

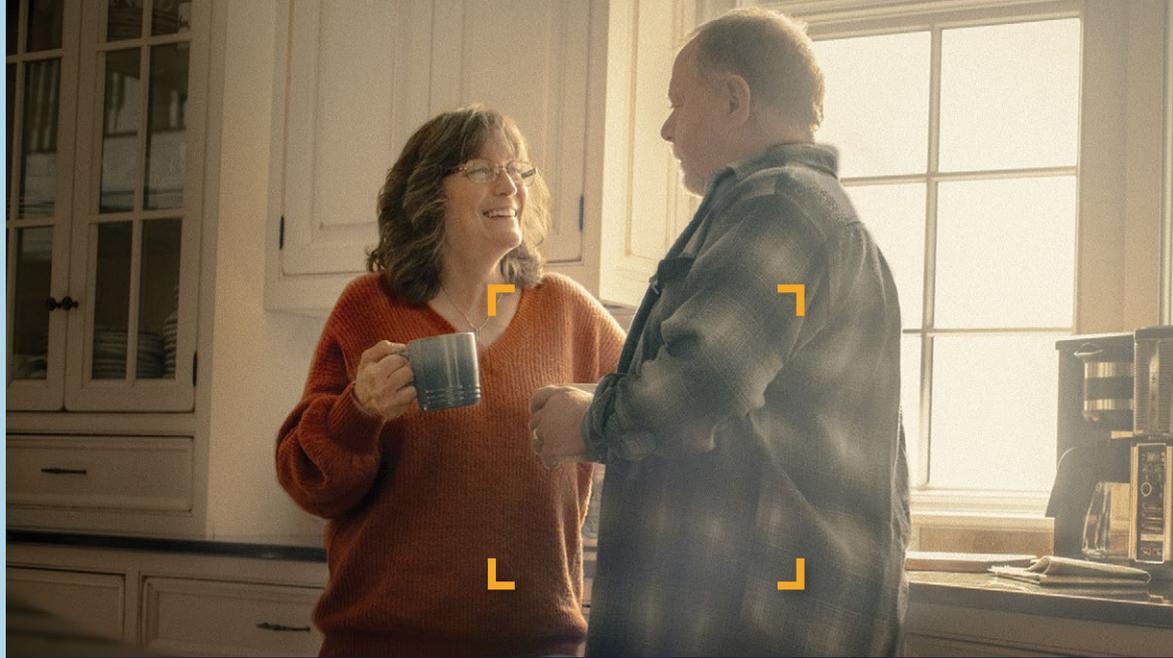


# DBS can help

Medtronic Deep Brain Stimulation (DBS)  
Therapy for Parkinson's

**Medtronic**

[DiscoverDBS.com](https://www.DiscoverDBS.com)



GARY, RECEIVING DBS THERAPY, AND HIS WIFE, PATRICIA

# Get connected

Visit [DiscoverDBS.com](https://www.DiscoverDBS.com)  
to view educational  
resources and webinars,  
to find a specialist, or to  
talk with someone receiving  
Medtronic DBS Therapy.



Scan me with  
your smartphone  
camera.

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**Text DBS to 858 858**  
**or call (877) 438-3574**  
Monday to Friday,  
9 am to 5 pm CT to sign up  
to receive more information.

# DBS can mean a **new lease on life**

Losing control of your movements due to Parkinson's can leave you feeling like you're missing out on important parts of your relationships, or worse—like you're losing part of yourself.

By managing some of the movement symptoms of Parkinson's, DBS may help you regain control again. Restoring capabilities can bring a renewed sense of self and reconnection with the world around you.

