



DBS THERAPY  
FOR  
**PARKINSON'S**

GETTING  
**BACK**  
TO YOU

**Medtronic**  
Further. Together

# GET CONNECTED

We're here to help you get the information you need to make a confident decision about DBS.



For more information about DBS and Medtronic, please visit our website.

[MEDTRONIC.COM/PD](https://www.MEDTRONIC.COM/PD)



For news, updates, and events, follow the Medtronic Parkinson's Facebook page.

[FACEBOOK.COM/MEDTRONICPARKINSONS](https://www.FACEBOOK.COM/MEDTRONICPARKINSONS)



Watch patient stories and videos about DBS Therapy on our YouTube page.

[YOUTUBE.COM/MEDTRONICDBSTHERAPY](https://www.YOUTUBE.COM/MEDTRONICDBSTHERAPY)

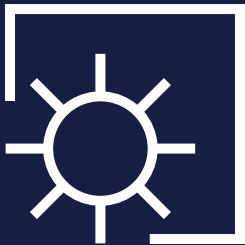


GETTING  
BACK TO  
**MAKING THE  
MOST OF  
YOUR DAY**

"I don't have to time my hikes. I don't have to time my games. I don't have to time my meals. I can do pretty much whatever I want whenever I want. Yes, I still have a bit of an 'off' period but it's—but it's not very bad."

**Brian**  
Receiving DBS Therapy

EXPLORE MORE PATIENT STORIES AT  
[MEDTRONIC.COM/PDSTORIES](https://www.MEDTRONIC.COM/PDSTORIES)



## DBS MOVES YOU FORWARD WHEN PARKINSON'S IS HOLDING YOU BACK

Living well with Parkinson's means being able to do what's important to you — taking care of yourself, having lunch with friends, continuing to work or volunteer, enjoying your favorite activity. The right treatment may control your symptoms so you can live life your way.

Deep brain stimulation (DBS) may help control the movement symptoms of Parkinson's disease, including tremor (shaking), slowed movement (bradykinesia), and stiffness (rigidity), so you can *Get Back to You*.

The quotes in this brochure recount the experiences of individuals who are receiving Medtronic DBS Therapy for Parkinson's disease. Not everyone who receives Medtronic DBS Therapy will experience the same results. Some people may experience significant symptom relief from DBS Therapy, and others may experience minimal relief. Talk to your doctor to see if Medtronic DBS Therapy is right for you.



*Actual patients not pictured*

## GETTING BACK TO COFFEE DATES

"We are so grateful for each other and the new lease on life DBS Therapy gave us."

**Karen and Jim**  
Both receiving DBS Therapy

READ KAREN AND JIM'S FULL STORY AT  
[MEDTRONIC.COM/PDSTORIES](https://www.medtronic.com/pdstories)



## A 24-HOUR THERAPY THAT FITS YOUR LIFESTYLE

DBS helps control some of your movement symptoms when your medications aren't working as well as they used to. For many people with Parkinson's, DBS makes a difference when even small tasks have become challenging. DBS has helped some people stay as independent as possible and keep doing the activities they love.

Compared to medications alone, DBS provides additional hours of good movement control each day.<sup>1</sup> Good movement control makes it easier to do everyday things like writing, bathing and dressing, and drinking and eating.

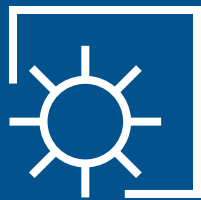
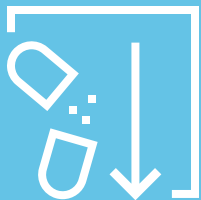
At this point, you may be scheduling activities for the time during the day when the medications tend to be working better. With DBS, some people have been able to get back to planning their lives around what they want to do, rather than around their medications.



DBS uses a small, pacemaker-like device, placed under the skin of the chest, to send electronic signals through 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.

SEE THE DIFFERENCE DBS CAN  
MAKE — WATCH THE VIDEOS AT  
[MEDTRONIC.COM/PDDemo](https://www.medtronic.com/pddemo)

# THE BENEFITS OF DBS THERAPY



## 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). Less medication may also simplify your medication routine, with fewer pills or less frequent doses.

## A BETTER START TO YOUR DAY

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

## A THERAPY THAT FITS YOUR DAILY LIFESTYLE

Unlike some other therapies used to treat Parkinson's symptoms, the DBS system requires no daily cleaning or refilling; you can bathe and shower without worrying about your device.

## ADDITIONAL HOURS OF GOOD MOVEMENT CONTROL<sup>1,2</sup>

DBS Therapy provides additional hours of good movement control ("on" time) without unintended movements (dyskinesia) each day compared to medication alone.

