A small change can make a big difference

An introduction to VNS Therapy

Information brochure developed for health care providers to help them explain VNS Therapy to patients
You may be a candidate for VNS Therapy if you have been unable to adequately respond to several antiepileptic drugs or cannot tolerate the side effects of antiepileptic medications and are considered to have difficult-to-treat epilepsy. Studies suggest that globally speaking approximately one in three people with epilepsy suffer from difficult-to-treat epilepsy.

When other therapeutical options have not worked out for you, vagus nerve stimulation (VNS Therapy) is still a promising therapy.

VNS Therapy is indicated and has been approved in many countries as an adjunctive therapy, i.e. a treatment to be used in conjunction with another therapy, usually medication. VNS Therapy is indicated for reducing the frequency of seizures in children, adolescents and adults with partial onset seizures, with or without secondary generalisation, or generalised seizures that are refractory to antiepileptic medications.

To date (2009), approximately 49,000 people with epilepsy have been treated worldwide with VNS Therapy.

What are the components?

VNS Therapy works 24 hours a day, every day, for many years.
VNS Therapy uses a small medical device (the generator) that will send small electrical pulses to the left vagus nerve in the neck.
The vagus nerve is a major communication link between the body and the brain. It delivers these electrical impulses to the brain where seizures are believed to start.
VNS Therapy helps to prevent the electrical irregularities that cause seizures.
**What does VNS Therapy involve?**

**STEP1: Implanting the VNS Therapy generator and lead**

VNS Therapy is not brain surgery.

Implanting the device requires a simple surgical procedure, which will involve just a short stay in the hospital.

The vagus nerve is periodically stimulated at the neck. Stimulation is provided by the generator sitting under the skin just below the left collar bone or close to the armpit. A small incision is made in the neck to attach two tiny wires (electrodes) to the left vagus nerve. The wires are threaded beneath the skin from the generator to the vagus nerve in the neck.

Aside from small scars (which usually fade with time and blend in with the natural fold of your neck) and a slight bulge in your chest, the device should be barely noticeable.
**STEP 2: Adjusting the VNS Therapy parameters**

During outpatient visits, your doctor or nurse will be able to read and adjust the stimulation settings. This is a typically painless procedure and can even be performed through your clothes. The device will function 24 hours a day, every day on a continuous cycle as programmed by your doctor or nurse, meaning that you will not have to worry about it. Once the device has been programmed, your doctor or nurse will then schedule a series of follow-up visits to review your progress.

Initially, you might be required to see your doctor or nurse once every two weeks to ensure that the stimulation settings are working optimally for you. Later, you will simply need to visit your doctor or nurse every few months.

![Kristof, on VNS Therapy for 1.5 years](image)

**What results can you expect?**

**VNS Therapy may bring you seizure relief**
Successful VNS Therapy most often decreases seizure rate. The extent of the seizure reduction is variable for each person. And whilst the effects of VNS Therapy may take between a few months to one or two years to reach their optimum level, the positive effects typically will not decline; on the contrary, they could potentially further improve over time.

**Improving your quality of life**
By using VNS Therapy, you could experience fewer and less severe seizures. In addition, many patients using VNS Therapy have also reported they have had improvements in mood, increased alertness and enhanced memory. Furthermore, physicians have confirmed that some patients have been able to reduce the quantity and/or doses of medications over time. And many patients using VNS Therapy no longer have to make as many visits to the hospital.

**Are there potential side effects?**
The most common side effects of VNS Therapy include temporary hoarseness changes in voice tone, coughing, a tickling sensation in the throat and shortness of breath. These side effects occur during the stimulation periods and typically decrease over time.
What is the function of the VNS Therapy magnet?

The magnet may provide additional benefits for some people, but it is not necessary to use it for your regular stimulation.

By swiping the VNS Therapy magnet over the generator, either you or your caregiver will immediately activate therapy, which can be done either when you feel a seizure coming on or during a seizure. Using the magnet could potentially stop the seizure, shorten the seizure or decrease the intensity of the seizure. Furthermore, it might also improve the recovery period following the seizure.

You can also fix or hold the magnet over your VNS Therapy device to temporarily stop stimulation during times (for example while undertaking certain activities) when even mild side effects could be inconvenient.

If you experience troublesome side effects for an extended period of time, contact your physician.

Frequently asked questions

Will electrical and electronic equipment affect the VNS Therapy device?

- **What about using household electronic equipment?**
  Generally, household appliances, such as microwave ovens, toasters, hair dryers and mobile phones, will not affect the VNS Therapy device. Nor does the device affect the normal operation of these household devices.

- **What about metal detectors, especially airport security systems?**
  Again, these should not affect the VNS Therapy device. However, as a precaution, we recommend that you move through them at a steady pace rather than linger in the area.

Is VNS Therapy safe for pregnant women?

Although the safety and effectiveness have not been established during pregnancy, healthy, to-term births have been reported with VNS Therapy. In addition, animal studies have not shown any harm to the foetus. In case you want to become pregnant or you are pregnant, please contact your doctor.
Frequently asked questions

**What about playing sports and driving?**
You should always consult your doctor or nurse before engaging in unsupervised activities, such as driving and swimming, and in strenuous sports that could harm you or others.

**If I have VNS Therapy, will I still need to take medications?**
VNS Therapy is an added treatment to your current medications. It is not a replacement for them. Some people in the clinical trials were able to reduce their medications over time. You and your physician will determine your ongoing treatment regimen. It is important to always follow your physician’s recommendations about your medications.

**Are there risks linked with the surgery?**
Any surgery has some type of risk, such as infection. It is important that you discuss this question with your surgeon; however, VNS Therapy has a good safety profile and has been safely implanted in more than 49,000 patients with epilepsy to date (2009).

**What will happen when the battery in my VNS Therapy device goes out?**
Another procedure is required to replace the generator once the battery is depleted. This procedure requires only one incision and usually takes less than an hour to perform.

**What will happen if VNS Therapy doesn’t work for me?**
If VNS Therapy has not helped you after one or two years, or you and your doctor consider VNS Therapy as ineffective in any way, there are several options. The device can simply be turned off and remain in your chest for an indefinite period of time. The generator may also be removed if you prefer or your doctor recommends it. This will involve a minor surgical procedure. Importantly, if you have VNS Therapy, you are still a candidate for any new treatment that could emerge in the future, for instance, new surgical procedures or new drugs.
EUROPEAN INDICATION FOR USE
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 generalisation) or generalised seizures, which are refractory to antiepileptic medications.

CONTRAINDICATIONS
The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

WARNINGS
Physicians should inform patients about all the potential risks and adverse events discussed in the VNS Therapy System Physician’s Manual including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming and bathing, or in strenuous sports that could harm them or others.

Patients who have pre-existing swallowing, cardiac or respiratory difficulties (including but not limited to obstructive sleep apnoea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition.

The VNS Therapy System may affect other medical devices and other medical devices may affect the VNS Therapy System. MRI can be safely performed; however, special equipment must be used.

ADVERSE EVENTS
The most common reported side effects from stimulation include hoarseness, paresthesia (prickling feeling in the skin), dyspnoea (shortness of breath) and increased coughing. The most commonly reported side effect from implant surgery is infection.

References
- Ben-Menachem E. et al. Analysis of direct hospital costs before and 18 months after treatment with vagus nerve stimulation therapy in 43 patients. Neurology 2002;59 (Suppl. 4):S44-S47.
- Labar D.R. Antiepileptic drug use during the first 12 months of vagus nerve stimulation therapy. Neurology 2002;59 (Suppl. 4):S38-S43.