LIVE YOUR BEST LIFE

TAKE CONTROL WITH DBS THERAPY

St. Jude Medical
Pouring your morning coffee, buttoning your shirt or sitting still in a meeting...
Simple activities that were once easy and natural can be challenging when you suffer from essential tremor.

What if you could take control of your symptoms and get back to the everyday activities you previously enjoyed?

With safe, clinically proven deep brain stimulation (DBS) therapy, people with essential tremor, like you, are finding greater control over their symptoms and more time to live the lives they want.1
DBS THERAPY CHANGES LIVES

DBS is a treatment option that provides personalized, clinically proven control of essential tremor symptoms. Since its introduction in 1990, DBS therapy has helped over 120,000 people worldwide.² It works by sending targeted stimulation signals to areas in the brain that cause involuntary movements using an implanted device similar to a pacemaker. A DBS device can be turned off or removed.

For people with essential tremor, there is no specific time frame for when you can consider DBS. Generally, patients consider DBS:

- When medications fail to adequately control symptoms
- When disabling tremor affects your ability to perform activities of daily living³

² Approved use: DBS for tremor is approved by the U.S. Food and Drug Administration (FDA) for the treatment of essential tremor (ET) as monotherapy in adults whose ET is not adequately responding to medications. Approval was extended to include ET as monotherapy in patients age 60 and older who are not able to continue on levodopa therapy due to motor fluctuations (such as “on/off” phenomena, “wearing off,” and “dyskinesia” or “dyskinesia” when levodopa is given). ³ DBS therapy is not appropriate or effective for every person with essential tremor. Consult your doctor or other qualified health care professional to determine if DBS therapy is right for you.
In a study of people with essential tremor, those who received DBS therapy experienced positive results.

**DBS THERAPY IS PROVEN TO REDUCE ACTION TREMOR AND IMPROVE QUALITY OF LIFE**

- **Demonstrated a significant improvement in tremor** allowing patients to return to normal daily activities such as handwriting, pouring and working.¹

- **Resulted in nine out of 10 patients being satisfied or very satisfied** with the system’s ability to control their symptoms.¹

- **Showed an improvement in overall quality of life** including improvements in physical roles, social functioning and mental health.¹
As with any surgery or therapy, DBS has risks and complications. Most side effects of DBS surgery are temporary and correct themselves over time. However, some complications can be more serious and/or permanent. Risks of brain surgery may include serious complications such as coma, bleeding inside the brain, paralysis, seizures and infection. Some of these may be fatal. While most complications will have no after-effects, some people may experience lasting, stroke-like symptoms, such as weakness, numbness, problems with vision or slurred speech. In the event that side effects are intolerable or you are not satisfied with the therapy, the DBS system can be turned off or surgically removed.

The St. Jude Medical Infinity™ DBS system with directional lead technology and a wireless iOS™ software platform is designed to give you a discreet, personalized experience.
Receive DBS therapy with revolutionary directional lead technology designed to precisely customize therapy to help maximize your on-times and reduce side effects.4

Streamline your therapy with the first and only wireless iOS™ software platform that provides a discreet, personalized therapy experience.5 You will use an Apple™ iPod touch™ mobile digital device to adjust your programming.

Get enhanced convenience and comfort with the smallest recharge-free DBS neurostimulator device on the market and take advantage of our “upgradeable” feature—meaning you can access new technology via software updates upon approval and without the need for more surgery.6,7

THE REVOLUTIONARY NEW ST. JUDE MEDICAL INFINITY™ DBS SYSTEM OFFERS YOU THE OPPORTUNITY TO:
The St. Jude Medical Infinity™ DBS system is made up of three components:

**The lead** is a thin wire that will be placed in the area of your brain that affects involuntary movement. The lead will connect to the neurostimulator.

**The neurostimulator** is the device that sends the signal used to communicate with the brain. It is typically located in your chest.

**Programmers** are used by you and your doctor to manage your therapy—turn the therapy on and off or adjust settings as needed (within certain limitations set by your doctor).
HOW THE ST. JUDE MEDICAL INFINITY™ DBS SYSTEM WORKS

1. Brain sends electrical signals to your body, causing involuntary movements.

2. Neurostimulator device sends stimulation pulses to the directional lead.

3. Directional lead delivers these pulses to a targeted area of your brain.

4. Pulses block the brain’s signals that cause involuntary movements to help reduce symptoms.
THE DBS JOURNEY:
PREPARING FOR DBS SURGERY

Before you receive final approval to undergo DBS surgery, you will go through evaluations to determine if you are a good candidate. This will most likely include an evaluation by a neurologist to determine if your symptoms will respond to DBS. If you and your health care team decide you are indeed a good candidate for DBS, you will be scheduled for surgery.

Discuss any questions and concerns with your doctor. Having questions and concerns is normal and expected. Your doctor will be able to answer your questions or provide you with additional resources.

