

A photograph of a young woman with dark hair, wearing a red top, smiling warmly. She is sitting at a wooden table with a white mug and a glass of dark liquid in front of her. The background is a bright, slightly blurred indoor setting.

Starting your VNS Therapy™ Journey

**Welcome to the
community of over
135,000 people who have
chosen VNS Therapy™!**



**This booklet will help you understand
what to expect from the next step in
your VNS Therapy™ journey.**

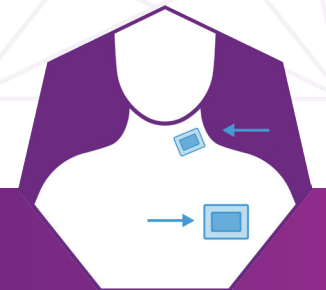
- ✔ Advice on recovering after surgery
- ✔ What to expect from your first programming appointment
- ✔ Tips for living with VNS Therapy™

Resting and recovering after surgery



After your VNS Therapy™ surgery, it's time to rest and recover before your device is turned on.

- **Be kind to yourself** - recovery from surgery is different for everyone, it's normal to need rest.
- **Encourage yourself** to take some gentle exercise and breathe in the fresh air!
- **Drink plenty of water** and eat healthy foods to help your body recover.
- **Ask your friends, family or neighbours for help** if you need it.
- **Get back into your usual routine** as quickly as possible.



Caring for your wounds

You'll have two wound dressings from where your surgeon made the incisions to implant your VNS Therapy™ System - on the left side of your chest and neck. You may feel some soreness, but this is normal.

Your doctor or nurse has given you advice on how to keep the wounds clean during the healing process. The most common side effect from the surgery is infection – so contact your doctor if you have any concerns.

Switching on your VNS Therapy™ System

Two weeks after the procedure, when your wounds have healed, you'll have an appointment with your doctor to switch on your VNS Therapy™ System!

Your doctor will use a **tablet** and a **wand** to connect to your **generator**, then switch on your VNS Therapy System and begin to program the settings.



Connecting the programming system

- 1 Your doctor will hold the wand over where the generator was implanted. Once the wand and the generator have connected, the tablet will show your doctor the details of your VNS Therapy™ generator.
- 2 Each setting will be programmed by your doctor with the tablet. The generator can now start sending signals through the lead to the vagus nerve in an effort to control your seizures.
- 3 Over a series of appointments, your doctor will continue to use the programming system to adjust your stimulation settings to your needs and check that the generator and lead are functioning correctly. It's important to keep attending your appointments as planned by your doctor.

During stimulation, you may notice a tingling feeling or a change in your voice. This usually becomes less noticeable over time, but if it's uncomfortable, your doctor can adapt the settings. If you have any concerns, speak to your doctor immediately.



More seizure-free moments with VNS Therapy™

Exercise, sports and activities

- Regular exercise is encouraged to stay healthy - talk to your doctor before starting something new and continue to proceed with care during activities that could be risky.
- If you enjoy high impact contact sports - be aware that physical trauma to the generator or lead can cause damage, so it's important to discuss these types of activities with your epilepsy team first to advise on precautions.

Travelling with VNS Therapy™

- Planning a holiday? Great! Whilst the security systems at the airport shouldn't affect your VNS Therapy™ System, move through them at a steady pace, keeping around 40cm away from the equipment (do the same for supermarket scanners).
- You may find it useful to keep your **Patient Information Card** with you, to show to airport security if necessary or if you need any help when you're away from home.



Quick tips The VNS Therapy™ Magnet

1

Remember to keep your VNS Therapy™ Magnet with you at all times, ready to swipe if you notice a seizure about to start, or to hold over the generator if you need to temporarily stop stimulation.



01

2

You could also give a magnet to a family member or someone else you trust. If you'd like to help your school or workplace understand how to swipe the magnet, please ask your doctor for a VNS Therapy™ Magnet poster.



02

3

Keep your magnet at least 25 centimetres away from credit cards, televisions, microwaves, watches or any items affected by strong magnetic fields as your magnet could damage these items.

The VNS Therapy™ generator is affected by strong magnetic fields, which can be found in some household items containing magnets such as children's toys, induction hobs, and tablet computers. It's best to keep these items at least 20cm away from your generator to avoid an extra stimulation or temporarily stopping stimulation.

So, if you're watching a film or browsing on your tablet, resist the temptation to rest it on your chest! Take a look at page 14 for further information or talk to your doctor for advice.

Medical procedures with VNS Therapy™

Before you have any other medical procedure, it's important to tell your doctor and any treating technician or nurse that you have a VNS Therapy™ System implanted.

MRI scans with VNS Therapy

Many people with VNS Therapy™ implanted can still have an MRI scan safely performed under certain conditions.

- Before an MRI scan, tell the medical team that you have a VNS Therapy™ System implanted to ensure the correct conditions are met depending on the location and model of your generator.
- Do not take the magnet into the scanning room.
- Your doctor has access to detailed MRI information for VNS Therapy™ in the physician's manual.

