

Safety Information for the VNS Therapy

Brief Summary of Safety Information for the VNS Therapy™ System [Epilepsy Indication] (February 2025)

1. INTENDED USE / INDICATION

The VNS Therapy system is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epilepsy disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications.

2. CONTRAINDICATIONS

Left Vagotomy — The VNS Therapy system should not be used in people who have had the left vagus nerve cut to treat another disorder (a left vagotomy).

Diathermy — Inform anyone who treats you that you CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy anywhere on your body because you have an implanted VNS Therapy system. Injury or damage can occur during diathermy treatment whether your VNS Therapy system is turned "ON" or "OFF." Diagnostic ultrasound is not included in this contraindication.

3. WARNINGS — GENERAL

Avoid Excessive Vagus Nerve Stimulation — Excessive stimulation of the vagus nerve can be produced by frequent magnet activation or more than 8 hours of continuous stimulation due to repeated magnet activations.

Safety and Efficacy Not Established — The safety and efficacy of the VNS Therapy system have not been established for uses outside its approved indications for use. The safety and efficacy of VNS Therapy have not been shown for people with these conditions: ; History of dysautonomias; History of fainting (vasovagal syncope); History of lung diseases or disorders, including shortness of breath and asthma; History of previous therapeutic brain surgery or brain injury; History of ulcers (gastric, duodenal, or other); Irregular heart beats (Heart arrhythmias) or other heart abnormalities; Only one vagus nerve; Other concurrent forms of brain stimulation; Pre-existing hoarseness; Primary generalized seizures; Progressive neurological diseases other than epilepsy; ;

Swallowing Difficulties — Difficulty swallowing may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Use of the magnet to temporarily stop stimulation while eating may mitigate the risk of aspiration.

Shortness of Breath — Shortness of breath may occur with active VNS Therapy, especially if you have chronic obstructive pulmonary disease or asthma.

Obstructive Sleep Apnea (OSA) — Use of the VNS Therapy device can cause or worsen pre-existing obstructive sleep apnea (episodes where breathing stops for short periods of time while sleeping). See your doctor if you have any signs or symptoms of obstructive sleep apnea or worsening obstructive sleep apnea.

Device Malfunction — Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage and other associated problems.

Device Removal — Removal of the VNS Therapy system requires an additional surgical procedure. When a device is removed, the surgeon may leave part of the lead behind. This may pose certain risks

Device Manipulation — Do not manipulate the generator and lead through the skin, as this may damage or disconnect the lead from the generator and/or possibly cause damage to the vagus nerve.

Device Trauma — Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted could possibly cause damage to the lead.

The VNS Therapy System Does Not Stop All Seizures — Continue to avoid activities that can be hazardous to you and others, such as driving and swimming alone.

Cardiac Arrhythmia — If you have a cardiac arrhythmia, the automatic stimulation feature is not suitable for you. This includes heart conditions or treatments that do not allow necessary changes in your heart rate, such as atrial fibrillation, pacemaker dependency, implantable defibrillator, or cardiac medications such as beta blockers.

4. WARNINGS — MRI

Before an MRI is Performed — Call your doctor, so your VNS Therapy system can be discussed with the MRI personnel. In many cases, an MRI can be performed safely under certain conditions. However, for a few other cases, surgery may be required to remove the VNS Therapy system prior to an MRI. Before an MRI scan is performed, the VNS Therapy system diagnostic information will be collected and the current turned off. The current will be turned on again after the scan is completed. Your doctor has access to detailed MRI-related information in the physician's manual.

Patient Magnet MR Unsafe — The LivaNova patient magnet is MR Unsafe. Do not carry the patient magnet into the MR scanner room. The magnet could become a dangerous flying object if attracted by the strong magnetic field of the MRI scanner.

Pain Or Other Sensation During MRI Scan — If, during an MRI scan, you have any pain, discomfort, heating, or other unusual sensations, notify the MRI operator, so the MR procedure can be stopped.

5. PRECAUTIONS

Use During Pregnancy — The safety and effectiveness of the VNS Therapy system have not been established for use during pregnancy.

Laryngeal Irritation — Patients who smoke may have an increased risk of laryngeal irritation from stimulation.

Use During Exercise — **Generators with AutoStim:** Exercise or physical activity may trigger Automatic Stimulation if the feature is ON due to heart rate changes detected by the device.

Heart Rate Changes Not Associated with Seizures — **Generators with AutoStim:** Situations, including but not limited to exercise or physical activity, that cause rapid increases in heart rate may trigger Automatic Stimulation if the feature is ON. If this is a concern, talk to your doctor about ways to stop stimulation during these situations. This could include using your magnet or having your doctor turn the AutoStim feature OFF.

Battery Drain — Generators with AutoStim: If your doctor has turned on the AutoStim feature, there will be a greater impact on battery life than if the feature is turned off, which may require more frequent generator replacements.

Time-Based Features — Model 1000 / 1000-D Only: Optional time-based features (e.g., Day-Night Programming, Scheduled Programming) do not automatically adjust for Day Light Savings Time or time zone changes. If you are using one of these features, you will need to go back to your doctor for reprogramming of the generator for any time changes.

