SPINE SURGERY OF IDAHO
A PIONEER AND LEADER IN EFFECTIVE TREATMENTS

STEPHEN MARANO, M.D. JAMES COOK PA-C

Patient Consent for Surgical Neurostimulation Procedure

Patient Name: _____

After careful consideration, I have decided to undergo surgery to try to lessen my chronic pain. I authorize Dr. Marano and such assistants as may be selected and supervised by him to perform my surgery. I have been advised to carefully read and consider this operative consent form for the neurostimulation procedure. I realize it is important that I understand this material. I also understand that if certain sections are not clear to me, I have the opportunity to ask for clarification. I understand that Stephen R. Marano, M.D. is my doctor, and that he will participate in and supervise my hospital and surgical care. I understand that, in his absence, other designated physicians and/or assistants might be involved in my follow-up care.

I understand that I am scheduled to undergo:

implantation removal revision temporary trial

of a neurostimulation system by Dr. Marano to try to provide relief from my chronic pain symptoms, which include pain in the (circle the appropriate ones below):

head face neck upper back chest lower back arms legs

- I understand that the goal of the procedure is not to cure or completely eliminate my chronic pain. The goal of the procedure is to try to reduce my pain to a more tolerable level.
- I understand that even with the best efforts and with the most competent care, there is no guarantee that the procedure will result in any improvement.
- I understand that even though Dr. Marano and his team are competent in treating my condition, medicine is still an inexact science; much is still unknown about the function of the nervous system and how individuals react to various forms of treatment.
- I understand that treating chronic pain is a difficult, time-consuming and sometimes less-than-rewarding process, both for the patient and for the physician. Sometimes a lot of efforts are spent with minimal or no positive results. Sometimes treatments can paradoxically result in temporary or permanent worsening of the condition. Of course, every effort is made to avoid such circumstances.
- I understand that, even though most of the time implantation of neurostimulation devices is performed safely and with minimal side effects, some risks do exist. They include but are not limited to the following:

1. Medical complications, including pneumonia, clot formation in the veins of the legs, pulmonary embolism, and urinary tract infections.
2. Paralysis of the arms or legs, or impairment of bowel/bladder and/or sexual function.

3. Death. This is an extremely rare occurrence, and its risks increase with age, with severity of the pre-existing problems (particularly severe heart and lung problems) and with the occurrence of postoperative medical complications.
4. Loss of sensation in the arms and/or legs.
5. Infection. The risk of infection increases with the length and complexity of the operation, as well as with other risk factors (for example, diabetes, poor nutrition, advanced age, pulmonary or cardiac disease). Infection can be limited to the wound or the implanted hardware, or spread to the nervous system (meningitis) and/or the blood (sepsis). Depending on its severity, infection may be treated with oral or intravenous antibiotics, or might require removal of the implanted hardware.
6. A severe infection might require removal of the stimulator, followed by a regimen of intravenous antibiotics. If the implant was providing satisfactory results, it can possibly be reimplanted a few months after the infection has subsided. For a variety of reasons, however, a second implantation is technically more difficult, with reduced chances of success.
7. In the case of implantation for pain control, there might be aggravation of the original pain or occurrence of new pain areas which may include the operative site(s). This is a rare event, which has been experienced mostly by patients with Reflex Sympathetic Dystrophy or Thoracic Outlet Syndrome. In patients with these conditions, the surgery can "flare up" the pain. In most instances, the aggravation is temporary; however, it could be permanent.
8. Leakage of spinal fluid. This is related to implantation or removal of the system. It is usually managed by conservative measures. If persistent, it must be treated with temporary insertion of a catheter in the spine, or by surgical repair.
9. Overstimulation might result in a burst of excessive stimulation, which could result in sudden, very strong jolts, which could potentially be strong enough to throw the person to the ground and cause permanent damage. Jolts can occur with sudden changes in position, and can be due to slight shifting of the nerves and/or the spinal cord, or shifting of the lead in the early postoperative period. Sometimes individuals might perceive jolts or surges for which no apparent cause can be identified.
10. Breakage of the leads or other parts of the implanted hardware. This usually results in the loss of stimulation.
11. Malfunction of the implanted pulse generator. This could result in: loss of stimulation or erratic stimulation bursts of excessive stimulation. This could result in sudden, very strong jolts which could potentially be strong enough to throw the person to the ground and cause permanent damage.
12. Excessive bursts of stimulation can also be caused by metal detectors and other anti-theft devices located in stores, libraries and airports, to mention just a few locations.

- I understand that the above list is not comprehensive of all possible complications that can occur during or following implantation of a neurostimulation system. This is due to the variety of medical problems encountered in a patient population, and to the complexity of the therapeutic modality involved.
- I understand that the subject of MRI imaging following the implant is controversial, and that the manufacturers of neurostimulation devices advise that no MRI should be performed following implantation.

- I also understand that controversy exists about the use of the stimulator during pregnancy. I have had opportunity to discuss this issue with Dr. Marano (applicable only when appropriate).
- I understand that patients with pain problems occasionally require a great deal of narcotic medications to suppress their pain. These narcotic medications (e.g. Percocet, Codeine, Demerol, etc.) can be addicting. Medications will be provided on a temporary basis to suppress the pain associated with surgery. However, narcotics will not be prescribed for long-term use.
- I have a physician who is responsible for the overall management of my pain condition and medications. I understand that Dr. Marano will not be involved with the long-term management of my pain condition.
- I understand that in a small percentage of patients, the results of the temporary test trial cannot be replicated with the permanently implanted device. The reasons for this are unknown and are most likely related to changes in the nervous system that make it refractory to the benefits of the stimulation.

I have carefully read/viewed the material on neurostimulation given to me by Dr. Marano and I have had the opportunity to ask questions about the upcoming procedure. I have been given a copy of this consent if asked for, so that I can further review it at my leisure. If I have further questions or issues, I will contact Dr. Marano and/or his team.

I understand that alternative methods of treating my condition(s) exist. They have been considered and discussed, but at the present time, my choice is to proceed with the neurostimulation implant.

I have carefully read this 3-page consent form and feel comfortable that I understand the risks and implications of the surgical procedure proposed by Dr. Marano.

I consent to the administration of anesthesia by the hospital's anesthesia team. They will explain the anesthetic procedure, risks, and possible complications to me separately.

Dr. Marano has gone over the procedure and risks with me in person. My signature below authorizes my acknowledgement and agreement of the above-mentioned factors, and I hereby consent to the neurostimulation procedure to be performed by Dr. Marano.

Name_____ Signature _____

Date_____Relationship to patient _____
(if not signed by patient)