

A woman with short reddish-brown hair and black-rimmed glasses is hugging a man from behind. They are on a beach with the ocean in the background. The woman is wearing a ring on her finger. The man has short, thinning brown hair. The overall mood is warm and intimate.

WHAT IF ...

the small
things became
easier?

An introduction to
VNS Therapy[®]

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

A woman wearing a straw hat and a light-colored shirt is shown from the chest up, focused on pruning a tree branch with red-handled shears. The background is filled with lush green leaves, creating a natural and serene atmosphere.

Why your doctor has recommended VNS Therapy®

WHAT IF

› Why do I need VNS Therapy®?

Despite trying multiple standard antidepressant treatments, we have struggled to get you well or keep you well for a prolonged period of time.

You are not alone. Approximately **50%** of all patients with depression will experience a **chronic** or **recurrent** course of illness for which long-term treatment is recommended.

We would like to try a different approach alongside the tablets and therapies that you are currently having.

Depression **generates one of the greatest burdens of all diseases worldwide** and patients with Treatment Resistant Depression are expected to have a more difficult course of illness compared to those who achieve remission.

➤ What is VNS Therapy®?

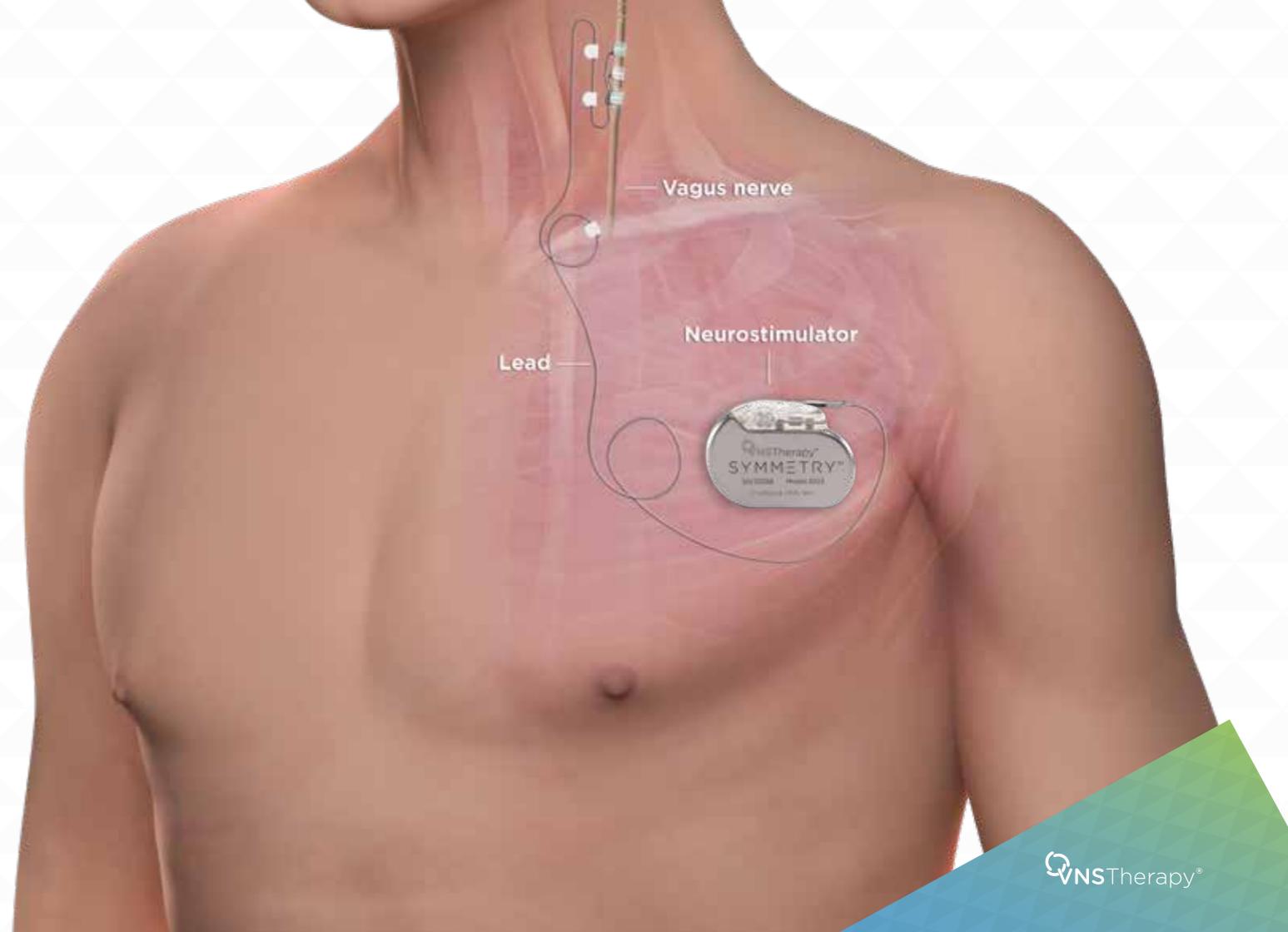
VNS Therapy® is a **non pharmacological treatment** and stands for **Vagus Nerve Stimulation Therapy**. The vagus nerve is the longest nerve in your body and is the main nerve that connects your brain to the rest of your body.

