

EXPECT PROGRESS. RECLAIM CONTROL.





EVERY DAY, WE'RE MAKING PROGRESS

WE'RE MAKING PROGRESS IN THE TREATMENT OF MOVEMENT DISORDERS

It may seem like your symptoms go in only one direction.

Tremors. Disruption. Less control. But Abbott's directional deep brain stimulation (DBS) therapy has helped people with movement disorders, like Parkinson's disease and essential tremor, control these symptoms and live a better, fuller, more active life.

PEOPLE WITH **PARKINSON'S DISEASE**, WHO WERE STUDIED USING DBS THERAPY, HAVE SHOWN SUSTAINED IMPROVEMENT IN QUALITY OF LIFE FOR UP TO 10 YEARS OR MORE.^{1*}

More than 10 million people worldwide are living with Parkinson's disease.² As many as 5% of people over 40 have essential tremor.³ That's why Abbott is continually innovating to treat the symptoms of movement disorders more effectively, minimize side effects and help people get back their every day.

WITH DBS THERAPY, MOST PEOPLE WITH

ESSENTIAL TREMOR MAINTAIN BETTER CONTROL

OF TREMOR FOR 10 YEARS OR MORE.4*



LIFE CAN MOVE IN A DIFFERENT DIRECTION. FIND OUT WHETHER THE ABBOTT INFINITY[™] DBS SYSTEM CAN HELP YOU TAKE CONTROL AND BE YOU AGAIN.



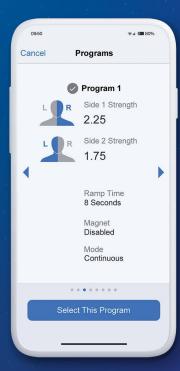
ABBOTT'S DIRECTIONAL DIFFERENCE

DBS has been used safely and successfully to treat the symptoms of movement disorders for more than 20 years.^{5*} When Abbott introduced a groundbreaking new directional DBS system in 2016, the outlook for people with movement disorders became even better.

DBS systems are implanted devices, similar to pacemakers, that deliver mild electrical pulses through thin wires, called leads, to stimulate specific areas of the brain. Conventional DBS leads use circular bands that require 360-degree activation to deliver stimulation to any brain target.

With the Abbott Infinity[™] DBS System's directional lead technology, single segments can be activated for focused stimulation.





YOUR DOCTOR WILL HAVE THE ABILITY TO PRECISELY TARGET AND TAILOR YOUR THERAPY WITH MORE OPTIONS, OPTIMIZING SYMPTOM CONTROL WHILE LIMITING POTENTIAL SIDE EFFECTS.6-8



"Abbott DBS has brought me to a new place. A place where I feel confident and comfortable. A place where life is better."

MARY | AN ABBOTT INFINITY™
DBS SYSTEM USER WITH
PARKINSON'S DISEASE

ABBOTT DBS THERAPY FOR PARKINSON'S DISEASE

TAKE CONTROL

The largest directional DBS study (PROGRESS) showed that

PARKINSON'S
DISEASE PATIENTS



COULD BENEFIT FROM
ABBOTT'S DIRECTIONAL DBS
COMPARED TO
CONVENTIONAL DBS^{6,9**}



HAVE BETTER CONTROL

Abbott DBS therapy can offer better control of Parkinson's disease motor symptoms during medication "off-time." ¹⁰



REDUCE MEDICATION

Abbott DBS therapy has been shown to help people with Parkinson's disease reduce medication, among those surveyed at 1 year. ¹⁰



ENJOY MORE QUALITY TIME

For people with Parkinson's disease, Abbott DBS therapy can reduce "off-time" and add hours of good quality "on-time," compared to using the best medical therapy alone. ¹⁰





ABBOTT DBS THERAPY FOR ESSENTIAL TREMOR

BE YOU AGAIN

It is estimated that nearly 50% of people with essential tremor cannot tolerate the side effects of medication or still have disabling tremor.¹¹



GET BACK TO DAILY ACTIVITIES

Abbott DBS therapy helps people with essential tremor get back to daily activities like handwriting, pouring a drink and working with their hands.¹²



SIGNIFICANTLY REDUCE TREMOR

For people with essential tremor, Abbott DBS therapy significantly reduces tremor severity and improves motor symptoms overall.¹²



IMPROVE OVERALL HEALTH

Both patients and caregivers report that Abbott DBS therapy helps people with essential tremor improve their physical activity and social activity, as well as their mental health.¹²



RECLAIM YOUR EVERYDAY

Whether you want to pour your morning cup of coffee, go out for a meal with friends or work an 8-hour day, the Abbott Infinity™ DBS System is designed to fit seamlessly into your life and help you reclaim your everyday activities.