## ENJOY A BETTER QUALITY OF LIFE

With DBS Therapy, some people have been able to continue the everyday things that are important to them — things like dressing and bathing, brushing their teeth, and putting on makeup. In fact, when combined with medication, people with DBS therapy experience improved quality of life, compared to those taking medication alone.<sup>1</sup>

## KEEP YOUR OPTIONS OPEN

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

FOR MORE ON DBS, VISIT  
[MEDTRONIC.COM/PD](https://www.medtronic.com/pd)





## SYMPTOMS DBS TREATS

While some people believe deep brain stimulation treats **tremor (shaking)** only, DBS also treats other movement symptoms of Parkinson's disease, including **slowed movement (bradykinesia)** and **stiffness (rigidity)**.

Symptom control may help you continue to do what's important to you, like taking care of family, continuing to work, or participating more fully in an event like a vacation or a family wedding.

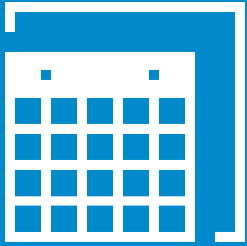


## GETTING BACK TO THE FARM

"When you think you're down for the count, and you get your life back, it's indescribable. It's a second chance. Every day is precious."

**Gary**  
Receiving DBS Therapy

WATCH GARY'S FULL STORY AT  
[MEDTRONIC.COM/PDSTORIES](https://www.medtronic.com/pdstories)



## WHEN IS THE RIGHT TIME FOR DBS?

Research shows that DBS may be appropriate for people who have had Parkinson's for at least 4 years with at least 4 months of movement symptoms not well controlled by medications or medication side effects such as unintended movements (dyskinesia).<sup>1</sup>

DBS Therapy is also appropriate for people who have had movement symptoms for a longer period of time, and there is no upper age limit.<sup>2</sup>

If you wait until your medications no longer help, DBS will no longer be an option — so don't think of DBS as "a last resort." Instead of just putting DBS off until someday in the future, talk with your doctor about it now. That way, you will be ready to start at the right time.

## WHY WAIT TO GET BACK TO YOU? YOU MAY BE ELIGIBLE FOR DBS IF YOU MEET THESE CRITERIA:



Parkinson's diagnosis for at least **4 years**



Movement symptoms or medication side effects for a **minimum of 4 months** or longer-standing



**Responds** to Levodopa  
(a common Parkinson's medication)



Movement symptoms **not** adequately controlled with medication

Only your doctor can determine if DBS therapy is right for you.

# TALKING TO A DOCTOR ABOUT DBS

When you're ready to start the conversation about DBS, look for a neurologist who specializes in treating Parkinson's. The right doctor will understand your needs and treatment options and will be your partner through this journey.

A movement disorder specialist is a neurologist with extra training in movement disorders, like Parkinson's disease. These specialists have experience with the full range of treatment options. Some general neurologists are also experienced in treating Parkinson's.

Whether you see a general neurologist or movement disorder specialist, be honest about your symptoms and how your treatment is working. Ask about other options you could try. And don't hesitate to get another opinion.

1 Use the Symptom Tracker to track three days of your symptoms

2 Bring the completed Symptom Tracker to your next doctor visit

3 Discuss available treatment options with your doctor

READY TO TALK TO A DOCTOR ABOUT DBS? FIND A SPECIALIST IN YOUR AREA AT [MEDTRONIC.COM/PDSPECIALIST](https://www.medtronic.com/pdspecialist)

## DAILY TRACKER

	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																				
	<b>Parkinson's Medications (tablet strength in mg)</b>																			
Parcopa®, Rytary®, Sinemet® Carbidopa/Levodopa (    mg)																				
Stalevo® Levodopa/Entacapone (    mg)																				
Symmetrel® Amantadine HCL (    mg)																				
Azilect® Rasagiline (    mg)																				
Requip® Ropinirole HCL (    mg)																				
Mirapex® Prampipexole DIHCL (    mg)																				
Comtan® Entacapone (    mg)																				
Artane® Trihexphenidyl (    mg)																				
Other: _____																				
Other: _____																				

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

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

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	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																				
	<b>Parkinson's Medications (tablet strength in mg)</b>																			
Parcopa®, Rytary®, Sinemet® Carbidopa/Levodopa (    mg)																				
Stalevo® Levodopa/Entacapone (    mg)																				
Symmetrel® Amantadine HCL (    mg)																				
Azilect® Rasagiline (    mg)																				
Requip® Ropinirole HCL (    mg)																				
Mirapex® Prampipexole DIHCL (    mg)																				
Comtan® Entacapone (    mg)																				
Artane® Trihexphenidyl (    mg)																				
Other: _____																				
Other: _____																				

