

PATIENT'S GUIDE for Depression



October 2023

This Patient's Guide is a supplement to the physician's manuals. It is not intended to substitute for advice from your doctor. For a complete discussion of indications for use, contraindications, precautions, warnings, and potential side effects, talk to your doctor.



CAUTION: Your doctor is your first source for health-related questions and information. LivaNova cannot provide healthcare advice or services.

Your doctor's phone number: _____

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1.0. Introduction

See the "[Glossary](#)" on [page 36](#) for terms and definitions used in this guide. This Patient's Guide is posted at www.livanova.com.

1.1. Introduction to VNS Therapy

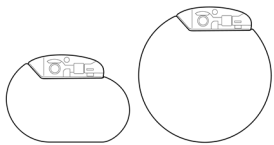
Many people have depression. Through the years, doctors and scientists have learned a lot about depression and have developed drugs and other treatments. Despite these efforts, some people still have depression symptoms. Your doctor has proposed the VNS Therapy system for you to reduce the symptoms of your depression because other treatments have failed to control them adequately.

The VNS Therapy system sends a mild electrical pulse to a nerve that goes to the brain. This nerve is called the vagus nerve. The treatment is vagus nerve stimulation therapy (VNS Therapy).

1.2. Parts of the VNS Therapy System

1.2.1. Implantable Parts

1.2.1.1. Generator



The main implantable part is the generator, sometimes called a stimulator. The generator is computer-controlled and battery-powered. It sends signals through the electrodes of the lead to the brain through the left vagus nerve in the neck.

The generator has many settings. Your doctor will choose the settings for your generator. The stimulation settings can be changed at any time with the programming system. Most of the time, this is a painless procedure that takes only a few minutes and can be done in your doctor's office.

i NOTE: See "[Follow Up After Surgery](#)" on [page 19](#) for more information.

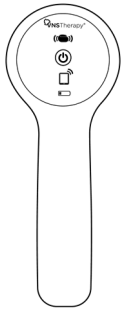
1.2.1.2. Lead



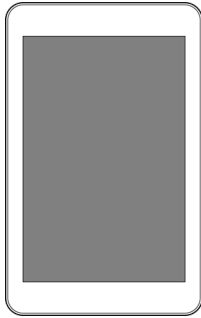
The lead connects the generator to the vagus nerve.

1.2.2. Non-Implantable Parts

1.2.2.1. Programming System



Wand



Programmer

The programming system includes the programming wand (Wand) and programming computer (Programmer) with pre-installed software.

1.2.2.2. Magnet



Your doctor provides a magnet for you to stop stimulation if and when you need to.



NOTE: See "[LivaNova Magnets](#)" on [page 21](#) for more information.

2.0. Who Uses VNS Therapy?

VNS Therapy has been approved for people with chronic or recurrent treatment resistant depression. It *is not right* for everyone who has depression. You and your doctor will decide if VNS Therapy is right for you. Your doctor will also decide if you have any other medical conditions that might be affected by VNS Therapy.

2.1. Indications for Use

The VNS Therapy system is indicated for the treatment of chronic or recurrent depression for patients who are in a treatment-resistant or treatment-intolerant major depressive episode.

2.2. Contraindications

VNS Therapy should not be used (is contraindicated) in the following situations or procedures:

- **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.”



NOTE: Diagnostic ultrasound is not included in this contraindication.


Diathermy is a treatment to promote healing or relieve pain. It is provided by special medical equipment in a doctor’s office, dentist’s office, or other healthcare facility.

Energy from diathermy therapy may cause heating of the VNS Therapy system. The heating of the VNS Therapy system that results from diathermy can cause temporary or permanent nerve, tissue, or vascular damage. This damage may result in pain or discomfort, loss of vocal cord function, or possible death if blood vessels are damaged.

Diathermy may also damage parts of your VNS Therapy system. This damage can result in loss of therapy from your VNS Therapy system. More surgery may be required to remove or replace parts of your implanted device.

3.0. Benefits of VNS Therapy for Depression

The effectiveness of VNS Therapy in decreasing depressive symptoms was primarily demonstrated by improved scores on standardized tests after 12 months and 24 months of VNS Therapy in the D-02 study.

 NOTE: See ["Side Effect and Safety Profile of VNS Therapy Observed in Clinical Studies in Depressed Patients" on page 31](#) for a description of the D-02 study.

3.1. Effectiveness Results — D-02 Clinical Study

3.1.1. Three-month Results

At the end of the first 3 months, the proportion of patients who had at least a 50% reduction in depression symptoms was 15% in the group of patients receiving active stimulation, slightly better than for patients who were not receiving stimulation (10% of these patients had at least a 50% reduction in symptoms). See ["Effectiveness Results — D-02 Clinical Study" on the next page](#) for these results. This finding suggested that the full effects of VNS Therapy might require more than 3 months of treatment.

3.1.2. One-year Results

After 1 year of VNS Therapy, the results showed that 30% of the study patients were responders (at least a 50% improvement in depressive symptoms) and 17% were remitters (minimal to no depressive symptoms). The results from a second rating scale of depression symptoms showed that 22% of the group were responders and 15% were remitters, and the results from a third rating scale showed that 32% were responders and 23% were remitters. See ["Effectiveness Results — D-02 Clinical Study" on the next page](#) for these results. It should be noted that about one in four or five people who were implanted with the device during the study were not included in these calculations of success at 12 months. Therefore it is possible that the percentage of patients having successful outcomes may be lower than is represented by the results described above.

