

Patient Information on Lumbar Spinal Fusion Surgery
BRETT A. TAYLOR, M.D.

Patient's Name: _____

Diagnosis: _____

Nature of Treatment Proposed: _____

(Performed by Dr. Taylor and Dr. Taylor's Spine Team)

Layman's Description: _____

Other treatment options and their risks: _____

Dr. Taylor believes every patient has the right to determine what should be done with his or her body. This information is provided to help you understand the risks of your upcoming operation. It may also help you uncover areas you do not understand. This is an educational tool to be used in addition to your discussions with Dr. Taylor and his staff.

“This is an informed exercise of choice”

Please initial after reading and agreeing to each numbered item if Dr. Taylor and his staff have answered your questions and concerns. Please include the consent by signing your name with a witness present.

1. _____ My Surgeon has informed me that the decision to have this surgery is mine and I am proceeding with this surgery at my request. **I am consenting that I choose to have surgery, and I feel I have exhausted non-surgical treatments.**
2. _____ Reasonable alternative treatments and their risks, outcomes, and probable benefits have been discussed with me, including doing nothing, conservative therapy with drugs and/or exercise and/or nerve blocks or injections.
3. _____ Medical personnel may be present to observe surgery. Pictures or videotapes of your surgery or x-rays may be used for educational purposes. These educational efforts in no way affect your care. Your identity will not be disclosed if your x-rays, pictures or videotapes are used at any time.
4. _____ There is no one right answer regarding treatment for spinal problems. Dr. Taylor has provided me with his suggested management of your problem. I am aware that I am free to seek other opinions about the proposed surgery; **Dr. Taylor and his team encourage me to do this if I wish.**

5. _____ I understand that after surgery I may have continued problems or worsening of symptoms. I understand that less common problems which may occur as a result of surgery include: paralysis, numbness, change in voice or loss of voice, difficulty swallowing [up to a **50%** risk of voice or swallowing problems with neck surgery], spinal fluid leakage, loss of bowel and bladder control, scarring of the nerves in the dural sac [*arachnoiditis*], loss of sexual function, and infertility [retrograde ejaculation]. Other problems might develop within your spine, which may require additional treatment or even another operation. You understand that it is **not possible to cure or totally correct your spinal problem.**
6. _____ More serious risks of surgery include: blindness, DVT (blood clot), pulmonary embolism, phlebitis, infection, pneumonia, stroke, anesthesia complications, blood loss, allergic reaction to medications or materials[implants], and diseases transmitted by blood transfusions or other means.
7. _____ I consent to the spinal surgery despite the risks mentioned here and any other risks associated with surgery.
8. _____ In procedures requiring bone grafting, healing of your bone graft into a bone fusion is largely a function of your body. Failure of the bone graft to heal may result in persistent symptoms requiring additional surgery.
9. _____ Patients that have any of the following may be at risk of surgical wound infections: **diabetes, cigarette smoking and the use of nicotine products, obesity (>20% ideal body weight)**, systemic steroid use, tooth abscess, urinary tract infection, older than age 65, nutritional status and transfusion of certain blood products.
10. _____ I understand and **agree** to refrain from smoking ,using tobacco products, or nicotine patches prior to my surgery and for a period of at least 6 months following my surgery.

a. Patient's Signature

11. _____ Dr. Taylor has determined that to best treat your spinal problem is with a fusion. A fusion is an operation to remove movement between two or more spine bones. Dr. Taylor will take bone from your body or bone from a cadaver and place this around spine bones that are meant to be fused. Too much motion, failure to wear brace, smoking, steroid use, and certain medical conditions such as diabetes and renal disease may cause the fusion to not heal. In an effort to provide the best chance that your fusion will heal, Dr. Taylor may use metal screws and or rods are appropriate. Spine fixation devices consist of screws, hooks, rods, plates, or wires with or without the use of bone cement, in your surgery. These devices

have the potential to break, become loose, or not work. When Dr. Taylor implants these devices there is the possibility of injury to bones, nerves, or tissues such as blood vessels, tendons, or ligaments. In addition, these devices may need to be taken out at a later date. Alternatives to use of these devices include the use of no internal fixation at all or the use of a brace or cast.

