Desert Institute for Spine Disorders, PC

PATIENT INFORMED CONSENT FOR SPINE SURGERY

Surgical treatment has been agreed upon and selected by you and Duane Pitt M.D. to address your symptoms or condition. This form will serve as an educational tool for you, and will contain important information for you to read. All pages will need to be signed by you prior to surgery signifying you have read and understand the contents of each page and all questions have been answered. We also invite you to visit our website prior to your pre-operative visit with the physician. This site provides more information that will likely answer other questions you may have. Go to www.AZSpineSurgeon.com for this information.

You should not sign this form if all items, including all questions, have not been answered to your satisfaction, or if you do not understand any of the terms or words contained in this consent form.

Procedure:_____

_____

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The risks listed below are the significant risks for surgery of the cervical, thoracic, lumbar, or sacral spine. These risks have been reported in the literature world wide and are recognized by most spine surgeons as **potential yet uncommon risks** of surgery that patients will need to be aware of prior to making a decision to undergo surgery. Explanation of each risk is noted in the following pages. **The risks include, but are not limited to:**

- Nerve Injury
- Paralysis
- Loss or change in Speech (Applies to Anterior Cervical Spine surgery)
- Hoarseness
- Blindness
- Dural leak
- Retrograde Ejaculation (Applies to Lumbosacral Procedure through the Abdomen in Men)
- Arterial Thrombus
- Hardware failure
- Fusion failure (aka Pseudarthrosis)
- Need for further surgery

Below is a list of complications that are recognized as being related to most surgical procedures in general, and should be considered by you prior to your decision

for a surgical procedure. This list is not created to be exhaustive. Though uncommon, these risks are significant and possibly fatal.

- Infection
- Bleeding
- Gastrointestinal Problems
- Allergic Reaction
- Pneumonia
- Pulmonary Embolism
- Blood clots
- Renal Failure
- Heart Attack
- Stroke
- Coma

EXPLANATION AND CLARIFICATION OF SIGNIFICANT RISKS:

Nerve Injury: This is any injury to a nerve regardless of origin or timing that results in pain, weakness, or numbness. This could occur as a result of your disease process, pre or post surgical inflammation, or direct injury to the nerve. Its occurrence or prognosis can not be predicted with any accuracy. This is a rare but known risk of spine surgery.
Paralysis: This is the loss of normal muscle strength, which could vary in severity. Depending on the level of surgery, this can be complete loss of motor function below the surgical level, or may be limited to a particular motor group powered by one or more nerve roots. This is a rare but known risk of spine surgery.
Loss or change in Speech: This risk is limited to surgery of the cervical spine (neck) through an Anterior (Front) approach. This is a known risk of Anterior Cervical Fusion, and could result in permanent loss or change in speech or more likely temporary hoarseness or change in Speech.
Hoarseness: Temporary change in normal vocalization is a common problem as a result of intubation and the surgery. Hoarseness as a result of intubation usually resolves with time, but in rare cases it can result in a permanent change in speech.
Blindness: This is a newly documented complication of spinal surgery which cause has yet to be clearly explained. It may be a result of large surgical procedures that require large blood volume changes and long anesthesia times in the setting of hypotension (low blood pressure), and preexisting vascular disease of the eye. This is a very rare risk, and has been reported in the Orthopaedic and Anesthesia literature.
Dural leak: The dura is the sack that covers the spinal cord, and nerve roots. A clear fluid called CSF(Cerebral Spinal Fluid) bathes the cord and nerves within the dura. This column of fluid in the spine communicates directly with the brain which produces this fluid. If there is a leak of this fluid, it can result in severe headaches and light sensitivity, but does not usually result in nerve injury. This is treated with direct repair, bed rest, or a CSF(Cerebral Spinal Fluid) shunt. This is a rare risk, and is commonly associated with patients undergoing a revision decompression surgery (laminectomy), or after a epidural, spinal tap, or myelogram.

