

PSE — LUMBAR STABILIZATION

Informed Consent Document

Form No: AOF-004

Rev. No / Date: 2026 v09 / 10.07.2026

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

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1. Dear Patient,

It is your most natural right to be informed about your medical condition and about all the 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 up to you to consent 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 more consciously in the decisions to be made about matters concerning your health. If you wish, all information and documents regarding your health can be given to you or to a relative of your choosing. 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, accepting or not accepting the procedures to be performed is your own decision. Except in situations involving legal or 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 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 regarding the procedure in question have been resolved by your physician.

2. General Information About the Disease and Treatment

What Is Posterior Segmental Instrumentation Surgery? It is the procedure of fixing the vertebrae to one another by means of implants placed into the spine from the back of the vertebrae; spinal implant surgery is a procedure performed in particular to correct disorders occurring in the spine due to various causes by means of stabilization (surgery to fix the spine using metal plates, screws, rods, bars and similar devices). In Which Situations, in What Way and How Are Spinal Implant Surgery and Posterior Segmental Instrumentation Surgeries Performed? Spinal Stenosis: It is the condition in which the spinal canal narrows due to calcification and compresses the spinal cord or nerve tissue by pressing on these structures. In the treatment of spinal stenosis, a skin incision is made in the posterior-midline of the body at the relevant level (which may be in the cervical, thoracic or lumbar region) and the muscles on the sides of the spine are stripped away. The posterior parts of the vertebrae (spinous processes and

laminae) are removed, and the bone and ligament fragments compressing the spinal cord are thoroughly cleared. If, during this procedure, it is decided that there is a stabilization disorder, stabilization is performed. If surgery is not performed, depending on the location of the stenosis in the neck, thoracic or lumbar region, problems such as loss of strength in the arms and legs (partial or total paralysis), sensory disturbances such as burning, tingling and numbness in the arms and legs, cramp-like or lightning-like pains in the body, difficulty walking, inability to work with the hands and arms, and urinary and fecal incontinence or loss of sensation may be experienced.

Spondylolisthesis: This is the term for slippage of the vertebrae. The vertebrae are normally aligned neatly one below the other from the neck to the lower back. After slippage in 2 or more vertebrae, the continuity of the canal located in the posterior part of the vertebral bones, through which the spinal cord passes, is disrupted, and this may cause problems ranging from low back pain to paralysis. In the treatment of spondylolisthesis, a skin incision is made in the posterior-midline of the body at the relevant level (which may be in the cervical, thoracic or lumbar region) and the muscles on the sides of the spine are stripped away. If the patient has a neurological deficit (paralysis, urinary incontinence, numbness in the arms and legs, etc.), or if there is compression of nerve tissue due to a disc herniation, the posterior parts of the vertebrae (spinous processes and laminae) are removed totally or partially depending on the situation, the bone and ligament fragments compressing the spinal cord are cleared, and where necessary a discectomy is performed and a cage may be placed in the disc space. Then, the vertebral slippage is corrected as far as possible with stabilization systems, and posterior stabilization is performed with the nerve tissue decompressed. If surgery is not performed, depending on the location of the slippage between the vertebrae in the neck, thoracic or lumbar region, problems such as loss of strength in the arms and legs (partial or total paralysis), sensory disturbances such as burning, tingling and numbness in the arms and legs, cramp-like or lightning-like pains in the body, difficulty walking, inability to work with the hands and arms, and urinary and fecal incontinence or loss of sensation may be experienced. Although improvement of the patient's pre-operative neurological deficits is difficult, they may worsen further over time.

Vertebral Fractures: Fractures may occur in the spine due to various causes. What percentage of the vertebral body is compressed, whether there is compression of the spinal cord, and whether there is a neurological deficit are of importance.