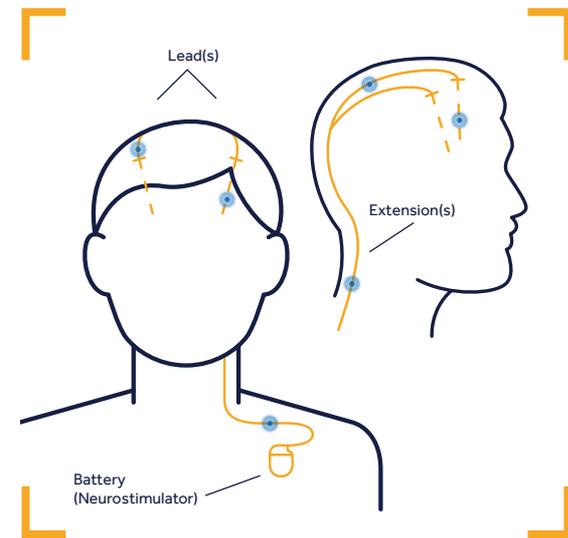


*For 5 years  
I couldn't turn a screwdriver.*

ACTUAL PATIENT NOT PICTURED



DBS HELPS IN SMALL WAYS EVERY DAY



# What is DBS?

Deep Brain Stimulation (DBS) uses a small pacemaker-like device, placed under the skin of the chest, to send electrical signals through extensions and very thin wires (leads) to an area in the brain that controls movement. To give you relief, these signals block some of the brain messages that cause the movement symptoms of Parkinson's.

When medications aren't as effective as they used to be, DBS may help control some of the movement symptoms of Parkinson's: tremor (shaking), slowed movement (bradykinesia), and stiffness (rigidity).

As your Parkinson's symptoms change, signals in your brain also change. Now with **BrainSense™ Technology**,<sup>†</sup> Medtronic offers a DBS neurostimulator that can also capture and store brain signal data directly from your implanted SenSight™ directional leads. Using this data, your physician may adjust your settings—personalizing the therapy to ensure the best possible outcome.\*

\* Signal may not be present or measurable in all patients. Clinical benefits of brain sensing have not been established.



# Medtronic DBS Therapy Benefits

## Less medication, more relief

Medtronic DBS Therapy may reduce Parkinson's medication.<sup>1</sup> This may reduce medication-related side effects like unintended movements (dyskinesia), while simplifying your medication routine, with fewer pills or less frequent doses.

## Better mornings

DBS delivers therapy 24 hours a day—it doesn't wear off while you sleep. It's already working the moment you wake up.

## Minimal Maintenance

The DBS system requires no daily cleaning or refilling.

## More good hours of movement control

Each day, DBS provides additional hours of good movement control ("on" time) without unintended movements (dyskinesia), compared to medication alone.<sup>1</sup>

## A better quality of life

In combination with medication, DBS Therapy has helped people with Parkinson's enjoy an improved quality of daily life, compared to those taking medication alone.<sup>1</sup>

## Keep your options open

Unlike some surgeries for Parkinson's, DBS is reversible. The system can be turned off or removed, in most cases, and won't limit your future treatment options.

## Greater satisfaction

Watch stories of real people with Parkinson's and the relief they've experienced with Medtronic DBS Therapy at [DiscoverDBS.com](https://www.DiscoverDBS.com).

### **Refer to pages 31–34 of this brochure for additional safety information.**

Medtronic DBS Therapy for Parkinson's is not for everyone. Not everyone will receive the same results. Patients should always discuss the potential risks and benefits of the therapy with a physician. A prescription is required. DBS Therapy requires brain surgery. Risks of brain surgery may include serious complications such as coma, bleeding inside the brain, stroke, seizures and infection. DBS Therapy may cause worsening of some symptoms. See Important Safety Information at [medtronic.com/PDSafety](https://www.medtronic.com/PDSafety) or call Medtronic at 800-328-0810.



## Is DBS for me?

*DBS has arrested my husband's tremors and has given us a brighter future together!*

DBS Therapy is a personal decision—one you and your doctor should make together. In general, you may be a candidate for DBS if you:

- ✓ Have had Parkinson's for 4+ years
- ✓ Have had movement symptoms and/or medication side effects for 4+ months
- ✓ Respond well to Levodopa
- ✓ Have movement symptoms not adequately controlled by medication

Only your doctor can determine if DBS is right for you. Make an appointment with a movement disorder neurologist to get an evaluation.