Other medical procedures

- Most routine diagnostic procedures, such as diagnostic ultrasound, CT scans, and radiography (X-rays) shouldn't affect your VNS Therapy™ System.
- For some procedures, like a mammography, you may need to be positioned specifically to account for your generator placement.
- Other procedures such as radiation treatment may damage the generator but no testing has been done to date. Discuss with your doctor first.
- The generator may affect other implanted medical devices being implanted, such as cardiac pacemakers.
- Refer to the Patient Guide for more details or speak with your doctor.



Your VNS Therapy™ journey

Throughout your VNS Therapy™ journey, remember to be kind to yourself, and allow yourself time to adjust.

Your doctor will continue to support you, so make sure that you see them at least once every 6 months.

Keep in mind that the effects of VNS Therapy™ can take some time and each person's experience is different. You may be interested in keeping track of your journey - ask your epilepsy team for a VNS Therapy™ Experience Journal to guide you.

Safety Information for the VNS Therapy™ System

Brief Summary of Safety Information for Patients VNS Therapy™ System [Epilepsy Indication] (August 2020)

1. INDICATIONS

The VNS Therapy System 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.

If you have the AspireSR™ (Seizure Response) Model 106, SenTiva™ Model 1000 or SenTiva DUO™ Model 1000-D device, it has a feature called the Automatic Stimulation Mode. This feature is for patients who experience seizures that are associated with an increase in heart rate. The feature can also be turned off by your physician, allowing the device to operate the same way as other VNS Therapy™ System models

2. CONTRAINDICATIONS

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

Diathermy— Inform anyone treating you that you CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (hereafter referred to as “diathermy”) anywhere on your body because you have an implanted VNS Therapy System (sometimes referred to as a “Vagus Nerve Stimulator” or “Vagus Nerve Stimulation”). 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

Avoid excessive vagus nerve stimulation — Excessive stimulation of the vagus nerve can be

produced by frequent magnet activation or more than 4 hours of continuous stimulation due to repeated magnet activations.

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: history of previous therapeutic brain surgery or brain injury, dysautonomias, lung diseases or disorders, including shortness of breath and asthma, ulcers (gastric, duodenal, or other), fainting (vasovagal syncope); irregular heartbeats (heart arrhythmias) or other heart abnormalities; other concurrent forms of brain stimulation; pre-existing hoarseness; progressive neurological diseases other than epilepsy or 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). You should see your physician if you show 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.

Not a cure — 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.

Before having any MRI 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 undergoing an MRI scan with your VNS Therapy™ System, the VNS 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 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.

Cardiac Arrhythmia (Model 106 or 1000/1000-D only) — If you have a cardiac arrhythmia, the Automatic Stimulation feature of the Model 106 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. PRECAUTIONS — IMPLANTABLE DEVICE: GENERAL

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

Laryngeal irritation may result from stimulation — Patients who smoke may have an increased risk of laryngeal (commonly called the “voice box”) irritation.

AutoStim Devices (Model 106 and 1000/1000-D)

Use during exercise — 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 — 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 — 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. AutoStim follow-up visits — Use of the AutoStim feature will reduce battery life. Once the AutoStim feature has been activated, your doctor will work with you to determine a treatment plan to get to the most benefit.

Time-based Features (Models 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.

**5. PRECAUTIONS — IMPLANTABLE DEVICE:
ENVIRONMENTAL & MEDICAL HAZARDS**

Being close to certain types of equipment can affect the generator. Move away from or avoid equipment such as transmitting antennas.

Pacemaker Warning signs — Talk to your doctor before going 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 tests to date show that they do not affect the generator.

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 device. Move at least 1.8 meters (6 feet) away from any equipment that interferes with your device.

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 — Electrical or electromechanical devices with a strong static or pulsing magnetic field can cause the generator to start suddenly. Such devices may include strong magnets, tablet computers and their covers, hair clippers, vibrators, antitheft tag deactivators, and loudspeakers. 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 device may return to regular operation.

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 in this section. 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 the implanted device.

Radiation treatment — Treatment with radiation, cobalt machines, and linear accelerators may damage the generator. No testing has been done to date. 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.

While the generator is stimulating or being set or tested, it may briefly interfere with nearby

equipment. If this happens, move at least 1.8 meters (6 feet) away from such 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. In theory, the generator could affect them, but no effects have yet been reported. No detailed testing has been done, so the effects are unknown.

Other 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.

6. PRECAUTIONS — MAGNETS

After your operation, your doctor will give you two magnets and accessories. The magnets contain a high-power magnet that is surrounded by a plastic casing in the shape of a watch. With normal use, they should remain powerful for approximately 3 years

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

Other implanted devices — 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.

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

If you are not sure how to use the magnet or have questions, ask your doctor to show you how.

7. SIDE EFFECTS

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); hypoesthesia (impaired sense of touch); increased coughing; infection; insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; paresthesia (prickling of the skin); pharyngitis (inflammation of the pharynx, throat); voice alteration (hoarseness); vomiting. Adverse events reported in clinical investigation of the AutoStim feature were comparable.

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For more support, visit www.VNSTherapy.co.uk



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