- Traumatic Vertebral Fracture:** It occurs after an accident, fall or impact.
- Pathological Fracture Due to Spinal Tumors:** Tumors originating from the spine itself or spreading to the spine from other organs cause this type of vertebral fracture. For stabilization surgery, the patient's remaining life expectancy and the nature of the tumor are very important.
- Vertebral Fracture Due to Osteoporosis (Bone Loss):** It is seen frequently, especially in elderly women. It can also be seen in people with disorders of bone metabolism. In the treatment of a burst-type or compression (wedge-shaped) fracture of the spine, factors such as whether there is compression of the spinal cord, the percentage of compression in the vertebral body, the patient's level of pain, and the patient's age are evaluated. Stabilization may be performed so as to include the vertebra (or vertebrae) above and below. If surgery is not performed, depending on the location of the vertebral fracture in the neck, thoracic or lumbar region, the severity of the neurological deficit occurring at the time of the fracture, and whether the existing fracture is stable or unstable, problems such as loss of strength in the arms and legs (partial or total paralysis), sensory disturbances such as burning, tingling and numbness in the arms and legs, cramp-like or lightning-like pains in the body, difficulty walking, inability to work with the hands and arms, and urinary and fecal incontinence or loss of sensation may be experienced. What is essential in this surgery is to remove the pressure on the nervous system after the fracture, to fix unstable fractures, and to stop or slow the progression toward kyphosis (increased hunchback) in later periods. If surgery is not performed, improvement of the patient's pre-operative neurological deficits may be difficult, and they may worsen further over time.

Congenital or Acquired Anomalies of the Spine: These are congenital or subsequently developing abnormalities of the vertebrae. The spinal cord remains under compression, causing progressively increasing loss of strength, urinary incontinence, respiratory problems, and numbness in the arms and legs. After close follow-up, stabilization surgery may be recommended. In the treatment of congenital or acquired anomalies of the spine, long-term follow-up of the patient,

knowledge of the course of the disease, and whether there is deterioration in the patient's neurological status are important. The disorder in the patient's spinal cord is corrected using posterior stabilization systems. Recurrent Disc Herniation: In disc herniations that have been operated on more than once at the same level and that recur at the same level (especially recurrent lumbar disc herniation), an abnormal movement problem in the spine is generally observed. For this reason, stabilization may be required. In the treatment of recurrent lumbar disc herniations, after the possible stabilization disorder has been evaluated and the disc has been evacuated, the relevant segment or segments can be treated by posterior stabilization. If surgery is not performed, depending on the location of the disc herniation in the neck, thoracic or lumbar region, problems such as loss of strength in the arms and legs (partial or total paralysis), sensory disturbances such as burning, tingling and numbness in the arms and legs, cramp-like or lightning-like pains in the body, difficulty walking, inability to work with the hands and arms, and urinary and fecal incontinence or loss of sensation may be experienced. Although improvement of the patient's pre-operative neurological deficits is difficult, they may worsen further over time.

3. Alternatives to the Surgery, If Any

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

- As verbally explained to me by my doctor: accepting all risks and not having this surgery, waiting for the bone fractures to heal with prolonged bed rest
- Accepting all risks and follow-up with computed tomography or magnetic resonance imaging.
- Trying to relieve pain or muscle spasm by means of a brace, immobilization, or medication.
- Trying to relieve the complaints with physical therapy methods.
- Trying to relieve the complaints with algological (pain management) treatment methods.
- 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

It is improvement in the patient's current neurological status 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; it is intended to decompress the neural structures under pressure, to ensure the stabilization of the spine, to eliminate or reduce pain, and to completely resolve, or halt the worsening of, the neurological deficits existing before the surgery (paralysis, loss of strength, numbness, loss of reflexes, urinary incontinence, etc.) and complaints such as pain and spasms by means of the surgical treatment to be applied.

5. Estimated Duration of the Surgery

The duration of the procedure to be performed may vary according to the disease and the patient's condition, and is on average - hours. In addition, procedures to be carried out on patients by the anesthesia doctors before and after the surgery are not included in this period. Depending on the circumstances of the case, the procedure may take longer than the stated period. Your doctor will give you detailed information at the end of the procedure.

6. Risks and Complications of the Surgery

In addition to its benefits, the surgical procedure to be performed also carries possible risks.

Anesthesia risk: There are risks during and after local and general anesthesia procedures (due to the position given to the patient during surgery). Furthermore, in every form of anesthesia and in sedation, there are also complications and harms that may arise from the drugs. The anesthesia

procedure to be applied and the related risks and complications have been explained to me, and I approve the procedure recommended 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 required. In such a case, I approve the necessary blood transfusion and other treatments. Certain medications that I use and/or that must 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: A blood clot may form after any type of surgery. Clots forming at the bleeding site may obstruct blood flow and lead to complications such as pain, edema, inflammation or tissue damage. If the use of blood thinners is discontinued, the risk of clotting may increase.