**Don't have a doctor?  
See our physician finder:  
[DiscoverDBS.com](https://www.discoverdbs.com)**

DBS Therapy is also appropriate for people who have had movement symptoms for a longer period, and there is no upper age limit.

**Refer to pages 31–34 of this brochure for additional safety information.** Medtronic DBS Therapy for Parkinson's is not for everyone. Not everyone will receive the same results. Patients should always discuss the potential risks and benefits of the therapy with a physician. A prescription is required. DBS Therapy requires brain surgery. Risks of brain surgery may include serious complications such as coma, bleeding inside the brain, stroke, seizures and infection. DBS Therapy may cause worsening of some symptoms. See Important Safety Information at [medtronic.com/PDSafety](https://www.medtronic.com/PDSafety) or call Medtronic at 800-328-0810.

# A decision that won't wait

Don't think of DBS as a "last resort." If you wait until your medications no longer help, DBS is no longer an option. So talk with your doctor about it now, so you can be ready for DBS at the right time for you. It's never too soon to learn more.



*For 8 years,  
I could barely play*



Parkinson's offers you a window of opportunity when DBS Therapy may be effective.

1

### Appearance of symptoms

Oral medications are controlling symptoms.

**Ask your doctor when DBS might be right for you.**

2

### Window of opportunity

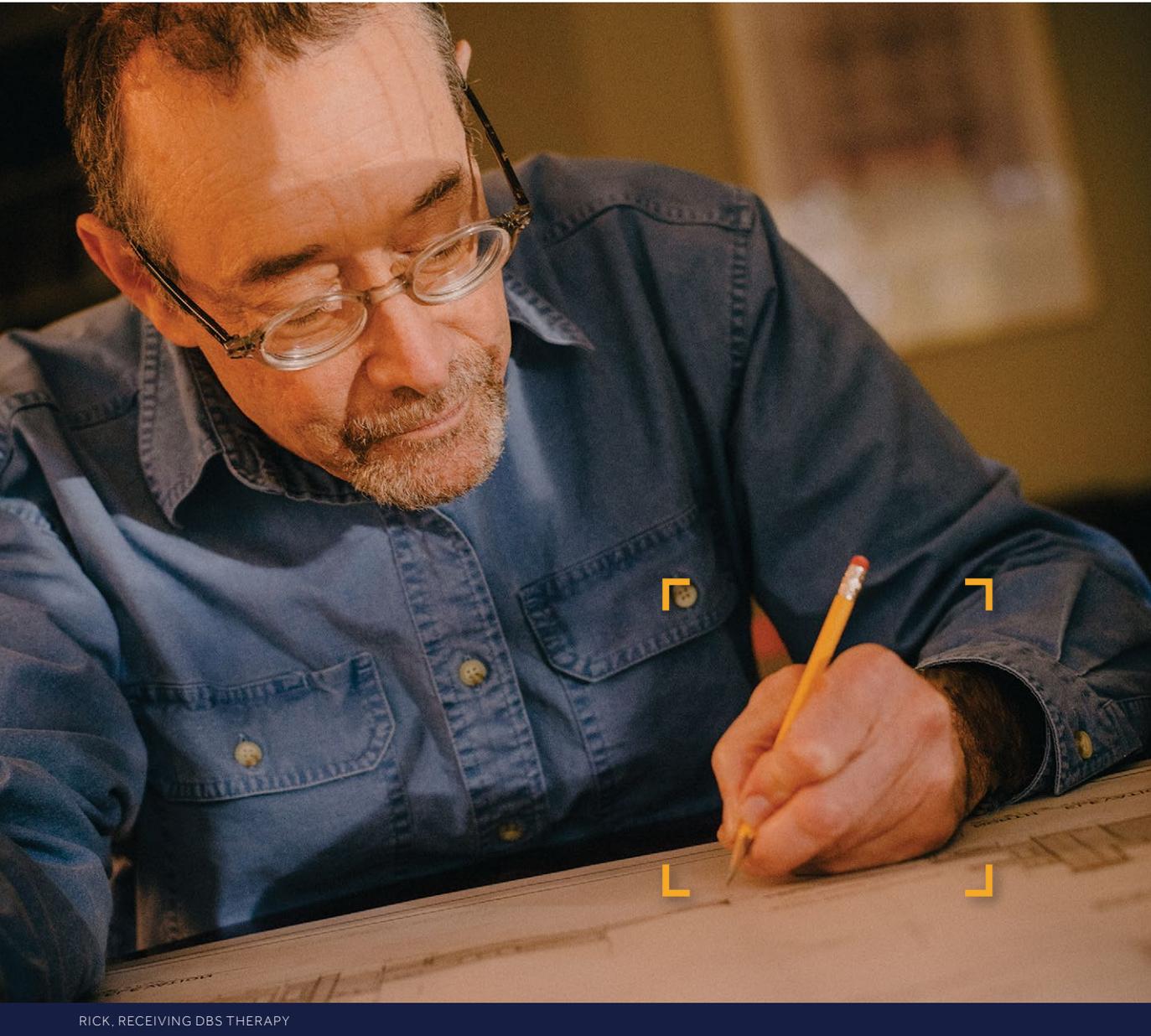
Oral medications are still working, but not as well.