3.1.3. Two-year Results

After 2 years of VNS Therapy, the results showed that 32% of the patients were responders and 17% were remitters. The results from a second rating scale of depression symptoms showed that 27% of the group were responders and 13% were remitters. See ["Effectiveness Results — D-02 Clinical Study" on the next page](#) for these results. It should be noted that about one in three people who were implanted with the device during the study were not included in these calculations of success at 24 months. Therefore it is possible that the percentage of patients having successful outcomes may be lower than is represented by the results described above.

Table 1. Effectiveness Results — D-02 Clinical Study

Standardized Test	HRSD24		IDS-SR30		MADRS	
	Responders	Remitters	Responders	Remitters	Responders	Remitters
3 months	15%	7%	14%	6%	17%	10%
12 months	30%	17%	22%	15%	32%	23%
24 months	32%	17%	27%	13%	N/A	N/A

Responders – $\geq 50\%$ improvement in depressive symptoms.

Remitters – minimal to no depressive symptoms.

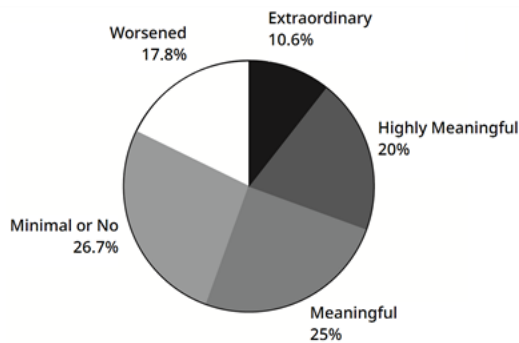
3.1.4. Additional Categorization of Clinical Benefit

After 12 months of VNS Therapy, the patients were also assessed to categorize the degree of improvement in their depression symptoms. The amount of improvement was categorized as follows:

- **Worsened** – depressive symptoms worse than when VNS Therapy was started
- **Minimal to no change** – 0% to 24% improvement in depressive symptoms
- **Meaningful clinical benefit** – 25% to 49% improvement in depressive symptoms
- **Highly meaningful clinical benefit** – 50% to 74% improvement in depressive symptoms
- **Extraordinary clinical benefit** – over 75% improvement in depressive symptoms

The image shows the percentage of patients who were in the different categories after 12 months of VNS Therapy. It should be noted that about one in four people who were implanted with the device during the study were not included in these calculations of success at 12 months. Therefore, it is possible that the percentage of patients having successful outcomes may be lower than is represented by the results shown in the image.

Figure 1. Categories of Clinical Benefit After 12 Months of VNS Therapy (HRSD₂₄)



i NOTE: 56 percent of patients experienced at least a meaningful clinical benefit after 12 months of adjunctive VNS Therapy.

3.1.5. Maintenance of Benefit Over Time

Although less than one in three or one in four patients (depending on the rating scale used) appeared to respond to VNS Therapy, most—but not all—of those patients continued to be responders over time. For example, among the 30 patients who were responders on the HRSD₂₄ rating after their first 3 months of VNS Therapy, 60% continued to be responders after one year of VNS Therapy, and 70% were responders after two years of VNS Therapy. Among the 54 patients who were responders after 12 months of VNS Therapy, 69% continued to be responders after two years of VNS Therapy.

3.2. Quality of Life Measurements in the D-02 Clinical Study

In addition to improvements in depressive symptoms, patients who received VNS Therapy for one year in the D-02 study reported improvements in quality of life.

3.3. Expected Rate of Response to VNS Therapy

For patients in whom VNS Therapy is effective, the benefits are not always seen right away. In fact, the 12-week acute studies did not show a significant difference between patients receiving VNS Therapy and those who were not receiving it. Depressive symptoms may improve slowly over the first year of treatment.

3.4. Treatment Continuation Rates

Not all patients continue on VNS Therapy. During the D-02 study, 92% of the patients continued to receive therapy at 12 months and 82% continued to receive therapy at 24 months.

3.5. Limitations of VNS Therapy

VNS Therapy has not been shown to cure depression and it does not work for everyone.

For most patients in whom it is effective, improvement in depressive symptoms will be slow. Some patients may have no change in symptoms with VNS Therapy, and some may actually get worse while receiving VNS Therapy. At present, doctors have no way to predict which patients will respond to VNS Therapy.



NOTE: See "[Expected Rate of Response to VNS Therapy](#)" above.

4.0. Warnings and Precautions

As with all types of treatment for depression, VNS Therapy carries some risks. Talk to your doctor about the following warnings, precautions, side effects, and hazards. Ask about other risks not covered in this guide that you should know about.

4.1. Warnings

4.1.1. General Warnings

Use

This device is a permanent implant. It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

Worsening Depression / Suicidality

You will need to be observed closely for clinical worsening and suicidal thoughts or behavior (suicidality), especially at the time of drug or drug dose changes, or VNS Therapy stimulation parameter changes.

Unapproved Uses

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:

- Acute suicidal thinking or behavior
- 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 rapid cycling bipolar disorder
- History of schizophrenia, schizoaffective disorder or delusional disorders
- 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
- Progressive neurological diseases other than depression

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

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. See ["Medical Hazards" on page 16](#).

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.

4.1.2. Magnetic Resonance Imaging (MRI) Warnings

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.



