

LUMBAR SPINE SURGERY

Informed Consent Document

Form No: AOF-001

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PATIENT PROTOCOL NO		DATE	
TURKISH ID / PASSPORT NO		DATE OF BIRTH	
PATIENT'S FULL NAME		SEX	
DIAGNOSIS			

1. Dear Patient,

It is your most natural right to be informed about your medical condition and about all medical / surgical treatments and diagnostic procedures proposed to you for the treatment of your illness. After learning the benefits and possible risks of medical treatments and surgical interventions, it is again your own decision whether or not to consent to the procedure to be performed.

The purpose of this explanation is not to frighten or worry you, but to involve you in a more informed way in the decisions to be made concerning your health. If you wish, all information and documents concerning your health can be given to you or to a relative you deem appropriate.

Although this form has been prepared to meet the needs of most patients under most circumstances, it should not be regarded as a document containing the risks of all forms of treatment. Depending on your personal health condition, your physician may give you different or additional information.

After learning the benefits and possible risks of diagnosis, medical treatment and surgical interventions, it is your own decision whether or not to accept the procedures to be performed. Except in situations involving legal and medical necessity, you may refuse to be informed or withdraw your consent at any time.

This form has been prepared to inform you about the risks of the surgery and about alternative treatment methods. Please read this form completely and carefully, and sign this consent form only after you have read it and after all your doubts about the procedure concerned have been resolved by your physician.

2. General Information About the Disease and Its Treatment

Lumbar spine surgeries are performed to relieve pain, numbness and loss of strength, particularly in the legs or hips. I have understood that my surgeon will perform one of the following surgical methods.

[Mark the applicable one]

☐ **Decompressive Lumbar Laminectomy:** This procedure is performed to relieve complaints caused by a narrowing of the spinal canal, a condition called spinal stenosis. Narrowing of the spinal canal often goes hand in hand with aging and is characterized by degenerated (herniated) discs, thickened ligaments, and the formation of bony protrusions due to calcification in the bones surrounding the spinal cord. During the operation, following a skin incision made in the lower back, the bony protrusions and thickened ligaments pressing on the spinal cord and nerve roots will be removed.

□ **Lumbar Disc (Herniated Lumbar Disc) Surgery:** This operation is performed to relieve the pressure on the nerve roots caused by disc herniation (herniated lumbar disc). Between the bones of the spine there are soft, jelly-like structures called discs, which act as natural shock-absorbing cushions. The soft central part of the discs can, for various reasons, herniate through the relatively harder disc wall surrounding it and press on neighbouring nerves. During the procedure, the surgeon will make a skin incision in the lower back and, working between the muscles and the vertebral bones, remove the herniated disc fragments using a microscopic technique.

I am aware that no guarantee has been given that the outcome of the intervention will be favourable. I also accept that, should a currently unforeseen or unexpected situation arise, my surgeon and his assistants may perform an intervention different from what has been described above.

3. Alternatives to the Surgery, If Any

As alternatives to the surgery, I have considered the following options:

- Not undergoing this surgery, accepting all the risks that my physician explained to me verbally
- Trying to relieve pain or muscle spasm through medication
- Doing exercises to strengthen the lower back and back muscles
- Trying to relieve the complaints with physical therapy methods
- Having steroid and local pain-relief injections
- Other possible treatment options

I have also considered the other treatment methods explained to me by my doctor. The advantages and disadvantages of these alternative methods were also explained to me by my doctor.

4. Expected Benefits of the Surgery

The expected benefit is an improvement in the patient's current neurological condition and complaints. The surgery is performed with the aim of eliminating the complaints and with the expectation of preserving or improving the function of the nervous system.

WITH THE SURGERY TO BE PERFORMED;

- To relieve the neural structures under compression
- To eliminate or reduce pain

The aim is that the neurological deficits existing before the surgery (paralysis, loss of strength, numbness, loss of reflexes, urinary incontinence, etc.) and complaints such as pain and spasm be completely resolved by the surgical treatment to be performed, or that their worsening be halted.

5. Estimated Duration of the Surgery

The duration of the procedure to be performed may vary depending on the disease and the patient's condition, and is on average – hours.

In addition, the procedures to be carried out on patients before and after the surgery by the anaesthesia doctors are not included in this time. Depending on the circumstances of the case, the procedure may take longer than the stated time. Your doctor will give you detailed information at the end of the procedure.

6. Risks and Complications of the Surgery

Alongside its benefits, the surgical procedure to be performed also carries potential risks.

Anaesthesia risk: There are risks during and after local and general anaesthesia procedures (due to the position given to the patient during surgery). In addition, in every form of anaesthesia and in sedation, there are also complications and harms that may arise from the drugs used. The anaesthesia procedure to be applied and the related risks and complications have been explained to me, and I approve the procedure proposed in this regard.

