

Spinal Cord 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

Spinal cord stimulation (SCS) uses electrical impulses to relieve chronic pain in your body and extremities. These electrical pulses prevent pain signals from being received by the brain. This surgery will be a two-stage procedure the first of which is a trial implantation period. During state 1, one or more lead wires will be inserted into the space surrounding the spinal cord (epidural space). The leads are connected to an external trial stimulator for approximately 1 week to determine if SCS will help your pain. If the amount of pain relief is acceptable, the system may be permanently implanted. At the end of the trial period, the leads are removed in preparation for stage 2. The lead wires will be placed in the predetermined location in the epidural space. Next, a small incision is created and the implantable pulse generator (IPG) is positioned under the skin (usually the buttocks or abdomen). The leads are then connected to the IPG. The implant is programmed with an external wireless programmer and can be adjusted as needed.

I understand that the goal of the procedure is to provide relief of symptoms and improvement of neurologic condition by implanting an electrode that delivers rapid electrical pulses to dampen pain messages send to the brain. This procedure it not intended to eliminate all of my pain, address the source of pain, or correct any underlying anatomical problem. 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 alternatives to this procedure, which include:

- Observation of the condition without having surgery
- Continue medical therapy for relief of pain or muscle spasms
- Alternative medical approaches including acupuncture
- Alternative surgical approaches including seeking another opinion
- Physical therapy that may include deep heat and massage, ultrasound and traction
- Injections (i.e. steroid)
- Braces or splints
- A series of follow-up visits with repeat neuro-imaging or other tests
- Exercises to strengthen the muscles in the area of pain
- Peripheral nerve ablation
- Neurectomy or complete sectioning of the nerve
- Percutaneous rhizotomy
- Radiation therapy including focused or stereotactic radiotherapy, radiosurgery, biopsy

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:

- **Abdominal complications** - Placing the implantable pulse generator (IPG) may cause a tear of the abdominal wall, hernia, hydrocele, peritoneal cyst, pseudocyst or other injury. Such a complication could require additional surgery.
- **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
- **Allergic reactions** – As with any implanted device, your body may react and cause an allergic reaction to the IPG or the stimulator system.
- **Alternative diagnosis:** The suspected diagnosis is based on radiographs and other information gathered prior to surgery. It is possible that this diagnosis could be wrong and you may have a different problem that may require different treatment.
- **Ataxia** – Difficulties with coordinated movements should be expected for a few days, but can last longer and even be permanent.
- **Balance problems** - Difficulties with balance or vertigo may occur as a result of the surgery. Nausea and vomiting may also occur after surgery.
- **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 surrounding the 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.
- **Cauda equina syndrome** - There is a risk of developing loss of perineal sensation and the inability to void urine or stool after a lower back surgery.
- **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. You will be positioned with a Mayfield clamp and do face unintentional risks of penetrating sinus cavities, skull fracture, intracranial hematomas, scalp lacerations, air embolism, and other complications due to previous intracranial pathology.

- **Death** - Although the risk is remote, death may occur during or soon after *any* surgical procedure.
- **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.
- **Erosion or malfunction** - Insertion of electrodes too deep into soft tissues tends to cause unpleasant muscle spasms during stimulation whereas placing them too superficially may result in lead or connector erosion. The lead may also disconnect from the battery.
- **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). SCS does not work for everyone. There is a chance that the signs and symptoms may reoccur.
- **Functional Loss** - It is possible to experience problems such as opening the mouth, chewing after surgery, facial weakness, decreased facial sensation, speech, language, and memory difficulties may occur after surgery. There is a possibility that the procedure may result in lost or diminished function of the affected nerve.
- **Hearing difficulties** – It is possible that some hearing loss/difficulties will be experienced after the procedure due to cranial nerve injury. This risk is much higher during a second operation.
- **Implantable Pulse Generator** - Battery failure and/or battery leakage requiring a surgical incision to remove and replace the battery may be needed in rare cases. Skin breakdown/erosion over the generator may occur which may also require surgery.
- **Increased pain** - It is possible, though unlikely, that pain or other symptoms will increase following the procedure.
- **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.
- **Migration** – The electrode lead may migrate from the original position resulting in loss of coverage, painful stimulation, and possible need for revision of surgery.
- **Nerve root injury** - The system may cause undesirable or unpleasant stimulation of the chest or rib area as a result of nerve root involvement. Injury to the nerve roots may result in weakness in the arm, paralysis in the affected muscle group or loss of sensation in the affected area.
- **Paralysis** - It is possible that some weakness, paralysis, clumsiness, 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.
- **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 or other symptoms. Undesirable changes in stimulation may occur over time due to scar tissue forming around the leads.
- **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.
- **Sinusitis** – In some procedures, the air-filled sinuses of the skull are opened. It is possible that you may experience an increase in sinus mucous production, pain, or sinus obstruction as a result of surgery.
- **Spinal cord injury** - There is a slight risk of injury to the spinal cord during this procedure, which may result in paralysis and loss of normal bowel and bladder functions.
- **Spinal fluid leakage** - There is a possibility that spinal fluid may leak through the surgical site and require drainage or additional surgery. You may develop headaches from leakage.
- **Stroke/hemorrhage** - Though unlikely, there is a possibility that a stroke or hemorrhage will occur during the procedure which may result from retraction and injury to an artery or venous plexus.
- **Swallowing Difficulties** –It is possible that the esophagus or cranial nerves involving the esophagus and surrounding areas may be perforated or injured during the surgery resulting in difficulty swallowing which could be permanent or transient.
- **Visual Disturbances** – It is possible that there may be some cranial nerve injury including changes in visual function, double vision, and decreased corneal reflex resulting in corneal injuries to the eye resulting from the procedure.

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 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 diseases, 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.

Signature of Patient/Next of Kin/Guardian

Date

Witness

Date