

# Live On

Medtronic DBS therapy for  
Parkinson's disease



**Medtronic**

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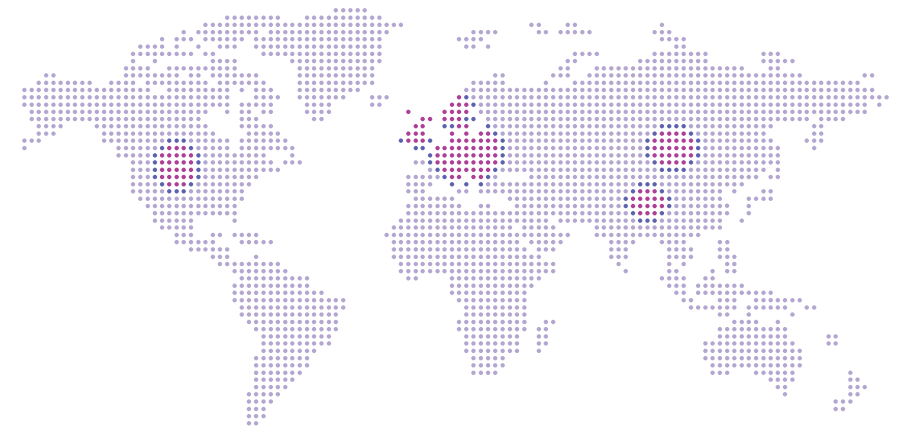


## Live On

**Medtronic DBS may help you or a loved one take back the moments that matter.**

For someone living with Parkinson's disease, everyday tasks like holding a cup of coffee can feel out of reach.

Medtronic DBS may be a path to symptom improvement.



For over 30 years, Medtronic has transformed the lives of over 200,000 people with Parkinson's and other neurological disorders with DBS therapy.<sup>1</sup>

# About Parkinson's disease

It is estimated that over 10 million people have Parkinson's disease worldwide,<sup>2</sup> affecting all races and cultures.

According to available statistics, 1.2 million people in Europe have the condition.<sup>3</sup> If you're one of them, you probably know this neurological movement disorder is neurodegenerative - treatments are therefore focused on reducing the symptoms.

10M+

people have Parkinson's disease worldwide<sup>2</sup>

## Leading the way in DBS

For over 30 years, Medtronic has transformed the lives of over 200,000 people living with Parkinson's and other neurological disorders with deep brain stimulation (DBS) therapy.<sup>1</sup>

Our story is rooted in an important mission: to help you reclaim meaningful moments, embrace life on your terms, and find renewed hope for the future.



# What is DBS therapy?

Medtronic DBS is a treatment that helps people living with Parkinson's improve motor symptom control like tremor, slowness, and stiffness.

It can also help reduce motor fluctuations – those unpredictable changes in movement and symptom control that occur throughout the day and night.