DBS IS A WELL-ESTABLISHED SURGERY THAT HAS BENEFITED HUNDREDS OF THOUSANDS OF PEOPLE.^{10,12,13*}

While the specifics of the procedure may vary slightly by clinician, the basic steps are usually similar. A thin lead is placed in the brain and connected to a stimulator that is typically placed in the chest. The stimulator device, similar to a pacemaker, sends electrical pulses through the lead to regulate signals in the brain. The stimulation level is managed by your physician and can be adjusted through your patient controller.

THE ABBOTT INFINITY™ DBS SYSTEM

is intended to remove the limits of other DBS systems and give you back the freedom and possibilities your movement disorder symptoms can interrupt every day.



CONTROL OF YOUR EVERYDAY

Achieve a new normal with truly wireless control every day. We designed our patient controller to fit seamlessly into your life, without noticeable wires or confusing accessories. Our platform is so discreet, we call it **Invisible Therapy™**. With Abbott's DBS system, you can manage your prescribed stimulation settings using an app on a familiar Apple⁺ mobile digital device from a Bluetooth® wireless technologyenabled connection.



UNLOCKED POTENTIAL FOR THE FUTURE

Technology advances quickly and with it comes new improvements and possibilities for movement disorder treatment. Get access to the latest therapy advancements with less disruption. Abbott's DBS system updates wirelessly as new software is approved.*** That means you always have access to the latest updates, without the need for more surgery.



LEAVE YOUR OPTIONS OPEN

The Abbott Infinity DBS System allows for scanning with a wide variety of medical imaging techniques, including magnetic resonance imaging (MRI),[†] so you have options where your health is concerned.

FREEDOM

Make every minute count with Abbott's recharge-free stimulator.

ABBOTT'S DBS SYSTEM IS LOW MAINTENANCE, GIVING YOU^{††}:



3.5 ADDITIONAL 1-HOUR WORKOUT SESSIONS PER WEEK



15 EXTRA HOURS PER MONTH FOR LUNCH WITH FRIENDS



3 MORE WEEKEND-LONG TRIPS WITH FAMILY EVERY YEAR



WHAT WILL YOU CHOOSE?

HERE'S WHAT PEOPLE WHO USE THE ABBOTT INFINITY™ DBS SYSTEM HAVE TO SAY:

PARKINSON'S DISEASE PATIENTS

Twice as many patients with Parkinson's disease, who tried both conventional and directional DBS, preferred Abbott directional DBS.^{6§}

"I used to say to myself: if I could just have one day. Just give me one day. And now I've got every day."

OLSON | AN ABBOTT INFINITY™ DBS SYSTEM USER WITH PARKINSON'S DISEASE OF USERS WITH
PARKINSON'S DISEASE
RECOMMEND ABBOTT
DBS TO OTHERS¹⁰
(N = 135)

DOCTORS PREFER ABBOTT DBS

Doctors, who tried both conventional and directional DBS, preferred Abbott's directional DBS for their patients due to the superior symptom relief and lower rate of side effects.⁶⁸

"That's the advantage of the Infinity System, giving us better options, more options, and being able to customize more for the patient."

DR. RAJESH PAHWA | NEUROLOGIST

ESSENTIAL TREMOR PATIENTS

NINE OUT OF TEN



WERE SATISFIED OR VERY SATISFIED WITH ABBOTT DBS THERAPY'S SYMPTOM CONTROL¹²

Cenerators IPG1

Mode Program

programs

Program Side 1 Strength

R 2.25

R Side 2 Strength

Program1

Side 1 Strength

1.75

96%

OF ESSENTIAL TREMOR
PATIENTS WITH
ABBOTT DBS WOULD
RECOMMEND IT TO
OTHERS¹²
(N = 127)

"It's amazing how it changed my life."