6. HAZARDS — ENVIRONMENTAL

Certain types of equipment can affect the generator if you are too close. Move away from or avoid equipment that interferes with your generator (e.g., antennas that transmit).

Pacemaker Warning Signs — Talk to your doctor before you go into places with pacemaker warning signs.

Small Appliances — Properly operating microwave ovens and other small electrical appliances, such as toasters, hair dryers, and electric shavers, should not affect the generator.

Cellular Phones — Cellular phones can affect some implanted cardiac defibrillators and pacemakers, but current test data shows that they do not affect the generator. Cellular phones may contain magnets

Transmitting Devices — Properly operating electrical ignition systems and power transmission lines should not affect the generator. Sources with high energy levels, such as transmitting antennas, may interfere with the generator. Move at least 1.8 meters (6 feet) away from any equipment that interferes with your generator.

Antitheft Devices, Airport Security Systems, and Other Metal Detectors — Antitheft devices and metal detectors should not affect the generator or be affected by it. As a precaution, however, move through them at a steady pace; do not linger in the area and stay at least 40 centimeters (16 inches) away from such equipment.

Electronic Article Surveillance (EAS) System Tag Deactivators — The tag deactivators found in many retail stores can interfere with VNS Therapy when it is used near the generator. It can cause accidental activations or stop pulses. Stay at least 60 centimeters (2 feet) away from tag deactivators to avoid potential interference.

Devices with Strong Electromagnetic Fields — Strong magnets, tablet computers and their covers, hair clippers, vibrators, loudspeakers, cellular phones, smart watches, wearable devices, and other similar electrical or electro-mechanical devices with a strong static or pulsing magnetic field can cause your generator to start suddenly. Keep this type of equipment at least 20 centimeters (8 inches) away from your chest. If your generator stops while you are in a strong electromagnetic field, move away from the source so the generator can return to regular operation.

7. HAZARDS — MEDICAL

Medical equipment, procedures, and surgery using certain electrical instruments can affect the VNS Therapy system's operation and sometimes damage the generator or lead. Make sure that medical personnel know you have a device implanted in your chest. Always call your doctor before you have any medical tests that may affect, or be affected by the VNS Therapy system as described. Precautions may be needed.

Routine Diagnostic Procedures — Most routine diagnostic procedures, such as diagnostic ultrasound and radiography (x-rays), should not affect the VNS Therapy system.

Mammography — Because the generator is in your chest, you may need to be specially positioned for a mammogram. Otherwise, the device may be seen as a shadow on the mammogram. It could make a lesion or lump in that area hard or even impossible to detect. Make sure that your doctor and the mammography technician are aware of your implanted device.

Radiation Treatment — Treatment with radiation, cobalt machines, and linear accelerators may damage the generator. No tests have been done to date, so the effect of radiation on the device is not known. Talk with your doctor if you plan to have radiation treatment.

Other Procedures — External cardiac defibrillation and other procedures for heart problems, as well as extracorporeal shockwave lithotripsy, diathermy, and electrocautery, may damage the generator. If you had any of these procedures and your doctor did not know about it, have the generator checked. While diagnostic ultrasound should not affect the VNS Therapy system, therapeutic ultrasound therapy could damage the generator or inadvertently harm you.

8. HAZARDS — INTERFERENCE WITH OTHER DEVICES

While the generator stimulates or is being programmed or tested, it may briefly interfere with nearby equipment. If this happens, move at least 1.8 meters (6 feet) away from the equipment.

Radios and Hearing Aids — The generator can interfere with devices that operate in the 30 kHz to 100 kHz range. Hearing aids and transistor radios operate in this range. Potentially, the generator could affect them, but no effects have been reported. No detailed tests have been done, so the effects are unknown.

Implanted Devices — The generator may affect other implanted medical devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems. These could lead to inappropriate responses from the generator.

9. MAGNET PRECAUTIONS

Always carry the magnet with you. Show your family members or caregivers how to use it.

Do not place the magnet over a pacemaker since it may affect pacemaker function and could change the pacing rate.

Never put or store the magnet near credit cards, televisions, computers, computer disks, microwave ovens, watches, other magnets, or items affected by strong magnetic fields. Keep it at least 25 centimeters (10 inches) away.

Do not drop the magnet. It can break and lose magnetic strength if dropped on a hard surface.

10. SIDE EFFECTS

The following is a partial alphabetical list of the side effects possibly associated with the VNS Therapy system and reported during clinical trials of the VNS Therapy system: Lack of coordination in the voluntary muscles (ataxia); Difficulty breathing, shortness of breath (dyspnea); Hoarseness (voice alteration); Impaired sense of touch (hypoesthesia); Inability to sleep (insomnia); Increased coughing; Indigestion (dyspepsia); Infection; Inflammation of the throat (pharyngitis); Muscle movements or twitches generally associated with stimulation; Nausea; Pain; Prickling of the skin (paresthesia); Throat, larynx spasms (laryngismus); Vomiting

CYB 03098/1 (CE English)