Deep Brain Stimulation

Boston Scientific
Advancing science for life™

A BRIGHTER FUTURE IS TAKING SHAPE

Treating Essential Tremor with Deep Brain Stimulation

A Personalized Approach

If you're living with essential tremor, you know all too well how the disease disrupts your life. Losing the ability to perform simple, everyday tasks limits your independence and can strain your relationships. And the increasing side effects of medications sometimes feel even worse.

Luckily, medication isn't your only treatment option. At Boston Scientific, we offer a unique, personalized therapy that can put you on the path to a better tomorrow. It's called deep brain stimulation, or simply DBS.

*"DBS has impacted my life in so many ways that I used to take for granted. Before, I couldn't even eat with utensils - the food would fall off. I'd go to a dinner party and either have to hold my glass with two hands or not pick up a glass at all. My life has changed - 150% - and I am so grateful."**

- Judy P., Boston Scientific DBS Patient

*Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

What Is DBS?

Although it is not a cure, deep brain stimulation (DBS) is a safe and proven medical treatment that has helped hundreds of thousands of patients manage their symptoms when medication alone is no longer effective.[1]

DBS uses a small, surgically implanted device called a "stimulator" to send signals to a targeted portion of your brain.
This stimulation can improve your motor function by reducing tremor. For many Boston Scientific patients, this procedure has been life-altering.

Up to 10 million Americans are estimated to have essential tremor; 10 times the number of people with Parkinson's disease.[2]

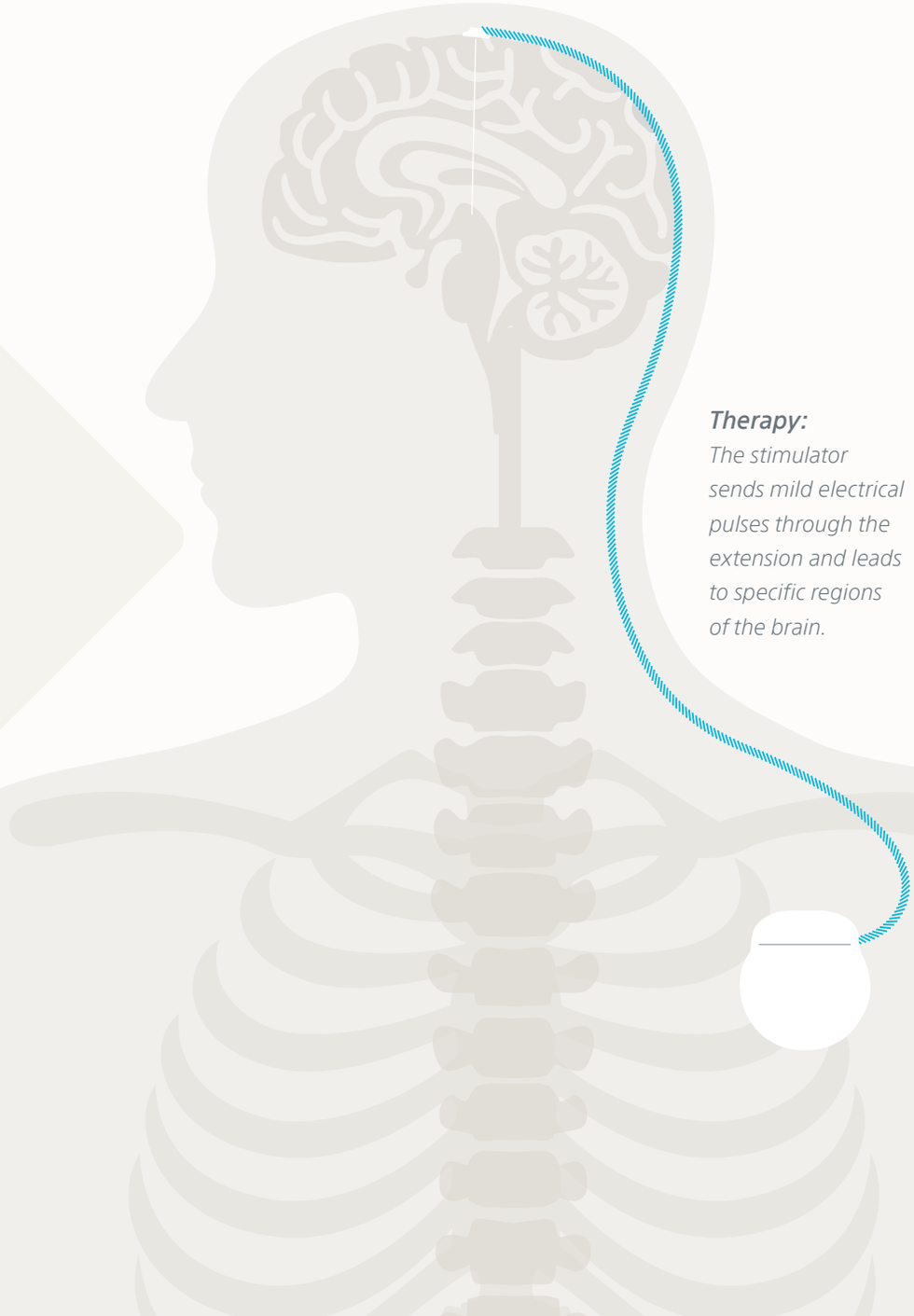
How Does DBS Work?