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

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	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																				
	<b>Parkinson's Medications (tablet strength in mg)</b>																			
Parcopa®, Rytary®, Sinemet® Carbidopa/Levodopa (    mg)																				
Stalevo® Levodopa/Entacapone (    mg)																				
Symmetrel® Amantadine HCL (    mg)																				
Azilect® Rasagiline (    mg)																				
Requip® Ropinirole HCL (    mg)																				
Mirapex® Prampipexole DIHCL (    mg)																				
Comtan® Entacapone (    mg)																				
Artane® Trihexphenidyl (    mg)																				
Other: _____																				
Other: _____																				

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

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Tear at perforation



# AFTER COMPLETING THE 3-DAY TRACKER ANSWER THE FOLLOWING QUESTIONS



**1** How troublesome are your "off" periods (periods when medication is not helping enough and you are experiencing symptoms)?

*Circle the option that applies.*

- |                           |  |                                     |                                     |
|---------------------------|--|-------------------------------------|-------------------------------------|
| I barely notice I'm "off" | I have difficulty, but I can do all I want to do | I can't do some things I want to do | I can't do most things I want to do |
|---------------------------|--|-------------------------------------|-------------------------------------|

**2** How troublesome is your dyskinesia (involuntary excessive movements)?

*Circle the option that applies.*

- |                  |                                     |                                     |                                     |
|------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| I don't have any | I barely notice them, but others do | They interfere with some activities | They interfere with most activities |
|------------------|-------------------------------------|-------------------------------------|-------------------------------------|

**3** What are your most troublesome movement symptoms?

\_\_\_\_\_

\_\_\_\_\_

**4** What are your most troublesome side effects?

*Circle all that apply.*

- |                                   |                               |                                |
|-----------------------------------|-------------------------------|--------------------------------|
| Sleepiness                        | Nausea                        | Hallucinations                 |
| Confusion/other thinking problems | Lightheadedness upon standing | Behavioral/personality changes |

Other:

\_\_\_\_\_

## INSTRUCTIONS FOR COMPLETING YOUR SYMPTOM TRACKER

	5 AM	6 AM	7 AM	8 AM	9 AM	10 AM	11 AM
		X					
Dyskinesia				X			
Out dyskinesia					X	X	
		X					
ry®, Sinemet® dopa (100 mg)		1	1	1			
pone ( mg)							



# SYMPTOM TRACKER

You can help your doctor make good treatment decisions by tracking your symptoms. A well-kept Symptom Tracker provides a clear picture of when you are taking your medications, when you are feeling well, and when you are not feeling so well. The tracker will help your doctor determine if DBS Therapy may be right for you.

## SYMPTOM CONTROL CATEGORIES

You will be recording your symptom control every hour in one of four categories:

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

## 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 (see sample).
- When you take medications, write how many pills you took (see sample).
- In the notes section at the bottom of each day, write any troublesome side effects you experience.

## SUMMARY FOR HEALTHCARE PROFESSIONAL USE ONLY



Idiopathic Parkinson's disease?	<b>YES</b>	<b>NO</b>
Years since diagnosis:	_____	years
At least 4 months since onset of motor complications not adequately controlled with medication?	<b>YES</b>	<b>NO</b>
Good levodopa response (even if brief)?	<b>YES</b>	<b>NO</b>
Recommend Medtronic DBS Therapy evaluation?	<b>YES</b>	<b>NO</b>

*Circle the option that applies.*

Referring physician name: \_\_\_\_\_

Signature: \_\_\_\_\_

Referring physician phone number: \_\_\_\_\_

Movement Disorder Center/Practice name: \_\_\_\_\_

Medtronic DBS Therapy Center fax: \_\_\_\_\_

Center physician: \_\_\_\_\_

Scheduling phone number: \_\_\_\_\_

Patient name: \_\_\_\_\_

Patient phone number: \_\_\_\_\_

### NOTE TO HEALTHCARE PROFESSIONAL:

You can photocopy and fax this and the patient questionnaire to a DBS Center of your choice, as well as ask your patient to take the Symptom Tracker to the evaluation at the DBS Center.

## WHY CHOOSE MEDTRONIC?



*Actual patient not pictured*

## GETTING BACK TO INDEPENDENCE

"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."

**Jerry**  
Receiving DBS Therapy

WATCH JERRY'S FULL STORY AT  
[MEDTRONICDBS.COM/STORIES](http://MEDTRONICDBS.COM/STORIES)

← OPEN HERE

Medtronic



## OUR SUPPORT, TECHNOLOGY, AND EXPERIENCE — ALL FOR YOU

Medtronic is a global leader in medical technology, services, and solutions — serving millions of people around the world every day. Your Medtronic DBS will be backed by our decades of research, innovation, and experience. Our technology is designed to meet your needs now and into the future.

