

INFORMED CONSENT FOR SPINAL CORD STIMULATION TRIAL

The procedure involves implanting small electrodes on a wire near the spinal cord. This provides low-level electrical impulses to interrupt transmission of pain at the level of the spinal cord, before the impulses get to the brain. In successful procedures, painful sensations are replaced with a tingling sensation known as a paresthesia.

Before a permanent implantation can be performed, a trial implantation is needed to see if this device will be effective for your pain. If this trial spinal cord stimulation is successful, you will then be referred for a permanent implantation, in which new leads will be positioned, and a small stimulator device will be implanted under your skin.

Dr. _____ and/or an associate has explained the nature and purpose of this procedure, and has answered my questions. I do understand that this is considered an elective procedure. I understand my current condition for which I am having the procedure is no life threatening.

Possible side effects associated with this procedure include:

1. Breakage of an electrode or hardware failure.
2. Tear of spinal membranes and leakage of spinal fluid.
3. Scar tissue developing around the electrode.
4. Vasovagal reactions (fainting) could occur during or after the procedure with possible heart and blood pressure problems.
5. Reactions to medication include minor or temporary allergic reaction and/or a temporary decrease in blood pressure. These problems may require more aggressive treatment including IV or other medications.
6. Increased pain.
7. Less than one percent (1%) of patients may have a headache after the procedure. Treatment of the headache may necessitate additional procedures and/or hospitalization.
8. Infection eight around the injection site or deep in the spine is also a potential risk.
9. Other rare complications might include temporary or permanent nerve or spinal cord impairment, severe bleeding, seizures, stroke, paralysis, collapsed lung, bowel/bladder/sexual dysfunction and death.

I have discussed treatment alternatives with Dr. _____ including no treatment.

I, _____ consent to this procedure to be performed by

Dr. _____ and/or his/her associate.

As required by my physician, I am aware that I am **NOT** to drive myself home or operate a vehicle for 12 hours after the procedure.

Patient Signature

Date

Physician Signature

Date

Witness Signature

Date

<input type="checkbox"/> Time out process performed prior to procedure _____	_____ <small>Procedure room Tech/MA Signature</small>
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