CARILION CLINIC

Vagal Nerve Stimulation Information Sheet

Before you agree to this treatment, it is important for you to know the reason why it is being done and the process it will involve. It is important to know the potential risks and benefits you might receive. Read the information below and discuss it with family and friends as you wish. Ask a nurse or care provider if there is anything that is not clear, or if you would like more details. Take your time to decide.

Indications	**Procedure**
1. VNS is an FDA-approved treatment for recurrent severe depression. 2. VNS is a device that sends electrical signals along the Vagus nerve to the brain. It can promote positive change in brain areas known to be involved in clinical depression. 3. VNS is used as a treatment adjunct, and this therapy should be used along with other evidence-based treatments for depression, including counseling and medications. 4. Patients on VNS therapy often have a gradual improvement in symptoms, and up to 70% of patients have a significant clinical response. Up to 40% of patients achieve a complete or near-complete resolution of depressive symptoms. 5. The VNS device offers long-lasting treatment. The duration of effect is specific to the individual patient. Patients who respond to the treatment may have benefits extending up to 5 years according to a clinical research trial.	• Patient is referred to the interventional psychiatry outpatient clinic to determine if VNS is appropriate. • Patient is then referred to the neurosurgery clinic to discuss the plan for implantation of the device. • The VNS generator device is implanted under the skin on the chest wall and electrodes are attached to the Vagus nerve by a neurosurgeon. Usually this is a same-day procedure and takes 1-2 hours. • The device is activated in an outpatient clinic, and settings are later adjusted in an outpatient clinic by a psychiatric care provider based on side effects and clinical efficacy.

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Side Effects/Risks

- Common (between 1 and 10% of patients)
  - Hoarseness
  - Sore Throat
  - Unusual Skin Sensation
  - Dry Cough
  - Shortness of Breath
- Rare
  - Indigestion
  - Insomnia
  - Nausea/Vomiting
  - Pain
  - Laryngospasm (abnormal muscle tone of the vocal cords leading to difficulty with speaking or breathing)
- There is a risk of infection with the implant.

Warnings

- Patients with pre-existing difficulty swallowing, cardiac and pulmonary problems may have a worsening of their condition during stimulation.

Who Should Not Receive VNS

- Individuals with a history of left sided Vagus nerve cut (Vagotomy)
- Patients with VNS treatment cannot have Diathermy, which is heat therapy involving short wave, microwave, or therapeutic ultrasound to the neck, as this may damage the Vagal Nerve Stimulator. Diagnostic ultrasounds are acceptable with VNS.

Alternative Treatments
(Include but are not limited to the following)

- Other Antidepressant Medicines
- Psychotherapy/Counseling
- Electroconvulsive Therapy
- Transcranial Magnetic Stimulation

General Considerations:

- VNS is an adjunct treatment for depression and can be used along with most psychiatric medicines and ECT.
- Special considerations are necessary if a patient with an implanted VNS system requires a Magnetic Resonance Imaging (MRI).
- If a patient requests removal of the VNS system, the generator can be explanted, but the electrodes are usually left intact due to a concern for risk of damaging the nerve.

Patient Instructions:
Patients will need a referral to the Interventional Psychiatry Clinic. This referral can be from any advanced care provider or physician involved in your care. If you are evaluated to be a good candidate for VNS, you will be referred to neurosurgery for the VNS implant. After implantation you will have subsequent follow-ups in the Interventional Psychiatry Clinic, and device settings can be changed as needed.

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