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

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

Cardiac complications: The surgery carries a low risk of leading to 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; After Posterior Segmental Instrumentation surgery, there is a risk that pain, numbness, loss of muscle strength or other complaints may not be relieved.

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 field, and even in the bone in the surgical field. Risks associated with infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (accumulation of pus).

Nerve tissue and/or spinal cord injury: Although rare, it may occur unexpectedly during or after surgery. This condition may cause weakness in the arm and/or leg and respiratory distress.

Recurrence: Some of the complaints may recur in the early or late period after surgery, and in this case an additional surgical intervention may also be required.

Respiratory difficulty: Respiratory distress may occur through brainstem injury during surgery, through the pressure effect of a clot on the brainstem or spinal cord after surgery, through lung infection (pneumonia), and through the effect of a clot in the pulmonary artery (pulmonary embolism). Additional treatment may be required.

Stroke (paralysis): Although rare, weakness in the arm and/or leg may develop during or after surgery, following the lodging of air or a clot travelling from the veins to the brain. Additional treatment may be required.

Misplacement of the screws: the screws sometimes cannot be placed in the desired location. For this reason, the screws may be weak. If the screws are placed too far anteriorly, death may occur due to injury to a large vessel or internal organs. If the screws are placed toward the spinal canal, they may lead to paralysis due to compression of a nerve root or the spinal cord.

Non-union (failure of fusion) of the vertebrae: After attempts to correct the fracture and dislocation of the spine, despite bones taken from the trauma site for bone healing, or bones taken from the pelvic bone through a separate incision, or bones obtained from a bone bank or of cadaveric origin, the vertebrae may fail to fuse together, and this condition may lead to various spinal deformities and/or pain.

Instrument failures: during long-term follow-up, problems such as breakage, displacement, or loosening within the vertebra may develop in the implanted instruments, and these situations may create the need for additional surgeries.

I have also understood that, in the event of an unexpected situation during my surgery, such as bleeding, injury to an adjacent tissue or organ, 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 the risks written above that may occur during and after the surgical procedure to be performed on me.

7. Consequences to Be Faced If the Surgery Is Not Performed

The patient's current complaints and clinical condition may not improve and may worsen. The restriction of your mobility in daily life may progressively increase, and your quality of life may decrease further. As the disease progresses, the treatments to be applied may become more complex and their chances of success decrease.

8. Important Properties 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 administered according to the reason for admission or newly developing conditions. During the use of medications, side effects may emerge 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 MEDICATION:** 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, 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-edema medications may be used. In this case, blood sugar balance may be disturbed. **INTENSIVE CARE-DELIRIUM:** In elderly patients and during prolonged intensive care stays, medications regulating mental health, recommended by a psychiatrist, may be used for psychological symptoms that may arise in patients. These medications may damage the heart, kidneys and other organs. In addition to these, anesthesia-related medications are used. The narcotic (general anesthesia) 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, **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 sedatives/narcotics. The effects of the use of 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 properties of the medications to be used for diagnosis and treatment (what they are used for, their benefits, side effects, how they are to be used).

9. Lifestyle Recommendations Critical for Patient Health

Tobacco and Tobacco Products: It has been 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. In patients who smoke, anesthesia risks are higher, and death due to anesthesia is seen more frequently. If you smoke, you should know that the success of your treatment/surgery will be lower than the general success average.

Follow your doctor's recommendations (exercise, nutrition program, etc.) and, if applicable, do not neglect your outpatient clinic follow-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, person-specific circumstances are recorded at the end of the form under
Section 14 — Signatures.

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

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

I have received information on how to access medical assistance 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 confirm that my doctor has explained all the information above, that I have understood this information, and that all my questions regarding this intervention have been answered. Therefore, I give my consent for **POSTERIOR SEGMENTAL INSTRUMENTATION (PSE) SURGERY** and for any different or additional surgery and supplementary treatment interventions deemed necessary by my doctor.

Use of tissue: Any tissue not required for medical diagnosis may be used for medical research within the framework of ethical rules. I consent to the use of any tissue, medical device or body parts that may have been removed during the surgical procedure.

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

Photographs/Observers: I consent to the photographing or video recording of the surgery to be performed for scientific, medical or educational purposes, on the condition that the images do not reveal my identity.

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 possibility 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 to me what is written here, item by item, 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.

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

All blanks on 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 PSE — LUMBAR STABILIZATION, 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:)			
Head of Surgical Team, Responsible Specialist	Dr. Özgür Akşan		