We provide you with unparalleled resources and one-on-one support while you are deciding whether DBS is right for you. We are committed to making sure you have the information and support you need to decide whether Medtronic DBS Therapy is right for you.



### LEADING THE WAY IN DBS

Deep brain stimulation development started in 1987 and Medtronic has been the leader in the field ever since. The Medtronic DBS Therapy system has been rigorously tested with clinical evidence and is FDA approved for people with Parkinson's who had recent onset of movement symptoms as well as those with longer-standing movement symptoms.



### ACCESS TO MRI SCANS ANYWHERE ON THE BODY

We know it's important that you have safe\* access to MRI if you need this important test to diagnose a medical condition or injury. We now offer the first full-body MR Conditional DBS systems, which means it is safe to have scans anywhere on the body with some Medtronic DBS devices under certain conditions.



### PERSONALIZED FOR YOU

Your doctor programs your DBS system to provide the best symptom control for you. As your symptoms change over time, the programming can be changed.



### MINIMIZE SIDE EFFECTS

DBS may cause some of your symptoms to get worse or may affect your speech. Your doctor can adjust the settings to minimize side effects while providing the best possible symptom control.

LEARN MORE ABOUT THE  
ADVANTAGES OF MEDTRONIC DBS AT  
[MEDTRONIC.COM/PDWHYMEDTRONIC](https://www.medtronic.com/pdwhymedtronic)

\*Medtronic DBS systems are MR Conditional which means they are safe for MRI scans only under certain conditions. If the conditions are not met, the MRI could cause tissue heating, especially at the implanted lead(s) in the brain, which may result in serious and permanent injury or death. Before having an MRI, always talk with the doctor who manages your DBS Therapy to determine your eligibility and discuss potential benefits and risks of MRI. For further information, please call Medtronic at 1-800-328-0810.



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](http://medtronic.com). 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. A prescription is required. This therapy is not for everyone. 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. This therapy should not be used 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, depression, suicidal thoughts and suicide have been reported.

Rev 12/17

In a study of people with Parkinson's who had recent onset of movement symptoms, over the course of 2 years: Patients experience an additional 11% of serious adverse events (SAEs) compared to those taking medications alone.<sup>1</sup>

1% of all people with DBS Therapy experience SAEs that were ongoing when the study was completed.<sup>1</sup>

DBS patients experience comparable rates of serious adverse events (SAEs) regardless of recent onset or longer-standing movement symptoms.<sup>1</sup>

1. Schuepbach WMM, Rau J, Knudsen K, et al. Neurostimulation for Parkinson's disease with early motor complications. *N Engl J Med*. February 14, 2013;368:610-227.

This therapy should not be used 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. The DBS system may interact with other medical devices and electromagnetic interference.

There are risks to performing MRI scans in people with DBS implants. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.



*Actual patient not pictured*

## GETTING BACK TO PAINTING

"DBS doesn't make things exactly like they used to be, but it makes things possible."

**Anna**  
Receiving DBS Therapy

READ ANNA'S FULL STORY AT  
[MEDTRONIC.COM/PDSTORIES](http://MEDTRONIC.COM/PDSTORIES)



## ASK A NURSE YOUR QUESTIONS

Schedule a free phone consultation with a nurse who specializes in caring for people with DBS.



## TALK WITH SOMEONE WHO HAS DBS

Talk one-on-one with someone who already has DBS for Parkinson's. Ask the questions that only people living with DBS Therapy can answer.\*



## FIND A PARKINSON'S SPECIALIST

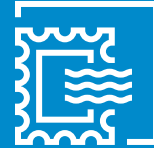
Use our online directory to find a Parkinson's specialist in your area.

\*Medtronic does not monitor for control, and cannot be responsible for, an ambassador's statements. Ambassadors are instructed not to disclose your personal information, but we cannot guarantee this will not happen. Therefore, please do not share your personal information with the ambassador unless you wish to do so. Ambassadors' comments relate to their particular experience only. As with any treatment, individual results will vary.

## GET SUPPORT TODAY



ONLINE AT  
**MEDTRONIC.COM/  
PDSUPPORT**

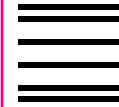
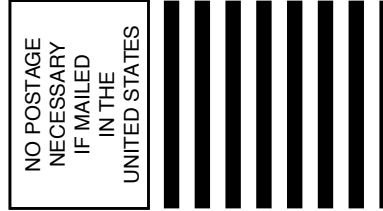


BY MAIL USING THE  
**FORM ON THE  
NEXT PAGE**



BY PHONE BY CALLING  
**1-877-438-3574**  
(8AM – 5PM CT,  
MONDAY TO FRIDAY)

Tear at perforation. Mailer on next panel.