Retrograde Ejaculation: This rare risk is mainly for males undergoing lumbar surgery through the abdomen, and normally resolves with time. Retrograde ejaculation is synonymous with sterility, and may require an Urologist evaluation after surgery.
Arterial Thrombus: This risk (blood clot in the artery) could affect one or both legs and is evaluated and treated by the Vascular surgeon who will be responsible for your vessels during the lumbar surgery performed through the abdomen. This could result in a vascular related compartment syndrome which will also be treated by the Vascular Surgeon. This is also a rare event. An assessment of patients at risk will be performed by your primary care physician if you are over 30 years of age.
Hardware failure: The metal implants used for your surgery intended to give you temporary support and stability while your bone graft heals, may break or loosen if the bone graft does not heal. This may be an early sign that you have not healed (pseudarthrosis), and you may need more surgery in order to deal with the issue.
Fusion failure (Pseudarthrosis): If the bone graft does not heal to your vertebrae, it could result in pain, and require more surgery and bone grafting and new metal implants. (See hardware failure above). Those patients at increased risk of pseudarthrosis are smokers and/or diabetics. The risk of pseudarthrosis is different for each patient and depends on other medical issues.
Need for further surgery: Due to the nature of degenerative arthritis and the fact that the spine will naturally progress into further degeneration due to normal wear and tear, very few if any spinal procedures will result in a permanent fix to all of your spinal issues. Many patients will re-experience different or similar pain that may require further surgery to manage their problem. This can occur soon after a surgery or many years or decades later. Some of the other risks of surgery outlined in this document my necessitate the need for further surgery
Infection: This is a standard risk of all surgery, and for spine surgery it occurs <1% of the time. Those patients that are smokers and/or diabetics are at an increased risk. This may require further surgery and antibiotics as indicated. An assessment of patients at risk will be performed by your primary care physician if you are over 30 years of age.
Bleeding: This is a normal and correctable risk of surgery. Bleeding after surgery could result in nerve injury and require further surgery. Some patients have a predisposition to bleeding. All aspirin type medications which include anti-inflammatory must be discontinued 7 days prior to surgery to decrease your bleeding risk. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Allergic Reaction: Allergies to various drugs used for anesthesia, pain control, and infection control have been reported in the literature, and could change the normal outcome of surgery. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Pneumonia: Lung infections could result after surgery, and will be treated aggressively. Pneumonia can result in death, and this risk is higher in smokers and diabetic patients. An assessmenr for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Pulmonary Embolism: Development of a blood clot in a vein (not an artery) can lead to the clot traveling to the lung resulting in severe problems which can include death from lack of oxygen. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Blood clots: This refers to clots in the veins of the leg, which cause pain, cramping, or a piece of the clot breaking off and floating into the lung, which is Pulmonary

Embolism, as previously noted. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Heart Attack: Otherwise known as Cardiac Arrest or Myocardial Infarction that can result in death. It is a lack of blood carrying oxygen (ischemia) to the muscle of the heart. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Stroke: Is similar to the description of a heart attack above, but occurs in the brain. An assessment for those patients at risk will be performed by your primary care physician if you are over 30 years of age.
Coma: An unconscious state of the brain where there is limited to no response to external stimulus.

If you think you have, or have had any of the above risks following your surgery, you must notify our office and your primary care physician as soon as possible.

FDA (Food and Drug Administration): The FDA has been slow to approve many medical devices (i.e. instrumentation) within the modern field of Spinal Surgery, as well as other subspecialties in medicine. The safe and efficacious use of many "off label" medical devices has been well documented in the spine pier review literature, and have been accepted as the "standard of medical care" by the leading spine experts in the United States as well as world wide for many years. Such instrumentation systems has been scrutinized and tested mechanically for durability, and biomechanically in both animal and human models for safety prior to wide spread use. It is because of the use of many such medical devices for spine surgery and research that we are able to advance and improve the specialty, for the care of our patients.

Commonly used non-FDA approved devices includes, but not limited to:
1. Pedicle Screws

2. Cervical lateral mass screws

3. Bone Morphogenic Protein (BMP)

ADDITIONAL PROCEDURES: If my physician discovers a different, unsuspected condition at the time of surgery, I authorize him to perform such additional procedures as he deems necessary, to potentially help my condition.
Except:_____
(If none, leave blank)

OTHER MEDICAL PROVIDERS: You are responsible for reviewing your insurance benefits regarding coverage for other providers (Anesthesiology, Pathology, Medicine, 1st Assistants, etc) who may be involved in your care. Keep in mind that during your hospitalization there may be other providers involved in your case that are integral to your outcome, that may not be contracted with your insurance carrier, and you will be responsible for part or all of their bill.

The first assistant we use is not an employee of Desert Institute for Spine Disorders. Stefan Farrell CRNFA-CNS is a subcontractor, and may not be contracted under your plan which is the case for the majority of surgical 1st assistants in Arizona. He has been an integral part of my success and has assisted me on over 98% of all of the surgeries I have performed in the last 10 years, providing unparalleled continuity of care for my patients. If you have any questions concerning your financial responsibility for his services, please contact him at (480) 844-9817.

It is not always possible to have everyone involved in your care contracted with your insurance.

RESULTS NOT GUARANTEED: I understand that no guarantee or assurance has been made as to the results of the procedure, and that it may not cure the condition.

All questions presented to my physician have been answered to my satisfaction, and by signing each page of this form, I have read, thoroughly understand, and accept the potential risks of my upcoming surgery.

Patient Name:_____

Patient Signature:_____ Date:_____

Witness:_____ Date:_____