

# A reason to be hopeful.

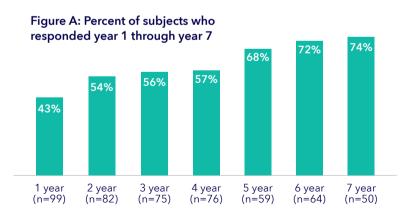
Medtronic deep brain stimulation (DBS) therapy for epilepsy



# **Get more** out of life

### Expect more freedom from worry - knowing DBS therapy for epilepsy is helping to keep your seizures under control.<sup>1</sup>

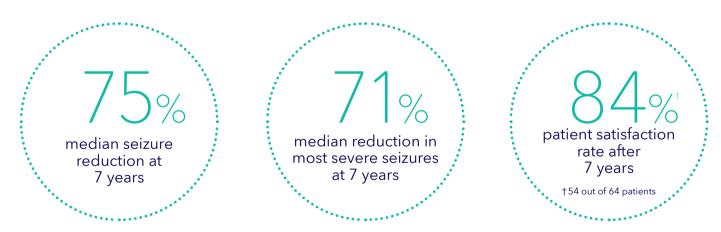
During year one of a clinical study, the responder rate – defined as those experiencing a 50% or greater reduction in total seizures – for patients receiving DBS therapy for epilepsy was 43%. This rate improved over time, to reach 74% at year seven (*Figure A*). Seizure control with DBS therapy for epilepsy is significant and sustained through seven years.<sup>1</sup>





# More life, fewer seizures

Medtronic DBS therapy for epilepsy may improve your quality of life. The clinical study also showed a significant reduction in overall seizures, including patients' most severe seizures, with some experiencing months of seizure freedom.<sup>1</sup>



### ... and fewer injuries

During a 3-month comparison period of the clinical study, patients receiving DBS therapy for epilepsy experienced significantly fewer epilepsy-related injuries than patients who did not receive stimulation.<sup>1</sup>

### What is DBS?

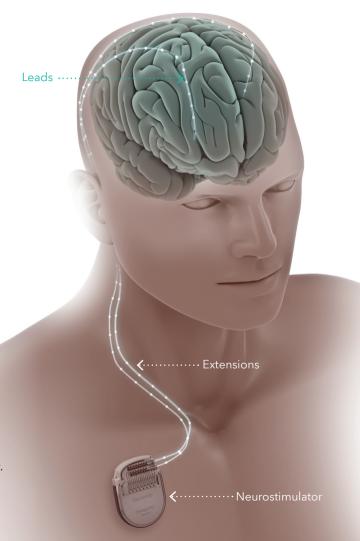
Deep brain stimulation (DBS) therapy for epilepsy delivers controlled electrical stimulation to targeted areas in your brain involved with seizures with a small implanted device—similar to a cardiac pacemaker.

- Your surgeon places thin, insulated wires called "leads" in the brain, which are connected with extensions to a small neurostimulator placed under the skin in the chest or abdomen.
- Your healthcare provider uses a wireless programming device (clinician programmer) to set and adjust your individualized therapy settings.
- Every individual is different, so fine adjustments may take place over several months to find the stimulation settings that best reduce your seizures and potential side effects.

Over time, your healthcare provider will adjust the therapy settings to adapt your stimulation to your specific needs.

DBS therapy for epilepsy, unlike other epilepsy surgeries, does not involve removal of your brain tissue. It is fully reversible, and can be easily turned off with a handheld patient programmer device. If necessary, the DBS system can also be fully removed from your body.

 $Graphic\ shown\ is\ for\ illustrative\ purposes\ only.$ 

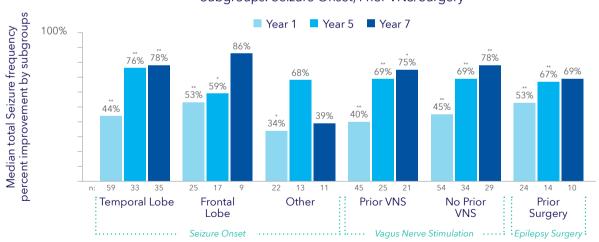


# Proven effective, even after prior surgeries

DBS therapy for epilepsy is also proven to be effective in patients who have had prior brain surgeries, including Vagus Nerve Stimulation (VNS).<sup>1,†</sup>

#### **Total Seizure Frequency**

Subgroups: Seizure Onset, Prior VNS/Surgery



\*p-value  $\leq 0.05$  \*\*p-value  $\leq 0.001$ 

<sup>†</sup> If you already have a VNS system implanted, the power source (battery) for your VNS system will be removed and the lead will be removed or trimmed and capped. Please talk with your physician to determine if DBS is right for you.

## **Percept™ family** with BrainSense™ technology



SenSight<sup>™</sup> directional leads (image enlarged to show detail)

### Designed to meet your needs today and tomorrow:

- Equipped with BrainSense<sup>™</sup> technology<sup>†</sup> to enable clinicians to personalize and adapt therapy to your individual needs.
- Designed small for comfort—with the thinnest DBS neurostimulators available.<sup>‡</sup>
- Access to 1.5T and 3T MRI with ability for DBS therapy to remain on during an MRI scan.§
- Ready for future advancements when software updates become available.
- Choice of recharge-free (PC) or rechargeable (RC) battery options

<sup>†</sup> The sensing feature of the Percept™ PC system 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. Signal may not be present or measurable in all patients.

