Twin Cities Pain Clinic

7235 Ohms Ln, Edina, MN 55439

Tel: (952) 841-2345
Fax: (952) 841-2346
twincitiespainclinic.com

Spinal Cord Stimulation Trial 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 there will be a trial period to see if the Spinal Cord Stimulation is helping in my pain management. This will last from three to seven days and will be on an outpatient basis.

7) During the trial of the stimulator, I understand that I will need to restrict certain activities to avoid possible movement of the lead/electrode and loss of the stimulation.

8) I understand that for the duration of the trial I will:
   - NOT raise my arms above my head.
   - NOT twist, bend, or stretch my body at the waist,
   - NOT lift items weighing more than five (5) pounds.
   - Avoid sitting for long periods of time.
   - NOT drive a car with the stimulator on (Medtronic/Boston Scientific/Nuvectra – dependent on settings).

Patient initials: _____

9) I understand that I will be expected to monitor my response to the stimulation in a written or mental log. This log will record the level of pain relief that I experience at different settings and in different situations.

10) I understand that after the trial period the temporary stimulator will be removed. If the trial is successful, TCPC will then submit to my insurance for approval for the implantable device.

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

Risks:

Any surgical procedure has risks and this includes the trial 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.
- Surgical complications associated with spinal cord stimulation include injury to the spinal cord, paralysis, and spinal headaches.
- Tenderness at the external trial battery site or lead insertion site is common until the system is removed. If I notice persistent or increased pain at the lead insertion site, I should call the clinic.
- Mechanical complications with the system include dislodgment of the lead/electrode, breaks in the wiring or problems with the battery.
- I understand that when approaching theft detectors or security systems found in public libraries, department stores, grocery stores, etc. I may (though rare) 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 MRI scans, diathermy, demand driven cardiac pacemakers, etc.
- *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:

- Persistent pain or excessive bleeding at the lead insertion sites.
- Unusual changes in sensation or stopping of sensation.
- Painful sensations (turn off the stimulator, and then call the pain physician).
- 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: _____