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FACT SHEET

Vivistim® Paired VNS™ System
Vivistim Therapy™

What is the Vivistim Paired VNS System (Vivistim System)?

- The FDA-approved Vivistim® (pronounced: vĭh-vĭh-stĭm) System is a first-of-its-kind breakthrough technology that uses vagus nerve stimulation (VNS) during rehabilitation therapy to help improve upper limb function for ischemic stroke survivors.
- Studies in chronic stroke survivors have demonstrated that upper limb rehabilitation used in conjunction with the Vivistim System resulted in two to three times greater arm and hand function than rehabilitation therapy alone.

How does Vivistim Therapy work?

- Vivistim Therapy is an innovative FDA-approved implantable stroke-rehabilitation intervention that involves stimulation of the vagus nerve during high-intensity task-specific occupational or physical therapy to improve stroke survivors' hand and arm function.
- The vagus nerve is a part of the autonomic nervous system that traditionally controls involuntary body functions.
- However, stimulation of the nerve also sends electrical pulses to brain regions that release neuromodulators important for learning and memory.
- VNS used in conjunction with rehabilitation therapy (Paired VNS™) helps strengthen neural connections to enhance the relevance of occupational or physical therapy and improve hand and arm function.
- VNS has previously been FDA-approved for treatment-resistant epilepsy and treatment-resistant depression with a good safety profile.

Who can benefit from Vivistim Therapy?

- Vivistim Therapy can be implanted in chronic ischemic stroke survivors who have limited hand and arm function six months or more after their stroke and are considered to have moderate to severe deficits by a healthcare professional.
- Every year approximately 800,000 people in the United States have a stroke[2] of which up to 200,000 would qualify for the clinical indications for Vivistim Therapy.
- With Vivistim Therapy, stroke survivors can improve their hand and arm function enough to regain more independence and improve many aspects of their quality of life.

The Patient Journey

- Vivistim Therapy includes three therapeutic components:
    - Implantation of the Vivistim device during a short out-patient procedure
    - Therapist-led Vivistim Therapy in a rehabilitation setting
    - Self-activated Vivistim Therapy at home or outside the rehabilitation setting

Implantation of the Vivistim Device

- Vivistim , a small medical device (similar to a pacemaker) that can fit in the palm of a hand, is placed under the skin in the upper left chest wall and neck region during a same-day outpatient procedure.

- The Vivistim device can be compared to the size of a car key fob, metal Zippo® lighter, or AirPods® case.
- Procedures of this type –involving similar-sized medical devices for other therapeutic indications—have been safely performed for over 25 years.

Therapist-Led Vivistim Therapy

- Two to three weeks after the Vivistim device is implanted, the stroke survivor starts Vivistim Therapy with a therapist in a rehabilitation setting.
- The therapist will use a remote that sends a wireless signal to the implanted device via a laptop computer which delivers a brief, gentle pulse to the vagus nerve while the stroke survivor performs various rehabilitation tasks.
- The tasks selected by the therapist and stroke survivor are based on functional goals that the stroke survivor wants to improve.
- The simultaneous pairing of the rehabilitation with VNS helps create or strengthen neural connections to improve upper limb function and increase the relevance of occupational or physical therapy.

Self-Activated Vivistim Therapy

- Vivistim therapy is also done outside the rehabilitation environment (e.g. at home) and patients are encouraged to start rehabilitation as early as the first day of therapy in the clinic. Patients activate a session on their own with a simple swipe of the Vivistim Magnet.
- While practicing rehabilitation based on their functional goals or performing routine tasks at home or outside of the home setting, stroke survivors can do blocks of therapy sessions several times a day.
- Example tasks include folding laundry, preparing a meal, getting dressed, or even playing games, tasks that helps stroke survivors improve what matters most to them.

What is the evidence?

- Vivistim Therapy is a rehabilitation-based intervention that was demonstrated to be safe and effective in clinical trials for improving upper limb function in stroke survivors who have not yet regained functional use of their arm and hand.
- The results of Vivistim's pivotal 108-person, multicenter, triple-blinded, randomized controlled clinical trial were published in *The Lancet* and showed that Vivistim generates two to three times greater improvement in hand and arm function for stroke survivors than rehabilitation therapy alone.
- Vivistim users also reported improvement across participation and quality-of-life measures, including functional mobility, self-care, and daily living.
- The Vivistim System received FDA approval in August 2021 following a decade of pre-clinical research and after successful completion of two pilot clinical studies and the pivotal study.
- Patient testimonials:
    - Rick, *62*, enrolled in our paired VNS clinical trial 28 months after surviving a stroke and continues to report positive results from Vivistim Therapy. He recommends the Vivistim System as an essential component of stroke recovery because it made his therapy more effective and boosted his confidence. He says:
      "The daily activities that I can do now, I could not do prior to (paired VNS) therapy. I can do a lot better job of getting dressed by myself…and every morning I tie my shoes, which is a huge accomplishment coming from where I was. My whole outlook has gone up dramatically because I see a light at the end of the tunnel…I can do anything."

- Kathy, 69, was implanted in New Jersey 2.5 years after her stroke and began to see improvement after two Vivistim Therapy sessions. She is now able to knit and write her name. Kathy says:
  "Vivistim Therapy has been life-changing. I am doing things that I never thought I'd be able to do again."
- Emily, a teacher from Florida, was implanted on her 30th birthday – 1 year after her stroke. She started noticing improvements within the first 2 weeks of Vivistim Therapy and can now cut a steak, tie her students' shoes, and even groom her dog. Emily can also communicate better through sign language now because she can use both hands more effectively. She says: "Knowing that after a short amount of time in Vivistim Therapy I was able to do things I couldn't do after my stroke, it just lit that fire in me. If this is what I can do in two weeks, imagine what I can do at the end of six and imagine after that what I can do in six months to a year. And it was just really that motivation, that fire to keep on going. It's working. You can see that it's working. I can't wait to see what else I can do!"
- Individual results may vary. Please visit www.vivistim.com/safety for full safety information.
- For more testimonials, please visit www.vivistim.com/vivistim-victories/.

Who manufactures Vivistim?

- Vivistim is manufactured by MicroTransponder®, Inc., a privately held, global medical device company based in Austin, Texas.
- MicroTransponder is committed to developing research-based neuroscience solutions to restore independence and dignity for people suffering from neurological conditions that impair sensory and motor function.
- TIME recognized MicroTransponder by naming the Vivistim Paired VNS System as one of the "best inventions of 2023."
- For more information, visit Vivistim.com.

Note: All promotional content related to Vivistim and MicroTransponder requires internal review and approval to maintain clinical accuracy and regulatory compliance. Please send all review requests to your MicroTransponder Marketing/PR team representative or media@microtransponder.com and allow 2 weeks for processing.

The MicroTransponder® Vivistim® Paired VNS™ System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. Do not use if you have had a bilateral or left cervical vagotomy. Risks may include, but are not limited to pain after surgery, hoarseness, bruising, swelling, coughing and throat irritation. Infection leading to explant is a risk associated with any device surgery. For full safety information, please see www.vivistim.com/safety. Individual results may vary.

[1] Office of the Commissioner. "FDA Approves First-of-Its-Kind Stroke Rehabilitation System." FDA, 31 Aug. 2021, www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-stroke-rehabilitation-system.
[1] Tsao CW, Aday AW, Almarzooq ZI, Alonso A, Beaton AZ, Bittencourt MS, et al. Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association. Circulation. 2022;145(8):e153–e639.