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**MEDTRONIC**

**MS RCE230**

**7000 CENTRAL AVENUE NE**

**MINNEAPOLIS MN 55432-9987**



## START GETTING BACK TO YOU

By completing and submitting this form, you are granting Medtronic permission to add your personal information, including your contact information and basic healthcare information, to its patient database, and to share that information with Medtronic representatives as appropriate. You also agree to being contacted by Medtronic in the future by mail, telephone, or by non-password protected electronic communications, such as emails or text messages.

Medtronic may exchange information regarding our products or services, inquire about your experience, or determine how Medtronic can support you through your journey.

*Medtronic respects the confidentiality of your personal information. We will not share your personal information except as described above. If at any time you wish to revoke all or part of this permission, you can email us to [rsneuropatientsupport@medtronic.com](mailto:rsneuropatientsupport@medtronic.com) or send a request in writing to: Medtronic Patient Support, 7000 Central Ave NE, RCE 230, Minneapolis, MN 55432. This permission will expire 10 years after the date of your signature.\**

\*If you live in Maryland, the consent expires automatically in one year. We may contact you then to see if you would like to renew it.



# LEARN MORE ABOUT DBS FOR PARKINSON'S

Medtronic

I HAVE PARKINSON'S

I CARE FOR SOMEONE WITH PARKINSON'S

RELATIONSHIP TO PATIENT

FIRST NAME

LAST NAME

ADDRESS

CITY

STATE

ZIP

EMAIL

PHONE

PARKINSON'S DIAGNOSIS YEAR

PHYSICIAN NAME

CLINIC NAME

SIGNATURE (IF 18 OR OLDER)

DATE

WHICH PARKINSON'S SYMPTOMS/SIDE EFFECTS ARE YOU EXPERIENCING?

*Check all that apply*

Stiffness rigidity

Slowed Movement bradykinesia

Shaking tremor

Unintended Movements dyskinesia

ADHESIVE PANEL



COMPLETE REGISTRATION FORM BEFORE SUBMITTING



GETTING BACK TO **GIVING BACK**

"Shortly after my DBS surgery I took over running our local Parkinson's Support Group. We try to educate people to keep things upbeat. I want people to realize there's hope."

**Beverly**  
Receiving DBS Therapy

READ OTHER DBS STORIES AT [MEDTRONIC.COM/PDSTORIES](https://www.medtronic.com/pdstories)



## GETTING BACK TO GARDENING

"I feel so much better. My energy level is improved and I'm smiling all the time. If I didn't have DBS Therapy, I believe I'd be in a nursing home."

**Clare**  
Receiving DBS Therapy

EXPLORE MORE PATIENT STORIES AT  
[MEDTRONIC.COM/PDSTORIES](https://www.medtronic.com/pdstories)

## References

1. Medtronic DBS Therapy for Parkinson's Disease and Essential Tremor Clinical Summary, 2015.
2. Schuepbach WMM, Rau J, Knudsen K, et al. Neurostimulation for Parkinson's disease with early motor complications. *N Engl J Med*. February 14, 2013;368:610-22 7.

## Brief Statement: Medtronic DBS Therapy for Parkinson's Disease

**Medtronic DBS Therapy for Parkinson's Disease: Patients should always discuss the potential risks and benefits with a physician.**

**Indication:** 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.

**Contraindications:** Medtronic DBS Therapy is contraindicated 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 and Precautions:** 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 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 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. Tunneling the extension too superficially or too deeply may result in nerve or vascular injury, or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant ("rebound effect"). Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders, although no direct cause-and-effect relationship has been established.

**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, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients who are pregnant; and patients under 18 years.

USARx only Rev 11/17



# Medtronic

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TREATMENT  
AS UNIQUE  
AS YOU