12. _____ It is quite common and legally and medically appropriate to use FDA approved devices or medications for uses other than those for which they are specifically approved. Dr. Taylor believes that he can safely use BMP, bone morphogenic protein, and screws in the spine in spite of the investigational nature of these devices in these areas.
13. _____ Studies show that Bone morphogenic proteins [BMP] works as well as autograft [your own bone] in achieving bone fusion However, BMP in the setting of a laminectomy [spine nerve decompression] may cause unwanted bone growth at the decompression site. Additionally, in the setting of a dura tears, it may result in bone growth within the dura around your nerves. When BMP is used in neck surgery, it may cause increased complications including requirement for further surgery. BMP usage has the risk of excessive overactive bone formation as well as antibody formation. There is a concern about BMP crossing the placenta and affecting the development of the fetus, as well as metastatic potential for some cancers. **Women should avoid pregnancy for at least 18-24 months after the use of BMP.** The significance of antibody formation is unknown.

Please check the following boxes if they apply to you:

- No history of cancer/malignancy
- (Women of childbearing age) I agree to avoid pregnancy for 18-24 months after surgery.

Patient's Signature

14. _____ PEEK, cage (polyetherketone), is a polymer material that has had a long and successful application in various medical technologies including cardiac surgery and dental implants. The stiffness of PEEK is very similar to bone and for this reason we feel it might offer patients an improved rate of fusion. It is radiolucent [does not show up on x-rays] and biocompatible. If you have further questions about this PEEK material or its application in your surgery, please discuss this with Dr. Taylor or his staff prior to signing this form.
15. _____ Patients who undergo surgery for herniated discs have a 25% risk of recurrent disc herniation at the same site. Patients who undergo fusion surgery can have up to a 40% risk of breakdown with arthritis above or below the fusion within 10 years of surgery.
16. _____. Usage of narcotics prior to surgery will increase your risk of a pain problem after procedure. Dr. Taylor will prescribe pain medication after your operation for 8 weeks

(2 months). **Additional narcotic pain management beyond 2 months will require a consultation with a pain specialist.**

17. _____ I understand that I must obtain HIBICLENS Soap and that I am to scrub my back/neck as instructed on the directions. I understand that this may help to reduce my risk of infection.
18. _____ I understand that I may require one or more blood transfusions during or after my spine surgery. Dr. Taylor may ask that I donate my own blood in preparation for my surgery. My questions/concerns about blood donation/transfusion have been answered by Dr. Taylor or his staff.
19. _____ I understand that Dr. Taylor may ask that I see a family doctor (Internal medicine doctor) or an anesthesiologist to obtain medical clearance before my surgery. I also understand that this medical clearance is not a guarantee against a complication or medical problem during my stay.
20. _____ I understand that once my pain is controlled on an oral pain medication, I will be able to go home. If I am unable to go home due to weakness or inability to properly care for myself at home, I may be transferred to either a rehabilitation unit or a skilled nursing facility until I can function and care for myself at home.
21. _____ I understand that risks/complications are possible with spine surgery and these risks/complications listed on this, Taylor Spine Consent form, have been explained to my satisfaction.

Business hours are Monday-Friday 8:00 a.m. – 4:30 p.m., except holidays.

IMPORTANT: Refills of medications need to be done during business hours

NO pain medications will be given over the phone after hours or on weekends.

a. **Patient's Signature** _____

b. **Witness' Signature** _____

The above information is provided to help you understand the complications associated with spine surgery and to highlight areas where you feel you need additional information. This information is provided to educate you on the risks of surgery that can result in injury. As well you should know about any risk that might effect your decision to undergo surgery.

Pain Management

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

Dr. _____ is prescribing a controlled substance/medications to me for the diagnosis of _____

This decision was made because other treatments have not been effective for my diagnosis. I understand this and any medical treatment is initially a trial, and that continued prescription is contingent on evidence of benefit. Failure of pain symptoms to diminish in response to my prescriptions within reasonable doses will cause by doctor to choose another form of treatment.

Initials _____

I will only obtain prescriptions for pain medications from the doctor signing below, and will only fill my pain medicine prescriptions at this pharmacy:

_____ Ph. No.: _____

I have told the prescribing doctor about all other medicines and treatments I am receiving and will continue to keep the prescribing doctor informed of any changes made. I am aware any medication is unlikely to provided complete pain relief. I have been informed f the potential risks and benefits of treatments not involving these medications. I will obtain approval from my primary care physician prior to filling my prescriptions.

Initials _____

I am aware that the use of such medicine has certain risks associated with it such as sleepiness or constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, physical dependence, tolerance to analgesia, and addiction. I am aware of these medications may impair my ability to drive a vehicle, operate heavy equipment, to be safe in a hazardous work environment, or care for another person.