You may be experiencing involuntary rhythmic tremors of the hands and arms. This may be occurring both at rest and during movement. Although the exact cause of essential tremor is unknown, it is believed that the abnormal activity occurs between the thalamus and cerebellum connections in your brain.

Deep brain stimulation can help regulate that activity by sending targeted stimulation to specific regions of the brain. As a result, tremors are often reduced.

Leads:
Your doctor will place an insulated wire, called a lead, in the brain, which will connect to a thin wire called an extension.

Stimulator:
A small device called a "stimulator" is implanted under the skin in the chest, which also connects to the extension.



Therapy:
The stimulator sends mild electrical pulses through the extension and leads to specific regions of the brain.

View our "How DBS Works" video at DBSandMe.com.

WHY CONSIDER DBS FOR ESSENTIAL TREMOR

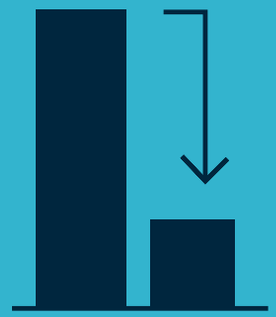
Essential tremor is a neurological disorder that causes involuntary and rhythmic shaking. Although it can impact any part of your body, trembling is most often seen in the hands and arms.

Essential Tremor Has Progressed

Most likely, your tremor gradually appeared and has worsened over time. Perhaps your condition started with involuntary, rhythmic shaking in the upper extremities including hands, head, and voice. You may have noticed simple tasks – drinking from a glass, cutting food, writing, tying shoelaces – have become more difficult.

Medication Is Not Enough

Upon diagnosis, you were probably prescribed medication. There are many medications aimed at reducing tremor – propranolol and primidone are among the most common. Unfortunately, 30-50% of essential tremor patients may not respond to medical therapy.[3] Additionally, medications come with side effects and their ability to reduce tremor may diminish over time.



REDUCTION IN TREMOR

According to research, patients who have undergone DBS exhibit 60% - 90% improvement of tremor.[3]

PATIENT SATISFACTION

Over 200,000 people have been through the DBS procedure.[1] 98% of them would recommend it to others.[4]

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MEASURED RESULTS

In a 26 Patient Questionnaire, patients reported an average score of 10 out of 10 in overall satisfaction with ventral intermediate nucleus of the thalamus (VIM) - DBS treatment.[5]

VAS Scale 1-10, where 0 is no effect of VIM-DBS on tremor and 10 is maximum effect.

What Makes Boston Scientific's DBS Unique?

For DBS to be effective, your physician must be able to precisely control the placement and intensity of your therapy, modulating the areas of your brain affected by essential tremor while avoiding regions associated with potential side effects.

Boston Scientific is uniquely capable of delivering this precision thanks to a technology called Cartesia™ 3D.*

*Note: Stimulation using Multiple Independent Current Control (MICC) with a directional lead is referred to as Cartesia 3D.

Cartesia™ 3D: A System Approach

Boston Scientific pairs directional leads with a stimulator that is capable of independently powering each electrode on the lead. The result is Cartesia 3D—a set of programming capabilities that offers more focused therapy with less risk of side effects.

Cartesia 3D also makes it easier for your doctor to adapt and fine-tune your stimulation over time, so you can be confident you'll continue to receive the therapy you need.