VNS Therapy® modulates established pathways involved in depression.

The neurostimulator is placed under your skin on the left side of your chest (similar to a pacemaker). This battery transmits small electrical signals that are sent through a thin lead under the skin to your vagus nerve.

The lead is placed around the vagus nerve in the neck.

VNS Therapy is not brain surgery.



➤ What is the implantation procedure like?

Your psychiatrist will refer you to a local surgeon who will assess you and perform the procedure.

You will normally be asleep during your procedure which will take anywhere between **1 and 2 hours**.

In many cases, the procedure is done as a day case with you going home the same day (although some centers may want to keep you in overnight).

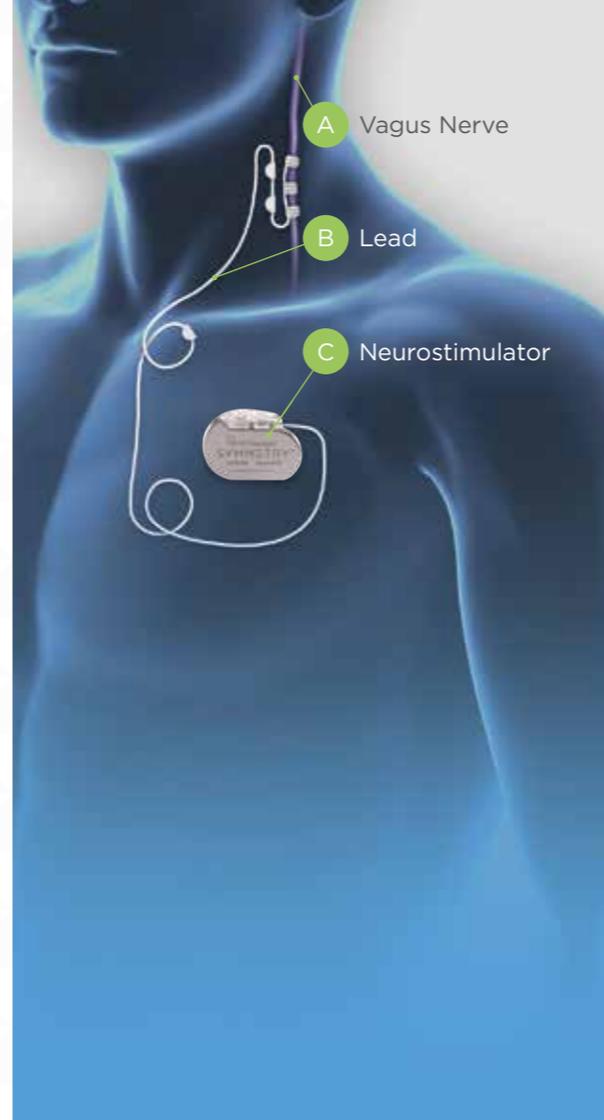
Ask your surgeon to tell you more about the anesthetic, the procedure, and the hospital stay so that you will know what to expect.