KEITH | AN ABBOTT INFINITY DBS SYSTEM USER WITH ESSENTIAL TREMOR

EXPECT PROGRESS RECLAIM CONTROL

Today there's a therapy specifically for people who want to walk, talk, eat and socialize without the burden of movement disorder symptoms. Abbott's Infinity™ DBS System features precisely targeted stimulation and tailored treatment that is shown to help people get back to everyday activities and reclaim their quality of life.

The Abbott Infinity DBS System is designed to remove the burdens of other therapies and give you back the freedom and possibilities your movement disorder symptoms have limited. Most important, it's highly recommended by people like you who are living with a movement disorder.

LEARN MORE ABOUT HOW THE ABBOTT INFINITY™ DBS SYSTEM MAY HELP YOU.

Visit AbbottDBS.com



IS DBS THERAPY RIGHT FOR YOU?

TALK TO YOUR DOCTOR ABOUT DBS THERAPY

If you think you may be a candidate for DBS therapy, a next step could be visiting a neurologist who specializes in movement disorders to talk about how it could help.

You may find it helpful to write down your questions before meeting with your doctor and to have a friend or family member accompany you to your appointment.

FIND A MOVEMENT DISORDER SPECIALIST NEAR YOU.

If you are in the United States, go to FindDBSclinic.com

FOLLOWING: **WOULD DBS THERAPY** BE HELPFUL FOR ME? **HOW DOES A DBS** SYSTEM WORK? WHAT IS INVOLVED IN THE IMPLANTATION PROCEDURE? HOW LONG WILL IT TAKE FOR ME TO HEAL AFTER MY SURGERY? WHAT ACTIVITIES MUST I LIMIT AND FOR HOW LONG? ■ WHEN CAN I RESUME MY NORMAL DAILY **ACTIVITIES?** WHAT ARE THE RISKS AND BENEFITS OF

DBS THERAPY?

SOME OF THE QUESTIONS

YOU MIGHT WANT TO

DISCUSS INCLUDE THE

PARKINSON'S DISEASE

YOUR DOCTOR CAN HELP YOU DECIDE WHETHER DBS THERAPY IS RIGHT FOR YOU.

You may be a good candidate for DBS therapy if:

- You've had Parkinson's disease for at least 5 years.
- Your primary symptoms include tremors and dyskinesia.
- Medication has helped control your symptoms, but is becoming less effective or you need more of it, potentially causing side effects.
- You can be considered for surgery because you aren't suffering from other serious medical, cognitive or psychiatric conditions.

AT YOUR APPOINTMENT, THE MOVEMENT DISORDER SPECIALIST MAY WANT TO KNOW MORE ABOUT WHAT YOU ARE CURRENTLY EXPERIENCING WITH PARKINSON'S DISEASE.

Have you experienced inconsistent symptom control, despite adjustments to your medication?

YES NO

OBSERVATIONS CHART

Your doctor may ask questions regarding the times of the day your medication manages your motor symptoms well ("on-time") and the times when your medication does not adequately manage your motor symptoms ("off-time"), and if you experience sudden, uncontrolled movements of the neck/face, arms, legs, torso or the entire body (known as dyskinesia). This chart can help you organize your observations regarding your medical management.

TIME OF DAY	ON	OFF	DYSKINESIA
WAKING UP			YES NO
MORNING			YES NO
AFTERNOON	©		YES NO
EVENING	\odot		YES NO
BEDTIME	\odot		YESNO

ESSENTIAL TREMOR

YOUR DOCTOR CAN HELP YOU DECIDE
WHETHER DBS THERAPY IS RIGHT FOR YOU.

You may be a good candidate for DBS therapy if:

- Your symptoms are having an intolerable impact on your quality of life.
- Medication has helped with your symptoms, but has not adequately controlled them.
- Other rehabilitation strategies have become less effective for you.
- You can be considered for surgery because you aren't suffering from other serious medical, cognitive or psychiatric conditions.