Bleeding: Although very rare, I am aware of the existence of a risk of bleeding, which may be severe, during or after my surgery. In the event of bleeding, additional treatment or a blood transfusion may be needed. In such a case, I approve the necessary blood transfusion and other treatments. Some medications that I use and/or that need to be used during my treatment may increase the risk of bleeding through drug interactions and/or side effects. In some cases, it may be necessary to use blood-thinning medications earlier than expected, and this may also increase the risk of bleeding.

Blood clot formation: Blood clots can form after any type of surgery. Clots forming at the bleeding site can obstruct blood flow and lead to complications such as pain, oedema, inflammation or tissue damage. If the use of blood thinners is discontinued, the risk of clotting may increase.

Postoperative Neurological Deterioration: Due to problems such as bleeding at the surgical site, nervous system functions may deteriorate after the surgery.

Respiratory problems: After surgery, respiratory distress or pneumonia, which are usually temporary, may occur. Pulmonary embolism (blockage of the blood vessels of the lungs) may occur.

Cardiac complications: The surgery carries a low risk of causing an irregular heart rhythm or a heart attack.

Death: Although very rare, there is a risk of death during or after the surgery.

Failure of the surgery

Increase in pain complaints: Although rare, pain complaints may increase after the surgery.

Infection: Infection may occur at the skin incision site as well as in the surgical area, and even in the bone in the surgical area. Risks related to infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (accumulation of pus).

Nerve root injury: This may cause pain in the leg, weakness in the related muscle groups, and sensory disturbances in the related dermatomes (nerve territories).

Spinal cord injury: Although very rare, paralysis due to spinal cord injury may occur during the surgery.

Cauda equina syndrome: Although very rare, due to nerve damage during the surgery or pressure on the nerves from a blood clot (hematoma) accumulating in the surgical area after the surgery, weakness in the legs together with loss of control of urination and defecation (bladder-bowel dysfunction) and sexual dysfunction may develop. This condition may require emergency intervention (additional surgery) and may be permanent.

Risk of cerebrospinal fluid leak: After the surgery, cerebrospinal fluid may leak from the wound site to the outside. For its treatment, a spinal (spinal cord) catheter or an additional intervention to repair the same wound site may be required.

Recurrence, Residual (Remnant): After the surgery, symptoms may reappear and additional surgery may be required.

Injury to organs or major vessels: Although rarely seen, injury to organs or vessels within the abdominal or thoracic cavity may occur. These risks can lead to death.

I have also understood that, during my surgery, in the face of an unexpected situation such as bleeding, injury to adjacent tissue or organs, etc., my doctor may perform other procedures necessary for my health beyond the planned procedure, and I approve this.

I have understood and accept all of the risks written above that may occur during and after the surgical procedure to be performed on me.

7. Consequences of Not Undergoing the Surgery

The patient's current complaints and clinical condition may not improve, and there may be a worsening.

8. Important Characteristics of the Medications to Be Used

If you have a previously identified drug allergy, you must inform your physician and your nurse about this.

During your current treatment process, medications appropriate to the patient's medical condition (painkillers, antibiotics, medications supporting the circulation and the heart, blood products, intravenous fluid therapies, medications specific to your disease) will be given according to the reason for admission or newly developing conditions. During the use of medications, side effects may occur and cause damage to the heart, kidneys and other organs. New medications will be added to the treatment to correct organ damage.

PROPHYLAXIS: Before and after your surgery, appropriate preventive antibiotic treatment is administered in order to reduce the risk of surgical site infection.

USE OF BLOOD-THINNING MEDICATIONS: If you are using anticoagulant, blood-thinning medications, different drug treatments or blood products may be given to you to counteract the effects of these medications.

SPINAL CASES: In the event of severe pain after spinal operations, medications sold with a green prescription (the Turkish controlled-substance prescription), which may be addictive, may be used. After spinal surgeries, in cases where weakness in the arms and legs does not change, or where new weakness develops, anti-oedema medications may be used. In this case, the blood sugar balance may be disturbed.

INTENSIVE CARE-DELIRIUM: In elderly patients and during prolonged intensive care stays, for psychological symptoms that may arise in patients, mental health-regulating medications recommended by a psychiatrist (physician for mental and nervous disorders) may be used. These medications may damage the heart, kidneys and other organs.

In addition to these, anaesthesia-related drugs are used. The narcosis (general anaesthesia) drugs given during surgery may have toxic (poisonous) effects / side effects on organs such as the lungs, heart, brain, kidneys and liver. For this reason, a **DANGER OF DEATH** may arise.

I have informed my doctor about all my known allergies. I have also informed my doctor about the prescription medications I use, over-the-counter medications, herbal medicines, dietary supplements, illegal drugs, alcohol and narcotics/sedatives. The effects of using these substances before and after surgery were explained to me by my doctor and recommendations were made. During my stay in the hospital, I received information about the important characteristics of the medications to be used for diagnosis and treatment (what they are used for, their benefits, their side effects, how they are to be used).