NOTE: Your generator must be turned off by a healthcare professional.



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.

Questions?

Call your doctor if you have questions about having an MRI scan.

4.2. 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.

Time-Based Features

Model 1000

Model 1000-D

The optional Day-Night Programming feature does not automatically adjust for Day Light Savings Time or time zone changes. If you're using this feature, you will need to go back to your doctor for reprogramming of the generator for any time changes.

4.3. Hazards

4.3.1. Environmental Hazards

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 (see "[Devices with Strong Electromagnetic Fields](#)" below).

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 stop stimulation. 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.

4.3.2. Medical Hazards

Medical equipment, procedures, and surgery using certain electrical instruments can affect the VNS Therapy system's operation and sometimes damage the generator or lead.



CAUTION: Make sure that medical personnel know you have a device implanted in your chest.



CAUTION: 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.

4.3.3. 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.

Credit Cards and Computer Disks

The magnet is very strong. It *can damage* televisions, computer disks, credit cards, and other items that are affected by strong magnetic fields. Keep your magnet at least 25 centimeters (10 inches) away from these items. **Do not carry or store the magnet near them.**

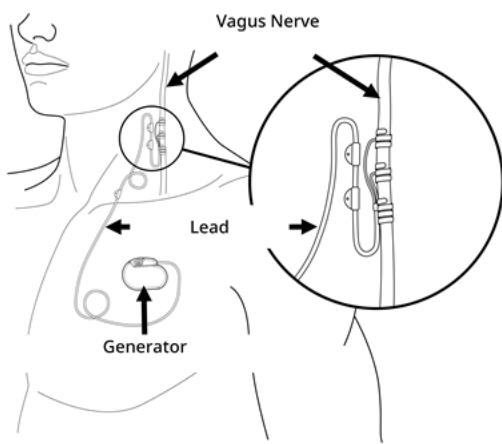
5.0. Implant Surgery

The VNS Therapy system requires surgical placement of the generator and lead by a surgeon. At follow-up office visits, your doctor checks the settings and changes them as needed.

5.1. Generator and Lead Placement

The generator is placed under the skin of the upper chest. The lead is attached to the vagus nerve on the left side of the neck and runs under the skin to connect to the generator.

Figure 2. Generator and Lead Placement




5.2. Surgery

The implant surgery lasts about 1 to 2 hours and typically involves general anesthesia, although local anesthesia is sometimes used. You may stay in the hospital overnight.


The surgeon makes a small incision on the left side of the neck and a second incision below the collarbone in the chest or armpit. The lead is passed under the skin between the two incisions. The surgeon attaches the lead to the vagus nerve in the neck and then plugs the other end of the lead into the generator. The generator is placed in a “pocket” created at the site of the incision below the collarbone on the same side as the lead. Finally, the surgeon closes the incisions. See ["Generator and Lead Placement" above](#).

The operation can be reversed if you and your doctor decide to have the VNS Therapy system removed. Removal of the generator and/or lead requires another surgical procedure.

 CAUTION: Sometimes, when a surgeon removes a VNS Therapy system, the surgeon decides to leave a portion of the lead behind to avoid the risk of damage to the vagus nerve. This may pose certain risks (see ["Medical Hazards" on page 16](#)).

6.0. Follow Up After Surgery


The generator is usually turned on 2 weeks after it is implanted. Your doctor programs the generator to the proper settings for you. At the first follow-up visit and at subsequent visits, your doctor checks the VNS Therapy system. Your doctor makes sure that it works well and that the treatment is comfortable for you. Tell your doctor at your next visit if you no longer feel the routine stimulation. Your doctor may decide to change your settings.

 **CAUTION:** It is recommended that you see your doctor **at least once every 6 months**. Your doctor will check the VNS Therapy system for safe and effective operation.

6.1. Resources

You will receive the following documents:

- Implant and Warranty Registration Form — The implant and warranty registration form has information about your generator and lead.
- Patient Implant Card — The patient implant card has details about your generator and lead, your doctor's name and number, and other information needed in case of a device-related emergency.

 **CAUTION:** Carry the patient implant card at all times.

Consider registering with an emergency service such as MedicAlert® Foundation (www.medicalert.org), so information about the VNS Therapy system will be available to hospital and emergency response personnel when needed. If you have questions about the MedicAlert Foundation, discuss it with your doctor.

6.2. Antidepressant Medications

Most patients treated with VNS Therapy in the clinical studies also continued to take antidepressant medications. A significant number of patients had new medications added or doses of their old medications increased during the studies.


Your doctor may advise you to continue to take your antidepressant medications after you begin receiving VNS Therapy. Your doctor may also decide to add new medications to your treatment. Always follow your doctor's instructions regarding your medications.

6.3. After Treatment Begins

6.3.1. Common Side Effects

Call your doctor right away if any of the following occur:

- Your voice is constantly hoarse.
- Stimulation becomes painful or irregular.
- Stimulation causes choking, trouble breathing, trouble swallowing, or significant change in heart rate.
- You or someone else notices changes in your level of consciousness (e.g., you become constantly drowsy).
- You think that the generator may not be stimulating properly or that the VNS Therapy system battery is depleted (stops stimulation).
- You notice anything new or unusual that you relate to the stimulation.
- The sensation that you usually have during stimulation becomes stronger or weaker.
- Your depressive symptoms increase or suicidality (suicidal thoughts or behavior) increases.