The Cartesia 3D Advantage
When a directional lead is paired with a single-source DBS system, you don't get the entire benefit of the directional technology. Only multiple-source systems (such as those with Cartesia 3D) allow for true directional programming.[6]

Note: Stimulation using Multiple Independent Current Control (MICC) with a directional lead is referred to as Cartesia 3D.

Comfort Meets Convenience

Boston Scientific offers a choice of two types of stimulators: a non-rechargeable (or "primary cell") stimulator and a rechargeable one.

The non-rechargeable stimulator lasts 4-7 years* and never requires charging. The rechargeable stimulator does require charging, but lasts at least 15 years,* which helps to minimize future battery replacement surgeries. And since the Vercise Genus charging system and remote control are completely wireless, you can enjoy the freedom of staying active while recharging.

Both types of stimulators are designed to be thin and lightweight, with smooth, gently rounded edges. This not only improves comfort, but also helps to conceal signs of the implant. Talk to your physician about which option is best for you.

*Battery life is dependent on the stimulation settings and conditions.

Frequently Asked Questions

1: Is DBS safe?
Two decades of DBS treatment to over 200,000[1] patients has shown both the short- and long-term safety of DBS.[7,8,9,10] DBS surgery should be carried out by an experienced neurosurgeon working as part of an interdisciplinary team. As with any surgical procedure, there are risks and potential side effects, which vary by patient. Though most are temporary and will go away as your therapy is optimized, you should discuss these risks with your physicians.

2: Could I be a candidate for DBS?
DBS should be considered when essential tremor keeps patients from maintaining a good quality of life and medications are no longer effective. For example, if essential tremor makes it very difficult for a patient to eat and drink, DBS could be an option to consider.

3: Will my insurance cover DBS therapy?
For Medicare patients, DBS therapy will be covered. Most other health plans will also cover DBS, though your doctor or hospital may need to provide an authorization prior to the procedure. Call our Pre-Authorization Support Team at 855-855-4506 to learn what your insurance will and will not cover.

4: How long will my DBS system last?
The rechargeable Vercise Genus™ System is designed to last at least 15 years.* The non-rechargeable Vercise Genus™ System should last 4 to 7 years.*

5: Is it possible to have an MRI with a DBS implant?
The Vercise Genus™ DBS System does provide full-body MRI access** under certain conditions. If your system does not meet those conditions, other imaging options (including X-rays, CT scans, PET scans, and ultrasounds) may be available. Always consult your doctor to learn which imaging modality will be your best option.

6: Can I have a DBS implant if I already have a pacemaker?
Typically, DBS batteries are placed in the upper chest, near the area a pacemaker would be. However, a DBS implant can be inserted on the other side of your chest.

7: Can I travel with my DBS implant?
Yes, you can travel with your DBS system. Metal detectors, X-ray machines, security scanners, and other security devices will not damage the implant, but may cause unintentional stimulation. The implant may also activate metal detector alarms, so carrying your patient ID card with you at all times is recommended. If traveling abroad, you may need an outlet adapter to charge your system (this would apply only if your device is a rechargeable one).

8: What will I feel when my DBS device is switched on?
During initial programming, you may experience a tingling sensation. This helps pinpoint your ideal settings. Afterward, most patients hardly notice the device—though some do experience a slight tingling in the arm or leg, or mild tension in facial muscles that often subsides.

9: Does the DBS device make a noise?
No, the DBS device is completely silent.

10: Will other people be able to notice my DBS device?
Since the DBS stimulator and wires are placed under the skin, they are hardly noticeable from the outside. For thin patients, the stimulator site will be slightly raised and the wire may appear like a slightly larger vein, but this should not be noticeable through clothing. The incision usually leaves a small scar.

*Battery life is dependent on the stimulation settings and conditions.
**MRI conditional when all conditions of use are met.

How Can I Get Started?

Talk to your neurologist about DBS, and visit DBSandMe.com to:

- ☐ *Speak to a Patient Ambassador who's undergone DBS.*
- ☐ *Sign up for a physician-led DBS webinar.*
- ☐ *Connect with a Boston Scientific Representative.*
- ☐ *Locate a physician near you.*

To speak with a Boston Scientific representative, call our Customer Care Team at 833-DBS-INFO.

Go to DBSandMe.com/ET or scan the QR code below to learn more about deep brain stimulation, and ask your doctor if DBS is right for you.

