

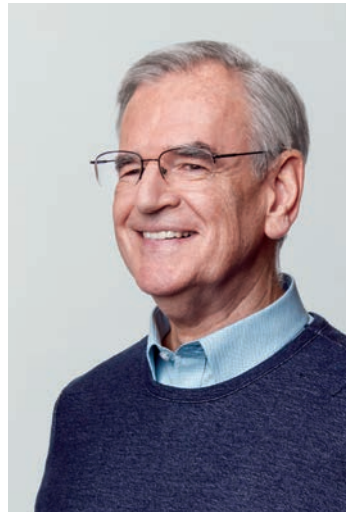
VERCISE™
Deep Brain Stimulation Systems

Boston
Scientific
Advancing science for life™



DBS and Parkinson's Disease

An Educational Guide
for Patients and Caregivers




If you suffer from Parkinson's, you know all too well how the disease disrupts your life.

Losing the ability to perform simple, everyday tasks not only limits your independence, it can strain relationships and even affect your job performance. And the increasing side effects of medications can sometimes feel even worse.

Luckily, medication isn't your only treatment option. At Boston Scientific, we offer a unique, personalized therapy that can help get you closer to feeling like you did when you first started medication. It's called Deep Brain Stimulation or simply DBS.

DBS PATIENTS (CLOCKWISE FROM TOP):

Kenneth B., Suzanne F., Bill D., Kenny and Tonia H., Ken G., Brendan C.



Suzanne is one of roughly one million Americans¹ and ten million people worldwide² who have Parkinson's. See how DBS is helping her live a more active life at DBSandMe.com.

"I waited 7 years for a medicine to make me feel better. Finally, I started researching DBS because I wasn't ready to throw in the towel."*

- SUZANNE F.

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 Parkinson's patients manage their symptoms when medication alone is no longer effective.

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 symptoms such as tremor, slowness, and rigidity. For many Boston Scientific patients, this procedure has been life-altering.

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

1. <https://www.apdaparkinson.org/what-is-parkinsons> | Accessed 6JUN2018.

2. <http://parkinson.org/understanding-parkinsons/causes-and-statistics> | Accessed 6JUN2018.

How Does DBS Work?

When Parkinson's patients experience motor symptoms, it's because low dopamine levels in the brain are causing abnormal signaling.

Deep Brain Stimulation can help regulate those signals by sending **targeted electrical stimulation** to specific regions of the brain. As a result, Parkinson's symptoms are often reduced.



Leads:

Your doctor will place one or two insulated wires called "leads" in the brain, which connect to a thin wire called an "extension."



Stimulator:

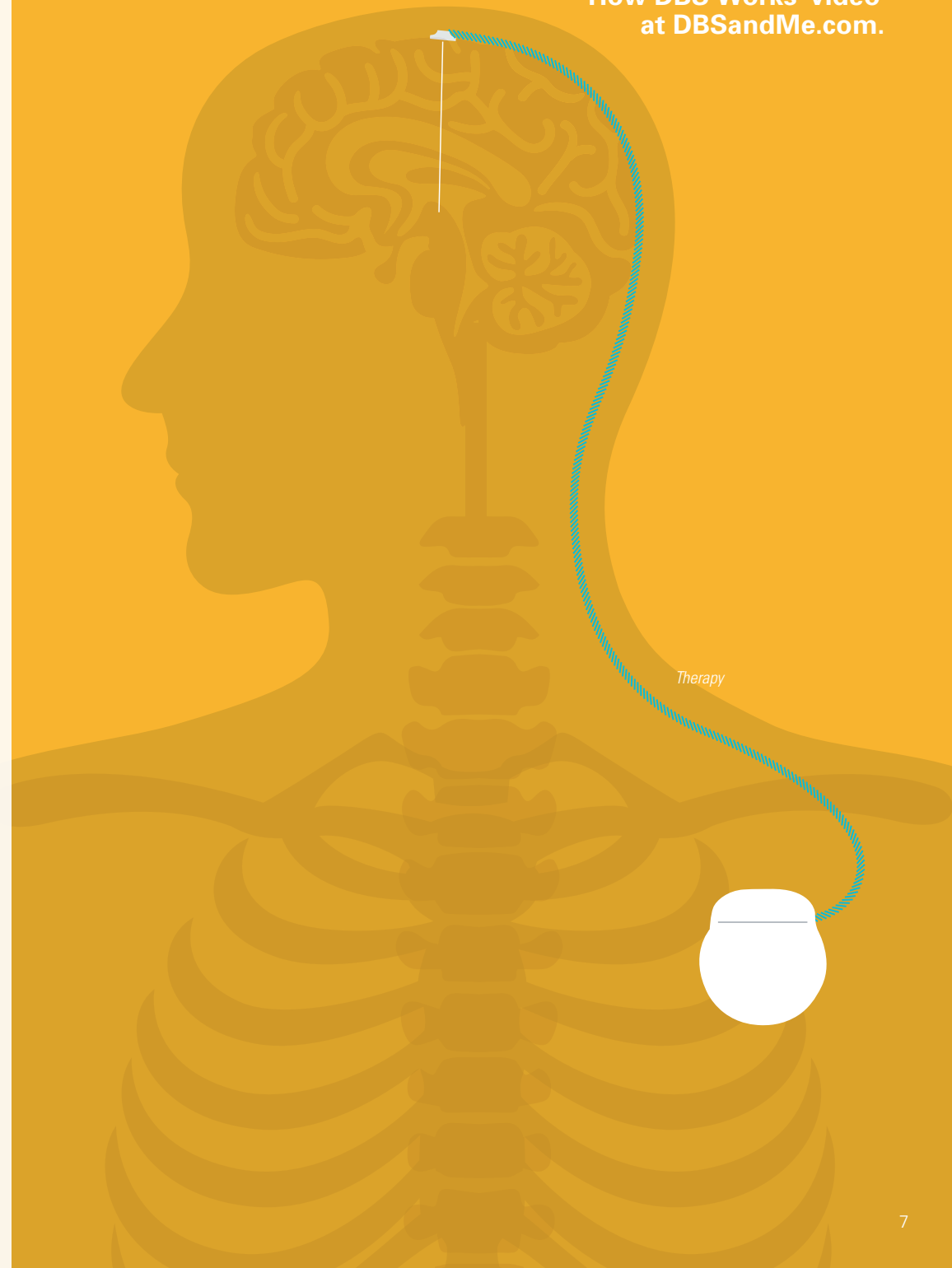
A small device called a "stimulator" is implanted under the skin in the chest, which also connects to the extension.



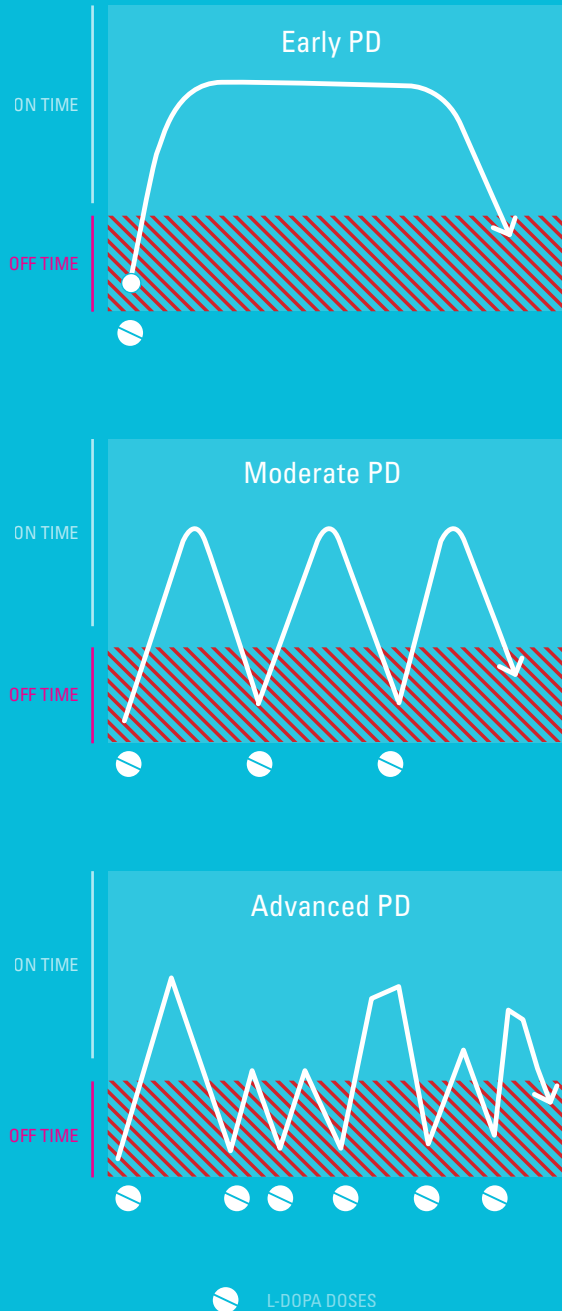
Therapy:

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.