The surgeon makes a small cut on the left side of the neck and a second cut below the collarbone in the chest or armpit.

The lead (B) is passed under the skin between the two cuts.

The surgeon wraps the lead around the left vagus nerve (A) in the neck and plugs the other end of the lead into the neurostimulator (C).

The neurostimulator is placed in the “pocket” created at the site of the incision below the collarbone. Finally, the surgeon closes the cuts with stitches or clips.



➤ Are there risks linked with the procedure?

All surgery comes with some risks. The most commonly reported side effect from the implant procedure is infection.

Your surgeon or anesthetist will run through the risks of the procedure with you and will make sure that any questions you have are answered.

It is important that you discuss any worries or concerns you have with your surgeon or anesthetist.

➤ Will the scars be noticeable?

The surgeon will try his/her best to make the scar on your neck in one of the natural skin folds so once healed it will be difficult to see.

However, each person has different healing and scarring results, and some scars are easier to see than others.

Most people do not think the scarring after the VNS procedure is a major concern.

If this is a special concern for you, please discuss it with your surgeon.

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

The lead that travels under the skin in your neck is not visible.

The neurostimulator is shaped like a disk and is up to approximately 5 centimeters (2 inches) in diameter, depending on the model.

If you have a small frame or are very thin, the device may be visible below your left collarbone. This is the same as someone who may have a pacemaker for their heart.

Talk to your doctor if you have worries.

➤ What happens after the procedure?

After your procedure (usually 2 weeks later), your psychiatrist will turn your device on with a special computer tablet and 'a wand' that talks to the neurostimulator through your skin.

This starts the 'ramp up' process. As of this moment, the VNS Therapy® is active.

The ramp up process is where your psychiatrist will see you frequently over the first couple of months and will gradually turn up the settings to get you to the right treatment 'dose'.

The speed of this process will be led by you and how quickly you are able to move through the settings.

If the stimulation feels uncomfortable, your doctor can change it to make you more comfortable.

Your doctor will monitor your progress regularly and may change your treatment over time.



➤ Will I be able to tell when the neurostimulator is on?

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.

➤ Will I still need to take my medication?

VNS Therapy® is known as an adjunctive treatment – this means that it is given along with your normal treatments.

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.

➤ How do most people respond to VNS Therapy®?

When the device 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.

➤ Will VNS Therapy® work for me?

Your psychiatrist has assessed you for VNS Therapy® based on your treatment history. The clinical data shows that, when VNS Therapy® is combined with traditional treatment, over two thirds of patients did respond to VNS Therapy® but it is impossible to predict response for individual patients.

➤ Can I go through the body scan at the airport?

Metal detectors should not affect the neurostimulator 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.

➤ What effect will VNS Therapy® have on my depression?

The effect of VNS Therapy® is not immediate, but over the course of months, you may notice a significant improvement of your symptoms.

In the majority (67,6%) of patients who have battled depression for a long time and whose standard treatments have failed, depressive symptoms become significantly less severe when VNS Therapy® is combined with treatment as usual and Quality of Life improves.

Experiencing periods of **remission** (which means you have very few symptoms of depression) was also found to be more likely with adjunctive VNS Therapy® than without over a 5-year period.

➤ What if it doesn't work?

Most patients (67,6%) do feel better by adding VNS Therapy® to standard treatment, but if you belong to the 30% that don't, then you can talk to your psychiatrist and if you are having some benefit you may wish to continue with the therapy, or your psychiatrist can turn the device off for a period of time.

If you and your psychiatrist decide that there was no benefit from the VNS Therapy® it can be removed or left in-place (but switched off) depending on your preference.

You can also always begin with any other treatment at any time with VNS Therapy®.

➤ What are the contra-indications?

The VNS Therapy® System cannot be used in patients if they have had their vagus nerve removed.

There are certain procedures involving diathermy (a medical electrical procedure) which cannot be given to patients implanted with the VNS Therapy® System.