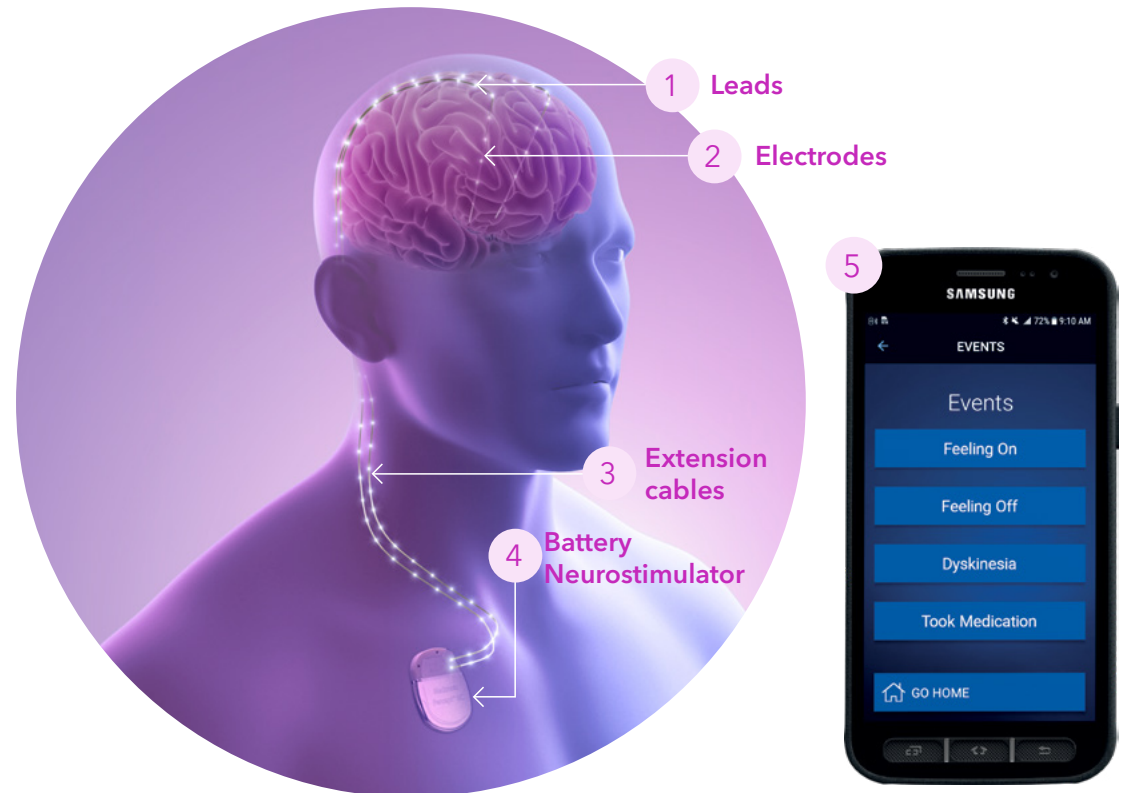
Just like a pacemaker for the heart, a small neurostimulator is surgically placed under the skin in the chest or abdomen to deliver DBS therapy. The device sends electrical pulses through extension cables to the leads and electrodes that are placed in an area of the brain that controls movement.

These pulses disrupt some of the brain's messages that cause the symptoms associated with Parkinson's.

As your Parkinson's symptoms change, signals in your brain also change.



## How DBS therapy works.



- 1 The leads are kept in place with the cap
- 2 Thin electrodes placed in the target area of the brain (subthalamic nucleus, thalamus or globus pallidus)
- 3 Flexible extension cables under the skin
- 4 Medtronic DBS neurostimulator
- 5 Patient programmer (enables you to switch the stimulator on and off, check the battery level and modify settings in certain instances)

# How can DBS help me?

## Reclaim the moments that matter.

DBS therapy extends the control of movement symptoms that your medication already provides. Here you can find out about the benefits of DBS therapy and safety considerations.

## It's very important to mention that the success of Medtronic DBS depends on:

### Good candidate selection

This is essential as DBS therapy is not for everybody.

### Good surgical placement

of the DBS electrodes.

## DBS is now a standardised procedure performed in more than 1,200 hospitals around the world.

DBS therapy has helped more than 200,000 people<sup>1</sup> continue working, care for their families, return to favourite activities, and experience the joy of doing the simplest things in life once again.



Live  
steady,  
like Doris



Suddenly you can get up and it's ok, you can walk, you don't need to be afraid of freezing of gait."

**Parkinson's may interrupt life.  
But it doesn't get to control it.**



### **Reduces dyskinesia and fluctuations**

Medtronic DBS therapy reduces complications of drug therapy, such as dyskinesia and fluctuations in "On" and "Off" time.<sup>4,7</sup>

It reduces complications of drug therapy by 37% and troublesome side effects are reduced by 61% compared to medication alone.<sup>5,6</sup>

Without DBS, people receiving best medical therapy (BMT) experience between a 5.4% reduction to a 13% increase in drug-related complications compared with their baseline.<sup>5,6</sup>



### **Less medication, more you**

Others find that the more medications they take, the less they seem to work. DBS is not a medication, and it does not contain medication. In many cases, DBS therapy may help patients reduce their Parkinson's drugs by up to 50%.<sup>8</sup>