 NOTE: For more information, see ["Additional Safety Considerations" on page 34](#).

 NOTE: For more information see ["Device Complications" on page 24](#) and ["Side Effects That may Occur from Stimulation of the Vagus Nerve" on page 33](#).


6.3.2. Medical Tests and Other Devices

Call your doctor *before* you have any of the following:

- **Medical tests** that might affect, or be affected by, the VNS Therapy system.


 NOTE: For more information, see ["Medical Hazards" on page 16](#).

- **An MRI scan.** Because you have a VNS Therapy system, you can have certain types of MRI scans, but not others. If you have an MRI scan, it must be done under specific conditions. **Call your doctor before you have an MRI scan.**

 NOTE: Your generator must be turned off by a healthcare professional.

 NOTE: For detailed MRI warnings, see ["Magnetic Resonance Imaging \(MRI\) Warnings" on page 14](#).

- **Other medical devices implanted.**

 NOTE: For more information, see ["Medical Hazards" on page 16](#).

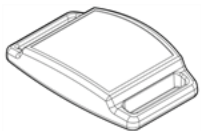
7.0. LivaNova Magnets

After your surgery, your doctor will give you two magnets and accessories. The magnets contain a high-power magnet surrounded by a plastic case in the shape of a watch. Clean the magnet with a soft cloth or sponge, and non-abrasive cleaner. With normal use, it should remain powerful for approximately 3 years.

7.1. Magnet Precautions

- **If stimulation hurts**, contact your doctor right away
- **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.
- **Do not place the magnet over a defibrillator** (sometimes called ICD) since it could turn the device OFF.
- **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.
- **To avoid cracking or damage to the plastic case**, the magnet should be stored at temperatures that range from - 20 °C (- 4 °F) to + 55 °C (+ 131 °F).
- **If you lose your magnet and need a replacement**, contact your doctor.
- **If you are not sure how to use the magnet or have questions**, ask your doctor to show you how.

7.2. Magnet, Accessories, and Use



The magnet can be carried or worn in the following ways:

On the wrist



- Compatible with watch bands designed for fixed lugs (e.g., NATO, G10).
- The magnet should sit on the inside of your wrist.

In a pager belt clip



- Compatible with a standard pager belt clip.
- If worn this way, the magnet does not need to be removed from the clip before use.

Regardless of how the magnet is carried or worn, ensure that the magnet can be placed directly over the generator to stop stimulation.

7.3. How the Magnet Works


VNS Therapy generators contain a component called a reed switch that can sense the presence of a magnetic field. When you hold a magnet over the generator, the reed switch inside the generator closes like a gate. When the magnet closes it, the Normal signal (stimulation) cannot pass. While the magnet closes the switch, the generator is temporarily turned OFF. When the magnet is removed, the generator is turned back ON and can stimulate again.

7.4. When to Use the Magnet

Use the magnet to stop stimulation temporarily or turn OFF the generator in the following situations:

- You plan to sing or speak in public (if stimulation bothers you when you do this)
- You eat (if you have swallowing problems)
- Stimulation becomes uncomfortable or painful

7.5. How to Use the Magnet

 CAUTION: The correct position for the magnet may vary from patient to patient. The position depends on how the generator is implanted. Find the position that works best for you.

7.5.1. Temporarily Stop Stimulation

1. Put the magnet over the generator. If the stimulation stays on, reposition the magnet over the generator until stimulation stops.

Figure 3. Stop Stimulation




2. Leave the magnet over the generator. You may tape it to your chest or use an elastic wrap-around bandage to keep it in place.
3. If you stopped the stimulation because it was painful or felt unusual, call your doctor right away.

With your doctor's permission, it is okay to leave the magnet in place for a short while, for example, to sing a song. The generator will not stimulate while the magnet is in place. The stimulation cycle begins again when the magnet is removed.

7.6. How to Replace the Magnet

To order a new magnet, contact your doctor.

 CAUTION: All magnets can **lose their effectiveness** over time. If you suspect that your magnet is not working, call your doctor.

8.0. Device Complications

Complications linked to the VNS Therapy system can result from the following:


- Surgery
- Generator malfunction (not working)
- Battery depletion (running out)
- The device is touched or moved through the skin

8.1. Surgery

All types of surgery carry some risks. In addition to the risks described in ["Side Effect and Safety Profile of VNS Therapy Observed in Clinical Studies in Depressed Patients" on page 31](#), there are potential mechanical complications related to the surgical implantation of the device. The generator and/or lead can, but rarely do, move or come through the skin. Also, the lead can break or become disconnected from the generator.

8.2. Generator Malfunction

Though rare, the generator can malfunction (not work right). The stimulation from a generator that does not work right can cause intense neck pain, hoarseness, choking, or trouble breathing.

 **CAUTION:** Stimulation from a generator that does not work right could damage the vagus nerve and lead to permanent hoarseness or other complications. Malfunction of the generator could cause the battery to run out sooner than expected. **If you have any of these symptoms**, or if stimulation becomes painful, irregular, or nonstop, place the magnet over the generator. Hold it there to stop stimulation (see ["How to Use the Magnet" on page 22](#)), and **call your doctor right away**.

8.3. Battery Depletion

The battery in the generator can last from 1 to 16 years. The lifespan depends on the following factors:


- Generator model
- Stimulation settings your doctor chooses
- Interaction of the lead and vagus nerve over time

The generator battery loses its power slowly. When it starts to run out, the generator begins to stimulate differently. You may sense this change as irregular stimulation. At the end of battery life, the stimulation stops completely.