**PERCEPT™ PC NEUROSTIMULATOR  
WITH BRAINSENSE™ TECHNOLOGY**

FOR DBS THERAPY

**Medtronic**



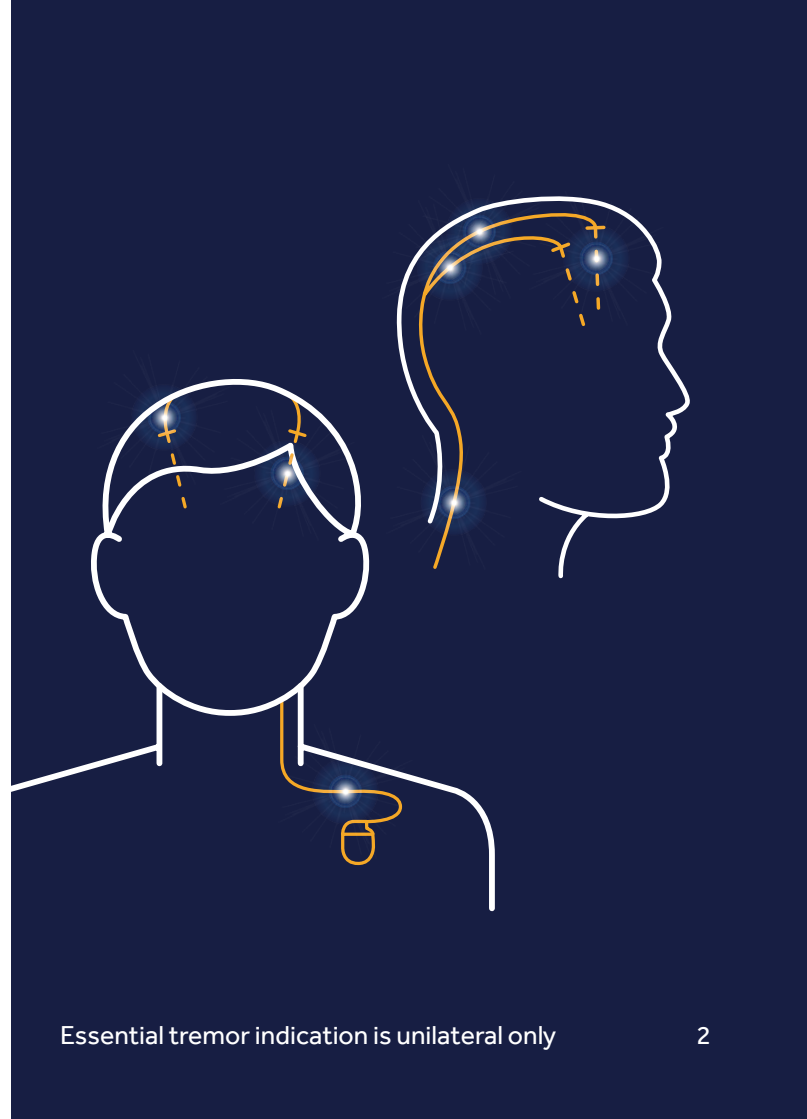
**LIVING  
WELL  
WITH DBS  
THERAPY**

**Medtronic is dedicated to helping people live their best lives.** And for decades we've partnered with doctors to help alleviate pain, restore health, and extend life. Our new deep brain stimulation (DBS) device continues that mission.

For many people with Parkinson's disease, essential tremor, dystonia\*, obsessive compulsive disorder\* (OCD), or epilepsy, DBS may make a difference when even small tasks have become challenging. **DBS has helped some people stay independent and enabled them to keep doing the activities they love.**

DBS uses a small pacemaker-like device, placed under the skin of the chest, to send electrical signals through very thin wires (leads) to an area in the brain related to the symptoms of your condition.

\*Humanitarian Device: The effectiveness of these devices for the treatment of dystonia and obsessive compulsive disorder has not been demonstrated.



Essential tremor indication is unilateral only

# PERSONALIZE YOUR THERAPY — GET A SENSE OF WHAT'S POSSIBLE

## **BRAINSENSE™ TECHNOLOGY**

Our new device, the Percept™ PC neurostimulator, features BrainSense™ technology. This innovative technology captures brain signal data direct from your implanted leads. It then stores the data, so your physician can access it.\*

Using this data, your physician may adjust your settings — personalizing your therapy for the best possible outcome. \*\*

As new features are added to the technology, you may not need to get a new device. They can simply be applied to your neurostimulator through software on your

physician's clinician programmer. This can enable you to continue to receive the latest innovations from Medtronic.

## **DIGITAL DIARY**

The neurostimulator is used with an intuitive 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.

Your doctor can see the events you've been logging at your next appointment via the clinician's programmer. This information may help your doctor deliver treatment that's as unique as you.

\*Signal may not be present or measurable in all patients.

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



# DBS CLINICIAN PROGRAMMER



# DBS PATIENT PROGRAMMER





# ENGINEERED FOR YOUR COMFORT

Percept™ PC neurostimulator  
is designed to provide you with  
more comfort.

SLEEK, CURVED DESIGN

20%  
SMALLER THAN  
PREVIOUS-  
GENERATION  
ACTIVA™ PC\*

20%  
THINNER THAN  
PREVIOUS-  
GENERATION  
ACTIVA™ PC\*\*

# DESIGNED TO LAST LONGER — AND KEEP YOU INFORMED

The Percept™ PC neurostimulator is smaller and features a battery that lasts longer.\*

You can check how much battery life is left on your device at any time, so you and your doctor will know when to schedule an appointment to replace your neurostimulator. The battery information is available on the easy-to-use patient programmer as well as on your clinician's programmer.