### **Up to 5 additional hours of good movement without dyskinesia**

Good movement control means no troubling symptoms such as shaking, stiffness, or difficulty moving. DBS therapy can provide up to 5 additional hours of good movement control without dyskinesia per day, compared to medication alone.<sup>†,4,6,8</sup>

† Measured by the UPDRS IV  
‡ Maintenance is required for rechargeable systems



### **Works day and night**

DBS therapy works 24 hours a day with minimal maintenance or effort. DBS therapy does not require removal at night, cleaning, refilling, or maintenance upon waking in the morning.<sup>‡</sup>



### **Adjustable**

The electrical stimulation is adjustable and can be changed as Parkinson's progresses with our BrainSense™ technology. No further surgery is necessary to make adjustments.



### **Treats tremors and rigidity**

DBS therapy has been CE marked and approved by the FDA to treat the movement symptoms of Parkinson's: shaking, stiffness, and difficulty moving.





### Keep your options open

DBS therapy is not permanent, so future treatment options remain open. The DBS system can be turned off or surgically removed if required.



### Improves activities of daily living

DBS therapy can make routine daily activities easier, such as: writing clearly, drinking, getting dressed, or bathing.



### Improves quality of life

75% of patients preferred DBS to medical therapy alone considering the PDQ-39.<sup>†,8</sup> Improved quality of life includes things such as feeling better emotionally, feeling less embarrassed in public, moving about more easily, and having less physical discomfort. In the same studies, patients receiving best medical therapy (BMT) without DBS showed no improvement in quality of life compared with their baseline.



DBS therapy improves quality of life by

**13-26%**

compared to quality of life prior to receiving DBS<sup>‡,5,8</sup>

† Per protocol analysis  
‡ Based on PDQ-39 Single index



DBS has stopped the dyskinesia by 90%, and now I can continue the activities that I enjoy, such as cooking and embroidery."

Live full,  
like Janet



# When is the best time to consider DBS therapy?

## Don't wait to move through life on your own terms.

Parkinson's is a progressive disease, meaning symptoms worsen over time. It's best to consider DBS therapy before your Parkinson's symptoms have progressed beyond what is called "the window of opportunity." This is when your Parkinson's medications are not as effective as they used to be, but before your symptoms stop responding to medication.




## DBS therapy will be most effective in treating your Parkinson's if you:

Have responded well to dopaminergic medication (e.g. levodopa)<sup>7</sup>

Still benefit from medication, but it's becoming less effective or causing intolerable side effects<sup>3</sup>

Require multiple medications, higher dosages, or more frequent doses to manage your symptoms<sup>3</sup>



Live with hope, like Christelle



Actually, I don't know whether it was the neurostimulation that made me feel well during pregnancy or the hormones or maybe both, but I felt very, very well when I was pregnant."

# When is the best time to consider DBS therapy?



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

Quality of life without DBS

The best time to consider DBS therapy<sup>9</sup> is when the side effects of medication have a negative impact on quality of life.



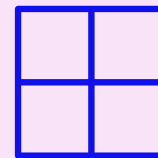
**Medication usually sufficient**

**Appearance of symptoms**

Oral medications are controlling symptoms:

Start thinking about DBS

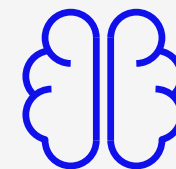
Quality of life benefit with DBS



**Window of opportunity for Medtronic DBS**

Oral medications are still working but not so effectively:

DBS may be a good option



**Late-stage Parkinson's Treatment refractory symptoms**

Symptoms no longer respond to oral therapies:

DBS is no longer an option.

## When every moment matters, the right time to act could be now.

We want to see you get the most out of DBS therapy. The earlier DBS is introduced - the greater the benefits. DBS may no longer be an option if you wait until:

- Your symptoms no longer respond to medication
- You develop medical conditions that prevent surgery such as dementia and balance problems
- You become severely disabled



### Talk with your neurologist

Give yourself the time to consider the potential benefits and possible risks of the therapy, so that you can choose whether DBS is right for you when the window of opportunity arrives.