As Parkinson's advances, medication may lose its ability to control your motor symptoms.



Why Haven't I Heard About DBS Before?

DBS isn't generally offered to patients when they are first diagnosed with Parkinson's disease because medications like levodopa (L-DOPA)* do a good job of maintaining your "ON time," giving you better control over your movements.

But over time, the effects of levodopa wear off faster. To reduce your "OFF time," you end up increasing your dose or taking even more medication, which in turn may lead to unintended side effects like intense, uncontrolled movements known as dyskinesia.³

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

When Should I Get DBS?

Five years after diagnosis, the average Parkinson's patient⁴ takes medication four times a day, totaling nine individual pills a day,* and has changed their medication regimen three times.

If this sounds familiar, if you're struggling to keep up with the increasing demands of your medication regimen, or if you feel your medications are becoming less effective, speak with a neurologist who specializes in movement disorders and ask if DBS could be an option for you.

*Inclusive of the following formulations of Parkinson's disease medications: tablet, transdermal patch, and injection.

Brendan's previous medication regimen was taking a heavy toll on his life. See how DBS helped him take back control of his appetite, his sleep, and his family time at DBSandMe.com.

"Before DBS, I was up to 4 pills, 5 times a day. Taking all that medicine was very, very unpleasant."**

- BRENDAN C.

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

96%

Patient Satisfaction

If given the choice, 96% of DBS patients would choose to do it again.⁵



More "ON Time"

DBS provides roughly 8 to 10 hours of "ON time", giving you control and independence to live your life without rigidity or freezing.^{6,7,8}



Sustained Results

Marked improvements in motor function are sustained for at least 5 years.⁸



Less Tremor

People with tremor experience an average of 70% reduction in tremor, depending on its type and location.⁹

Results from different clinical investigations are not directly comparable.
Information provided for educational purposes only.

How Effective Is DBS?

Not all Parkinson's patients are affected by the disease in the same way.

The severity, type, and recurrence of any symptom will vary by patient — as will his or her response to DBS treatment.

But quite often, **DBS allows Parkinson's patients to reduce the amount of medicine they take⁷** and live free from disruptive side effects such as uncontrolled movements, incontinence, and moodiness.

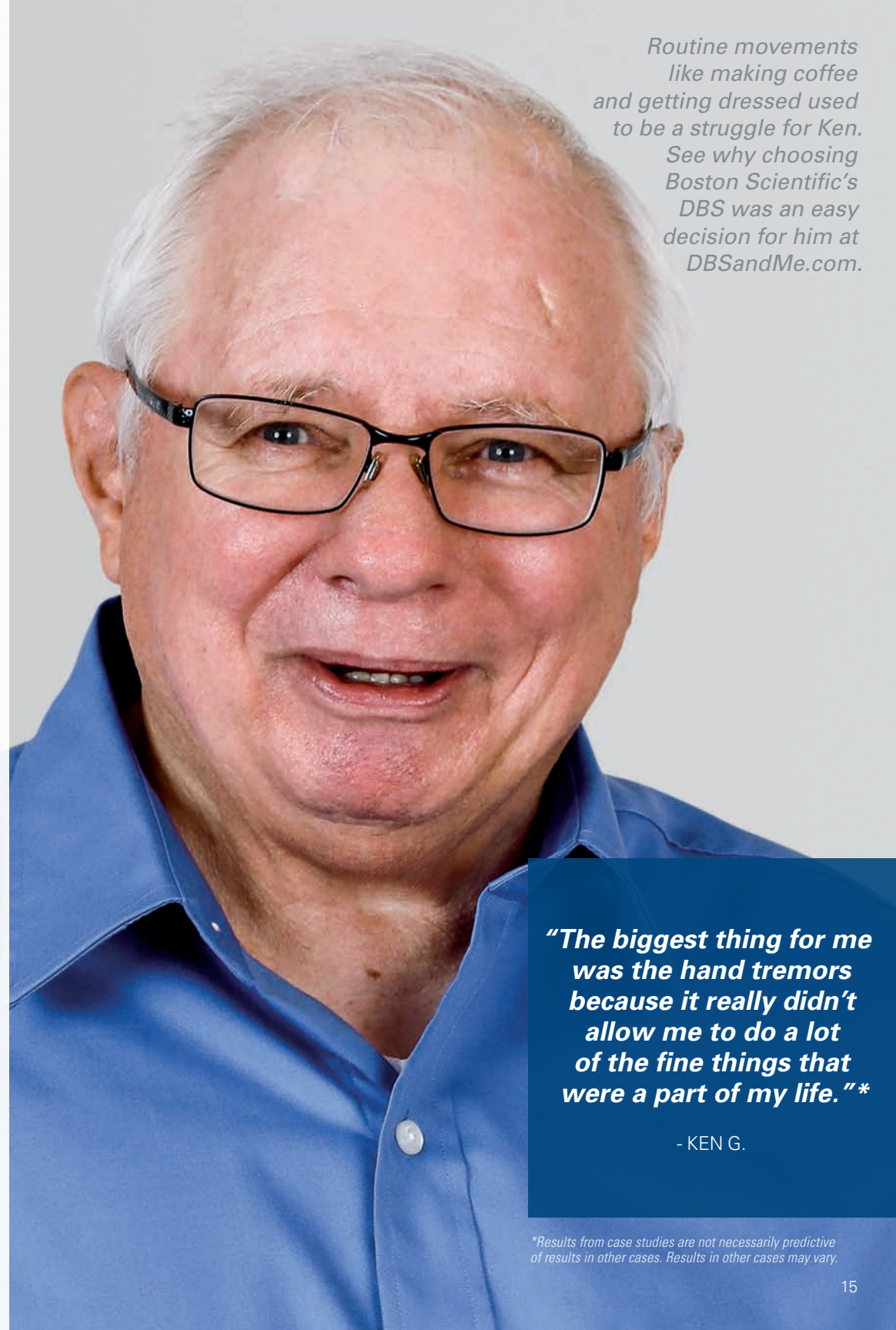
What Makes Boston Scientific's DBS Systems Unique?

