IT'S A NEW DAY.

DBS Therapy for Epilepsy.

Sara
Receiving Medtronic DBS Therapy
for Epilepsy since 2005

Improve your quality of life.

Medtronic
Further, Together

GET MORE OUT OF LIFE.

Life with seizures can be overwhelming and debilitating. But there is hope—with Medtronic Deep Brain Stimulation (DBS) Therapy for Epilepsy.[1]

In a clinical study, Medtronic DBS Therapy for Epilepsy significantly reduced the frequency and severity of even patients' most severe partial-onset (focal) seizures—and the incidence of epilepsy-related injury.

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

Ask your doctor if DBS Therapy for Epilepsy is right for you.

A REASON TO BE HOPEFUL WITH DBS THERAPY FOR EPILEPSY.

Imagine living a fuller, more independent life. If you're an adult suffering from partial-onset (focal) seizures that are uncontrolled by medications, DBS Therapy for Epilepsy may be an option for you.

DBS Therapy for Epilepsy, unlike other epilepsy surgeries, does not involve removal of your brain tissue. If DBS Therapy is ineffective or not tolerated, the DBS system can be turned off or surgically removed from your body.

75%

Median seizure reduction at 7 years[1]

18%

Of patients seizure free for ≥ 6 months[1]

84%

84% patient satisfaction rate after 7 years[1]*

* 54 out of 64 patients

A PROMISING OPTION **FOR YOUR FULLER LIFE.**

What is deep brain stimulation therapy?

Medtronic's DBS Therapy is a treatment for Epilepsy. A small neurostimulator is surgically placed under the skin in the chest or abdomen to deliver therapy. The device sends electrical pulses through flexible extension cables to very thin wires called leads that are placed in a specific area of your brain where seizures occur. A programmer enables you to switch the stimulator on and off, check the device battery level and modify stimulation settings that are pre-set by your physician.

Stimulation That May Reduce Seizures.

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.

Customized and Comfortable Control.

Deep Brain Stimulation Therapy for Epilepsy gives you the stimulation you need, and can be modified for individual control of therapy. The anterior nucleus of the thalamus – a central relay station of your brain – has connections to the parts of the brain where seizures can begin.

The clinical study showed that stimulation in this area reduces seizure frequency.[1] DBS Therapy for Epilepsy delivers customized, targeted stimulation to this specific area of the brain. If you experience side effects —such as a tingling sensation at the implant site—it typically can be resolved with adjustments in device programming.

Over 150,000 patients treated.

Today, more than 150,000 people worldwide have received Medtronic DBS Therapy for Parkinson's disease, Essential Tremor, Dystonia, Obsessive-Compulsive Disorder (OCD), as well as Epilepsy. Our DBS Therapy was first approved in Europe in 1993 under CE mark for certain movement disorders, and approved in Europe under CE Mark in 2010 for Epilepsy. DBS Therapy is now available in the United States as a well-established, effective, and sustained treatment option to reduce the frequency of seizures in patients suffering from medically refractory epilepsy.

Leading the evolution of care.

Medtronic understands that DBS Therapy for Epilepsy is a big decision. And we want you to know that there is a reason Medtronic is one of the most trusted leaders in medical technology. We've been around a long time – we developed the first battery powered pacemaker for cardiac patients, and led the development of deep brain stimulation in the 1980s and 1990s. And we do more clinical research on neuromodulation therapies than many other companies worldwide. All because we are driven by our Mission - to alleviate pain, restore health, and extend life. We're committed, and we're here to help you explore how DBS Therapy for Epilepsy may improve your life.

EFFECTIVE CONTROL WITH DBS FOR EPILEPSY.

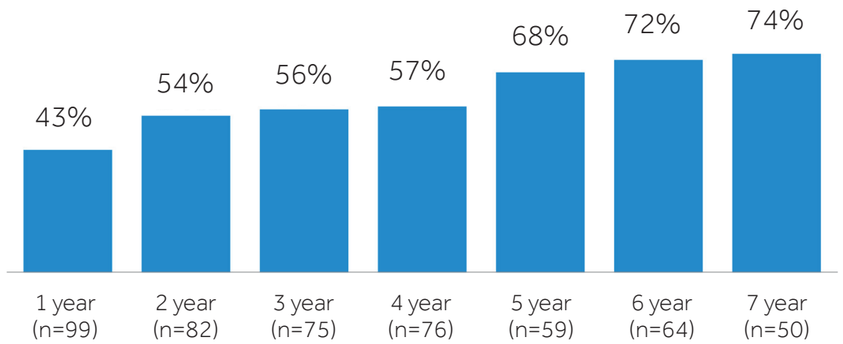
PROVEN POTENTIAL.

