performing surgery in the carotid sheath area and be familiar with the programming and use of the VNS Therapy System.

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

Dyspnea (shortness of breath) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties and those with a history of drooling or hyposalivation are at greater risk for aspiration. Use of the magnet to temporary stop stimulation while eating may mitigate the risk of aspiration.

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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. Physicians should be aware that reversal of polarity may not be possible in some patients and devices. In these patients, the physician may have to consider alternative programming in the event that lead polarity reversal is not possible.

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