Twin Cities Pain Clinic

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Spinal Cord Stimulation Implant Informed Consent:

This informed consent is meant to inform you of the more common risks, consequences, complications and precautions related to spinal cord stimulation. Upon reading this and having any questions you may have answered by your pain provider, you should be able to give informed consent to have or not to have this procedure.

I _____, understand:

1) Spinal Cord Stimulation may reduce but not cure or eliminate my pain. If Spinal Cord Stimulation works for me, I may or may not experience a tingling sensation instead of the pain. Successful stimulation means that at least the majority of pain will be reduced and that there may be improvements in my ability to function as a result. It will not eliminate the primary source of my pain, however.

2) Spinal Cord Stimulation will not solve my personal or family problems. Because chronic pain may affect one's life and relationships with others, sometimes anxiety, depression and other effects of chronic pain occur and need to be addressed separately.

3) I have been selected as a candidate for Spinal Cord Stimulation because alternative therapies have not worked or are not recommended to control my pain.

4) To make Spinal Cord Stimulation possible, a lead/electrode will be placed into my epidural space around my spinal cord using a needle. During this procedure, my pain physician will shift the position of the lead and attempt to provide stimulation at different settings and areas of my body to determine the best location (if any) of the lead in order to reduce my pain. The procedure is performed under fluoroscopy (X-ray) to help my pain physician place the lead over the correct area.

5) I understand that I may be woken up briefly and asked simple questions for parts of the procedure (most people do not remember this happened). To reduce my discomfort, I will be given local anesthesia and a sedative to help me relax. I understand that I must tell my pain physician the level and location of pain and/or stimulation as I experience it.

6) I understand that following placement of the leads I will restrict my activities for SIX (6) to EIGHT (8) weeks after the operation, to reduce the possibility of lead movement.

Restrictions include:

- NOT raising my arms above my head.
- NOT twisting, bending, or stretching my body at the waist,
- NOT lifting items weighing more than five (5) pounds (equivalent to a milk jug or sack of potatoes)
- Avoid sitting for long periods of time
- NOT driving a car with the stimulator on (Medtronic/Boston Scientific/Nuvectra – dependent on settings).

7) I understand that different activities, body positions, and changes in underlying pain may require that I learn to adjust the stimulator intensity and rate with a handheld device (programmer).

Patient initials: _____

Risks:
Any surgical procedure has risks and this includes both the trial and permanent implantation of a Spinal Cord Stimulator. Any complication that can occur following surgery or anesthesia is possible; including but not limited to bleeding, infection and even death.

- Significant bleeding in the epidural space where the lead is placed can lead to nerve damage.
- Infection in the epidural space could potentially lead to meningitis or an epidural abscess. Any infection in the epidural space would require removal of the spinal cord stimulator system.
- Surgical complications associated with spinal cord stimulation include injury to the spinal cord, paralysis, accumulation of fluid in the battery site (seroma), and spinal headaches.
- Tenderness at the battery or lead insertion site is common until healing occurs, but persistent pain at the stimulator site is possible, as is tissue damage at the site of the stimulator lead and connecting cable(s).
- Mechanical complications with the system include dislodgment of the lead/electrode, breaks in the wiring, or problems with the battery.
- If an implanted battery/generator has been placed in me, this battery may require replacing over time. The life of my implanted battery will depend on the settings and hours per day I use my stimulator. Replacement of the battery/generator is a minor surgical procedure usually done as an outpatient.
- I will need to carry my Spinal Cord Stimulator ID card with me at all times. I should show this to airport officials, etc. if I set off their security system.
- I understand that when approaching theft detectors or security systems found in public libraries, department stores, grocery stores, etc. I may briefly feel an increase in my stimulation levels (a "shock" or a "jolt").
- I will avoid procedures/devices that may damage my Spinal Cord Stimulator such as diathermy, demand driven cardiac pacemakers, etc.
- I understand that my device may or may not be MRI compatible. I can speak to my device representative and clinic provider to determine these specifications.
- *Only applicable if I can feel stimulation*:
  - I will avoid driving motor vehicles or operating potentially dangerous equipment (e.g. power tools, etc.) when my stimulator is ON to avoid the risk of a sudden surge of stimulation.

I will inform my pain physician if any of the following occur:

- Excessive or increased Pain, swelling, or drainage at the incision sites. These symptoms may indicate infection.
- Loss of bladder/bowel control, or new weakness
- New persistent painful sensations
  - If this occurs, turn off the stimulator and call the clinic or on call provider if after hours
- Narcotic pain medications that I request from other physicians.

Patient initials: _____

I HEREBY STATE AND AFFIRM THAT I HAVE READ AND UNDERSTAND THIS DOCUMENT AND TERMS OF THIS AGREEMENT. I HAVE HAD THE OPPORTUNITY TO ASK MY DOCTOR QUESTIONS ABOUT SPINAL CORD STIMULATION AND THESE QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. I BELIEVE THAT I HAVE ADEQUATE KNOWLEDGE OF SPINAL CORD STIMULATION AND ITS POTENTIAL RISKS, COMPLICATIONS AND BENEFITS TO GIVE MY INFORMED CONSENT FOR THIS TREATMENT.

Printed Name:_____ Date of Birth: _____

Patient Signature:_____ Date: _____

Witness to above Signature:_____ Date: _____