ESSENTIAL TREMOR



PARKINSON'S DISEASE



NO TREMOR

HANDWRITING SAMPLES§§

A handwriting sample is one common way for a specialist to differentiate between Parkinson's disease and essential tremor. In essential tremor, handwriting is usually large and tremulous, whereas in Parkinson's disease it tends to be abnormally small or cramped.¹⁴

— TRACE THE SPIRALS

With medication



Without medication



FAQs

WILL DBS THERAPY PREVENT MY CONDITION FROM PROGRESSING?

DBS therapy is not a cure. In addition, it is unlikely that DBS will eliminate all your symptoms or stop them from progressing. The goal of DBS therapy is to help improve your quality of life and provide an extended period during which your symptoms can be controlled. In addition, you may be able to decrease your medication and therefore reduce medication-related side effects.¹

CAN I TRAVEL WITH MY DBS SYSTEM?

Traveling with your DBS system is safe. When at the airport, you can go through scanners but should move through the machine quickly. You can also ask to be screened using a handheld wand.

AFTER SURGERY, WILL I BE ABLE TO RETURN TO MY NORMAL ACTIVITIES, SUCH AS WORKING AND EXERCISING?

It is best to discuss with your doctor expectations for activities you can participate in after surgery and recovery time. It is not uncommon for patients to be able to return to activities they participated in before, but not all patients will experience the same results.

CAN I USE HOUSEHOLD APPLIANCES?

People with DBS systems like the Abbott Infinity™ DBS System can use everyday household appliances. Refer to your patient manual for information on any potential interactions with your device.

HOW LONG WILL MY DBS SYSTEM LAST?

The Abbott Infinity DBS System contains a recharge-free battery. At each follow-up visit, your doctor can check the status of your battery.

Additionally, when the battery is approaching the end of its useable life, a notice will appear on the information screen of your patient controller. This is your indication that it is time to schedule an appointment with your doctor. How long a battery lasts depends on how much therapy is required to manage your symptoms and the device's settings. When the battery is near depletion, your doctor will replace it in a simple and minimally invasive procedure. With this type of procedure, the leads usually do not need to be removed or replaced, so the recovery time is often much shorter than the initial system implant.

neurological impairment. As with any surgery or therapy, DBS has risks and complications. New onset or worsening depression, which may be temporary or permanent, is a risk that has been reported with DBS therapy. Suicidal ideation, suicide attempts and suicide are events that have also been reported. Most side effects of DBS surgery are temporary and correct themselves over time. Some people may experience lasting, stroke-like symptoms, such as weakness, numbness, problems with vision or slurred speech. In the event that the side effects are intolerable or you are not satisfied with the therapy, the DBS system can be turned off or surgically removed. Risks of brain surgery include serious complications such as coma, bleeding inside the brain, paralysis, seizures and infection. Some of these may be fatal.

WHAT ARE THE POTENTIAL RISKS AND SIDE EFFECTS OF DBS THERAPY?

There is no cure for Parkinson's disease (PD) or essential tremor (ET), but there are options available to treat symptoms. The first-line therapy is medication. Surgical treatments are also available. It's important to discuss with your doctor what's right for you along with the risks and side effects of each option, such as motor fluctuations or permanent

- *Based on data from all manufacturers. Abbott DBS therapy has demonstrated safety and effectiveness out to 5 years. 15,16
- **Based on wider therapeutic window findings that increase the programming possibilities that could achieve beneficial symptom relief before sustained side effects appear.
- ***Upon regulatory approval.
- [†]Within approved parameters.
- ^{††}Based on 24 hours per day and recharging data (expected 30 minutes per day) from Boston Scientific[†]. Vercise Gevia[†] Information for Prescribers. U.S. 92152385-03.
- **** Based on 16 waking hours per day and recharging data (expected 30 minutes per day) from Boston Scientific*, Vercise Gevia** Information for Prescribers, U.S. 92152385-03.
- §Based on data of patients with Parkinson's disease and compared sequentially.
- §§ Based on generally understood depictions of patient drawings. 14
- Castrioto A. Ten-Year Outcome of Subthalamic Stimulation in Parkinson Disease. Archives of Neurology. 2011;68(12):1550. n = 18.
- Parkinson's Foundation. Understanding Parkinson's Statistics. https://www.parkinson.org/Understanding-Parkinsons/Statistics. November 2019.
- International Essential Tremor Foundation Web site. Facts about Essential Tremor [PDF]. https://www.essentialtremor.org/wpcontent/uploads/2013/07/FactSheet012013.pdf. Published 2012.
- Baizabal-Carvallo JF, Kagnoff MN. The safety and efficacy of thalamic deep brain stimulation in essential tremor: 10 years and beyond. *Journal of Neurology, Neurosurgery & Psychiatry*. 2013;85(5):567-572. n = 13
- U.S. Food and Drug Administration. Premarket Approval (PMA). P960009. July 31, 1997. https://www.accessdata.fda.gov/scripts/ cdrh/cfdocs/cfPMA/pma.cfm?id=P960009.

