Patient Consent for Surgical Neurostimulation Procedure

DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTAND ITS CONTENTS

Name: _____ Date of Birth: _____

Physician: ***Dr. Amit Bhandarkar***

The planned procedure: *Implantation /removal/ revision/temporary trial*

_____

_____

Diagnosis: _____

After careful consideration, I have decided to undergo surgery to try to lessen my chronic pain. I authorize Dr. Bhandarkar and any assistants as may be selected and supervised by him to perform my surgery. I understand that Amit W Bhandarkar 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 acknowledge and understand that the above procedure or treatment has been explained to me (sometimes referred to as the patient) in layman's terms. This information is given to me so that I can make an informed decision about having a neurostimulation procedure to treat my chronic pain. I also acknowledge that I had the opportunity to ask for clarifications and all my questions have been answered to my utmost satisfaction.

Neurostimulation is a procedure used to treat persistent pain in the low back and/or legs caused by pinched nerves in the spine. It is only performed when non-surgical therapies haven't improved symptoms.

I understand that the physician, medical personnel and other assistants will rely on statements by the patient, the patient's medical history, symptoms, and other information in determining whether to perform the procedure or the course of treatment for the patient's condition and in recommending the procedure or treatment which has been explained.

Expected outcomes

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 treating chronic pain is a difficult. 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.

Risks/Complications

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:

Anesthesia:

Risks of cardiac arrest/failure, pulmonary failure and/or death. 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.

I understand I may receive conscious sedation based on the nature of the procedure.

Nerve, spinal cord complications

Nerve root injury which could result in: numbness/tingling/pain in one or both legs, weakness in one or both legs, loss of bowel, bladder and/or sexual function.

Spinal Cord Injury- this may lead to paralysis and loss of bladder and bowel and sexual function.

Scarring around nerve roots (epidural fibrosis/arachnoiditis) which could result in intractable and untreatable leg pain/ numbness.

Dural tear (cerebral spinal fluid leak) which if unrecognized or persistent despite repair could result in headaches. 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.

Other Spine related complication

Progression of spinal stenosis at the same or other levels.

Instability may occur after decompression which might need fixation with instrumentation at the same time or subsequently by a different surgery.

Wound complications and 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).

Superficial (skin) infection which could result in: need for additional antibiotics or possibly further surgery.

Deep (below the skin) infection which could result in: abscess formation, bone infection or infection of the spinal cord or nerve roots that could result in paralysis and/or death. *Deep infection would result in need for additional surgery(s) and might seriously jeopardize the expected result of the surgery. There may be a need for prolonged IV antibiotics.

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 replanted 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.

Dehiscence or re-opening of the wound after closure. can increase the risk for infection and will need to be examined for treatment including repeat surgical closure.

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.

Aggravation of pain

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.

Overstimulation

This 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.

Failure and malfunction of the device

Breakage of the leads or other parts of the implanted hardware. This usually results in the loss of stimulation.

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.

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.

Blood Loss & replacement

Blood loss during or after surgery can result in the need for blood transfusion or replacement.

Blood from the blood bank would be used and although rare can expose you to the risk of blood borne disease such as hepatitis and AIDS.

General surgical complications:

- Atelectasis - mechanical pneumonia
- Pulmonary embolus (blood clot in the lungs) which can lead to death.
- Deep vein thrombophlebitis (blood clot in the leg).
- Complications related to urinary catheter.
- Urinary tract infection, sepsis/death.
- Heart attack due to strain on the heart
- Stroke or transient ischemic episodes (TIAs)

Other potential complications:

- Erectile dysfunction.
- Swelling.
- Gastrointestinal bleeding from the stress of surgery.

There are many more complications that could occur but they occur so infrequently that are not listed or discussed.

Complication prevention:

It is important for you to follow all the instructions provided to you by your surgeon and other care providers. Instructions are provided to assist you in your recovery and reduce the risks of surgical complications. Knowing the complications to be aware of and signs of potential complications help you to identify any problems early. Early discovery and intervention can potentially reduce the severity of complications if they do occur.

General complication prevention strategies: Pre-op

Reduce pre-operative anemia by taking oral iron supplements. This can reduce the need for blood transfusions/replacement.

Maintain good blood sugar control if you are diabetic. Elevated blood sugar can increase your risks for infection. Impair your wound healing. Increase the potential for organ failure such as kidneys.

Maintain good nutritional status before your surgery. This will help your immune system to aid in healing after surgery.

Stop smoking. Smoking can increase your risk of infection. Smoking can increase your risk of blood clots. Smoking can increase your risk of pneumonia. Smoking can impair oxygen to your wound causing delayed or poor healing of the incision. Smoking can increase the risk of surgical failure.

Alternatives to Proposed Surgical Care:

Rest and anti-inflammatory medications
Exercise/physical therapy/re-conditioning
Spinal Bracing

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 procedure. If I choose not to have the procedure, I have been informed that my prognosis (my future medical condition) is still fair.

MRI after surgery

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.

For women only

I represent to my physician that I am not pregnant nor am I breast feeding at this time, and understand that there are risks of sedation or of the procedure to an unborn child.

I also understand that controversy exists about the use of the stimulator during pregnancy. I have had opportunity to discuss this issue with Dr. Bhandarkar (applicable only when appropriate).

Pain medications

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.

Failure of trial

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.

Devices

Implants, devices and/or pharmacologic agents may be used in a manner considered to be an “off-label use” by the FDA. “Off-label use” refers to using a drug, implant or device for a reason not specifically approved by the FDA. The decision of whether or not to use an implant, device or pharmacologic agent for an off-label use is a matter of medical judgment.

Additional procedures

I understand that the practice of medicine is not an exact science and that no guarantees or assurances have been made to me concerning the results of this procedure or treatment. I understand that during the course of the procedure or treatment described above it may be necessary or appropriate to perform additional procedures or treatments that are unforeseen or not known to be needed at the time this consent was given. It may also be necessary or appropriate to have diagnostic studies, tests, anesthesia, x-ray examinations and other procedures performed in the course of my treatment. I consent to and authorize the persons described herein to perform such additional procedures and treatments, as they deem necessary or appropriate.

Depending on the patient's diagnosis and the procedure or treatment to be performed, it may be necessary or appropriate for tissues and specimens to be removed from the patient's body. I consent to the removal, testing, retention for scientific or teaching purpose, and disposal of such tissues and specimens within the discretion of the physician, facility or other healthcare provider.

Photography

I consent to the taking of photographs or the use of video recording equipment during the procedure for the purpose of medical education.

Summary

I have been counseled regarding the nature of the condition for which surgery is proposed. I understand the alternative(s) to surgery. The basic steps of the proposed procedure, the advantages, disadvantages, risks, possible complications, and alternative treatments have been explained and discussed with me by **Dr. Amit Bhandarkar**. I understand that there can be no guarantees on a surgical outcome or that a surgical complication will not occur. I understand that the proposed surgical procedure may not completely relieve all the pain I am experiencing and that the possibility exists that the pain I currently have could be the same or worse after the surgery.

I have carefully read/viewed the material on neurostimulation given to me by Dr Amit Bhandarkar 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. Bhandarkar and/or his team.

Patient's Printed Name: _____

Signature of Person Giving Consent Date and Time (and relationship to the patient if person giving consent is not the patient)

_____

If the person giving consent is not the patient, state the reason why the patient is unable to consent:

_____

Witness' Printed Name/Signature/ Date and Time:

_____

*Witness' Signature Date Time *Consent valid for 30 days from date of signature.*