**REAL-TIME  
ESTIMATION OF  
BATTERY LIFE\*\***

**>5 YEARS  
BATTERY LIFE\*\*\***

\*When compared to the previous generation Activa™ PC device

\*\*Based on current actual battery level and therapy settings from last seven days

\*\*\*For median energy use in DBS for patients with Parkinson's disease, with moderate (up to 2 months per year) BrainSense™ technology usage

# YOU DESERVE OPTIONS — NOW AND IN THE FUTURE

Medtronic is committed to ensuring you have safe access to cutting-edge diagnostic imaging technology. That includes MRI. MRI is short for magnetic resonance imaging, and it's 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. **Percept™ PC neurostimulator is the first and only device to have full-body MR Conditional\* access anywhere on the body for both 1.5T and 3T MRI scans.**



Approximately **7 out of 10** DBS-eligible patients with movement disorders may need an MRI within **10 years** of receiving their device.<sup>1</sup>

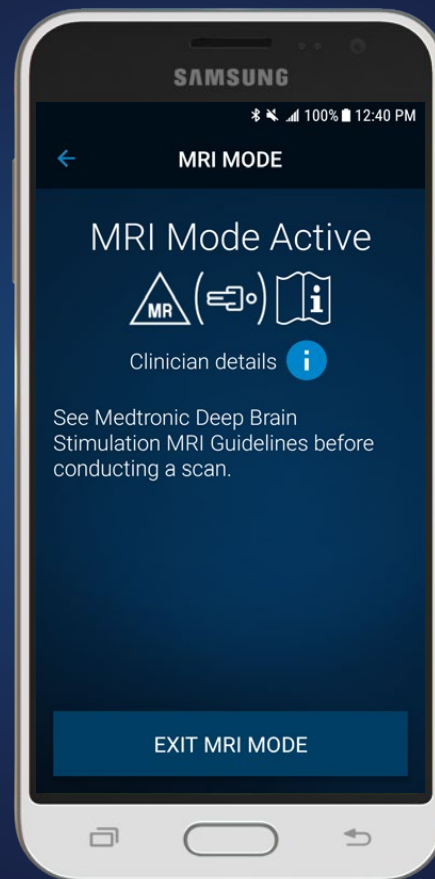
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\*Medtronic DBS systems are MR Conditional and safe in the MR environment as long as certain conditions are met. If the conditions are not met, a significant risk is tissue lesions from component heating, especially at the lead electrodes, resulting 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>.

1. Falowski S, Safriel Y, Ryan MP, Hargens L. The rate of magnetic resonance imaging in patients with deep brain stimulation. *Stereotact Funct Neurosurg*. 2016; 94(3):147-153.

# EXPANDED ACCESS TO MRI — NOW EVEN EASIER

Getting an MRI is now even easier for you. Simply check your patient programmer for compatibility and put the device into MRI mode. Because your patient device can perform a check before your scan, you may not need to schedule a doctor visit, and **you may even be able to leave your stimulation on during the MRI scan.**



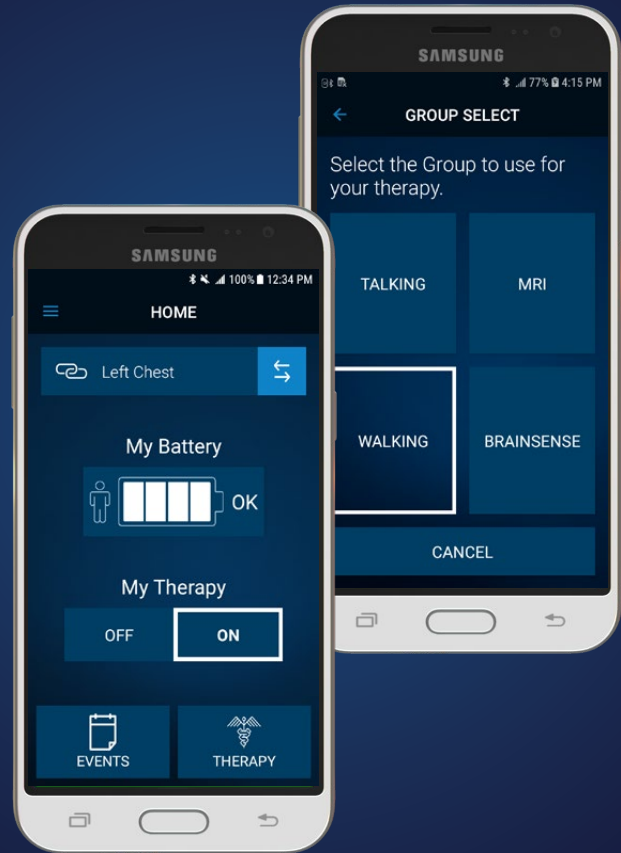
# SIMPLE. PERSONAL. SMART.