# Does DBS have a safety profile?

**Medtronic DBS is a well established therapy and many patients have benefited from it over the last 30 years.**

As with any major surgery, there are some risks associated with the procedure, but these are very low when DBS therapy is performed in specialised centres.<sup>10</sup> For example, published studies show the following risks with Medtronic DBS systems:



The risk of permanent health impairments is around 1%, mainly caused by bleeding within the skull.<sup>10</sup>



The risk of brain haemorrhage was 0% to 5% on average, in six high quality, multicentre studies conducted in different regions.<sup>4,5,7,8,12,13</sup>



As with other surgeries, death can occur. The risk of death is 0.4%.<sup>10</sup> Although surgical procedures are different, total hip replacement, for example, has the same risk of death (0.4%)<sup>11</sup> as DBS surgery.



The risk of infection from the device was 2.6% to 7.9% on average, in five high quality, multicentre studies conducted in different regions.<sup>4,8,10,12,13</sup>



**When complications do occur in DBS, they are generally mild, short-lived, and normally resolve around**

**30-90**

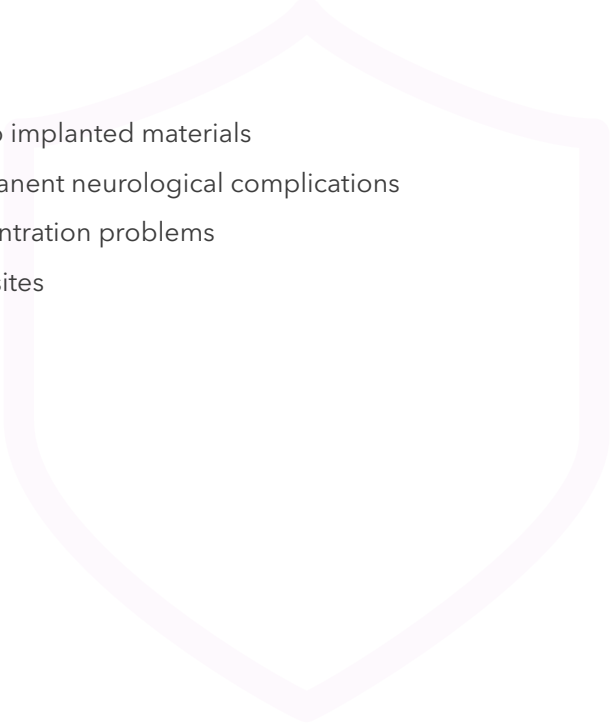
**days after surgery<sup>6,8</sup>**

# Safety information

## Risks

Risks of DBS therapy can include risks of surgery, side effects, or device complications. Implanting the neurostimulator system carries the same risks associated with any other brain surgery. Your doctor can provide more information about these and other potential risks and side effects.

### Risks of surgery may include:

- Paralysis, coma, and/or death
  - Bleeding inside the brain (intracranial haemorrhage)
  - Leakage of fluid surrounding the brain
  - Seizures
  - Infection
  - Allergic response to implanted materials
  - Temporary or permanent neurological complications
  - Confusion or concentration problems
  - Pain at the surgery sites
  - Headache
- 

## Talk with your doctor about risks that may apply in your personal situation.

Many side effects related to stimulation can be managed by adjusting the stimulation settings. Several follow-up visits may be needed to find the best stimulation settings for you.

### Possible side effects of brain stimulation may include:

- Tingling sensation (paraesthesia)
- Temporary worsening of symptoms
- Dizziness or lightheadedness (disequilibrium)
- Vision problems (eg. double vision)
- Speech problems such as whispering (dysarthria), and trouble forming words (dysphasia)
- Movement problems or reduced coordination
- Abnormal, involuntary movements (chorea, dystonia, dyskinesia)
- Facial and limb muscle weakness or partial paralysis (paresis)