**Talk with your doctor about DBS—today.**

3

### Late-stage Parkinson's

Symptoms no longer respond to oral medications. **DBS is no longer an option.**



RICK, RECEIVING DBS THERAPY

# What to expect

## Evaluation

Your neurologist—typically a movement disorder specialist—will evaluate you to see if DBS is a good option for you. This may include medical history, lab work, MRI and neuropsychological tests.

## About the procedure

DBS surgery consists of two parts:

- Implanting the leads (very thin wires) and extensions.
- Placing the pacemaker-like device, called a neurostimulator, under the skin of the chest.

The two parts may be done on the same day or on different days.

## Programming & follow-up

A few weeks after surgery, your doctor will turn on the neurostimulator and adjust it to best control your symptoms while minimizing side effects. It may take a few programming sessions to find the stimulation levels that work best for you—so don't get discouraged if it takes some time. You will attend periodic check-ups with your doctor to best control your symptoms, adjust stimulation and check the battery level of your device to monitor for a replacement.

# Talk with your doctor

Look for a neurologist who specializes in treating Parkinson's. The right doctor will understand not only your treatment options, but also you as a person, and be your guide.

While some general neurologists are also experienced in treating Parkinson's, a movement disorder specialist has extra training, and knows the full range of treatment options.

No matter which doctor you choose, be honest about your symptoms and how your treatment is working. Ask about other options, and don't hesitate to get another opinion.

Use our Medtronic Physician Finder to find a specialist in your area:

[DiscoverDBS.com](http://DiscoverDBS.com)



Use the questions and symptom tracker on the following pages to help guide a conversation with your doctor.



# How are you feeling about your symptoms?

## How troublesome are your "off" periods?

*(when medication is not helping enough and you are experiencing symptoms)*

Circle any or all that apply

I barely notice I'm "off"

I can't do some things I want to do

I have difficulty, but I can do all I want to do

I can't do most things I want to do

## How troublesome is your dyskinesia?

*(involuntary excessive movements)*

Circle any or all that apply

I don't have any

They interfere with some activities

I barely notice them, but others do

They interfere with most activities

## What are your most troublesome side effects?

Circle any or all that apply

Sleepiness

Confusion or other thinking problems

Nausea

Lightheadedness upon standing

Hallucinations

Behavior or personality changes

Other: \_\_\_\_\_



## Track your symptoms to help your doctor

A well-kept Symptom Tracker provides a clear picture of your medication use, when you are feeling well, and when you are not.

## Instructions

Track your symptoms for three full days, and then bring the completed Symptom Tracker to your doctor.

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### Before you start

Next to the name of the drugs listed, write the strength of the pills you take (in mg). Look at the container label if necessary. Use "other" row for Parkinson's drugs not listed.

