

# DBS Therapy FOR PARKINSON'S DISEASE

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IRIS C. Benefiting from Medtronic DBS Therapy since 2008

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Perry's story recounts the experiences of one patient who is receiving Medtronic DBS Therapy (deep brain stimulation) to reduce symptoms of Parkinson's disease (PD). Medtronic invited him to share his story candidly. Please bear in mind that these experiences are specific to this particular person. Not everyone who receives Medtronic DBS Therapy will receive the same results as the patient in this story; some people may experience significant symptom relief from DBS Therapy, and others may experience minimum symptom relief. Talk with your doctor to determine if Medtronic DBS Therapy is right for you.

# Perry's Story

In 2000, Perry was working as an emergency room nurse when he noticed tremors on the left side of his body. Two years and several doctors later, at age 42, he was diagnosed with Parkinson's disease.

For a time, Perry continued his work in the ER. But limitations presented by the tremors forced him to find a new career as a clinical consultant for a computer software firm.

"When I was presenting to clients, I would sit on my left hand or put it in my pocket," recalls Perry. "At night I had to button my shirt buttons and tie my tie in preparation for the morning because my meds didn't kick in before I needed to be dressed."

"When I was presenting to clients, I would sit on my left hand or put it in my pocket." Perry's left foot dragged and on occasion he would trip and fall, causing him embarrassment. A lifelong musician, he had to give up playing the stringed instruments that were his passion.

Initially, Perry's doctors prescribed a variety of medications. At one point, he was taking 14 pills a day.

**PERRY C.** Benefiting from Medtronic DBS Therapy since 2007

### Learning More About Treatments

Perry spent time on computer forums reading about other patients' stories and talking with them online. It was in those forums that he learned about Medtronic DBS Therapy. The treatment uses a surgically placed medical device, similar to a cardiac pacemaker, to deliver carefully controlled electrical stimulation to precisely targeted areas within the brain. He was convinced he could benefit from the procedure but wanted to wait until his two children graduated from high school before proceeding.

In 2007, with both kids out of high school, he seriously considered DBS Therapy. He learned that it was offered by a surgeon who was an old friend. At an information session on DBS Therapy, they reacquainted. At that same event he spoke with a DBS patient.

"Once I talked to my friend and met the patient who had it done, I was convinced I had to do it," he says.

## Receiving DBS Therapy

Perry's procedure took about 21/2 hours and he was awake the entire time.

"The doctor said beforehand that the hardest part would be getting the halo neck brace into position," Perry says. "But within 5 minutes I didn't even notice it anymore. I didn't have pain during the surgery. At the beginning of the procedure, I just felt vibration like the drill from the dentist office."

After the surgical team placed the leads, Perry remained in the hospital overnight and returned the following week to have the neurostimulator surgically placed near his collarbone.

Perry did not experience any complications from either surgery. However, implanting DBS Therapy carries the same risks associated with any other brain surgery, which may include serious complications such as coma, bleeding inside the brain, seizures and infection. Some of these may be fatal.



"Living in general is easier. I feel so good. This is a gift." Once implanted, the system may become infected, parts may wear through the skin, and the lead or lead/extension connector may move. DBS Therapy could stop because of mechanical or electrical problems. These could require surgery or cause your symptoms to return.

"They turned the system on and my tremor stopped," Perry says. "I started crying. I am a positive person and I tried to not let my Parkinson's get me down. But you get to a point where you just accept that you're the best you'll ever be, and I thought I'd always have a tremor. So when it stopped for the first time in 7 years, it was overwhelming."

After the second surgery, Perry went to a rehabilitation hospital for 5 days where he had occupational and physical therapy and his programming settings were optimized to give him the greatest relief. Although Perry didn't experience any side effects, stimulation may cause a temporary worsening of disease symptoms and speech problems. Typically, the stimulation parameters can be adjusted to minimize these side effects and maximize symptom control. In patients receiving DBS Therapy, depression, suicidal thoughts and suicide have been reported. Occurrence of "fall" has also been observed.