### Possible device complications may include:

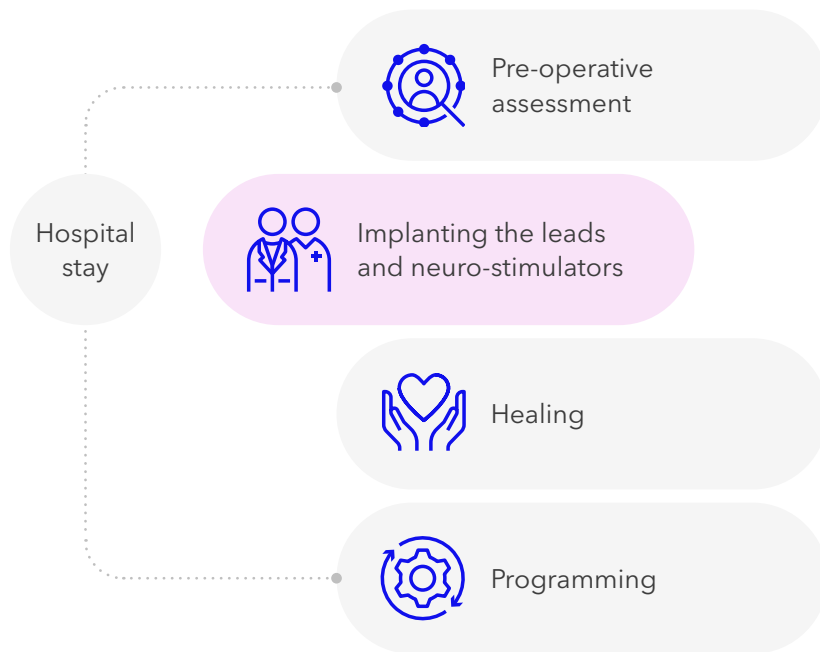
- Pain, lack of healing, or infection where the Medtronic DBS system components are implanted
- Infection or scarring caused by the system components wearing through your skin
- Readjustment surgery if the lead or lead/extension connector moves, or if mechanical or electrical problems occur
- An allergic reaction to or rejection of the system by your body
- Tissue damage resulting from programming parameters or a malfunction of one of the parts of the system
- Jolting or shocking sensation



# Understanding the DBS procedure

Learn more about what is involved in the DBS therapy surgical procedure with the summary that follows. Remember, the duration and procedural steps can vary by doctor and hospital.

**In general, you can expect the surgery to last several hours. You will spend a few days in the hospital for:**



## Your DBS surgical team may include

a neurosurgeon specialised in DBS therapy, neurologist, anaesthesiologist, radiologist, other healthcare professionals such as neuropsychologists, DBS specialised nurse, and speech therapist.



Since I had the operation, my life is much, much better. I've got a kind of energy again, the way others look at me has completely changed."

Live relaxed,  
like Giles





## Pre-operative assessment

This step is designed to get you and the surgical team ready for DBS surgery. You may need an MRI scan to capture an image of your brain.

The MRI scan helps the neurosurgeon to plan and place the leads exactly in the right place.



## Implanting the leads and neurostimulator

DBS therapy works through very thin wires called leads that deliver electrical stimulation from the neurostimulator to your brain. Using your brain images, your neurosurgeon places the leads precisely in specific areas of the brain. During this procedure you may be under local or general anesthesia.

In order to find the best lead position to control your symptoms, your neurosurgeon may stimulate different areas of the brain while you move your arms or leg, tap your fingers, or pretend to drink from a cup. Remember, the brain is not sensitive to pain, so you won't feel pain during this stimulation.

The same day - or shortly after the leads are implanted - your surgeon will implant the neurostimulator just under your collarbone or abdomen. You'll be asleep for this part of the procedure. Your surgeon will connect the leads to the device using stretchable extensions that are placed under your skin, from the chest up to the neck and head.



## Healing

Generally, you will be ready to return home or to be transferred to a rehabilitation unit for programming a few days after surgery. Healing at home can then continue for several weeks. It's normal to feel some discomfort or pain at the incision sites, and this is managed with medication. The neurologist or DBS specialised nurse will discuss resuming activity and exercise.