### Every Hour

- Mark with an "X" the row that best describes your overall motor control.
- When you take medications, write down how many pills you took.
- In the notes section, write any troublesome side effects you experience.

### Symptom control categories

Record your symptom control every hour in one of four categories:

- Asleep
- "On" Time with unintended movements (dyskinesia)—Periods when medication is giving you good symptom control but is causing troublesome, involuntary, excessive movements
- "On" Time without unintended movements (dyskinesia)—Periods when medication is giving you good motor control
- "Off" Time—Periods when medication is not helping enough and you are experiencing troublesome symptoms like tremor (shaking), slowed movement (bradykinesia), or stiffness (rigidity)

# Daily Symptom Tracker

\*Third-party brands are trademarks of their respective owners.  
All other brands are trademarks of a Medtronic company.

Day 1																			
	5 AM	6 AM	7 AM	8 AM	9 AM	10 AM	11 AM	12 PM	1 PM	2 PM	3 PM	4 PM	5 PM	6 PM	7 PM	8 PM	9 PM	10 PM	11 PM
Asleep																			
"On" Time with troublesome dyskinesia																			
"On" Time without troublesome dyskinesia																			
"Off" Time																			
Parkinson's Medications (tablet strength in mg)																			
Parcopa® Rytary®, Sinemet® Carbidopa/Levodopa™ ( mg)																			
Stalevo® Levodopa/Entacapone™ ( mg)																			
Symmetrel® Amantadine HCL™ ( mg)																			
Azilect® Rasagiline™ ( mg)																			
Requip® Ropinirole HCL™ ( mg)																			
Mirapex® Pramipexole DIHCL™ ( mg)																			
Comtan® Entacapone™ ( mg)																			
Artane® Trihexphenidyl™ ( mg)																			
Other: _____																			
Other: _____																			

Notes (e.g., troubling side effects):

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# Daily Symptom Tracker

\*Third-party brands are trademarks of their respective owners.  
All other brands are trademarks of a Medtronic company.

Day 2																			
	5 AM	6 AM	7 AM	8 AM	9 AM	10 AM	11 AM	12 PM	1 PM	2 PM	3 PM	4 PM	5 PM	6 PM	7 PM	8 PM	9 PM	10 PM	11 PM
Asleep																			
"On" Time with troublesome dyskinesia																			
"On" Time without troublesome dyskinesia																			
"Off" Time																			
Parkinson's Medications (tablet strength in mg)																			
Parcopa® Rytary®, Sinemet® Carbidopa/Levodopa™ ( mg)																			
Stalevo® Levodopa/Entacapone™ ( mg)																			
Symmetrel® Amantadine HCL™ ( mg)																			
Azilect® Rasagiline™ ( mg)																			
Requip® Ropinirole HCL™ ( mg)																			
Mirapex® Pramipexole DIHCL™ ( mg)																			
Comtan® Entacapone™ ( mg)																			
Artane® Trihexphenidyl™ ( mg)																			
Other: _____																			
Other: _____																			

Notes (e.g., troubling side effects):

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# Daily Symptom Tracker

\*Third-party brands are trademarks of their respective owners.  
All other brands are trademarks of a Medtronic company.

Day 3																			
	5 AM	6 AM	7 AM	8 AM	9 AM	10 AM	11 AM	12 PM	1 PM	2 PM	3 PM	4 PM	5 PM	6 PM	7 PM	8 PM	9 PM	10 PM	11 PM
Asleep																			
"On" Time with troublesome dyskinesia																			
"On" Time without troublesome dyskinesia																			
"Off" Time																			
Parkinson's Medications (tablet strength in mg)																			
Parcopa® Rytary®, Sinemet® Carbidopa/Levodopa™ ( mg)																			
Stalevo® Levodopa/Entacapone™ ( mg)																			
Symmetrel® Amantadine HCL™ ( mg)																			
Azilect® Rasagiline™ ( mg)																			
Requip® Ropinirole HCL™ ( mg)																			
Mirapex® Pramipexole DIHCL™ ( mg)																			
Comtan® Entacapone™ ( mg)																			
Artane® Trihexphenidyl™ ( mg)																			
Other: _____																			
Other: _____																			

Notes (e.g., troubling side effects):

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# Choose Medtronic, the leader in DBS

DBS development started in 1987, and Medtronic has been leading the way ever since. Medtronic DBS Therapy systems are rigorously tested and FDA approved.