The dose settings impact how long the battery in the generator will last. For example, the battery may last for 3 years at a higher setting, compared with 8 years at a lower setting. For the full range of settings in relationship to battery life, ask your doctor.


When the battery in your generator runs out, the generator must be replaced in order for you to continue to receive VNS Therapy. This requires an additional surgical procedure. The operation involves anesthesia and generally takes less than an hour to complete.

Replacement or removal of the lead is a different procedure. It is not required for routine replacement of the generator.

 CAUTION: **After stimulation stops completely** (e.g., the generator battery runs out), you may notice a change in your depressive symptoms. If you think your generator does not work right, call your doctor.


8.4. Manipulation of the Generator and Lead

The generator is secured into place during surgery, but the device can move slightly. It may be possible to feel the lead under the skin after surgery. This is normal and should become less obvious over several weeks. Manipulation of the lead should be prevented at all times.

 CAUTION: Never move or twist the generator or manipulate the lead. This can damage the lead or your vagus nerve. It could require that the generator and lead be replaced.

9.0. Patient Registration and Safety Listing

Government agencies require makers of implantable devices to contact people in case of emergencies related to the device. LivaNova has a list of people who have had the generator and lead implanted. The information is kept in confidential files and is a permanent record of the implantation surgery. LivaNova will release a file only if required by law.

 CAUTION: Send LivaNova a **change of address notice** if you move (see ["Contacts and Resources" on page 41](#)).

10.0. Frequently Asked Questions

How do most people respond to VNS Therapy?

When the generator was tested in the clinical trials, depressive symptoms decreased for most patients. Some patients had no change in depressive symptoms and some got worse while receiving VNS Therapy. Among those patients who did improve while receiving VNS Therapy, some did not improve until they had been receiving VNS Therapy for 6 months or longer.

Can I know if I will be helped before I am implanted with the generator and lead?

At this time, there is no way to predict what your response will be.

What are the results of the VNS Therapy clinical trials?

This guide provides a summary of important safety and effectiveness results from clinical studies. Your doctor can give you more information about the clinical trials (research studies). For details, see ["Clinical Studies" on page 31](#).

What are the side effects of VNS Therapy?

The most common side effects reported are voice alteration (often described as hoarseness), discomfort in the neck (typically mild pain or a tingling sensation), cough, shortness of breath, difficulty swallowing, and a feeling of tightness in the throat. Often these events only occur when the generator is ON. Other less common side effects are discussed in ["Side Effect and Safety Profile of VNS Therapy Observed in Clinical Studies in Depressed Patients" on page 31](#). In general, most side effects become less noticeable over time.

Are the generator and lead materials safe for my body?

Yes, all generator and lead materials that touch your body are safe. Examples of these materials include titanium, stainless steel, polyurethane, and silicone. These materials have a long history of being safely used in medical devices. Detailed information is in the physician's manual, so ask your doctor if you have more questions.

What is the size of the generator and the lead?

The size of the generator depends on the model. It is shaped like a disk and is up to approximately 5 centimeters (2 in.) in diameter. The lead is a thin flexible tube 43 centimeters (17 in.) long. Detailed dimensions are in the physician's manual, so ask your doctor if you have more questions.

What is the implantation surgery like?

You will be given a general or local anesthetic. The operation usually takes 1 to 2 hours. The surgery is typically done with you as an outpatient (you go home the same day) or you may stay in the hospital overnight. Ask your surgeon to tell you more about the anesthetic, surgery, and hospital stay so you will know what to expect.

Are there risks linked with the surgery?

Any surgery has some type of risk. It is important that you discuss this question with your surgeon.

Will the scars be noticeable?

Each person heals and scars differently. You should expect some surgical scars. Most people do not think the scars are a major concern. If this is a special concern for you, discuss it with your surgeon.

Will people be able to see the implanted device through my skin?

The lead is attached to the vagus nerve and not visible. The size of the generator depends on the model. It is shaped like a disk and is up to approximately 5 centimeters (2 in.) in diameter. If you have a small frame or are very thin, the generator may be visible below your left collarbone. Talk to your doctor if you have concerns.

What happens after the surgery?

After surgery (usually 2 weeks later), your doctor will program the treatment settings of your generator. If the stimulation feels uncomfortable, your doctor can change it to make you more comfortable. The doctor uses the programming Wand to check and fine-tune your stimulation settings at subsequent visits.

How long will my implanted lead last?

The lead lifespan varies with each person. A lead would need to be replaced if it is broken. Do not pick, twist, or hit at the areas where the generator and lead are implanted. This helps to avoid damage to the lead.

Will I be able to tell when the stimulator is on or active?

Many people note a change in their voice (often described as hoarseness) or discomfort in the neck (typically mild pain or a tingling sensation) during stimulation. In general, most side effects become less noticeable over time.

What does the magnet do?

The magnet is used to stop stimulation. To stop stimulation, hold the magnet over the generator. Remove the magnet to start stimulation again. For details, see ["Temporarily Stop Stimulation" on page 22](#).

When should I use the magnet?

Use the magnet to stop stimulation temporarily or turn OFF the generator in the following situations:

- You plan to sing or speak in public (if stimulation bothers you when you do this)
- You eat (if you have swallowing problems)
- Stimulation becomes uncomfortable or painful



NOTE: For details, see ["How to Use the Magnet" on page 22](#).

