DBS THERAPY FOR ESSENTIAL TREMOR

LIVE YOUR BEST LIFE

Take Control with DBS Therapy

Abbott

TAKE CONTROL
BE YOU AGAIN

Pouring your morning coffee, buttoning your shirt, brushing your teeth. 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 activities you enjoy? With safe, clinically proven deep brain stimulation (DBS) therapy, people with essential tremor are finding greater control over their symptoms and the freedom of having their lives back.[1]

DBS THERAPY CHANGES LIVES

DBS is a treatment option providing personalized, clinically proven control of essential tremor symptoms. Since its introduction over 20 years ago, DBS therapy has proven to be an effective treatment option.[2] A DBS system is similar to a pacemaker and provides therapy by stimulating areas of the brain associated with involuntary movements using a thin, implanted wire connected to an implanted stimulator. The DBS system can be turned off or removed, and the stimulation does not alter brain tissue.

For people with essential tremor, DBS therapy can be considered at any time. Generally, patients consider DBS when:

- The tremor is impacting quality of life and daily activities[3]
- Medications are not adequately controlling symptoms
- Other rehabilitation strategies have become less effective

DBS THERAPY IS PROVEN TO REDUCE ACTION TREMOR AND IMPROVE QUALITY OF LIFE[1]

In a study of people with essential tremor, those who received DBS therapy experienced positive results.

A SIGNIFICANT IMPROVEMENT IN TREMOR

allowing patients to return to normal daily activities such as handwriting, pouring and working.

9 out of 10

NINE OUT OF 10 PATIENTS REPORTED BEING SATISFIED OR VERY SATISFIED

with the system's ability to control their symptoms.

AN IMPROVEMENT IN OVERALL QUALITY OF LIFE

including improvements in physical roles, social functioning and mental health.

THE ST. JUDE MEDICAL INFINITY™ DBS SYSTEM OVERVIEW

The St. Jude Medical Infinity™ DBS system is made up of three components:

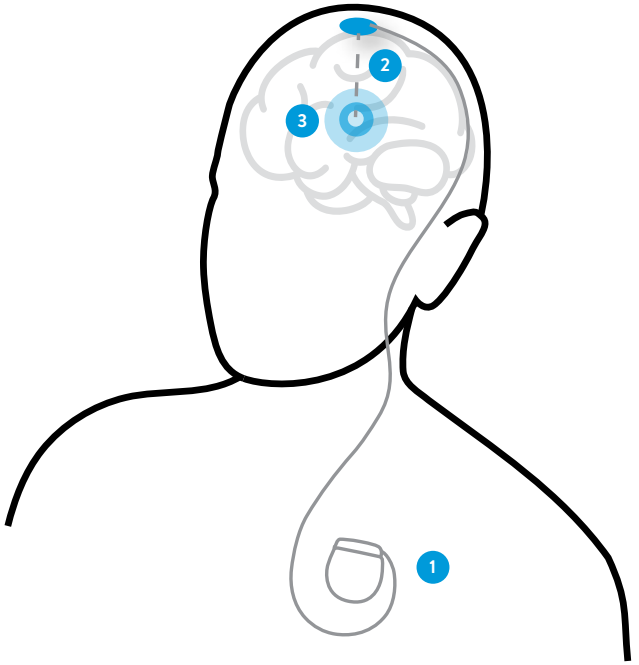
DIRECTIONAL LEAD. The lead is a thin wire that will be placed in the area of your brain that affects involuntary movement. The lead will connect to the stimulator and deliver electrical pulses to help return abnormal brain communication that causes tremors back to a more normal state.[4]

STIMULATOR. The simulator is the device that sends electrical stimulation to restore more normal communication within the brain. It is similar to a pacemaker battery and is typically placed in your chest below your collarbone.

PATIENT CONTROLLER AND CLINICIAN PROGRAMMER.

Wireless programmers are what you and your doctor use to manage your therapy. The doctor turns the therapy on and fine-tunes the settings. You can turn the therapy on and off or adjust programs and intensity as determined by your doctor.

HOW THE ST. JUDE MEDICAL INFINITY™ DBS SYSTEM WORKS



1. Stimulator sends electrical pulses to the directional lead.
2. Directional lead delivers this stimulation to a targeted area of your brain.
3. Stimulation stabilizes the brain's signals that cause involuntary movements, helping to reduce symptoms.

TECHNOLOGY DESIGNED FOR LIFE WITHOUT LIMITS*

The St. Jude Medical Infinity™ DBS System: Precision and Convenience

EFFECTIVE THERAPY WITHOUT COMPROMISE.

A revolutionary directional lead provides your doctor options to precisely target your therapy to help maximize tremor control while potentially limiting side effects.[5]

DISCREET AND EASY TO MANAGE.

With wireless communication through an app on an Apple‡ mobile digital device, managing your therapy is as simple as checking your email or sending a text message.

COMFORT AND CONVENIENCE.

