(Extreme Lateral Interbody Fusion /Direct Lateral interbody fusion / Anterior to Psoas interbody fusion/ Oblique Lumbar interbody Fusion. )

***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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

After careful consideration, I have decided to undergo surgery to try to lessen my pain and disability. 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 lumbar spinal fusion procedure to treat my spine related pain instability pain and stenosis. I also acknowledge that I had the opportunity to ask for clarifications and all my questions have been answered to my utmost satisfaction.

***Lumbar Fusion surgery*** is a procedure used to treat instability and disc degeneration in the spine leading to persistent back pain which is often associated with numbness and pain in legs caused by pinched nerves in the spine. It is only performed when non-surgical therapies haven't improved symptoms.

***Surgical Approach***

General anesthesia is used to keep you asleep and comfortable during the procedure. An optimal incision is made to the outer aspect of the back on the lateral side at the level identified to be causing the problem. The surgeon may take 1, 2 or 3 incisions based on the technique used to approach the spine for decompression and instrumentation. Stab incisions can be placed in addition to insert the screws.

***Decompression: An*** optimal portion of the bone/facet joint over the nerve root (where the nerve exits the spinal cord) and/or disc material from under the nerve root is removed to give the nerve root more space and provide a better healing environment. Indirect decompression may be achieved by reduction of the slip and increasing the disc height of the disc.

***Discectomy***  The offending disc is maximally removed. The endplates of the discs will be made raw for good healing surface.

***Spacer – cage insertion*** may be introduced in the disc space after removing the disc to promote fusion. The type and material of the cage to be inserted will be determined based on the specific needs and characteristics of the disc space. Usually titanium/PEEK /optimesh are used.

***Instrumentation*** Screws and rods will be inserted in the back to give it stability.

The purpose of the spinal instrumentation

(Metal hardware) is to hold the spacer in the disc space and prevent its extrusion at the same time

Temporarily make the segments of the spine stiff until the bone fusion heals.

Reduction of the slip may be attempted, limited by the stretch on the nerve roots. Complete Reduction of the slip of the vertebrae is usually not needed.

***Bone grafting*** will be done in spine joints and disc space so as to achieve fusion and make one bone. Bone from the bone bank is used to form the fusion. This bone may be supplemented with a bone graft or bone marrow harvested from the iliac crest (pelvis- the flat bone on each side) The purpose of the bone graft harvest is to obtain bone to pack around the spine so that the vertebrae heal together. Risk of infectious disease transmission from cadaveric bone is very minimal.

***Expected outcomes***

Fusion involves make the segment of the spine permanently stiff. It results in some permanent loss of motion of the spine.

The goal of decompression and fusion surgery is to improve or eliminate symptoms caused by pressure on the nerve root(s) and to provide stability to back. Some patients have immediate pain relief and patients wake up after the surgery feeling significant relief of their leg pain. Symptoms such as weakness and /or numbness can sometimes take time to improve depending on how much damage the pressure caused to the nerve. Sometimes symptoms may improve but do not ever go away completely. This procedure is more likely to help the leg pain as compared to back pain. Some patients may take longer time to get relief from the back pain.

Supplemental Procedures that may be required

* Urinary catheter
* Neuromonitoring equipment and needle electrode placement
* C- arm – X-ray imaging
* Drains
* local anesthetic infiltration at the incision site
* Bone marrow aspiration
* Bone graft harvesting – separate incision
* Inter Costal Drain placement
* ***Staged Surgery***
* A combination of anterior and posterior approaches may be indicated. This may be done:
*  On the same day under one anesthetic
*  Five to seven days apart
*  Eight to twelve weeks apart

***Risks/Complications***

The following are some but not all the risks associated with this procedure

***General anesthesia:***

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

***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.

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, and/or need further surgical care.

***Wound complications:***

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.

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.

***Pseudoarthrosis:***

– This means the bone fusion doesn’t heal. This could result in continued pain, hardware loosening or breakage and would lead to additional surgery. (Smokers are at four times the risk than non-smokers).

***Adjacent Segment Disease: There*** is a chance of the segments of spine which are near the fusion may degenerate and cause pain which may need surgery to fix it. The chances of they going bad with time is 3% per year.

***Instrumentation failure:*** There is chance that the instrumentation which is inserted to fix the spine may become loose or even break if the fusion does not heal in due time needing further surgery. Patients with osteoporosis may need bone cement augmentation to increase the strength of the instrumentation to increase the pullout strength of the screws. Bone cages in the disc space may subside in patients with osteoporosis.

***Risks to the nearby structures;*** Important viscera which are in close proximity to the area to be instrumented or operated upon are always at risk of getting an iatrogenic injury while doing the procedure. This may include but not limited to injury to major blood vessels, ureter, and colon. Injuries to these structures if recognized intraoperative are repaired immediately- but the injury is catastrophic and may even cause death.

***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.

Continued pain after surgery due to failure of the procedure to relieve pre-operative complaints of pain.

Progression of spinal stenosis at the same or other levels.

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

Prone position related complications

- include swelling of the face. Even blindness has been reported although very rare.

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

***Specific Complication related to Lateral approach***

1. ***Injury to the femoral nerve/ilioinguinal nerve./ iliohypogastric nerve due to approach***
2. ***Thigh muscle weakness and numbness temporary or permanent- lumbo-sacral plexus injury***
3. ***Hematoma ( blood clot)in the Psoas muscle***
4. ***Incisional Hernia***
5. ***Injury to nearby structures including but not limited to – URETER/ COLON/ BLOOD VESSELS/ LUNG/***
6. ***Graft Subsidence – caving of the spacer inside the Bony end plate.***

***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 surgical lumbar neuro-decompression. If I choose not to have the procedure, I have been informed that my prognosis (my future medical condition) is still fair

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.

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.

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

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 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.

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Patient or Authorized person Date

Signature

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Relationship to patient if authorized person signature