If you need to use the magnet for any of these reasons or any other reason, tell your doctor.

Is it possible to stop all stimulation using the magnet?

Yes. To stop stimulation, hold the magnet over your generator and keep it there. Use this method if you have unusual or painful stimulation, and call your doctor right away. The magnet will stop all stimulation while it is held in place. You may need to secure the magnet over your generator with tape.

What if the magnet is accidentally kept in place over the generator for an extended period?

No stimulation is delivered while the magnet is kept over the generator. Normal stimulation will resume only after the magnet is removed.

How does the magnet work?

The generator has a sensor (the reed switch) that recognizes the magnet and temporarily stops stimulation as long as the magnet is held or taped over the generator.

Can any magnet be used?

Only the magnet provided by your doctor should be used with your VNS Therapy system. If you lose your magnet or need extra magnets, contact your doctor. In an emergency, you may try other strong magnets. The use of other magnets not supplied by your doctor will not harm the VNS Therapy system, but there is no way to know whether a magnet other than the LivaNova magnet will work. Details about the LivaNova magnet can be found in the Patient Magnet Directions for Use at www.livanova.com.

Who should carry the magnet?

You should carry the magnet with you at all times. You may also want your family members or caregivers to carry a LivaNova magnet.

Is the magnet an environmental hazard?

The magnet can damage computer disks, credit cards, watches, and other items affected by strong magnetic fields. Keep your magnet at least 25 centimeters (10 inches) away from any of these items. Do not store magnets near such items.

Will my magnet's strength be affected if I drop it?

The magnet's strength should not be affected if the magnet is dropped. This is a common problem with low-power magnets. The LivaNova magnet is a high-power magnet and should not lose its strength when dropped or if the outer case cracks.

How long will my magnet last (does it have a use by date)?

Based on normal use, the magnet should have an approximate service life of 3 years.

Can my cellular phone, tablet computer and its cover, smart watch, or other similar device affect my generator?

Yes, these devices may contain magnets that can cause your generator to stop stimulation. Keep this type of equipment at least 20 centimeters (8 inches) away from your chest. See "[Devices with Strong Electromagnetic Fields](#)" on page 15 for more information on devices with strong electromagnetic fields.

Other Questions?

If you have other questions about the VNS Therapy system, any of its parts, or VNS Therapy in general, talk to your doctor.

11.0. Clinical Studies

11.1. Side Effect and Safety Profile of VNS Therapy Observed in Clinical Studies in Depressed Patients

This topic describes the side effects and safety concerns that were observed in the clinical studies that led to the approval of VNS Therapy as a treatment for patients with treatment-resistant depression. The side effects and safety concerns associated both with the surgical implantation procedure for the VNS Therapy system and those related to stimulation of the vagus nerve are discussed. In addition, this section discusses some specific safety considerations for the treatment of patients with depression.

11.1.1. Overview of Clinical Studies

Safety and effectiveness studies involved a total of 295 men and women who received VNS Therapy along with their usual antidepressant treatments. Sixty of them participated in a pilot study that compared depressive symptoms before and after VNS Therapy. The favorable results from that study prompted a second study. The second study (sometimes referred to as “D-02”) consisted of two “phases” and included people with treatment-resistant depression. In the first phase, which lasted 3 months, half of the 235 patients who were implanted with the device had it turned on while the other half did not. Patients did not know whether the device was on or not. In the second phase of the study (referred to as the “long-term phase of D-02”), all patients had the device turned on after the first 3 months and were followed for at least a full year. Patients in the long-term phase of the study were allowed to have adjustments in the doses of depression medications prescribed and were also allowed to have new medications or ECT prescribed during this time. These patients were compared to a separate group of 124 people with treatment resistant depression who received antidepressant treatments, but who did not have the device implanted.


11.1.2. Surgical Implantation Procedure


11.1.2.1. Side Effects that may Occur from Implantation of the VNS Therapy System

The following is a list of the side effects that were most commonly reported as being related to the surgical implantation of the VNS Therapy system during the D-02 study. The side effects that occurred in at least 3% of the patients in the D-02 study and the percentage of patients who experienced them were as follows:

- Incision pain (36%)
- Voice alteration (33%)
- Incision site reaction (for example, redness, itching, soreness) (29%)
- Pain around the device generator or leads (23%)
- Other reactions around the device generator or leads (for example, swelling, tenderness) (14%)
- Pharyngitis (inflammation of the throat) (13%)

- Difficulty swallowing (11%)
- Numbness (11%)
- Nausea (9%)
- Shortness of breath (9%)
- Headache (8%)
- Neck pain (7%)
- Pain elsewhere (7%)
- Increased cough (6%)
- Paresthesia (tingling sensation) (6%)
- Infection at the surgical site (4%)
- Chest pain (3%)
- Dizziness (3%)
- Increased tension of the muscles (3%)
- Vocal cord paralysis (3%)
- Skin rash (3%)
- Inability to pass urine (urinary retention) (3%)

 CAUTION: Implantation of the lead may cause nerve constriction (squeezing of the nerve). **Call your doctor right away** if your voice is always hoarse a few days after surgery. (There could be other explanations for this symptom.)