## Programming

The device will be turned on at the first programming session. At that time, medication may also be adjusted. Programming begins after you have healed from surgery. With the help of a clinician-programmer device which receives and sends signals from and to your neurostimulator, the neurologist can select the optimal stimulation parameters to control your symptoms.

**Don't just  
live with  
Parkinson's.  
Live beyond it.**

# The Percept™ family

provides options to meet your needs

## Percept™ PC neurostimulator

Recharge-free



### Designed for

People who are looking for all the benefits of the Percept™ family without the need to periodically recharge their neurostimulator.

### Charging

With the PC option, the neurostimulator does not require recharging.

### Size

Features a thinner,<sup>†</sup> curved design.

### Battery life

Experience a low maintenance battery with an expected 5 years of service life<sup>‡</sup> without ever having to recharge.

## Percept™ RC neurostimulator

Rechargeable



### Designed for

People who are looking for all the benefits of the Percept™ family with a long-lasting battery, and don't mind periodically recharging their neurostimulator.

### Battery life

Count on at least 15 years of service life with consistent stimulation and fast recharge performance. Medtronic patented battery technology has less battery fade than other rechargeable devices for a more reliable, long-lasting battery.<sup>◊</sup>

### Size

Features the smallest and thinnest rechargeable neurostimulator available.<sup>§</sup>

### Charging

Experience rapid recharging from 10% to 90% full charge in less than 1 hour.<sup>¶</sup> The typical number of days before needing to recharge can be up to 9 to 12 days.<sup>#</sup> If charging daily, recharging can take as little as 15 minutes.<sup>Δ</sup>

<sup>†</sup> Percept™ PC is 20% smaller in overall device volume as compared to Activa™ PC and 20% thinner in case thickness as compared to Activa™ PC

<sup>‡</sup> For median energy use in DBS for PD patients, with moderate (up to 2 months per year) BrainSense™ technology usage

<sup>§</sup> Percept™ RC is over 30% smaller than the Boston Scientific Vercise Genus™ R16. (Medtronic data on file)

<sup>◊</sup> The Boston Scientific Vercise Genus™ R16 has a variable 5-15 years of service life, depending on the stimulation settings and conditions (Vercise™ Deep Brain Stimulation Systems Information for Prescribers MP92366224-01 Rev G, accessed August 22, 2023)

<sup>¶</sup> For implant depths of up to 2.0 cm under normal conditions

<sup>#</sup> 50th percentile usage will typically have 12 days between required recharges and 80th percentile usage is expected to have 9 days between required recharges (100% to 0%) with sensing OFF

<sup>Δ</sup> With sensing ON at 80th percentile therapy settings for implant depth of 1 cm

# We do more for you

Medtronic provides services and technologies to optimise your surgery, such as imaging capabilities and brain signal recording. We are also dedicated to supporting the surgical team to help maximise clinical outcomes.



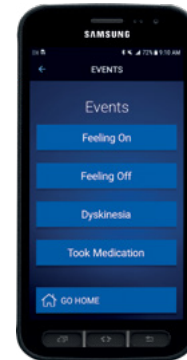
# DBS therapies

tailored to each individual's need



## SenSight™ directional leads

- Designed with contact spacing for the specific anatomy target site
- Give surgeons the right options for each patient's unique needs
- MR Conditional†
- Work seamlessly with Percept™ PC neurostimulator



## Medtronic DBS patient programmer

- The Medtronic DBS patient programmer has an intuitive interface that resembles familiar consumer technology
- Protects your device and your data with defense-grade security capabilities
- Empowers you to manage your therapy discreetly with a device that looks like a smartphone
- Battery checks are easier than ever with intuitive icons and labels
- Automatically generates calculation of expected battery longevity‡
- Tutorial videos are directly available in your Patient Programmer

† 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 +44 (0) 1923 205101.

‡ When used with Percept™ PC neurostimulator

# How can your decisions today protect your future?

About

7/10

People living with movement disorders who are eligible for DBS therapy may need an MRI within 10 years following their implant<sup>14</sup>

## What is MRI?

MRI is short for magnetic resonance imaging, and is a noninvasive 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. It produces high-resolution images that help diagnose a variety of problems.

