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SPINE TEAM
CONSENT FOR SPINAL SURGERY

PATIENT: _____ DATE: _____

1. _____ I have been strongly advised to carefully read and consider this operative permit. I realize that 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 clarifications. As I read each section, I will place my initials in the space provided to indicate that I understand what I have read.

2. _____ I am fully aware of the condition of my spine, and after careful consideration, I have decided to undergo surgery to try to improve my condition. I herby authorize my doctors and their assistants to perform my surgery.

3. _____ I understand that this permit will discuss spinal surgery in a general way including cervical, thoracic, lumbar or sacral disk removal; occipital, cervical, thoracic, lumbar or sacral decompression including foraminotomy, facetectomy and/or laminectomy, anterior or posterior occipital, cervical, thoracic, lumbar or sacral fusion with extension to the occiput or sacrum/the use of metal or other non-metallic implants or substances anteriorly or posteriorly to assist in fusion, deformity correction, or stability success; the use of instrumentation that may not be approved by the Food and Drug Administration such as posterior occipital, cervical and thoracic screws (e.g. occipital screws cervical lateral mass screws, pedicle screws in the cervical and thoracic spine) as well as various bio-implants, posterior spinal instrumentation with use of screws. This may also include the use of instrumentation or other spinal implants in other areas of the spine, which to date have not been approved by federal government, but which the surgeon believes is in my best interests as a patient.

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4. _____ I understand that my doctors may be able to more comprehensively evaluate the problems within my spine at the time of surgery. During the operation, they may deem it necessary to vary the exact nature of the procedure in order to best treat my problem and to obtain the best chance for a good outcome with the smallest possible operative risk. I therefore consent to the performance of surgical procedures in addition to, or different than, those now contemplated. If presently unforeseen conditions arise during my surgery, I authorize, and fully consent to, my doctors and his associates performing the necessary procedures.

5. _____ I understand that medical or non-medical personnel may be present to observe and assist with surgery. I also understand that pictures or videotapes of my surgery or x-rays may be used for educational purposes. I give my consent to these educational efforts and realize that they in no way affect my care. My identity will not be disclosed if my x-rays, pictures or videotapes are used at any time.

6. _____ I understand that I am free to seek other opinions about the proposed surgery and that my doctors encourage me to do this if I wish.

7._____ My doctors have discussed and fully informed me about the nature of my problem, the proposed operation, all known alternative treatments and the possible complications of both operative and non- operative care of my problem.

8. _____ Reasonable alternative treatments and their risks, consequences and probable effectiveness have been discussed with me including doing nothing, conservative therapy with drugs and/or exercise and/or nerve blocks or injections. I do not wish to engage in the alternative treatments.

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9. _____ I understand that, in general, the surgery is to help relieve pain and to improve function, but I also am aware that after surgery there may be unresolved symptoms or worsening of symptoms as well as other sensations which may have not been present before surgery. I understand that less common problems may occur as a result of surgery such as muscle weakness or paralysis, airway difficulties, hematoma, prolonged intubation, numbness, hoarseness (i.e., superior or recurrent laryngeal nerve palsy), lack of improvement or worsening myelopathy or neurogenic claudication, esophageal, great vessel or nerve injury or difficulty swallowing with anterior cervical procedures, spinal fluid leakage, loss of bowel or bladder control, arachnoiditis (i.e., scarring of the nerves in the dural sac) and , in men, impotence, loss of sexual function and retrograde ejaculation. I also understand that other problems may require additional treatment or even another operation. I am aware that it may not be possible to cure or totally correct my spinal problem and depending on the type of pathology, i.e. tumor or infection, there may be recurrence or spread.

10. _____ In procedures requiring bone grafting, I understand that healing of my bone graft into a bone fusion is largely a biological function of my body. Failure of the bone graft to heal may result in persistent symptoms necessitating additional surgery.

11. _____ I understand that other general problems may occur with any surgery such as death, deep venous thrombosis (blood clots), stroke, phlebitis, embolism, infection (wound, discitis, osteomyelitis, epidural abscess), pneumonia, stroke, cardiac arrest, anesthesia problems, worsening vision or blindness, blood loss, allergic reaction to medications or materials and diseases transmitted by blood transfusions or other means.

12. _____ I have had ample opportunity to discuss my condition, treatment and surgery with my doctor(s), his/their associates, and with my family. All of my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base my decision regarding the proposed operation and to sign this permit.