Boston Scientific's DBS Systems are the only ones with Multiple Independent Current Control (or MICC).

This unique technology allows doctors to precisely control the placement and intensity of therapy with precision.

Why does that matter? This can help your physician to stimulate areas in your brain that are responsible for coordinating movement and avoid regions associated with potential side effects. And as your condition changes, your **Boston Scientific DBS System will give you and your doctor the fine-tuning options** you need, exactly when you need them.

Routine movements like making coffee and getting dressed used to be a struggle for Ken. See why choosing Boston Scientific's DBS was an easy decision for him at DBSandMe.com.



"The biggest thing for me was the hand tremors because it really didn't allow me to do a lot of the fine things that were a part of my life."*

- KEN G.

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

Our easy-to-use remote control features a sleek design, simple interface, and wireless recharging.



Vercise™ PC System

- Non-rechargeable
- Lasts about 3-5 years¹⁰



Vercise Gevia™ System

- Rechargeable
- Lasts at least 15 years*



DBS Designed to Make a Difference

We designed all of our stimulators to be thin and lightweight with smooth, gently rounded edges.

This not only **improves comfort**, it helps to conceal signs of the implant.

The Vercise Gevia™ DBS system features a new rechargeable battery with a lifespan of at least 15 years, helping to **minimize battery replacement** surgeries.