 CAUTION: If you undergo generator replacement with a larger size device, you may initially experience increased discomfort or inflammation at the surgery site. Call your doctor if you experience symptoms that are concerning or do not improve.

Many of these side effects resolved within 30 days, but in some cases the side effects persisted beyond 90 days. Voice alteration was particularly likely to persist for longer than 90 days.

11.1.2.2. Infrequent Surgical Side Effects

Surgical side effects that were reported in the D-02 study less frequently than those listed above, but by at least 1% of patients, were as follows: allergic reactions, weakness, fever, bleeding, heart palpitations, difficulty sleeping, neck rigidity, loss of appetite, heartburn, vomiting, bruising, swelling, itching, ear pain, ringing in the ears, and tightness in the throat. Additional serious side effects (reported in less than 1% of patients) were: transient heart stoppage (occurred in the operating room), decrease in heart rate (occurred in the recovery room), abnormal thinking (occurred in the post-operative period, thought due to narcotics), aspiration pneumonia (occurred in the post-operative period), and acute kidney failure.

11.1.2.3. Surgical Scars

There are surgical techniques that may minimize surgical scars. Talk to your surgeon if you have specific concerns.

11.1.3. Stimulation of the Vagus Nerve

Side effects can occur from stimulation of the vagus nerve by the VNS Therapy system. Generally, the side effects become less noticeable over time for most patients. Only 3% of patients discontinued VNS Therapy system because of side effects during the first year of treatment in the D-02 study. Sometimes your doctor can lessen the side effects by changing the device settings.

The VNS Therapy system is not a drug. It does not cause drug-related side effects and does not interact with drugs, including antidepressant medications you may be taking.

11.1.3.1. Side Effects That may Occur from Stimulation of the Vagus Nerve

The table below shows the side effects that were most commonly reported as being related to stimulation of the vagus nerve by the VNS Therapy system during the D-02 study. Side effects reported in at least 3% of the patients are included. Table 2 shows the percentage of patients who had these side effects after 3 months, 12 months, and 24 months of stimulation.

Table 2. Stimulation Related Side Effects—Study D-02

Stimulation-Related Side Effects Reported by Greater Than or Equal To 3% of Patients—Study D-02			
	Months of Stimulation		
	3	12	24
Voice alteration	59%	54%	52%
Increased cough	24%	7%	4%
Shortness of breath	14%	16%	14%
Neck pain	16%	13%	15%
Difficulty swallowing	13%	5%	5%
Paresthesia (tingling)	11%	4%	4%
Tightness in throat	10%	6%	5%
Pain	6%	6%	5%
Nausea	6%	1%	1%
Pharyngitis (inflammation of the throat)	6%	5%	4%
Headache	5%	3%	3%
Chest pain	4%	2%	2%
Heart palpitations	4%	3%	2%
Difficulty sleeping	4%	1%	1%
Heartburn	3%	2%	2%

Table 2. Stimulation Related Side Effects—Study D-02 (continued)

Stimulation-Related Side Effects Reported by Greater Than or Equal To 3% of Patients—Study D-02			
	Months of Stimulation		
	3	12	24
Increased muscle tension	3%	4%	3%

While many of the incidences of these side effects resolved over time, some patients continued to report the side effects throughout the study. This was particularly true for voice alteration, shortness of breath, and neck pain. Some of the side effects caused by stimulation typically occur only during stimulation (the ON time of the stimulation cycle).

11.1.3.2. Other Side Effects Reported During VNS Therapy

The following is an alphabetical list of additional side effects reported as at least possibly due to vagus nerve stimulation during the 12-month D-02 study: abnormal dreams, abnormal thinking, agitation, amenorrhea (stoppage of menstrual periods), amblyopia (visual disturbance), amnesia, anxiety, arthralgia (joint pain), asthma, colitis, constipation, deafness, diarrhea, dry mouth, emotional lability, eructation (belching), eye pain, flatulence, flu syndrome/viral infection, gastritis, hiccup, hypertension (high blood pressure), hypotension (low blood pressure), increased appetite, laryngitis, migraine, myalgia (muscle ache), myasthenia (muscle weakness), nervousness, postural hypotension (low blood pressure upon standing), rhinitis, sedation, stridor, sweating, syncope (fainting), tachycardia (fast heart beat), tremor, twitching, vasodilatation (flushing), weight gain, weight loss.

11.1.4. Additional Safety Considerations

11.1.4.1. Worsening Depression

People who have depression can experience waxing and waning of their depressive symptoms even while receiving treatment. During the first phase of the D-02 study when half the patients had their VNS Therapy system turned on and the other half did not, the study doctors reported 12 serious events of worsening depression that required hospitalization. Four of these events occurred in patients who had their device turned on, and the other eight occurred in patients who did not have their device turned on. During the long-term phase of the D-02 study (months 3 through 12), study doctors reported 62 additional serious events of worsening depression in 31 patients. If your depression worsens during VNS Therapy, inform your doctor promptly.

11.1.4.2. Mania

Some patients being treated for depression may experience a manic or hypomanic episode characterized by an abnormal and persistently elevated or irritable mood. Patients with known bipolar disorder (manic depressive illness) are the people most likely to experience this phenomenon. It is believed that effective antidepressant treatments themselves can cause a manic or hypomanic episode. In the D-02 study (through

the 12-month long-term phase), six hypomanic or manic episodes were observed. Five of the six patients had a known history of prior hypomanic or manic episodes. One of these events was considered serious enough to require hospitalization; the other five events were either treated with medication or only required observation. If you experience symptoms of an elevated or irritable mood during VNS Therapy, inform your doctor promptly.