<sup>‡</sup> Percept<sup>™</sup> RC as compared to Boston Scientific Vercise Genus<sup>™</sup> R16 (MP92328632-05 REV B) and Abbott Liberta RC<sup>™</sup> IPG (ARTEN600337130 A). Percept<sup>™</sup> PC as compared to Boston Scientific Vercise Genus<sup>™</sup> P16 (MP92328632-05 REV B) and Abbott Infinity<sup>™</sup> 5/7 IPG (ARTEN600150429 B). Boston Scientific and Abbott DBS devices are not approved for the treatment of epilepsy.

<sup>§</sup> Medtronic DBS Systems are MR Conditional. Refer to product labeling for full list of conditions. https://manuals.medtronic.com/manuals/mri/region.

### Percept<sup>™</sup> PC neurostimulator

#### Recharge-free

Experience a low maintenance battery with several years of service life (under typical settings) without ever having to recharge.



### Percept<sup>™</sup> RC neurostimulator

#### Rechargeable

Count on at least 15 years of service life with consistent stimulation and fast recharge performance.



Talk with your doctor to determine which option is right for you.

# More personalized control

Once your DBS therapy is activated you'll receive a patient programmer that will enable you to turn the therapy on and off, check your neurostimulator battery level, turn on MRI mode, and modify stimulation settings that are pre-set by your physician.† You may also log a seizure event and activate stimulation by pressing a button.†

Log a seizure event



Check neurostimulator battery level



Turn on MRI mode



# Your smarter seizure diary

As part of your DBS therapy for epilepsy, it's important to track your symptoms closely. Your patient programmer enables you to do this easily, with its onboard seizure diary. Now you and your physician can digitally track and share important information that could lead to adjustments to your therapy parameters.

Your healthcare provider can choose up to 4 customizable events to track digitally over the course of the day such as:

- Auras
- Seizures types
- Medication changes
- Other (patient specific)

# MRI access, now even easier

Magnetic resonance imaging (MRI) is a common diagnostic procedure used for medical conditions related to the heart, brain and spine. Medtronic DBS with Percept™ neurostimulators are compatible with 1.5T and 3T MRI scans for when you need high-quality imaging.<sup>‡</sup> Simply check your patient programmer for compatibility, and put the device into MRI mode.

As your patient programmer can perform a check before your scan, you may not need to schedule a physician visit. Medtronic DBS stimulation can also remain on while you're getting an MRI.<sup>‡</sup>

<sup>†</sup> If configured by your clinician.

<sup>‡</sup> Medtronic DBS Systems are MR Conditional. Refer to product labeling for full list of conditions. https://manuals.medtronic.com/manuals/mri/region

### Am I a candidate

for DBS for epilepsy?

#### You may be a candidate if you:

- ✓ Are at least 18 years of age
- √ Have been diagnosed with epilepsy characterized by partial-onset (focal) seizures, with or without secondary generalization
- ✓ Are refractory to 3 or more antiepileptic medications
- ✓ Have averaged more than 6 seizures per month over the last 3 months, with no more than 30 days between seizures

"I've been seizure free for over a year. I'm just very grateful for this device, and I sleep soundly at night. I've been able to go back to a normal that I haven't known for a long time."

Al, recipient of Medtronic DBS therapy for epilepsy



# You might like to know.

#### Will DBS therapy cure my seizures?

No, deep brain stimulation therapy for epilepsy is not a cure. If the neurostimulator is turned off, seizures are expected to return. Individual results with DBS therapy vary.

#### Will I still need to take medications?

Medication is an adjunctive treatment to Medtronic DBS therapy. There may be some changes for patients related to anti-epileptic drug type and dosages.

### What are possible risks with the DBS procedure?<sup>2</sup>

Potential risks related to the device, therapy, or surgery can include implant site pain, tingling sensations, ineffective stimulation, and implant site infection.

Possible side effects with DBS therapy for epilepsy might include:

- Status epilepticus
- Changes in seizures: new seizure type or worsening seizures (increased seizure frequency, duration, and/or severity).

The quote in this brochure recounts the experience of an individual who is receiving Medtronic DBS therapy for epilepsy. Not everyone who receives this 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 find out if Medtronic DBS therapy is right for you,

#### References

- 1. Salanova V, et al. Epilepsia. 2021 Jun; 62(6):1306-1317.
- 2. Medtronic DBS Therapy for Epilepsy Clinical Summary, 2018.

Brief Statement: Medtronic DBS Therapy for Epilepsy

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

Medtronic DBS Therapy for Epilepsy: Deep Brain Stimulation (DBS) Therapy for Epilepsy is an adjunctive therapy (used along with medications) that delivers electrical stimulation to an area in your brain to reduce the frequency of seizures. You may be a candidate for this therapy if you are 18 years of age or older and diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are not adequately controlled by 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.

Placing the DBS system requires brain surgery, which can have serious and sometimes fatal complications including bleeding inside the brain, stroke, seizures, and infection. Once implanted, infection may occur, parts may wear through your skin, and the lead and/or extension connector may move. 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. Medtronic DBS Therapy may cause new or worsening neurological or psychiatric symptoms. Cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. Symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. Memory impairment has been reported, although no direct cause-and-effect relationship has been established.

In patients receiving Medtronic DBS Therapy for Epilepsy, depression, suicidal thoughts, and suicide have been reported, although no direct cause-and-effect relationship has been established.

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. 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.

A prescription is required. Not everyone who receives DBS Therapy will receive the same results.

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For further information, please call Medtronic at 1-(800) 328-0810 and consult the Medtronic website at www.medtronic.com/dbs.

#### Medtronic

LISA

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Medtronic Patient Services Toll-free: 1-(800) 510-6735 Available M-F, 8:00 a.m.-5:00 p.m. CT

medtronic.com/dbs

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