Initials _____

I am aware that certain other medications such as nalbuphine (Nubain), pentazocine (Talwin), buprenorphine (Buprenex), and butorphanol (Stadol), may interfere with my prescriptions, will not take any of these medicines, and will inform all my other doctors of my prescriptions and that I cannot take any of the medicines listed above.

I am aware that addiction is defined in part as the use of a medicine even if it causes harm of feeling the need to use the medicine even if not in pain. I am aware that the chance of becoming addicted to my pain medicine is very low, has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.

Initials _____

Because these drugs have potential for abuse or diversion, strict accountability is necessary. I will protect these medications from damage, loss or theft and will not be prescribed refills earlier than the refill due date in any case. Any sale or intentional distribution of these prescriptions will result in termination of care and further prescriptions by the prescribing physician and this practice group. Blood and/or urine tests may be done at anytime to evaluate for non-prescribed substances, and/or adverse responses to these prescriptions.

Initials _____

If the responsible legal authorities have questions concerning your treatment, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.

Initials _____

I understand that physical dependence is a normal result of using opioid medicines for a long time. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. I am aware that opioid withdrawal may include many different symptoms of illness, and is uncomfortable but not life threatening.

Initials _____

__ (Males Only) I am aware that chronic opioid use has been associated with low testosterone in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

__ (Females Only) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medications; the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid

Initials _____

Renewals are contingent on keeping scheduled appointments, and calls for prescriptions and/or refills are only received between the hours of 8:30 am and 4:00 pm, Monday through Friday

I have read this form or have had it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for the treatment of my symptoms with one or more controlled substances, and agree to all terms of the treatment agreements detailed above.

Patient Name (Printed): _____ DOB: _____

Patient Signature: _____ DOB: _____

Physician Signature: _____ DOB: _____

Physician Name (Printed): _____

If you are taking narcotic pain medication before surgery, you are at greater risk of pain management problems after surgery. As well, Dr. Taylor, will provide 6—8 weeks of pain medication after your surgery. If you need additional narcotics after 2 months, we will refer you to a pain specialist or refer you back to the physicians who originally prescribed your narcotic pain prescription.

Please list below any narcotic pain medication that you are currently taking and the name of the doctor who prescribed it to you.

Name of Pain Medication:

Prescribing Doctor's Name:

Dr. Taylor believes your present narcotic requirements are significant. We will need your pain management specialist to prescribe your postoperative narcotic medications after you are discharged from the hospital.

Patient's Signature: _____ Date: _____

Patient's Name (Please Print) _____

DOB: _____

Dr. Taylor's CT Protocol

Dr. Taylor may require a CT scan at the following intervals after surgery: 3 months, 6 months, 12 months, & 24 months. Dr. Taylor uses this test to assess for bone fusion

Please be aware that undergoing plain radiographs, CT scans, including plain CT, CT myelogram and a CT scan following a Discogram does result in exposure to radiation. Although these tests are performed to offer a more detailed view of spinal anatomy, the cumulative exposure to radiation should be monitored. Presently, the risk estimates for the development of cancer from ionizing radiation exposure in the form of medical imaging procedures are unknown.

Dr. Taylor Disclosure

Please be aware that Dr. Taylor and his partners, order, direct, and refer patients for treatment, testing, and/or rehabilitation at facilities in which he has a financial documented interest. These financial interests include partial ownership in facilities which perform imaging tests, provide DME services, and surgical centers.

Facilities: CT and MRI Partners, Imaging Partners of Missouri, & St. Louis Spine and Orthopedic Surgery Center.

You as a patient or employer of a patient have the right to refuse care at these facilities.

To all insurers, please notify any repricer you choose of Dr. Taylor's Disclosure provided.

Complex Elective Case

□ **If applicable**

Dr. Taylor feels you are at an increased risk for a poor outcome or a major complication. You are requesting an elective surgical procedure because you cannot live with your present symptoms and feel you have failed all non-surgical treatment therapies. Dr. Taylor has encouraged you to exhaust non-surgical management. However, you are refusing this option and want surgery instead of non-surgical care.

ALL PATIENTS UNDERGOING A SPINAL FUSION

Significant number of patients who undergo spinal fusion will have a poor outcome. Failure to improve after spinal fusion may be a result of non-union or pseudarthrosis which is failure of the bones to fuse. This can occur in up to 60% of patients depending on the number of levels fused and/or the use of internal screws and rods. Other risks for failure of the bone to fuse include:

- advanced age
- chronic diseases (for example, diabetes, renal disease, etc.)
- use of nonsteroidal anti-inflammatory medications
- use of other medications (for example, corticosteroids)
- use of nicotine products (for example, cigarettes, cigars, chewing tobacco, nicotine gum, patches, etc.)
- patient's overall bone quality

We ask that all patients undergoing spinal fusion contract with us to stop using all anti-inflammatory medications, as well as all nicotine products for up to six months after surgery.

