BRING THE FOLLOWING ITEMS TO YOUR APPOINTMENT:

- ☐ St. Jude Medical Patient ID Card
- ☐ Patient Controller

PREPARING FOR YOUR SURGERY

Before you undergo a surgical procedure, follow these steps:

1. Tell the physician who is performing your surgery that you have an implanted St. Jude Medical™ neurostimulation system.
2. Contact your neurologist to discuss your upcoming procedure and the possible effects it may have on your implanted device.
3. Schedule your procedure. When scheduling, provide the model numbers and locations of your implanted neurostimulation system parts and your neurologist's contact information. This information is located on your St. Jude Medical Patient ID Card.
4. Fully charge your patient controller before arriving for the procedure.

Rx Only

Brief Summary: Prior to using these devices, please review the Clinician's manual 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. Clinician's manual must be reviewed for detailed disclosure.

Device depicted may not be available for all displayed indications in all countries. Check with your St. Jude Medical representative for product availability in your country.

St. Jude Medical LLC
Global Headquarters
One St. Jude Medical Drive
St. Paul, MN 55117
USA
T +1 651 756 2000
F +1 651 756 3301

St. Jude Medical S.C., Inc.
Americas Division
6300 Bee Cave Road
Bldg. Two, Suite 100
Austin, TX 78746
USA
T +1 512 286 4000
F +1 512 732 2418

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11-Box F1
B-1935 Zaventem, Belgium
T +32 2 774 68 11
F +32 2 772 83 84

SJM.com

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BEFORE AND AFTER SURGERY

FOR PATIENTS WITH A ST. JUDE MEDICAL INFINITY™ DEEP BRAIN STIMULATION SYSTEM FOR MOVEMENT DISORDERS

ST. JUDE MEDICAL

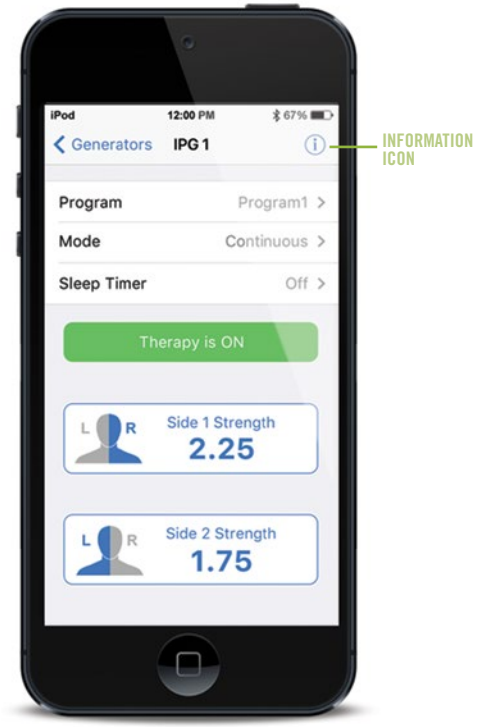
SURGERY MODE ON YOUR ST. JUDE MEDICAL™ PATIENT CONTROLLER

Implantable neurostimulation systems are active electronic devices designed to help treat your symptoms. These devices can be affected by conditions sometimes seen during surgery.

Your system has a feature called Surgery Mode that can be turned on to help reduce the possibility for interactions during surgery.*

This mode can be turned on directly from your patient controller.

*This feature does not completely eliminate the possibility of the neurostimulator being affected during surgery.



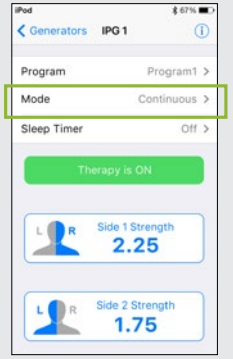
ST. JUDE MEDICAL™ PATIENT CONTROLLER

PLACING YOUR DBS SYSTEM INTO SURGERY MODE

Place your device into Surgery Mode before your procedure. Turning on Surgery Mode turns off your stimulation.

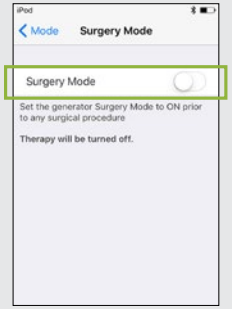
To turn on Surgery Mode

1. From the Therapy screen, tap **Mode** to display to the Mode screen.



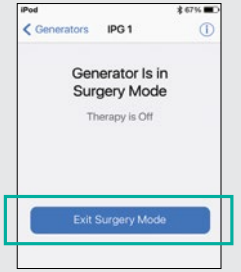
2. Tap **Surgery Mode** to view the Surgery Mode screen.

3. Tap the **Surgery Mode** toggle button.



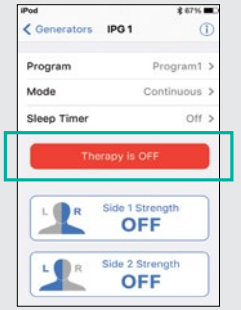
To turn off Surgery Mode

1. Launch the patient controller app and connect with your generator. The "Generator is in Surgery Mode" message appears.



2. Tap **Exit Surgery Mode** to turn off Surgery Mode.

3. The Therapy screen appears, showing that stimulation therapy is off.



4. Tap **Therapy is OFF** to start stimulation.

IMPORTANT ITEMS TO REMEMBER

Surgery Mode should be activated before entering the room where your procedure will be performed to help reduce the potential for interactions with the neurostimulator.

Turning off Surgery Mode before the completion of your procedure may cause unintended effects like unintended stimulation or damage to your neurostimulation system. Refer to your user guide for more information.

USING THIS GUIDE

This guide is intended to help you turn on and turn off Surgery Mode. If you feel uncomfortable completing the steps, contact your St. Jude Medical representative before your procedure. Contact your neurologist before your procedure to learn about any risks.

This guide should be used in addition to the Instructions for Use for your device.