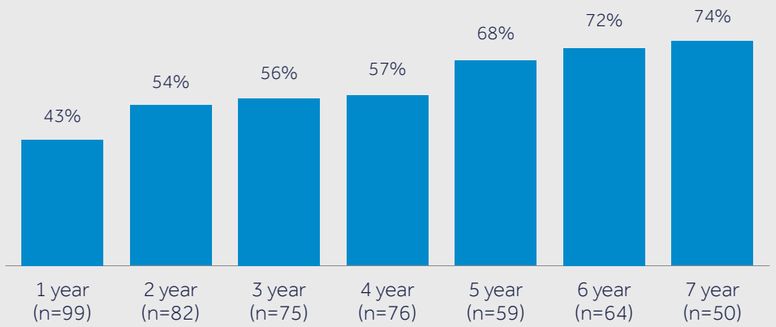

A REASON
TO BE
HOPEFUL.
DBS Therapy for Epilepsy
Medtronic
Further, Together

GET MORE OUT OF LIFE.

Expect more freedom from worry – knowing DBS Therapy for Epilepsy is helping to keep your seizures under control.[1]

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.[1]

Figure A: Percent of subjects who responded year 1 through year 7



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.

75%
MEDIAN SEIZURE REDUCTION AT **7 YEARS**

71%
MEDIAN REDUCTION IN MOST SEVERE SEIZURES AT **7 YEARS**

84%**
PATIENT SATISFACTION RATE AFTER **7 YEARS**

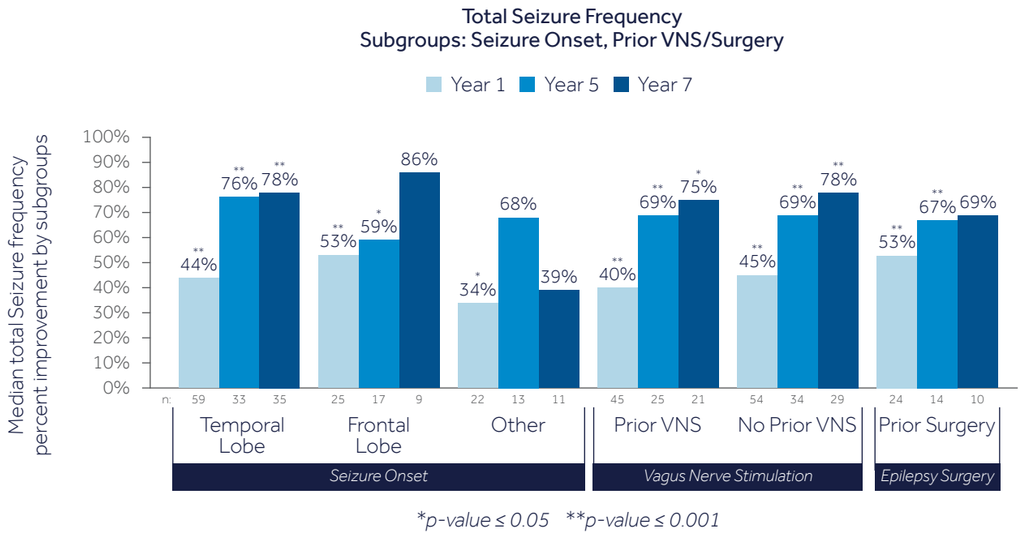
FEWER INJURIES.

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.

****54 out of 64 patients**

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.†



*p-value ≤ 0.05 **p-value ≤ 0.001

† 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 doctor to determine if DBS is right for you.

WHAT IS DEEP BRAIN STIMULATION THERAPY?

DBS Therapy for Epilepsy carefully delivers controlled electrical stimulation directly to the specific areas in your brain involved with seizures through a small implanted device—similar to a cardiac pacemaker.

1. Your surgeon places thin, insulated wires called "leads" in the brain, which are connected with extensions to a neurostimulator.
2. The Deep Brain Stimulation system is implanted under the skin of the chest or abdomen.
3. Your healthcare provider uses a wireless programming device to set and adjust your individualized therapy settings.
4. Every individual is different, so fine adjustments may take place over several months to find the settings that best reduce your seizures and potential side effects.
5. Over time, your healthcare provider will adjust the therapy settings to meet your specific needs.

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

ENGINEERED FOR YOUR COMFORT

The 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**

*In overall device volume
**Refers to case thickness

MORE PERSONALIZED. MORE 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 the device battery level, and modify stimulation settings that are pre-set by your physician. You may also log a seizure event by pressing a button.

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
- Falls
- Different types of seizures
- Missed medications, and more

MRI ACCESS — NOW EVEN EASIER.

Getting an MRI is now even easier for you. The Percept™ PC neurostimulator is full-body MR Conditional* for DBS, so you can benefit from the cutting-edge medical imaging when and if you need it. Simply check your patient programmer for compatibility, and put the device into MRI mode.

Because your patient programmer 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.

*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.

WHAT ARE THE POSSIBLE COMPLICATIONS OF DBS THERAPY FOR EPILEPSY?

SANTE CLINICAL STUDY—RISKS

During the comparison period of the study, more patients in the active group (device turned on) reported adverse events of depression or memory problems as compared to the control group (device turned off). During the study, the most frequent events related to the device, therapy, or surgery included implant site pain, tingling sensations, ineffective stimulation, and implant site infection.

In addition to the risks and side effects related to DBS therapy, the following side effects can occur with DBS Therapy for Epilepsy.

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

SURGICAL/POST SURGICAL RISKS

Medtronic DBS therapy includes risks from surgery and possible side effects after surgery, both of which may include device complications. Implanting the brain stimulation system carries risks similar to other brain surgeries and surgeries not involving the brain.

This document discusses benefits, risks and side effects associated with DBS Therapy. Be sure to discuss all benefits and risks of this therapy with your physician. This therapy is not for everyone. Individual results may vary. A prescription is required. For further information, please call Medtronic Patient Services at 800-510-6735 Monday to Friday, 8 a.m. to 5 p.m. Central Time and consult Medtronic's website at **medtronic.com/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. There may be some changes for patients related to anti-epileptic drug type and dosages.

Am I a candidate?

You may be a candidate if you are:

- At least 18 years of age.
- Refractory to three or more antiepileptic medications.
- Diagnosed with epilepsy characterized by partial-onset (focal) seizures, with or without secondary generalization.
- Experience six or more seizures per month over the three most recent months, with no more than 30 days between seizures.

"I have a new sense of independence and confidence. Now I'm able to do things that I haven't done in years."*

Sara
Receiving Medtronic DBS Therapy for Epilepsy since 2005 (participant in SANTE Clinical Trial)

*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. Medtronic DBS Therapy for Epilepsy Clinical Summary, 2018

Medtronic DBS Therapy for Epilepsy: Patients should always discuss the potential risks and benefits with a physician.

INDICATIONS: 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. 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 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. Extreme care should be used with lead implantation in patients with a heightened 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. 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. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct cause-and-effect relationship has been established. 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 symptoms 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. 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.

PRECAUTIONS: Loss of coordination in activities such as swimming may occur.

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.

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.

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