By signing this document you are agreeing to avoid the use of these products prior to your surgery and for 6 months after your surgery to give you the best chance of a good fusion outcome. As well you agree to comply with periodic laboratory studies to verify that you have no nicotine products in your system. If you do not feel that you can comply with this request, please do not pursue spinal fusion surgery.

Dr. Taylor encourages patients to understand fully the risks of surgery before proceeding with any type of surgical intervention. Below you will find a brief list of some of the many complications which can occur with spine surgery. Please review these complications and discuss with Dr. Taylor further any questions or concerns you have regarding your particular case.

The risks of surgery include:

- Harmful reactions to anesthesia
- Lung problems including inflammation, infection or collapse of the lung, blood clots in lung
- Infections of the wound or the skin around the wound
- The wound may not heal and open
- The tissues around the wound may die
- There may be swelling
- Blood clots can form in the legs. These clots can travel to the lung or brain
- Inflammation of a vein
- Changes in heart rhythm, including heart attack and death
- Strokes
- Complications of pregnancy
- Seizures, convulsions
- Loss of memory, confusion
- Hallucinations
- Changes in mental ability

Risks of allograft bone include:

- Transmission of hepatitis, HIV infection or AIDS
- Brain diseases
- Syphilis or bacterial infections
- Immune rejections
- Resorption of the transplanted tissue resulting in breakdown of the bone

Risks associated with surgery from the front of the spine through the abdomen include:

- Damage to the tissue around the abdomen
- Infections
- Scars can form and affect (negatively) the function of the abdomen
- Hernias
- Bowel problems
- Difficulty with bowel function including control of bowels
- Difficulty with urination including retention, inability to urinate or control urination
- Damage to the tube that carries urine from the kidneys to the bladder
- Damage to the kidneys
- Formation of kidney stones
- Nerve damage that results in sexual dysfunction
- Infertility or sterility
- Bleeding around the spinal cord resulting in temporary or permanent paralysis
- Warm or abnormal sensation in the groin or legs

Risks associated with metal implants in the spine include”

Loosening

Malposition

Migration or movement of the metal implants

Implants can break or fall apart. They can create debris

Your body can respond to the implant with an allergic reaction or inflammatory reaction termed
a foreign body response

The tissue reaction can form tumors

The bone can dissolve

The implants can sink into the bone

Risks of surgery on the spine include:

Damage to the membranes covering the spinal cord or leakage of spinal fluid

Failure of the bone to fuse

Infection or inflammation around the spinal cord, nerve roots or brain

Loss of alignment of the spine or loss of reduction in the spine

Slippage of vertebrae

Nerve root damage

Opening of the covering around the spinal cord

Scar formation

Problems with vision including blindness

Herniation and degeneration of levels above or below the surgical area

Abnormal growth of the nerves

Bleeding

Infection

Damage or failure of the wound to heal

Narrowing of the spinal canal causing nerve compression

Risks of Infuse Bone Morphogenic Protein include:

Abnormal bone or cell growth

Fusion at levels above or below the surgical area

Narrowing of the spinal canal

Fluid retention

A foreign body reaction

Anti-body formation

Formation of blood clots

The bone may break down around the region

The tissues including the nerves may stick together due to Infuse use

Allergic reactions

Irritation and inflammation

The need for further surgery

Patient Name: _____ DOB: _____

Patient Signature: _____ Date: _____

Staff Signature: _____ Date: _____

Physician Signature: _____ Date: _____

Off Label Use

Physician Discussed Use

- Dr. Taylor is using the following in off label use for your surgery:
 - BMP Use
 - Total Disc Replacement (included multilevel TDR)
 - Hybrid Technology/Disc Replacement and Fusion

- Dr. Taylor has a relationship with the device manufacturer.

- Dr. Taylor has no financial relationship with the device manufacturer.

- You have been **instructed** why this product is being used for your surgery.

- You have been **informed** of all the options for your surgery.

- You are **choosing** that this product is used for your surgery.

- Standard outcome measures are being used to follow results of product use.

- Patient has reviewed TST website education module.

My doctor feels this option would give me the best outcome therefore I,
_____, choose/decline the use of this product.

Patient name

Patient's Signature & Date

Patient Signature after completion of website module.

Patient's Signature & Date

