



Affix Patient Label

Patient Name:

Date of Birth:

### Informed Consent: Spinal Cord Stimulator

This information is given to you so that you can make an informed decision about having surgery to have a **spinal cord simulator implanted**.

#### Reason and Purpose of this Procedure:

In spinal cord stimulation a small paddle (electrode) is inserted under the bone in the spinal canal. The electrode is connected to a pulse generator usually implanted under the skin in your hip over your pelvis. A small amount of bone is removed from the lamina to make room for the electrode. Small electrical currents are applied to the areas of the spinal cord involved in pain. These impulses stop pain signals going to the brain. They can relieve pain without the side effects of medication.

A rechargeable pulse generator has a battery that can be charged through the skin with a wireless power charger so that it does not need to be replaced surgically when it loses charge.

The non-rechargeable pulse generator has a battery life of between 2 and 5 years and may need replacement more often.

#### Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Significant relief from back and/or leg pain.
- Increased function during normal activities
- You may be able to reduce or end the need for pain medication

#### General Risks of Procedures:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thromboses. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke.
- Bleeding may occur. If excessive you may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

#### Risks of this Procedure:

- **Changes in stimulation may occur over time.** This could be related to changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, or lead failure.
- **Failure to relieve symptoms.** There is a chance that the surgery will not relieve the pain or other symptoms. You may need more surgery.
- **Increased pain.** Pain or other symptoms may get worse after this procedure.
- **Infection.** Infection may occur in the wound, either near the surface or deep within the tissues. This could include the bone. You may need antibiotics or further treatment.
- **Lead movement.** Movement of the leads can result in changes in stimulation. This could mean less pain relief.
- **Nerve root injury.** Injury to the nerve roots may cause pain, paralysis in the affected muscle group or loss of feeling in the affected area.
- **Recurrence.** There is a chance that pain, or other symptoms may come back. This may need more surgery.

- **Spinal cord injury.** There is a small risk of injury to the spinal cord. This could mean you would be paralyzed. Your bowel or bladder may not work correctly or at all.
- **Spinal fluid leakage.** A spinal fluid leakage may cause a spinal headache. You may need more surgery to fix this.

**Risks Associated with Smoking:**

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and blood clot formation. Smoking has also been shown to slow down or stop the bone fusion.

**Risks Associated with Obesity:**

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

**Risks Associated with Diabetes or Immune System Compromise:**

The risk of infection and slow wound healing are increased in patients with:

- Diabetes
- Chemotherapy or radiation therapy
- AIDS
- Steroid use

**Risks Specific to You:**  

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**Alternative Treatments:**

Other choices:

- Physical or Occupational Therapy
- Pain Management
- Do nothing. You can decide not to have the procedure.

**If you Choose not to have this Treatment:**

- Your doctor can discuss alternative treatments with you.

**General Information**

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

**Medical Implants/Explants**

I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

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**By signing this form, I agree:**

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.

I want to have this procedure: **Spinal Cord Stimulation with**  **Rechargeable pulse generator**  
 **Non-rechargeable generator**

\_\_\_\_\_

- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

**Provider:** This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Relationship:  Patient       Closest relative (relationship) \_\_\_\_\_       Guardian/POA Healthcare

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: \_\_\_\_\_ ID #: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**For Provider Use ONLY:**  
I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.  
Provider signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Teach Back:**  
Patient shows understanding by stating in his or her own words:  
\_\_\_\_\_ Reason(s) for the treatment/procedure: \_\_\_\_\_  
\_\_\_\_\_ Area(s) of the body that will be affected: \_\_\_\_\_  
\_\_\_\_\_ Benefit(s) of the procedure: \_\_\_\_\_  
\_\_\_\_\_ Risk(s) of the procedure: \_\_\_\_\_  
\_\_\_\_\_ Alternative(s) to the procedure: \_\_\_\_\_  
**OR**  
\_\_\_\_\_ Patient elects not to proceed: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_  
*(Patient signature)*  
Validated/Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_