Over 175,000 people worldwide have received Medtronic DBS Therapy.



# You deserve options

Once you've made the decision to get DBS Therapy, you'll work with your doctor to select the DBS device that's right for you. Here are a few questions to consider.

## How will my DBS Therapy be personalized for me?

All DBS systems can be programmed, but only Medtronic's DBS system with BrainSense™ Technology\* captures and stores brain signal data directly from your implanted SenSight™ directional leads. Using this data, your physician may adjust your settings—personalizing your therapy for the best possible outcome.\*

## Can I get an MRI with my DBS device?

Medtronic is committed to ensuring you have safe access to cutting-edge diagnostic imaging technology, including magnetic resonance imaging (MRI). A non-invasive way to examine organs, tissues, and the skeletal system, MRI is used to diagnose causes of common medical conditions of the heart, brain, and spine. You may need an MRI in the future; approximately

seven out of 10 DBS-eligible patients with movement disorders may need an MRI within 10 years of receiving their device.<sup>2</sup> Some Medtronic DBS systems are full-body MR Conditional\*\* and you may even be able to leave your stimulation on during the MRI scan.

## Recharge-free or rechargeable?

Medtronic offers both rechargeable and recharge-free DBS devices to fit your needs. Our recharge-free devices don't require any maintenance between device replacements. Our 15-year rechargeable DBS system uses a wireless recharger designed to fit into your life.

**Find more information at  
DiscoverDBS.com**

\* Signal may not be present or measurable in all patients. Clinical benefits of brain sensing have not been established.

\*\* Medtronic DBS systems are MR Conditional and safe in the MR environment as long as certain conditions are met. If these conditions are not met, there is a significant risk of tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury, including coma, paralysis, or death. Refer to the MRI Guidelines for Medtronic Deep Brain Stimulation Systems for a complete list of conditions: <http://professional.medtronic.com/mri>.

## Percept™ PC Neurostimulator System:

Discover the only sensing-enabled Recharge-free DBS system



### Percept™ PC System Features

- A complete sensing-enabled DBS system that can capture information from your brain and personalize therapy to ensure the best outcome possible.\*
- A sensing-enabled lead, the SenSight™ Directional Lead, precisely directs stimulation — so you get therapy right where you need it.
- MRI access should you need one in the future. Percept™ PC Neurostimulator provides full-body MR Conditional\* access for both 3T and 1.5T MRI scans.
- A smartphone-like patient programmer that allows you to easily and conveniently manage your therapy and check the battery.
- A Digital Diary on your patient programmer that enables you to track your events, such as when you took medication. It can eliminate the need to carry a notebook or diary.

## Activa™ RC Neurostimulator System:

Explore the 15-year Rechargeable DBS System



### Activa™ RC System Features

- A rechargeable battery that lasts up to 15 years between replacements.
- The SenSight™ Directional Lead precisely directs stimulation — so you get therapy right where you need it.
- A wireless recharger for a faster, smarter recharging experience.
- MRI access should you need one in the future. Activa™ RC Neurostimulator provides full-body MR Conditional\* access for 1.5T MRI scans.
- A smartphone-like patient programmer that allows you to easily and conveniently manage your therapy and check the battery.



Wireless recharger

\*Clinical benefits of brain sensing have not been established.

\*\*Medtronic DBS systems are MR Conditional and safe in the MR environment as long as certain conditions are met. If these conditions are not met, there is a significant risk of tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury, including coma, paralysis, or death. Refer to the MRI Guidelines for Medtronic Deep Brain Stimulation Systems for a complete list of conditions: <http://professional.medtronic.com/mri>.