Compared to CT (X-ray), MRI is safer and provides your doctor with a much better chance of the correct diagnosis. It is now the preferred mode of diagnostic imaging for many disease states – both in terms of guidelines and clinical practice.

## The first full-body MR Conditional portfolio.

Medtronic offers the world's first full-body MR Conditional DBS device portfolio.<sup>†</sup> People with Parkinson's with implanted DBS systems feel reassured knowing that with proper safeguards, MRI is an option for them.

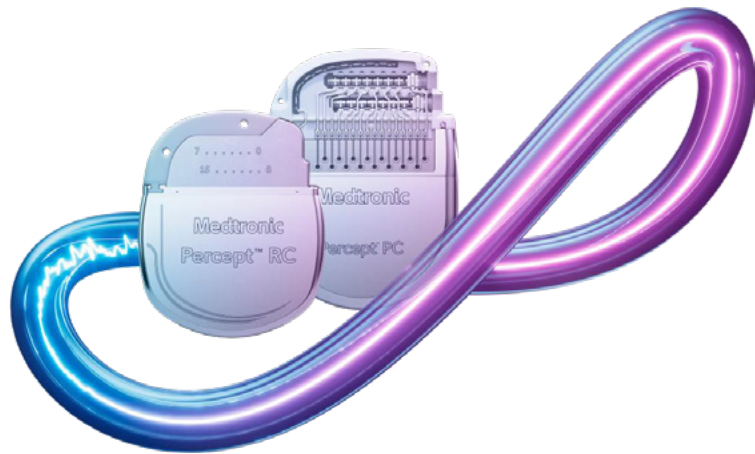
**The therapy decisions you make today, may impact your future**

<sup>†</sup> Under specific conditions of use. Before conducting an MRI examination on a patient with any implanted Medtronic DBS device, please refer to the MRI guidelines for Medtronic deep brain stimulation systems located at <http://www.medtronic.com/mri>

# Percept™ family

with BrainSense™ Adaptive deep brain stimulation (aDBS)<sup>†</sup>

Medtronic has engineered the most advanced DBS system that is adaptable to your individual needs.



<sup>†</sup> The sensing feature of the Percept™ PC and Percept™ RC system is intended for use in patients receiving DBS where chronically recorded bioelectric data may provide useful, objective information regarding patient clinical status.

<sup>‡</sup> 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 +44 (0) 1923 205101.

**Designed to meet your needs today and tomorrow.**

## Personalised therapy

Only the Medtronic DBS Percept™ family utilises BrainSense™ technology to capture and record real-time brain signals related to your symptoms. This sensing capability allows your clinician to see your brain activities at the exact time you are experiencing symptoms (even when symptoms occur outside of an office visit). As a result, your stimulation can be personalised and adapted by your clinician to optimise therapy and minimise side effects.

## Comfortable

The Percept™ neurostimulators are designed to have a low profile under your skin for your comfort and for minimal visibility of the implanted device. Unlike other DBS systems,<sup>2</sup> the Percept™ neurostimulators are compatible with 3T and 1.5T MRI scans for when you need high-quality imaging. For your comfort, Medtronic DBS stimulation can also remain on while you're getting an MRI (under certain conditions).<sup>†</sup>

## Discover adaptive DBS

Adaptive DBS is a new advancement feature in DBS therapy for Parkinson's disease. Adaptive technology self-adjusts your therapy with the goal of providing you with more motor symptom control throughout your day and night. This personalisation means that you may experience more "On" time (time when your Parkinson's disease symptoms are well-controlled) compared to traditional DBS therapy.

## Enhanced MRI access

Not all DBS systems can have stimulation remain on during a magnetic resonance imaging (MRI) scan. Medtronic DBS with Percept™ neurostimulators are compatible with 1.5T and 3T MRI scans for when you need high-quality imaging and DBS stimulation can remain on during a MRI.<sup>‡</sup>

# DBS frequently asked questions (FAQ)

## Does DBS prevent a person from using future treatments or cures?

No. DBS therapy will not reduce future therapy options. DBS therapy is reversible and the system can be removed.