## Celebrating Daily Victories

Life is easier now for Perry and he celebrates the daily victories he achieves with DBS Therapy. His left side doesn't shake, he can walk without stumbling, and he can play the banjo.

"Living in general is easier. I feel so good. This is a gift."

His family and friends noticed that his overall disposition changed after receiving DBS Therapy.

"My mood had dulled over time to the point where I was pretty flat. But I didn't realize it until after I started receiving the therapy, and then I just felt so good and more of me came out," he explains.

Perry feels he has a new attitude about his disease. "I have gained perspective. Things that bother other people mean nothing to me. I blow those things off and am even more of an optimist."

# About Parkinson's Disease

Parkinson's disease (PD) is an illness of the brain that gets worse over time and leads to problems with movement. It causes brain cells, in an area of the brain known as the substantia nigra, to die. Because these cells are involved in the production of dopamine, a chemical that enables communication among the brain cells involved in motor control, their death results in the motor control symptoms associated with the disease.

## Treating Parkinson's Disease

There is currently no cure for PD, but medications may reduce some of its symptoms. However, effectiveness can vary greatly from person to person, and increasing medication to better control tremors can lead to troubling side effects.

Another option for some people with PD is Medtronic DBS Therapy, a treatment proven to reduce symptoms of PD when medications alone aren't enough. DBS Therapy may help people reclaim life and achieve daily victories. Read on to learn more about the benefits DBS Therapy can offer.

## What Is DBS Therapy?

DBS Therapy is an FDA-approved treatment that has been proven to reduce some of the symptoms associated with PD. More than 75,000 people worldwide have received Medtronic DBS Therapy for movement disorders over the past 20 years.

DBS Therapy uses a medical device, similar to a pacemaker, and a thin, soft, flexible wire, called a lead. Placed completely inside the body, the device sends mild electrical signals to an area in the brain that controls movement. These signals block some of the brain messages that cause disabling motor symptoms. As a result, you may experience greater control over your body movements, making it easier for you to perform everyday tasks. Leads

**Implant Sites** 

# What Are the Benefits of Medtronic DBS Therapy?

Medtronic DBS Therapy can reduce several motor symptoms associated with PD:

- Rigidity—stiffness or inflexibility of the limbs or joints
- Bradykinesia/akinesia—slowness of movement/absence of movement
- Tremor—involuntary, rhythmic shaking of a limb, the head, or the entire body

In one major study, Medtronic DBS Therapy was shown to increase periods of good mobility (no symptoms or involuntary excessive movements) from a baseline of 27% to 74% in the waking day of patients.<sup>1</sup> In another study, Medtronic DBS Therapy maintained motor symptom improvements even after 5 years.<sup>2</sup>

Compared to medications alone, Medtronic DBS Therapy used in combination with medication has been found to reduce several symptoms of PD, and some drug side effects.<sup>3</sup>

Medications Alone	Medtronic DBS Therapy + Medications
0 hours of additional "on" time <sup>3</sup>	Average 5.1 hours additional "on" time without troubling dyskinesias*
Unpredictable motor fluctuations	More predictable motor fluctuations
Dyskinesias and nonmotor side effects	Medication reduction may lead to fewer drug-induced side effects

\* Mean results; DBS is adjunctive to medications.

# What Are the Potential Side Effects and Risks?

As is the case with any other brain surgery, there are some risks to consider with DBS Therapy. Please be sure to discuss the possible surgical complications and side effects with your physician.

- Some of the possible surgical risks may include serious complications such as coma, bleeding inside the brain, seizures and infection. Some of these may be fatal.
- Possible device complications include problems with lead/extension connector positioning, parts wearing through the skin, or an interruption in therapy because of mechanical or electrical problems. Any of these situations may require additional surgery or cause your symptoms to return.
- Some of the side effects associated with the stimulation may include worsening of some motor symptoms or speech and language impairments. Typically, these side effects are not permanent and can be resolved by adjusting stimulation parameters. Depression, suicidal thoughts, and suicide have been reported. Occurrence of "fall" has also been observed.