9. Lifestyle Recommendations Critical for the Patient's Health

Tobacco and Tobacco Products: It was explained to me that smoking tobacco and tobacco products (cigarettes, waterpipe, cigars, pipe, etc.) before or after my surgery may cause my recovery process to be prolonged. I know that if I use any of these substances, I have a greater risk of encountering wound-healing problems. In patients who smoke, anaesthesia risks are higher, and death due to anaesthesia is seen more frequently. If you smoke, you should know that the success of your treatment/surgery will be lower than the general average success rate.

Follow your doctor's recommendations (exercise, nutrition programme, etc.) and, if applicable, do not neglect your outpatient clinic check-up on the date requested of you.

I have received information about what I need to do regarding my lifestyle after my treatment/surgery (diet, bathing, medication use, mobility status and/or restrictions).

10. Patient-Specific Section

The patient's individual specific circumstances are recorded at the end of the form under **Section 14 — Signatures**.

11. How to Access Medical Help on the Same Matter When Needed

Refusing the treatment/surgery is a decision you will make of your own free will. If you change your mind, you may personally reapply to our hospital / to hospitals capable of performing the treatment/surgery in question.

I have received information on how to access medical help on the same matter when needed (my own physician, a different physician, the clinic where I am being treated, and, in emergencies, 112).

12. Permissions

I authorize the Head of the Surgical Team, Responsible Specialist Doctor **Dr. Özgür Akşan**, and his team to perform my surgery.

I understand that this intervention is performed with the aim of eliminating my complaints and with the intention of preserving or improving the function of the nervous system. I have understood that my disease described above and the intervention to be performed in relation to it involve many risks and complications, which I have read in this form and which were subsequently explained to me by my physician. I am also aware that the outcome of this procedure may not be as desired, both because of the natural course of my disease and because of complications that may be encountered at every stage of the procedure. I confirm that my doctor has explained all of the above information, that I have understood this information, and that all of my questions regarding this intervention have been answered. I certify that I understand this treatment agreement and that I am satisfied with the explanations I have received. Therefore, I give my consent to **LUMBAR SPINE SURGERY** and to all different or additional operations and supplementary treatment interventions that my doctor deems necessary. I have read and understood the content of the Informed Consent form. My doctor has answered all my questions. I am deciding of my own free will. I know that I have the right to refuse this proposed intervention or to withdraw at any time. I know that, once the intervention has begun, the withdrawal of the consent I have given is subject to the condition that there is no medical objection to doing so.

Use of tissue: Any tissue not required for medical diagnosis in the treatment of my condition may be used for medical research, provided that the research has been reviewed and approved by an ethics committee within the framework of ethical rules. I give my consent to the publication of the research results in the medical literature as long as the patient's identity remains confidential. I am aware that I may refuse to participate in such a study and that this refusal will in no way affect my treatment. I give my consent to the use of any tissue, medical device or body parts that may have been removed during the surgical procedure.

Medical research: I give my consent to the review of clinical information from my medical records for the advancement of medical study, medical research and physician education, provided that confidentiality rules are observed.

Photography/Observers: I consent to the surgery to be performed, including appropriate parts of my body, being photographed or video-recorded for scientific, medical or educational purposes, provided that the images do not reveal my identity. At the same time, I approve the admission of qualified observers into the operating room during the surgery for the benefit of advancing medical education.

13. Consent Verification

I know the alternative treatment methods and their risks.

I know the risks and side effects of the intervention.

I know the probability of success and failure.

I know what may happen if I am not treated.

I understand that the procedure to be performed may carry no guarantee of cure.

I have understood everything that has been told to me.

My doctor has answered all my questions.

My doctor explained everything written here to me one by one, in a clear, understandable and explanatory manner that I could comprehend.

I know the meaning of the Informed Consent form.

I have been informed about the approximate cost of the treatment.

I am deciding of my own free will.

I had enough time before the intervention to obtain a second opinion within a reasonable period, and to calmly consider what is written here, together with its advantages and disadvantages.

I have read and understood the content of the Informed Consent form.

I understand and accept that any additional intervention beyond those described in this form may be performed only to prevent serious harm to my health and to save my life.

I understand and accept that there is also a possibility that some or all of the intervention or interventions intended in this form may not be able to be carried out, in order to prevent serious harm to my health and to save my life.

All blanks in this form were filled in before I signed it, and I have received a copy.

Signatures

A) Patient-Specific Conditions

The patient writes in their own handwriting any personal conditions (allergies, medications, previous surgeries, etc.). If there are none, writing "NONE" is sufficient.

B) Handwritten Declaration

The patient writes the following sentence in their own handwriting:

"I have read this form carefully, I have been informed about LUMBAR SPINE SURGERY, my questions have been answered, and I consent to this procedure of my own free will."

C) Signatures

	Full Name	Signature	Date / Time
Patient			
Patient's Legal Representative / Relative (Relationship:)			

	Full Name	Signature	Date / Time
Head of Surgical Team, Responsible Specialist	Dr. Özgür Akşan		