The smallest recharge-free DBS battery on the market with the ability to upgrade without having to undergo surgery. As new technologies are approved, you receive software upgrades easily and painlessly — similar to how cellphone software upgrades are done.[6,7]

The directional lead provides multiple programming options to precisely target therapy. Directional leads allow your doctor to precisely target the areas of the brain associated with involuntary movements. This precision also provides options to potentially limit undesirable side effects that can result from stimulating areas outside the intended target.[5] Unlike previous DBS leads that send stimulation out in all directions, like a lamp, the directional lead is segmented so stimulation can be directed towards a desired area, like a spotlight. This gives your doctor more programming options in situations where you may have to trade optimal symptom control to limit side effects.[8]

DBS PROCEDURE OVERVIEW[9]

DBS is a well-established therapy and hundreds of thousands of patients have benefited from it since its introduction. While the specifics of the procedure will vary by surgical center based on the surgeon's preference, the basic steps are fairly standardized and the procedure is less invasive than other types of brain surgery.

1. **Imaging and planning:** An image will be taken of your brain to help the surgeon identify the exact location and path to take to implant the lead. With this imaging, the surgery can be entirely planned before you enter the operating room.
2. **Lead placement and verification:** The surgeon will create a small, dime-sized hole in the skull and place the lead in the target location. The surgeon will then use one or more techniques to verify that the lead is in the desired location.
3. **Secure lead and close:** Once proper lead placement has been verified, the lead will be secured in place and the incision closed.
4. **Connect lead to stimulator:** The surgeon will connect the lead to an extension wire and run it to the place where your stimulator will be placed. This may be done immediately following the lead or leads being implanted, or it may be done a few days or weeks later.
5. **Check stimulation and close:** Once the stimulator is connected, the system will be turned on to make sure it is operating properly. Upon confirmation, the stimulation is turned off, then the stimulator is implanted and the incision is closed.

Your doctor will decide the appropriate amount of time to wait between your surgery and turning the system on again. This allows your body time to recover from the procedure and may range from a few days to a few weeks.

There is no cure for essential tremor, but there are options available to treat symptoms. The first-line therapy is medication. Surgical treatments are also available. It's important to discuss with your doctor what's right for you along with the risks and side effects of each option, such as motor fluctuations or permanent neurological impairment.

As with any surgery or therapy, deep brain stimulation has risks and complications. Most side effects of DBS surgery are temporary and correct themselves over time. Some people may experience lasting, stroke-like symptoms, such as weakness, numbness, problems with vision or slurred speech. In the event that the side effects are intolerable or you are not satisfied with the therapy, the DBS system can be turned off or surgically removed.

Risks of brain surgery include serious complications such as coma, bleeding inside the brain, paralysis, seizures and infection. Some of these may be fatal.

VISIT SJM.COM/DBS

to watch videos and hear about patient's experience with the therapy.

"It has empowered me to make a choice — if I want to work, I can work, but it's on my terms. It has really given me my life back."*

CHARLENE, DBS patient

*This is one DBS patient's experience. Not everyone will experience the same results.

Learn more about the St. Jude Medical Infinity™ DBS System at SJM.com/DBS

*Based on technology assessments detailed in St. Jude Medical Memos SJM-INF-0815-0007 (2015), #SJM-INF-0815-0008 (2015), and SJM-INF-0815-0012 (2015); St. Jude Medical Engineering Reports 90191496, 90229064, 90245356, 90191496, and 90237167; St. Jude Medical System Test Report 90207342 (2015); and the St. Jude Medical Infinity™ IPG Clinician's Manual.

1. St. Jude Medical. Essential Tremor Final Report C-04-02. 2014. n = 127.
2. "Premarket Approval (PMA)." U.S. Food and Drug Administration (FDA) P960009, 31 July 1997, https://www.accessdata.fda.gov/cdrh_docs/pdf/p960009.pdf
3. Essential Tremor: Surgical Treatments (n.d.). Retrieved September 02, 2016, from http://www.essentialtremor.org/treatments/surgical-treatments.
4. Marks, W. J. (2011). *Deep Brain Stimulation Management*. New York, NY: Cambridge University Press.
5. Butson C.R., Venkatesan L. (2014). *Comparison of neural activation between standard cylindrical and novel segmented electrode designs,* MDS 2014 poster
6. St. Jude Medical. Document #SJM-INF-0815-0007. 2015.
7. St. Jude Medical. Document #SJM-INF-0815-0008. 2015.
8. Rebelo P et al., Thalamic Directional Deep Brain Stimulation for Tremor: Spend less, get more, *Brain Stimulation* (2017). https://doi.org/10.1016/j.brs.2017.12.015
9. By Mayo Clinic Staff Print. (2015). Deep brain stimulation. Retrieved November 16, 2016, from http://www.mayoclinic.org/tests-procedures/deep-brain-stimulation/details/how-you-prepare/ppc-20156714.

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St. Jude Medical is now Abbott.

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. The system is intended to be used with leads and associated extensions that are compatible with the system. **Indications for Use: US:** 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. **International:** Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease, unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of tremor, and unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia. **Contraindications: US:** 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. **International:** Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy and magnetic resonance imaging 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 ultrasonics 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.

25137-SJM-INF-0218-0170 | Item approved for global use.

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