## Is DBS just for tremor (shaking)?

No. DBS also treats stiffness and slow or reduced movement, and may provide some relief from dystonic muscle cramps and non-motor symptoms such as sleep disturbances and urinary symptoms.

## Is DBS something to put off as a last resort?

Definitely not. The window of opportunity is when Parkinson's medication isn't working as well as it used to, but it hasn't stopped working completely. If left too late, DBS therapy will not be able to help as much as it could have.

## How effective is DBS therapy?

DBS therapy extends the control you already get from your medication over the movement symptoms of Parkinson's.

It's very important to mention that the success of Medtronic DBS depends on:

### Good candidate selection

This is essential, DBS is not for everybody.

### Good surgical placement

of the DBS electrodes.

Based on studies comparing DBS to best medical therapy (BMT) in both early and advanced Parkinson's evaluating overall motor function, the following has been demonstrated regarding the success rate<sup>3</sup> of DBS:

85-89%

improvement from baseline (before DBS)<sup>1</sup>

7-13%

no change from baseline (before DBS)<sup>1</sup>

2-4%

worsening from baseline (before DBS)<sup>1</sup>

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

Typically, a DBS system is not activated until a patient has healed from the surgery. Once activated, troubling symptoms may decrease. Optimal results are usually achieved after multiple programming sessions with the doctor or nurse who programmes the device.

## Will I feel the stimulation?

Many people with a DBS system will not feel the stimulation at all. Some people may feel a brief tingling sensation when the stimulation is first turned on. If the stimulation changes or becomes uncomfortable, the doctor should be contacted immediately.

## Can normal daily activities be resumed?

For the first few weeks after surgery, patients who have received DBS should avoid strenuous activity, arm movements over the shoulder, and excessive stretching of the neck.

Each individual should talk with their doctor about gradually trying activities that were difficult before surgery.

## Will the neurostimulator be visible?

Depending on a person's body build, the neurostimulator may be noticeable as a small bulge under the skin. However, the therapy is fully implantable and generally not visible.

## Is DBS therapy permanent?

No. DBS therapy is adjustable so that the stimulation can be changed over time to maintain control over a patient's symptoms. The system can also be turned off or surgically removed if necessary.

## Will I be able to have an MRI scan with a DBS system?

About 7 out of 10 people living with movement disorders who are eligible for DBS therapy may need an MRI within 10 years following their implant.<sup>14</sup> Medtronic offers DBS systems that are CE approved for MRI full-body scans, under specific conditions of use. Patients should talk to their doctors if an MRI scan is prescribed.

## For more FAQ and further information, visit our website:

[europe.medtronic.com/parkinsons](http://europe.medtronic.com/parkinsons)



I can go swimming!  
I really like swimming  
or riding my bike."

Live  
active,  
like Stefan

//

I've got more energy to spend time with my boys, playing sports, & doing things we all enjoy."



Live in the moment,  
like John

# Learn more about deep brain stimulation for Parkinson's

Scan the QR code or visit

[europe.medtronic.com/parkinsons](http://europe.medtronic.com/parkinsons)



Contact  
the Medtronic  
Helpline on  
**+44 (0) 1923  
205101**

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The "gold standard" of evaluating the success rate of DBS is based on the overall motor function evaluation using the UPDRS III scale. The scientifically accepted method for evaluation of the MCIC (minimally clinically important change) is at least 5 points in the UPDRS III scale. The evaluation of "off medication" allows reflection of the impact of DBS, albeit an artificially created OFF condition. It has not been typically reported in the publications but we have done the above additional analyses of the databases available in both the published evidence (only randomized control trials have been considered for this). The above analysis works for Medtronic devices only.

## Brief Statement

Information contained herein is not medical advice and should not be used as an alternative to speaking with your doctor. Discuss indications, contraindications, warnings, precautions, adverse events and any further information with your health care professional. Please note that the intended use of a product may vary depending on geographical approvals. Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices.

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