

## ***Deep Brain Stimulation***

We have provided the following important information for you to better understand your surgery and to give you the opportunity to ask, and have answered, any questions that may be important to you.

### ***Procedure***

This procedure will be done in two stages. During the first stage, a craniotomy will be performed, the surgical removal of part of the bone of the skull. The tough covering around the brain, the dura, will be visualized and incised for electrode placement on both sides. The electrode will be inserted into the correct anatomical position in the brain using a microdrive. Intraoperative neurologic testing will be conducted to ensure that the electrodes are in the correct position and there are no stimulation related adverse effects. The hole in the skull will be covered and the scalp will be closed. After one week, the IPG or battery, is implanted during stage 2. The battery will be placed under the skin of your chest near the collarbone and a connecting wire will go from the battery, up the back of the neck, and under the scalp to the electrode.

I understand that the goal of this procedure is to relieve the motor symptoms of Parkinson's Disease or Essential Tremor. However, I am aware and accept that no guarantees about the results of the procedure have been made. I also recognize that unforeseen conditions may require my surgeon and his/her associates and assistants to use different procedures than those indicated above.

### ***Alternatives***

I have considered the non-surgical alternatives to deep brain stimulation, which may include:

- Not having the procedure
- Continue medical therapy
- Alternative medical approaches
- Alternative surgical approaches (pallidotomy or thalamotomy) including seeking another opinion

### ***Risks Related to the Procedure***

I agree that the decision to have this procedure includes weighing the risks of surgery as well as the benefits. I understand and accept possible risks and complications that include but are not limited to the following:

- **Adverse reaction to anesthesia** - Both local and general anesthesia involves risk. There is a possibility of complication or injury from all forms of anesthesia and sedation. The anesthesia team will discuss these with you prior to surgery.
- **Air embolism** – Air may enter the blood stream and cause a stroke, heart attack or death
- **Bleeding** - It is possible, though unusual, to experience an episode of bleeding, which may be excessive, during or after surgery. Bleeding may require additional treatment or transfusion. Certain medications, such as anti-inflammatory drugs, aspirin,

Coumadin/warfarin, Plavix/clopidogrel, heparin, and enoxaparin/Lovenox may increase the risk of bleeding. Please notify your physician if you are taking or plan to take any of these medications.

- **Blood clot development** - Blood clots may occur with *any* type of surgery. Clots can block blood flow and cause complications including pain, swelling, inflammation, neurological deficits, or tissue damage. This may require additional procedures for treatment of the blood clot.
- **Brain injury** - There is a risk that the procedure will cause injury of the surrounding brain. The symptoms that result from the injury depend on the location of the surgery.
- **Cardiac complications** - There is a small chance that having the procedure could cause an irregular heartbeat or a heart attack.
- **Cerebrospinal fluid leak** - A cerebrospinal fluid leak may occur and present as fluid drainage from the incision, mouth, nose or ear. Treatment may include reoperation or lumbar drain placement.
- **Complications related to positioning during surgery** – Although rare, complications such as compression on various nerves, pressure on the eyes, or cervical/thoracic spine injuries may occur as a result of positioning during surgery.
- **Death** - Although the risk is remote, death may occur during or soon after *any* surgical procedure.
- **Diminished function** - There is a possibility that the procedure may result in lost or diminished function.
- **Epidural hematoma** - Blood buildup between the skull and brain covering is possible with this type of surgery and may bleed into the spinal column. You may feel pain, muscle weakness, or bladder/bowel dysfunction which may need surgical decompression/craniotomy.
- **Failure of the procedure** - There is a chance that the symptoms will not go away as a result of the procedure. Your pain relief may get less over time or the stimulation itself may cause pain (stimulation-induced headache or pain at the electrode site).
- **Failure to relieve symptoms** - There is a chance that undergoing the procedure will not relieve motor symptoms.
- **Functional Loss** - It is possible to experience problems such as difficulty opening the mouth or chewing after surgery. Also, speech, language, and memory difficulties may occur after surgery.
- **Hydrocephalus** - Postoperatively, acute hydrocephalus or pneumocephalus may develop resulting in a decline of neurological status. This may require reoperation or other treatment.
- **Infection** - Infection may occur at the incision site. Infection-related risks also include the development of meningitis, an infection that causes inflammation of the membranes covering the brain and spinal cord. Infection may occur in other locations as well. Treatment of the infection may require additional procedures.
- **Paralysis** - It is possible that some paralysis or numbness may occur as a result of the surgery.
- **Postoperative Discomfort** - Pain and discomfort in neck, arms and interscapular area as well as a sensation or lump in throat may occur after the surgery. Blood clots can develop postoperatively and compress on the trachea, causing breathing difficulties.
- **Post-Operative neurologic decline** - There is a small risk that neurologic function will decline following surgery. These problems are sometimes caused by postoperative bleeding

into or on the surface of the brain or cerebral edema, which is the accumulation of fluid that results in swelling, and pressure on the brain.

- **Post-Operative pain** – It is possible, though unlikely, that pain or other symptoms will increase following the procedure. A headache may occur anywhere from one week to one month following the craniotomy and occasionally for a longer period of time.
- **Recurrence** -There is a chance that the signs and symptoms may reoccur.
- **Respiratory Difficulties** - Breathing difficulties, which are usually temporary, or postoperative pneumonia may occur as a result of surgery. Pulmonary embolus could occur from blood clotting in the veins. This may be life threatening and require further therapy.
- **Scar Formation** - It is possible that scar tissue could form in the area where the operation was performed and cause pain and other symptoms.
- **Seizure Activity** - It is possible that abnormal electrical activity in the brain may develop after the procedure and cause seizures. Seizure activity may result in the restriction of your driving privileges.
- **Stroke** - Though unlikely, there is a possibility that a stroke will occur during the procedure which may result from retraction and injury to an artery or venous plexus.
- **Subdural effusion** - Fluid release under the brain covering (subdural space) that usually consists of cerebrospinal fluid may need to be treated with drainage and rarely a permanent shunt may be placed.

### ***Important Additional Points***

**Allergies/Medications** - I have informed the doctor of all my known allergies. I have also informed my doctor of all the medications and drugs I am currently taking, including prescription drugs, over-the-counter medications, herbal/homeopathic therapies, nutritional supplements, illicit drugs and alcohol. I understand the advice I have been given about using any or all of these medications and drugs on the days before and after the procedure.

**Smoking** - It has been explained to me that if I smoke in the days or weeks before or after my surgery, I may be impeding my own recovery. I understand that if I smoke, I will have a greater risk of wound-healing complications. I understand that I may request from my physician a consult to help me stop smoking.

**Technology Failure** - It is possible during the surgical procedure that machines and technology will fail.

**Medical Conditions** - I have informed the doctor of all my known medical conditions and understand that certain conditions such as diabetes, obesity, long-term steroid use and heart and lung disease can increase the risks of this procedure.

I have been given the opportunity to ask questions and have explained to me the areas of information that I did not understand.

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Signature of Patient/Next of Kin/Guardian

Date

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Witness

Date