During year one of a clinical study, the responder rate (50% or greater reduction in total seizures) for patients receiving DBS Therapy for Epilepsy was 43% . This rate improved over time and reached 74% at year seven (Figure A). Seizure control with DBS Therapy for Epilepsy is significant and sustained through seven years.[1]

Nearly 1 in 6 patients receiving DBS Therapy for Epilepsy in the clinical study experienced at least six months of seizure freedom in the seven years after device implant.[1]

During a 3 month comparison period of the clinical study, patients receiving DBS Therapy for Epilepsy experienced fewer seizure-related injuries than patients who did not receive stimulation. The clinical study also reported a reduction in patients' most severe seizures of 71% at seven years. DBS Therapy for Epilepsy improves quality of life in the long-term. Nearly half (43%) of the patients receiving Medtronic DBS Therapy for Epilepsy in the clinical study experienced clinically meaningful improvements in their Quality of Life after seven years of implant.[1]

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



MORE LIFE. FEWER SEIZURES.

When it comes to coping with seizures – less can certainly mean more. Seizures can lead you to isolate yourself or become socially withdrawn, negatively affecting your quality of life. Fortunately, clinical data shows that – along with a reduction in seizures – Medtronic DBS Therapy for Epilepsy may improve a patient's quality of life. In fact, when asked one year after receiving Medtronic DBS Therapy for Epilepsy, more than 80% of the clinical study patients said they would choose this therapy again knowing the results – and would recommend the therapy to a friend.[1] Seven years after receiving DBS, 84% (54 out of 64) of the patients said they were "satisfied" or "greatly satisfied" with the results of this therapy.[1] Find out if our DBS Therapy for Epilepsy can make a difference for you, too.

YOU ARE IN CONTROL.

The Intercept™ patient programmer enables you to:

- Turn therapy ON and OFF
- Check the neurostimulator battery status
- Adjust programmed parameters within physician-prescribed limits (if appropriate for your condition)
- Log a seizure event
- View information about your implanted device.

If you sense a seizure coming, the programmer also gives you control to activate stimulation by pressing the seizure button. However, please note that this feature has not been proven to stop seizures.

YOU MIGHT LIKE TO KNOW.

How do I know if I am a candidate?

Research shows that DBS may be appropriate for people who are least 18 years of age and diagnosed with epilepsy characterized by partial-onset (focal) seizures, with our without secondary generalization, and who are refractory to three or more antiepileptic medications. Safety and effectiveness has been established in patients who averaged six or more seizures per month over the three most recent months with no more than 30 days between seizures.[1] The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures. Only your doctor can determine if DBS therapy is right for you.

What is the procedure like?

The DBS system is implanted inside your body by a trained neurosurgeon using three-dimensional imaging, such as magnetic resonance imaging (MRI) or computed tomography (CT). This imaging maps the brain and locates the site to be stimulated. The surgeon places thin, insulated wires called "leads" in the brain. The surgeon implants the neurostimulator, typically under the skin in the upper chest .

The duration of the procedure and the specific steps described can vary.

How does the therapy programming work?

DBS Therapy for Epilepsy delivers controlled electrical stimulation in programmed intervals to a targeted area of your brain. Over time, your doctor will adjust the therapy settings in your device to meet your specific needs. Individualized therapy settings are programmed in the clinic using wireless communication between the implanted device and a clinician programmer. Every individual is different, so programming optimization may take place over several months to find the settings that best reduce your seizures and potential side effects.[1]

Will I still be able to benefit from an MRI?

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 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.

Will DBS Therapy cure my seizures?

No, DBS Therapy for Epilepsy is not a cure. If the neurostimulator is turned off, your seizures are expected to return. Individual results with DBS Therapy vary. Some patients receive moderate or no improvement. Results from a clinical study show that most patients achieve significant seizure reduction, and some patients (18% of patients were seizure-free for at least 6 months at any time between implant and year 7) experienced an extended period of seizure freedom.[1]

Do I still need to take medications?

You will continue on antiepileptic medications. Your doctor will determine medication treatment and dosages that are right for you.[1]

*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.

YOU SHOULD KNOW

What are the risks and side effects?

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.[1]

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

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 such as increased seizure frequency, duration, and/or severity).

For complete safety information about Medtronic DBS therapy, call Medtronic at 1-800-328-0810 or visit Medtronic's website at medtronic.com.

A NEW HORIZON OF HOPE.

Suitable patients don't have to settle for a life defined by seizures.

There is hope.

Medtronic DBS Therapy for Epilepsy may help you get more out of life. DBS Therapy for Epilepsy provides you with an established treatment option to reduce the frequency of your seizures. In a clinical study, Medtronic DBS Therapy for Epilepsy significantly reduced patients' most severe seizures, partial-onset (focal) seizures, and the incidence of epilepsy-related injury.[1]

"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

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

Brief Statement: Medtronic DBS Therapy for Epilepsy

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 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 and Precautions: 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 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. 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. 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 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.

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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