REFERENCES: 1. Thomson C, et al. The impact of deep brain stimulation on personality, identity, and relationships in neurological and psychiatric conditions. *Brain Stimulation*. 2019;12(2):P500. doi:https://doi.org/10.1016/j.brs.2018.12.636. **2.** University of Michigan Health. Frequently Asked Questions: Essential Tremor. Retrieved October 20, 2021. https://www.uofmhealth.org/conditions-treatments/brain-neurological-conditions/frequently-asked-questions-essential-tremor. **3.** Zesiewicz TA, et al. Overview of essential tremor. *Neuropsychiatry Dis Treat*. 2010;6:401–408. doi: 10.2147/ndt.s4795. **4.** Wharen RE Jr, Okun MS, Guthrie BL, et al. Thalamic DBS with a constant current device in essential tremor: A controlled clinical trial. *Parkinsonism Relat Disord*. 2017 Jul:40:18-26. doi: 10.1016/j.parkreldis.2017.03.017. Epub 2017 Mar 30. **5.** Børretzen MN, Bjerknes S, Sæhle T, et al. Long term follow up of thalamic deep brain stimulation for essential tremor patient satisfaction and mortality. *BM C Neurol*. 2014;14:120. <https://doi.org/10.1186/1471 2377 14 120>. **6.** Eleopra et al. Brain impedance variation of directional leads implanted in subthalamic nuclei of Parkinsonian patients. *Clinical Neurophysiology*. 2019. 130: 1562-1569 **7.** Knoop et al. Bridging the gap in patient education for DBS surgery for Parkinson's disease. *Parkinson's Disease*. 2017;2017:9360354. **8.** Okun et al. Subthalamic deep brain stimulation with a constant current device in Parkinson's disease: An open-label, randomised, controlled trial. *Lancet Neurology*. 2012;11:140–149. **9.** Timmerman et al. Multiple-source current steering in subthalamic nucleus deep brain stimulation for Parkinson's disease (the VANTAGE study): a non-randomized, prospective, multi-centre, open label study. *Lancet Neurology*. 2015;14:693–701. **10.** Krack et al. Five-year follow up of bilateral stimulation of the subthalmaic nucleus in advanced Parkinson's disease. *N Eng J Med*. 2003;349:1925–1934.

MR Conditional

The Vercise Genus™ DBS System, Vercise Gevia™ DBS System, and Vercise™ DBS Lead-only system (before Stimulator is implanted) provide safe access to full-body MRI scans when used with specific components and the patient is exposed to the MRI environment under specific conditions defined in the supplemental manual ImageReady™ MRI Guidelines for Boston Scientific DBS™ Systems.

INDICATIONS FOR USE: The Boston Scientific Vercise PC, Vercise Gevia, Vercise Genus Deep Brain Stimulation Systems are indicated for use in:-Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.-Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication. -Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability. The Boston Scientific Vercise Deep Brain Stimulation System is indicated for use in -Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication. Contraindications: The Boston Scientific Deep Brain Stimulation Systems are not recommended for patients who will be exposed to the following procedures: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS). The safety of these therapies in patients implanted with the Vercise DBS System has not been established. Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with the Vercise Gevia™ or Vercise Genus™ or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Boston Scientific Deep Brain Stimulation Systems are not recommended for patients who are unable to operate the system or are poor surgical candidates or who experience unsuccessful test stimulation. Warnings: Unauthorized modification to the medical devices is prohibited. You should not be exposed to high stimulation levels. High level of stimulation may damage brain tissue. Patients implanted with the Vercise DBS System may be at risk for intracranial hemorrhages (bleeding in the brain) during DBS lead placement. Strong electromagnetic fields, such as power generators, security screeners or theft detection systems, can potentially turn the stimulator off, or cause unpredictable changes in stimulation. The system should not be charged while sleeping. If you notice new onset or worsening depression, changes in mood or behavior or impulse control, or have thoughts of suicide contact your physician or emergency services immediately. Chemical burns may result if the Vercise Stimulator housing is ruptured or pierced. The Deep Brain Stimulation System may interfere with the operation of implanted stimulation devices, such as cardiac pacemakers, implanted cardioverter defibrillators, or medication delivery pumps. Patients should operate motorized vehicles or potentially dangerous machinery with caution. It is unknown if the device may hurt an unborn baby. Your doctor may be able to provide additional information on the Boston Scientific Vercise DBS System. For complete indications for use, contraindications, warnings, precautions, and side effects see DBSandME.com or call 833-DBS-INFO or 833-327-4636. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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