For more information on risks and side effects, talk with your physician or visit medtronicdbs.com.

# Achieve Daily Victories

For many people with PD and their family caregivers, Medtronic DBS Therapy offers a new outlook on life.

With their PD symptoms under control, some people with PD are able to achieve daily victories like performing activities of daily living on their own, such as eating, dressing and writing. Others are able to return to work and renew their participation in hobbies.

"Before DBS Therapy, I couldn't tie my shoes, button my shirts, or tie my own tie. After the therapy, I could do all of those things myself, and facial expressions that had been gone for 4 years returned." – Jerry W.

"DBS Therapy gave me back years of a good job that I couldn't have hoped for without the therapy." – Chris J.

What might be possible for you?

"I used to paint quite a bit and then I had to stop. After my surgery, I painted each of my doctors a picture."



## Am I a Candidate for Medtronic DBS Therapy?

Medtronic DBS Therapy may be right for you if your PD symptoms significantly interfere with activities of daily living (such as eating, drinking, dressing, or writing) despite having tried medications, or if you are having troubling side effects from drugs to treat PD.

You can better understand if you might be right for DBS Therapy by answering the following questions.

- Do you experience troubling "off" periods (periods when medication is not helping enough and you are experiencing symptoms)?
   □ Yes
   □ No
- Do you experience significant difficulty with daily activities, such as eating, drinking, and writing? □ Yes □ No
- 3. Do you take frequent doses of dopaminergic drugs (levodopa, Sinemet®, Stalevo®, Parcopa®) in a typical day? □ Yes □No
- 4. Do you experience any of the following troubling side effects from your medications, despite having tried several drug combinations? (sleepiness, nausea, hallucinations, confusion/other thinking problems, lightheadedness upon standing, behavioral/personality changes)
  □ Yes
  □ No

If you answered "Yes" to these questions, you may be a candidate for Medtronic DBS Therapy. However, only a doctor can determine if you are a candidate, so you should consult with a neurologist who is familiar with the therapy.

Please contact Medtronic (1-877-438-3574) for help finding a neurologist in your area, or if you would like to discuss DBS Therapy with a current patient or registered nurse. More information is also available at medtronicdbs.com

# What Can I Do Next?

To learn more about Medtronic DBS Therapy and how it might help you or someone you love, join Discover Medtronic DBS today. This free Medtronic program will be tailored to ensure that you're getting the information you want and need to help you decide if DBS Therapy might be right for you or a loved one.

#### With Discover Medtronic DBS, you will have access to a variety of resources:

#### • Talk to Someone Receiving DBS Therapy

Interested in talking with someone who is receiving DBS Therapy for PD? Medtronic has volunteer ambassadors who are eager to share their stories and experiences and answer your questions.

#### • Find a Neurologist Experienced in DBS Therapy

Give us a call and let our patient advisors help you find a nearby neurologist who is experienced with DBS Therapy.

Ask an Expert

Register for a complimentary 20-minute telephone consultation with a registered nurse who is highly knowledgable about DBS Therapy. Our experts can help you understand what to expect before, during, and after surgery.

To take advantage of these resources, complete the enclosed business reply card, call Medtronic at 877-438-3574, or visit medtronicdbs.com.



## Get Involved

The following organizations offer people who have or are touched by someone with PD helpful information, support, and the chance to get involved in various PD activities and causes.

American Parkinson Disease Association, Inc. 718-981-8001 apdaparkinson.org

The Davis Phinney Foundation 866-358-0285 davisphinneyfoundation.org

Michael J. Fox Foundation 800-708-7644 michaeljfox.org

National Parkinson Foundation, Inc. 800-327-4545 parkinson.org Parkinson's Action Network (PAN) 800-850-4726 parkinsonsaction.org

Parkinson's Disease Foundation (PDF) 800-457-6676 pdf.org

The Parkinson Alliance 800-579-8440 parkinsonalliance.org; dbs-stn.org

WE MOVE 212-875-8312 wemove.org

"I can eat by myself and I can walk by myself—sometimes with a walker or a cane or sometimes nothing."