# Safety information

This therapy is not for everyone. Not everyone will receive the same results. For further information, please call Medtronic at (1-800) 328-0810 and consult Medtronic's website at [medtronic.com/PDsafety](http://medtronic.com/PDsafety). A prescription is required.

As you consider these possible benefits, you should also explore the risks. This brochure discusses the benefits, risks and side effects associated with DBS Therapy. Be sure to discuss the risks of this therapy with your physician.

Individual results may vary.

Placing the DBS system requires brain surgery which can have serious and sometimes fatal complications such as bleeding inside the brain, stroke, seizures and infection. This therapy is not for everyone. Implantation of a DBS system is contraindicated (not allowed) for patients who will be exposed to diathermy (deep heat treatment) or transcranial magnetic stimulation. Magnetic Resonance Imaging (MRI) should only be performed as described in the product labeling. Once implanted, infection may develop, parts may wear through your skin, and the lead or lead/extension connector may move. Tunneling the extension may cause nerve or tissue injury, and scar tissue may form around

the extension. Medtronic DBS Therapy could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return or worsen. The DBS system may interact with other medical devices and other sources of electromagnetic interference which may result in serious patient injury or death, system damage or changes to the neurostimulator or to stimulation. Medtronic DBS Therapy may cause new or worsening neurological or psychiatric symptoms.

In patients receiving Medtronic DBS Therapy for Parkinson's disease or essential tremor, new onset or worsening depression, suicidal thoughts, suicide attempts, and suicide have been reported.

Rev 12/19



*To Everyone at Medtronic. Thank you for all of your hard work.  
Because of all of you, I have my life back.*

— LISA, RECEIVING DBS THERAPY

# Brief statement

## Medtronic DBS Therapy for Parkinson's Disease and Tremor

Patients should always discuss the potential risks and benefits with a physician.

**INDICATION:** Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor 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.

**CONTRAINDICATIONS:** Medtronic DBS Therapy is contraindicated (not allowed) for patients who are unable to properly operate the neurostimulator and patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic

Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if the patient has an implanted Solettra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

**WARNINGS:** There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and a potential risk to drive tremor (cause tremor to occur at the same frequency as the programmed frequency) using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. 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. The DBS 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. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious and permanent injury including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor).

The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). New onset or worsening depression, suicidal ideations, suicide attempts, and suicide have been reported.

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement that may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Patients should avoid manipulating the implanted system components or burr hole site as this can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) as this could damage the neurostimulation system, before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician. Patients using a rechargeable neurostimulator must not place the recharger over a medical device with which it is not compatible (eg, other neurostimulators, pacemaker, defibrillator, insulin pump). The recharger could accidentally change the operation of the medical device, which could result in a medical emergency. Patients should not use the recharger on an unhealed wound as the recharger system is not sterile and contact with the wound may cause an infection.

**PRECAUTIONS:** Loss of coordination in activities such as swimming may occur. Patients using a rechargeable neurostimulator for Parkinson's disease or essential tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

**ADVERSE EVENTS:** Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy and weight gain or loss.

Safety and effectiveness has not been established for patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years. Safety and effectiveness of Medtronic DBS Therapy for Tremor has not been established for bilateral stimulation or for patients over 80 years of age.

USA Rx only Rev 03/20

# The Medtronic difference:

bringing decades of experience in improving lives through DBS therapy

As a global leader in medical technology, we continually seek ways to improve the lives of people. So you can be assured our DBS technology is backed by decades of research, innovation, and experience. We began developing DBS therapy in 1987, and our devices have been implanted in more than 175,000 patients worldwide.

## References

1. Medtronic DBS Therapy for Parkinson's Disease and Essential Tremor Clinical Summary, 2015.
2. Falowski S, Safriel Y, Ryan MP, Hargens L. "The rate of magnetic resonance imaging in patients with deep brain stimulation." *StereotactFunct Neurosurg.* 2016; 94(3):147-153.

# Medtronic

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Toll-Free: 1 (800) 510-6735 to speak to Medtronic Patient Services  
(Support for patients is available M-F 8 AM-5 PM CT)

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