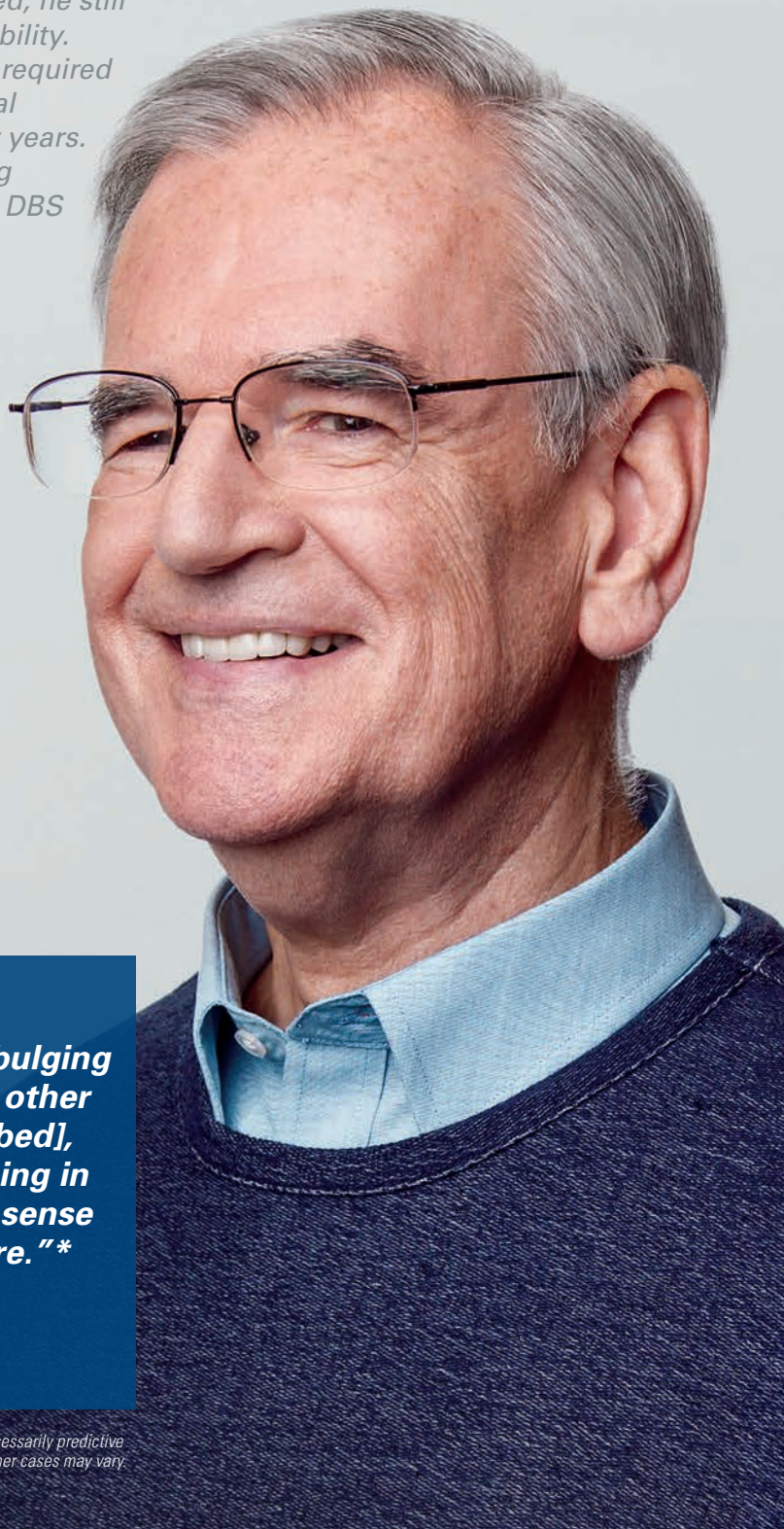
And since the Vercise Gevia™ charging system and remote control are completely cordless, you can enjoy the **freedom of staying active** while recharging.

Boston Scientific lets you choose whether to implant a **rechargeable or a non-rechargeable system**. Though the systems use the same core technology, each offers some unique benefits. Talk to your physician to determine which option will work best for you.

We offer a variety of leads designed for broad coverage and precise control of stimulation. That includes the Cartesia™ Directional Lead, which is part of the world's first fully directional DBS System.

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

Bill first had DBS in 2012. While the procedure helped, he still had issues with mobility. And his old system required him to get additional surgeries every few years. Learn why switching to Boston Scientific DBS was right for Bill at DBSandMe.com.



Convert With Confidence

If you are a DBS patient looking to switch to a Boston Scientific Stimulator from a Medtronic™ battery, the Vercise™ M8 Adapter conversion system† allows you to keep the wiring you have in place now and still receive the latest DBS therapy without undergoing lead revision surgery.

See if your battery needs a boost by watching our video at DBSandMe.com.

“Before, I had two bulging [generators]. The other night I was [in bed], I didn’t feel anything in my chest. I didn’t sense it was even there.”*

- BILL D.

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

Frequently Asked Questions

1: Is DBS safe?

Two decades of DBS treatment to over 100,000¹¹ patients has shown both the short- and long-term safety of DBS.^{5,6,7,8} 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.

**Please review the back cover of this brochure.*

2: Could I be a candidate for DBS?

The ideal candidate is a Parkinson's patient who continues to respond positively to levodopa treatment but is unable to control motor symptoms with medication alone. Ask your neurologist and other physicians if DBS is a suitable therapy for you and your symptoms.

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: Can I stop my medication after DBS surgery?

Sometimes successful DBS surgery can lead to a decrease in your medication and potentially reduce its side effects, though the treatment is not intended to replace your medication.

5: How long will my DBS system last?

The rechargeable Vercise Gevia™ System is designed to last at least 15 years.** The non-rechargeable Vercise™ PC System should last 3 to 5 years.¹⁰

6: Is it possible to have an MRI with a DBS implant?