The DBS patient programmer is enhanced so you can more easily and conveniently manage your therapy.

## EASY-TO-ADJUST STIMULATION OPTIONS

You may also be able to adjust therapy throughout your day with options programmed by your doctor.

Your doctor can create preset stimulation for up to four types of groups — such as walking, sleeping, and talking. Simply choose which preset stimulation you want for the activity you're doing.



## Medtronic DBS Therapy for Parkinson's Disease, Tremor, Dystonia, Obsessive-Compulsive Disorder, and Epilepsy: Patients should always discuss the potential risks and benefits with a physician.

### Indications:

**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.

**Medtronic DBS Therapy for Dystonia\*:** Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

**Medtronic DBS Therapy for Obsessive-Compulsive Disorder\*:** The Medtronic Reclaim™ DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

**Medtronic DBS Therapy for Epilepsy:** Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

**Contraindications:** Medtronic DBS Therapy is contraindicated (not allowed) for patients who are unable to properly operate the neurostimulator and, for Parkinson's disease and Essential Tremor, 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 they have an implanted Soletra™ 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, for Parkinson's disease and Essential Tremor, 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). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS therapy.

For Epilepsy, cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. For Epilepsy, symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. For Parkinson's disease or essential tremor, new onset or worsening depression, suicidal ideation, suicide attempts, and suicide have been reported. For Dystonia or Epilepsy, depression, suicidal ideations and suicide have been reported, although no direct cause-and-effect relationship has been established. For Epilepsy, preoperatively, assess patients for depression and carefully balance this risk with the potential clinical benefit. Postoperatively, monitor patients closely for new or changing symptoms of depression and manage these systems appropriately. Patients should be monitored for memory impairment. Memory impairment has been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct-cause-and-effect relationship has been

established. The consequences of failing to monitor patients are unknown. When stimulation is adjusted, monitor patients for new or increased seizures, tingling sensation, change in mood, or confusion. For Obsessive-Compulsive Disorder, patients should be monitored for at least 30 minutes after a programming session for side effects, including: autonomic effects (e.g., facial flushing, facial muscle contractions, or increased heart rate), hypomania, increased disease symptoms, and sensations such as tingling, smell, or taste. For Obsessive-Compulsive Disorder, during treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms.

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 for Parkinson's disease or essential tremor 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.

### Warning For Obsessive-Compulsive Disorder:

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

**Precautions:** Loss of coordination in activities such as swimming may occur. For Obsessive-Compulsive Disorder, the safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., vagus nerve stimulation) has not been established. 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.

For Parkinson's disease or essential tremor, 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. For Essential Tremor, safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. For Dystonia, safety of this device for use in the treatment of dystonia with or without other accompanying conditions (e.g., previous surgical ablation procedure, dementia, coagulopathies, or moderate to severe depression, or for patient who are pregnant) has not been established. Age of implant is suggested to be that at which brain growth is approximately 90% complete or above. For Epilepsy, the safety and effectiveness of this therapy has not been established for patients without partial-onset seizures, patients who are pregnant or nursing, patients under the age of 18 years, patients with coagulopathies, and patients older than 65 years. For Obsessive-Compulsive Disorder, the safety and probable benefit of this therapy has not been established for patients with: Tourette's syndrome, OCD with a subclassification of hoarding, previous surgical ablation (e.g., capsulotomy), dementia, coagulopathies or who are on anticoagulant therapy, neurological disorders, and other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus. In addition, the safety and probable benefit has not been established for these patients: those whose diagnosis of OCD is documented to be less than 5 years duration or whose YBOCS score is less than 30, who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation, who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT), who are pregnant, who are under the age of 18 years, and who do not have comorbid depression and anxiety. Physicians should carefully consider the potential risks of implanting the Reclaim DBS System in patients with comorbid psychiatric disorders (e.g., bipolar, body dysmorphic, psychotic) as the Reclaim DBS System may aggravate the symptoms.

**Humanitarian Device (Dystonia):** The effectiveness of these devices for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

USA Rx only Rev 02/20



A global leader in medical technology, Medtronic continually seeks ways to improve the lives of patients. 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.

Learn more about Percept™ PC neurostimulator with BrainSense™ technology at [medtronic.com/DBS](https://www.medtronic.com/DBS).

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