## Frequently Asked Questions

#### How long will it take for DBS Therapy to work after the procedure?

Typically, a Medtronic DBS system is not activated until you've healed from the procedure. Your symptoms may decrease at that time. Optimal results are normally not achieved until the health care professional who programs your device has gone through multiple programming sessions with you. This process may take several months.

#### Is this a new type of treatment for Parkinson's disease?

Medtronic DBS Therapy for the treatment of PD was developed by Medtronic in the 1980s and approved for use in the United States in 2002. It has been proven to reduce some of the symptoms associated with Parkinson's disease. It is currently included in the American Academy of Neurology Guideline Summary for Patients as a surgical treatment option for Parkinson's disease.<sup>4</sup>

#### Is this a permanent procedure?

Medtronic DBS Therapy is a reversible procedure. It is also adjustable, which means that the stimulation can be changed over time to match the need of symptom control. Finally, if necessary, the system can be deactivated or even removed. Removal would require additional surgery.

#### What does the stimulation feel like?

Most people don't feel the stimulation at all, but can experience the effects of the stimulation when it reduces some of their symptoms. However, some people may feel a brief tingling sensation when the stimulation is first turned on. During the initial programming, higher levels of stimulation have been described as uncomfortable, jolting, or shocking. These symptoms are typically immediately alleviated through programming adjustments. If the stimulation changes or becomes uncomfortable, contact your doctor immediately.

## Next Steps

Now that you've reviewed this brochure, we encourage you to take these next steps to learn more about Medtronic DBS Therapy.

- View the enclosed DVD.
- Visit medtronicdbs.com.
- Discuss this information with your physician.
- Register to discuss DBS Therapy with a current patient or registered nurse. To take advantage of these resources, contact Medtronic.
- Call 877-438-3574
- Visit us online at medtronicdbs.com.

## References

- 1. The Deep-Brain Stimulation for Parkinson's Disease Study Group. Deep-brain stimulation of the subthalamic nucleus or the pars interna of the globus pallidus in Parkinson's disease. *N Engl J Med.* 2001;345(13):956-963.
- 2. Krack P, Batir A, Van Blercom N, et al. Five-year follow-up of bilateral stimulation of the subthalamic nucleus in advanced Parkinson's disease. *N Engl J Med.* 2003;349(20):1925-1934.
- 3. Activa Clinical Summary, 2009.
- 4. AAN Guideline Summary for Patients and their families: Medical and Surgical Treatment for Motor Fluctuations and Dyskinesia in Parkinson's Disease, April 2006.

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### Activa® Parkinson's Control Therapy and Tremor Control Therapy: Patients should always discuss the potential risks and benefits with a physician.

#### Indications:

Parkinson's Control Therapy: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic<sup>®</sup> Activa<sup>®</sup> Parkinson's Control Therapy is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Tremor Control Therapy: Unilateral thalamic stimulation by the Medtronic<sup>®</sup> Activa<sup>®</sup> Tremor Control System 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 safety or effectiveness of this therapy has not been established for bilateral stimulation.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for patients for whom test stimulation is unsuccessful. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system.

Warnings/ Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Although some MRI procedures can be performed safely with an implanted Activa System, clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation. MRI image quality may be reduced for patients who require the neurostimulator to control tremor, because the tremor may return when the neurostimulator is turned off.

Severe burns could result if the neurostimulator case is ruptured or pierced. The Activa System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; or for patients who are pregnant, under 18 years, over 75 years of age (Parkinson's Control Therapy) or over 80 years of age (Tremor Control Therapy).

Additionally, the abrupt cessation of stimulation for any reason should be avoided as it may cause a return of disease symptoms. In some cases, symptoms may return with an intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation.

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Medtronic Neuromodulation 710 Medtronic Parkway Minneapolis, MN 55432-5604 USA Tel. 763-505-5000 Toll-free 1-800-328-0810