Your anesthetist or surgeon may also decide that there is a medical reason which may stop you from being put to sleep for your operation.

➤ What are the side effects of VNS Therapy®?

The most commonly reported side effect from the implant procedure is infection. Common implant issues include incision pain, voice alteration, incision site reaction, device site pain, device site reaction, pharyngitis, dysphagia, hypesthesia, dyspnea, nausea, headache, and neck pain.

Common stimulation issues include hoarseness or changes in voice tone, a prickly feeling in the skin, shortness of breath, sore throat, and coughing. These side effects generally only occur during stimulation and were less noticeable over time.

› Can I have an MRI?

Before having any MRI performed — Call your doctor, so that 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.

› Does VNS Therapy interfere with other devices?

The neurostimulator 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 neurostimulator could affect them, but no effects have yet been reported. No detailed testing has been done, so the effects are unknown.

The neurostimulator 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 neurostimulator.

› Can I still take other antidepressant medication?

The VNS Therapy® System is indicated as an adjunctive treatment for the treatment of chronic or recurrent depression in patients that are in a treatment-resistant or treatment-intolerant major depressive episode.

Patients treated with VNS Therapy® in the clinical studies also continued to take antidepressant medications.

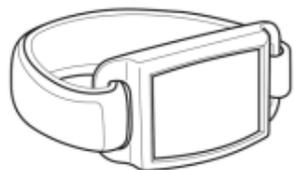
Your doctor may advise you to continue to take your antidepressant medications after you begin receiving VNS Therapy®.

Your doctor may also decide to add new medications to your treatment.

Always follow your doctor's instructions regarding your medications.

› What does the magnet do?

The magnet is used to stop stimulation.



**Watch-Style
(wristband)**



**Pager-Style
(belt clip)**

› When should I use the magnet?

Use the magnet to stop stimulation temporarily or to turn OFF the neurostimulator when you plan to sing or speak in public (if stimulation bothers you when you do this), when you are eating (if you have swallowing problems), or if stimulation becomes uncomfortable or painful.

› Is it possible to stop all stimulation using the magnet?

Yes. To stop stimulation, hold the magnet over the neurostimulator and keep it there. Use this method if you have unusual or painful stimulation.

Then call your doctor right away. You may need to visit the VNS Therapy® clinic to adjust your stimulation settings.

The magnet will stop all stimulation while it is held in place. You may need to secure the magnet by taping it over the neurostimulator.

› Can any magnet be used?

Only the VNS Therapy® magnet 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 will not harm the neurostimulator, but there is no way to know in advance whether a magnet other than the VNS Therapy® magnet will work.

Indications and Warnings

Indication for Use – The VNS Therapy® System is indicated for the treatment of chronic or recurrent depression in patients that are in a treatment-resistant or treatment-intolerant major depressive episode.

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.

Warnings – All potential risks and adverse events are discussed in the VNS Therapy® System physician's manuals.

VNS Therapy® may not be a cure for depression. Individual results will likely vary. Beneficial results might not become evident for months. Most patients will continue to require antidepressant medications and/or electroconvulsive therapy (ECT) in addition to VNS Therapy®. Patients being treated with adjunctive VNS Therapy® should be observed closely for clinical worsening and suicidality, especially at the time of VNS Therapy® stimulation parameter changes or drug dose changes. Patients who have pre-existing swallowing, cardiac, or

respiratory difficulties (including, but not limited to, obstructive sleep apnea 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. Patients with the VNS Therapy® System implanted should have MRI procedures performed only as described in the MRI Chapter of the Physician Manual.

Adverse Events – The most commonly reported side effect from the implant procedure is infection. Common implant issues include incision pain, voice alteration, incision site reaction, device site pain, device site reaction, pharyngitis, dysphagia, hypesthesia, dyspnea, nausea, headache, and neck pain.

Common stimulation issues include hoarseness or changes in voice tone, a prickly feeling in the skin, shortness of breath, sore throat, and coughing. These side effects generally only occur during stimulation and were less noticeable over time.

For full safety information, please see our website at www.symmetryvns.com.

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