The Vercise Gevia™ DBS System does provide Full-Body MRI access, under certain conditions. The Vercise™ PC DBS System is contraindicated for MRI. Other imaging options (including X-rays, CT scans, PET scans, and ultrasounds) are all compatible with Vercise PC and Vercise Gevia. Always consult your doctor to learn which imaging modality will be your best option.

7: Can I have a DBS implant if I already have a pacemaker?

Typically, DBS implants are placed in the same location as pacemakers. However, a DBS implant connected to an extension can be inserted on the right side of your chest or under the skin of the abdomen.

8: 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.

9: 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. Afterwards, 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.

10: Does the DBS device make a noise?

No, the DBS device is completely silent.

11: 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.

12: Where can I go to learn more?

For more information, go to [DBSandMe.com](https://www.DBSandMe.com) or call our Customer Care team at 833-DBS-INFO to speak with a Boston Scientific representative about your questions.

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

How Can I Get Started?

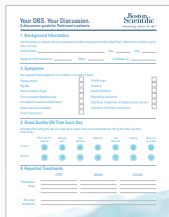
Now that you're ready to take the next step, here are three things you can do today.



1. Visit [DBSandMe.com](https://www.dbsandme.com) to learn more about how DBS is helping PD patients like you.



2. Use our self-assessment tool to see if DBS could be a treatment option.



3. Download a personalized discussion guide and talk to your neurologist about controlling your Parkinson's with DBS.

Often, family members of Parkinson's patients are thrust into the challenging and unfamiliar role of caregiver. Luckily, DBS can help them take back control. Learn more about DBS at [DBSandMe.com](https://www.dbsandme.com).



"Thanks to DBS, my husband Kenny has experienced a drastic improvement in his symptoms and reduction in his medicine. That was a huge relief."*

- TONIA H.

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

Learn more about Deep Brain Stimulation at DBSandMe.com and ask your doctor if DBS can help you control your Parkinson's symptoms.



The 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.

NOTATIONS: *A System that includes the Vercise™ PC or Vercise Gevia™ and the Vercise Cartesia™ Directional Lead(s) form the Vercise Directional System. †Not all patients who have a Medtronic DBS System will be eligible for an M8 Adapter. Only patients with a Medtronic 3387 or 3389 Lead and a 37086-(40,60,95) or 37085-(40,60,95) extension are eligible. Ask your neurosurgeon about whether you are a candidate for a Boston Scientific stimulator.

REFERENCES 1. <https://www.apdaparkinson.org/what-is-parkinsons> | Accessed 6JUN2018. 2. <http://parkinson.org/understanding-parkinsons/causes-and-statistics> | Accessed 6JUN2018. 3. <https://www.brainandlife.org/disorders-a-z/disorders/app/detail/parkinsons-disease> | Accessed 6JUN2018; <https://www.mayoclinic.org/diseases-conditions/parkinsons-disease/symptoms-causes/syc-20376055> | Accessed 6JUN2018; <https://www.michaeljfox.org/understanding-parkinsons/living-with-pd/topic.php?dyskinesia&navid=dyskinesia> | Accessed 6JUN2018. 4. Boston Scientific patient market research. Data on file. 5. Knoop *et al.* Bridging the gap in patient education for DBS surgery for Parkinson's disease. *Parkinson's Disease*. 2017. 2017: 1-6. 6. 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. 7. 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. 8. Krack *et al.* Five-year follow up of bilateral stimulation of the subthalamic nucleus in advanced Parkinson's disease. *N Eng J Med*. 2003. 349: 1925 – 1934. 9. Farris, S. and Giroux, M. (2013). *DBS: A Patient Guide to Deep Brain Stimulation*. Movement and Neuroperformance Center. Colorado. 10. Boston Scientific, Vercise™ Neural Navigator 2.1 Programming Manual. 2018. 11. Lozano and Lipsman. Probing and regulating dysfunctional circuits using deep brain stimulation. *Neuron*. 2013. 77: 406 – 424.

INDICATIONS FOR USE: The Boston Scientific 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. **CONTRAINDICATIONS:** The Vercise DBS 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 Vercise DBS Systems 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 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. The Vercise DBS System is 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 detections 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, 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.

Refer to the Vercise M8 Adapter Directions for Use for indications, warnings and cautions. The Vercise M8 Adapter is compatible with the following Medtronic lead and extension model numbers: 3387, 3389, 3708640, 3708660, 3708695, 3708540, 3708560, 3708595.

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