- 6. Schnitzler A, Mir P, Brodsky M, Verhagen L, Groppa S, Alvarez R, Evans A. Directional versus Omnidirectional Deep Brain Stimulation for Parkinson's Disease: Results of a multi-center, prospective, blinded crossover study. Poster presented at: International Congress of Parkinson's Disease and Movement Disorders; September 2019; Nice, France.
- Butson CR, Venkatesan L. Comparison of neural activation between standard cylindrical and novel segmented electrode designs. Poster presented at: MDS 2014.
- Rebelo P, Green AI, Aziz Tz, Kent A, Schafer D, Venkatesan L, Cheeran B. Thalamic Directional Deep Brain Stimulation for Tremor: Spend less, get more. *Brain Stimulation*. 2018. https://doi.org/10.1016/j.brs.2017.12.015.
- Abbott. Data on File. PROGRESS Largest Study Memo. SJM-INF-0419-0314.
- Abbott. Data on File. Parkinson's Disease Final Report C-04-01.
 n = 135.
- 11. Picillo M, Fasano A. Recent advances in essential tremor: surgical treatment. *Parkinsonism & Related Disorders*. 2016;22:S171-S175.
- Abbott. Data on File. Essential Tremor Final Report C-04-02. 2014. n = 127.
- Fukaya C, Yamamoto T. Deep brain stimulation for Parkinson's disease: Recent trends and future direction. *Neurologia Medico-Chirurgica (Tokyo)*. 2015;55(5):422-431. http://dx.doi.org/10.2176/nmc.ra.2014-0446
- Alty JE, Kempster PA. A practical guide to the differential diagnosis of tremor. Postgraduate Medical Journal. September 1, 2011;87(1031):623-9.
- 15. Abbott. Data on File. Essential Tremor Interim Report C-06-03. 2014. n=52.
- Abbott. Data on File. Parkinson's Disease Interim Report C-06-04.
 2014. n = 98.

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Rx Only

Brief Summary: Prior to using these devices, please review the User's Guide for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: U.S.: Bilateral stimulation of the subthalamic nucleus (STN) and internal globus pallidus (GPi) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications, and unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability. International: Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease, unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of disabling tremor, and unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia, for patients who are at least 7 years old.

Contraindications: U.S.: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy, electroshock therapy, and transcranial magnetic stimulation (TMS) are contraindicated for patients with a deep brain stimulation system. International: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Magnetic resonance imaging (MRI) is contraindicated in certain countries. Diathermy is contraindicated for patients with a deep brain stimulation system.

Warnings/Precautions: Return of symptoms due to abrupt cessation of stimulation (rebound effect), excessive or low frequency stimulation, risk of depression and suicide, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), electromagnetic interference (EMI), proximity to electrosurgery devices and high-output ultrasonics and lithotripsy, ultrasonic scanning equipment, external defibrillators, and therapeutic radiation, therapeutic magnets, radiofrequency sources, explosive or flammable gases, theft detectors and metal screening devices, activities requiring excessive twisting or stretching, operation of machinery and equipment, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Loss of therapeutic benefit or decreased therapeutic response, painful stimulation, persistent pain around the implanted parts (e.g. along the extension path in the neck), worsening of motor impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, and cognitive impairment. Surgical risks include intracranial hemorrhage, stroke, paralysis, and death. Other complications may include seizures and infection. User's Guide must be reviewed for detailed disclosure.

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