QUESTIONS TO CONSIDER BEFORE THE PROCEDURE:

- How many days will I be in the hospital?
- What pre-op visits need to be scheduled?
- How long will the surgery take?
- How many incisions will I have from my surgery, and where will they be?
- Will I need to shave my hair?
- How should I take my medications prior to my surgery?
- How should I take my medications on the day of my surgery?
- What should my caregiver be prepared for?
THE DBS JOURNEY: SURGERY DAY

IMAGING
The day of your surgery, at the direction of your physician, you will undergo either a head MRI or CT scan. These images help the neurosurgeon identify the exact location within your brain to place the leads.

LEAD PLACEMENT
After the images are complete, you will be taken into surgery for lead placement. In some centers you will be asleep for most of this procedure. In other centers, you may be semi-aware during part of the procedure. The time you are awake can be important because it can help the neurosurgeon determine if the leads are in the right place to help with your symptoms. You will be given local anesthesia to ease any pain at the scalp as well as medication to help you relax and relieve your anxiety.

NEUROSTIMULATOR DEVICE PLACEMENT
Prior to your surgery, your doctor will discuss with you when the neurostimulator will be implanted. The device may be implanted at the same time as the lead placement or the device may be implanted a few days to a few weeks later as determined by your doctor. The neurostimulator is usually placed in the chest similar to a pacemaker. You will be under general anesthesia (asleep) during this part of the procedure.

Following the surgery, you will be sent to a recovery area. Then you will be transferred to a ward, where you will begin your recovery process.
DURING THE FIRST 24 HOURS:

- You will be closely monitored for any sign of complications.⁸
- You may be able to eat a meal, get up and move around the ward.
- At your doctor’s discretion, you may be prescribed medication to help with post-surgical recovery.
THE DBS JOURNEY:
RECOVERING FROM
YOUR DBS SURGERY

Recovery is a process that involves your entire body. Allow yourself time to rest and heal. As you begin to recover, you may experience some discomfort around the incision areas or areas where the leads and extensions were placed. You will need to protect these incisions from infection. Follow your doctor’s instructions regarding the use of pain medications.

Over time this pain should decrease and your energy and activity levels should increase.

TURNING ON YOUR DEVICE
The time from surgery until your system is turned on could range from a few days to several weeks. Your doctor will decide what he or she thinks is best for you.

PROGRAMMING YOUR DBS SYSTEM
Setting up your DBS system with the right programming parameters is important in ensuring that the therapy is successful for you. You and the clinician programming your DBS system will work together to develop the right customized combination of stimulation and medication. Achieving the best programming settings may require multiple adjustments, so don’t get discouraged if you don’t experience immediate results. Discuss expectations, questions and concerns about your DBS system with your doctor.
The weeks and months following your DBS surgery can be an exciting time as you become familiar with your DBS system. Although individual results vary, over the course of the next several months you should gain more control over your symptoms. With an increase in activity, and reduction in noticeable symptoms, many people feel more confident and experience the freedom to live the lives they want. Ninety-six percent of people with a St. Jude Medical™ DBS device would recommend DBS therapy.  

Remember to be your own advocate—as you know your body and symptoms the best. Inform your doctors if things don’t feel right, as you may need a programming adjustment. As you learn to live with your DBS system, don’t hesitate to communicate your needs and concerns with your care partners and doctors.
As partners in caring for someone with essential tremor, it is important for you to get your questions answered and to have realistic expectations for how your life and role may change after your partner receives DBS.

Listed below are some specific questions you may want to discuss with the doctor. In addition, you may want to contact other resources for support such as online forums or caregiver support groups.

**QUESTIONS FOR CAREGIVERS TO CONSIDER**

- What can I do before the DBS procedure to make sure we have appropriate expectations about the possible benefits of DBS therapy?

- What will be required of me immediately following the surgery and over the next two to three months?

- Will there be any special needs to address over the first three to six months?

- Will the patient be able to work or drive after surgery?

- What are the potential side effects of DBS therapy?
Visit SJM.com/DBS to learn more

Rx Only
Brief Summary: Prior to using these devices, please review the User’s Guide for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Indications for Use: Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson’s disease that are not adequately controlled by medications, and unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Contraindications: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy, electroshock therapy, and transcranial magnetic stimulation (TMS) are contraindicated for patients with a deep brain stimulation system.

Warnings/Precautions: Return of symptoms due to abrupt cessation of stimulation (rebound effect), excessive or low frequency stimulation, risk of depression and suicide, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), electromagnetic interference (EMI), proximity to electrosurgery devices and high-output ultrasounds and lithotripsy, ultrasonic scanning equipment, external defibrillators, and therapeutic radiation, therapeutic magnets, radiofrequency sources, explosive or flammable gases, theft detectors and metal screening devices, activities requiring excessive twisting or stretching, operation of machinery and equipment, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Loss of therapeutic benefit or decreased therapeutic response, painful stimulation, persistent pain around the implanted parts (e.g. along the extension path in the neck), worsening of motor impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, and cognitive impairment. Surgical risks include intracranial hemorrhage, stroke, paralysis, and death. Other complications may include seizures and infection. User’s Guide must be reviewed for detailed disclosure.

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