11.1.4.3. Suicides

People with depression may experience the emergence of suicidal thoughts and behavior (suicidality) whether or not they are receiving treatment. In the D-02 study (through the 12-month long-term phase), there were one suicide and seven additional suicide attempts in six patients. If you or someone else notices your depression worsening or indications of suicidality, inform your doctor promptly. Additionally, if you or someone else notices any of the following symptoms, inform your doctor immediately as they may indicate an increased risk of suicide: new or worse anxiety, feeling agitated or restless, panic attacks, difficulty sleeping, new or worse irritability, acting aggressive, being angry or violent, acting on dangerous impulses, an extreme increase in activity and talking, other unusual changes in behavior or mood.

11.1.4.4. Deaths that Occurred During the Depression Studies

In the D-02 study (through the 12-month long-term phase), there were four deaths. One occurred in a patient who had enrolled in the study but had not yet received a VNS Therapy system implant. The causes of death for the other three patients were as follows: suicide (described above), sudden death of unknown cause, multi-organ system failure.

Glossary

A

adjunctive therapy

Additional, add-on; therapy that is added on to other treatments

adverse event (AE)

Complications and side effects

aspiration

Accidental sucking in of food particles or fluids into the lungs

C

clinical benefit

Categories assigned to describe change in depressive symptoms on Hamilton Rating Scale for Depression-24 Item after VNS Therapy; meaningful clinical benefit - 25% to 49% improvement in depressive symptoms; highly meaningful clinical benefit - 50% to 74% improvement in depressive symptoms; extraordinary clinical benefit - over 75% improvement in depressive symptoms

clinical studies

Tests of the effectiveness and safety of a therapy on humans

D

diathermy

Diathermy is a treatment to promote healing or relieve pain

dysautonomia

A term used to describe several different medical conditions that cause a malfunction of the Autonomic Nervous System, which controls the “automatic” functions of the body that we don’t consciously think about (e.g., heart rate, blood pressure, digestion, dilation, and pupil constriction, kidney function and temperature control)

E

electrode

Part of the lead that transfers electrical current to the vagus nerve

electromagnetic interference

EMI; A disturbance generated by an external source that affects an electrical circuit

G

generator

A device implanted in the patient's chest; holds the battery and electronics that deliver stimulation to the vagus nerve through the lead

H

HRSD24

Standardized test to measure depressive symptoms as reported by the doctor; Hamilton Rating Scale for Depression-24 Item

I

IDS-SR30

Standardized test to measure depressive symptoms as reported by the patient, Inventory of Depressive Symptomatology Self-Report

L

laryngeal

Commonly called the "voice box"

lead

Small flexible insulated wire that connects the generator to the vagus nerve

LivaNova

Company that makes the system

M

MADRS

Standardized test to measure depressive symptoms as reported by the doctor, Montgomery-Åsberg Depression Rating Scale; commonly used in Europe

magnet

LivaNova-provided magnet included in Patient Kits

MR

Magnetic resonance

MR Conditional

A medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields

MR Unsafe

A medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment

MRI

Magnetic resonance imaging

P

Programmer

Programming computer; tablet-style touchscreen computer loaded with programming software used to program LivaNova generators

programming system

Non-implantable parts of the System used to program the generator; consists of a computer, software and a wand

R

reed switch

A mechanism that works like a gate. When the magnet closes it, the normal signal (stimulation) cannot pass; the generator is temporarily turned OFF

remitter

Study participant who was essentially free of depressive symptoms after receiving VNS Therapy; determined by scores of standardized tests; also called complete responder

responder

Study participant whose depressive symptoms were reduced by 50% or more after receiving VNS Therapy; determined by scores of standardized tests

S

stimulate

Send electrical signal; the generator sends an electrical signal through the lead to the vagus nerve

T

treatment-resistant depression (TRD)

Depression that has not responded to multiple antidepressant treatments

V

vagus nerve

A nerve that extends from the brain through the neck to the major organs (e.g., heart, lungs, and stomach, etc.) in the torso

vagus nerve stimulation

The electrical signal sent from the generator to the vagus nerve

vascular

Relates to the veins, arteries, etc., that carry fluids (such as blood) through the body.

VNS

vagus nerve stimulation

VNS Therapy

Treatment received from vagus nerve stimulation

VNS Therapy system

All of the parts that provide VNS Therapy: generator, lead, programming wand, programming computer, programming software, and magnets

W

Wand

Programming wand; instrument used to check or change generator settings

Contacts and Resources

For information and support in use of the system or any of its accessories, contact your doctor.

Contacts

		
Manufacturer	European Authorized Representative	Swiss Authorized Representative
LivaNova USA, Inc. 100 Cyberonics Blvd Houston, Texas 77058 USA	LivaNova Belgium NV Ikaroslaan 83 B-1930 Zaventem BELGIUM	LivaNova Switzerland Rue de Grand-Pont 12 CH-1003 Lausanne SWITZERLAND

Regulatory Authority Websites

Report all adverse events related to the device to your doctor and to your local regulatory authority.

Australia	https://www.tga.gov.au/
Canada	https://www.canada.ca/en/health-canada.html
UK	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EU	https://ec.europa.eu/growth/sectors/medical-devices/contacts_en