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13. _____ It has been determined that, to best treat my spinal problem, a fusion may be necessary. A fusion is an operation designed to eliminate movement between two or more adjacent vertebrae. My doctor may take bone from my body or use bone from a cadaver and place this around vertebrae that are meant to be fused. Thereafter, my body must complete the healing process. Unfortunately, not all fusions heal. Excessive motion, smoking, steroid use and the use on non-steroidal anti-inflammatory medications within six to ten weeks of surgery and certain medical conditions such as diabetes and renal disease may act to cause the fusion not to heal. In an effort to provide the highest probability that my fusion will heal, my doctor has determined that the use of a spinal fixation device, bio-implant or fusion enhancer maybe appropriate. These devices, or substances, may consist of screws, hooks, connecting rods, plates, wires, various polymers, cement, bio-implants (absorbable or non-absorbable) or various bone graft alternatives, enhancers or extenders. These devices may be anchored by screws or other attachments inserted into the bony pedicles, vertebral bodies, the cranium or the lateral masses of the vertebral bodies. Rods, plates, or wires may than be connected to these implanted screws or anchors, thus constructing a rigid framework to hold the bones immobile until the fusion heals. It is my doctor's conviction that the use of the fixation devices will significantly increase the probability that my fusion will heal. My doctor has completed a fellowship in spinal surgery. His elected practice is primarily the evaluation and treatment of spinal disorders. By this virtue of his special training and extensive practice experience, he has developed the knowledge and ability to safely use these internal fixation devices and bio-substances. Any fixation device may fail or break. If my fusion does not heal, the graft, screws wires, rods, cages, intervertebral devices or plates may break or disengage and there may be loss of spinal correction. This may cause injury to the surrounding soft tissue structures. When my doctor implants these devices, there exists the possibility of injury to the bones, nerves or adjacent tissues such as blood vessels, tendons or ligaments. There also is the possibility that these devices may need to be removed at a later date. Alternatives to use of fixation devices include the use of no internal fixation at all or the use of brace or cast. I do not wish to engage in these alternatives.

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14. _____ The Food and Drug Administration has not approved screws for use in certain pedicles of the spine or in several spinal disorders. The use of methyl methacrylate or bone cement is also not approved by the FDA for use in the spine. These devices and substances are considered investigational by the FDA. Pedicle screws are approved for use in the sacrum and various lumbar disorders. It is quite common, and legally and medically appropriate, to use FDA approved devices, substances or mediations for uses other than those for which they are specifically approved. My doctor believes that use of a pedicle fixation device, occipital screw attachment, lateral mass screw, or other devices or substances within my spine will significantly improve the chances that my fusion will heal or my condition will improve. In spite of the risk inherent in their use and in spite of the investigational nature of the devices, I am aware that my physician strongly believes that he can safely use them to increase the probability that my fusion will heal.

15. _____ Pre-operative and post operative bracing may be prescribed for any spinal disorder. I have been instructed on the use of this immobilization device, when I must wear it, and various activities that are contraindicated during the bracing period. I consent to such bracing.

16. _____ Donor site complications may result from harvesting my bone which includes numbness and tingling, pain, infection, nerve damage, damage to the vessels and muscles and pelvic or bony instability due to bone loss.

17. _____ My surgeon, due to his interest in spinal research, may ask me to participate in research protocols sponsored by various spinal research societies, industry or of his own design. If I decide to participate in such research, I understand I will be asked to read and sign separate consent from that has been approved by, a committee that approves and monitors research in which humans are involved.

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18. _____ My surgeon, due to his experience and expertise in spinal research, has designed many spinal implants and procedures that may or may not be approved by the FDA which may be utilized in my spinal procedure. I am aware that my surgeon at times maybe participating as a paid consultant or have a financial interest in the development of products that may be used in my planned spinal procedure.

19. _____ During my surgery, neurologic monitoring may be necessary to protect my spinal cord or nerves from injury. I understand that, although neurologic monitoring is useful to provide information on the status of my spinal cord or nerves during surgery, there are risks to its uses including infection, tongue or oral laceration, seizures or failure of the monitoring to effectively determine the status of my spinal cord or nerve roots. For certain technical reasons including the severity of my spinal disease, monitoring may not be able to provide useful information or may fail to provide reliable signals during the course of my surgery. In this event, my surgeon would be blinded as to the status of my spinal cord or nerves. I understand that this may increase the risk of a permanent neurological deficit from surgery. I have had the opportunity to discuss my wishes with regard to halting surgery or continuing with the planned procedure in the event that spinal cords signals are not available or become lost during the planned procedure. The method of neuro-monitoring may not be FDA approved and may require specific anesthetic protocols necessary for optimal neurologic assessment.

20. _____ I understand smoke and nicotine exposure from cigarette, cigars, nicotine patches, chewing tobacco, and other forms of smoke/nicotine may significantly worsen the outcome of my surgery. It is my responsibility to avoid these and other sources of smoke, nicotine exposure. If I choose not to avoid these sources of smoke and nicotine, I understand that my actions may increase my risk of infection, poor healing, scarring, persistent pain, bony non-healing, failure of the surgery. I am aware that it is medically important that, to achieve my best possible recovery after discharge from the hospital, I must avoid all potential sources of smoke and nicotine.

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21. _____ I understand the necessity for my compliance with the post-operative and post-discharge directions that have been explained to me, including among others, possible immobilization, and/or physical therapy, and/or required medications. I am aware that it is medically important that to achieve my best possible recovery after discharge from the hospital I must continue on the regimen prescribed for me.

I have read and fully understand the information presented above.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date

_____ _____

Physician Signature Date