VERTEBROPLASTY / KYPHOPLASTY

Informed Consent Document

Form No: AOF-009	**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 the medical / surgical treatment recommended to you for the treatment of your illness, as well as all diagnostic procedures. 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 more consciously in the decisions to be made regarding 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 designed to meet the needs of most patients under most circumstances, it should not be regarded as a document covering 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 of 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 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 Its Treatment

Kyphoplasty / vertebroplasty aims to restore a degree of strength and height to the fracture and to relieve / reduce pain by entering, with the help of a thick needle, vertebrae that have collapsed (lost their height) due to causes such as osteoporosis, bone tumors (metastases of breast, lung or prostate cancer, etc.), blood diseases (leukemia, multiple myeloma) or trauma, and injecting bone cement into the fractured bone. If deemed necessary during the procedure, a sampling (biopsy) procedure may also be performed. It is carried out under operating room conditions, under local or general anesthesia. Although the risks and complications of this intervention are few, there may be specific complications related to the placement of the needle and the injection of bone cement.

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, as explained to me verbally by my doctor, • Follow-up with computed tomography or magnetic resonance imaging, accepting all the risks. • Trying to relieve pain or muscle spasm through medication. • Trying to relieve the complaints with physical therapy methods.

Trying to relieve the complaints with pain medicine (algology) 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

Improvement in the patient's current neurological condition and complaints. The procedure is performed with a view to 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 or reduce pain The aim is for the complaints you had before the surgery to be completely resolved by the surgical treatment to be applied, or for their worsening to be halted.

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, the 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 duration. Your doctor will give you detailed information at the end of the procedure.

6. Risks and Complications of the Surgery

In addition to the benefits of the surgical procedure to be performed, there are also risks that may arise.

Anesthesia risk: There are risks during and after local and general anesthesia procedures (due to the position given to the patient during surgery). In addition, in every form of anesthesia and in sedation, there are also complications and harms that may occur due to the medications. The anesthesia procedure to be applied and the related risks and complications have been explained to me, and I approve the recommended procedure 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 situations, 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 may form after any type of surgery. Clots forming at the site of bleeding 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 worsen after surgery due to problems such as bleeding at the surgical site.

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; The surgical intervention to be performed may not bring about the improvement of all or some of the complaints.

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

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

Respiratory difficulty: Respiratory distress may occur through brainstem damage 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 of the arm and/or leg may develop during or after surgery, following the lodging in the brain of air or a clot coming from the veins. Additional treatment may be required.

A state of paralysis existing before the surgery or developing after the surgery may require intensive care and mechanical (artificial) ventilation treatment, and during this process all kinds of undesirable systemic problems (lung and urinary tract infections, sepsis as a result of the spread of infection through the body, kidney and liver failure, bleeding-coagulation disorders, etc.) may be added to the clinical picture, and death may occur as a result of these problems.

Wound Site Hematoma: Although very rare, there may be a risk of severe bleeding during or after the surgery. In the event of bleeding, additional treatment or a blood transfusion may be needed. The use of anti-inflammatory medications may increase the risk of bleeding. During the surgery, bleeding, a state of shock and death may occur due to injury to the large vessels located in front of or beside the spine.

Infection: It may occur in the skin / subcutaneous tissue and in the region of the muscles around the spine, in the vertebral bones, in the discs, and also in the anatomical areas adjacent to the spine. Sometimes meningitis (inflammation of the membranes surrounding the brain and spinal cord) may also occur. For this reason, long-term treatment and repeated surgeries due to this infection may be required.

Spinal Cord and/or Nerve Injury: Surgical treatment aims to improve the neurological deficits existing before the surgery (paralysis, loss of strength, loss of sensation, urinary and fecal incontinence, muscle wasting / loss of reflexes, pain and burning sensations, spasms, hoarseness, etc.) or to halt their worsening; however, after the surgery these deficits may become even more severe (a state of partial or complete paralysis) or may not improve. Even if no neurological deficit exists before the surgery, an injury to the spinal cord or a nerve root may occur during the surgical treatment, and a neurological deficit may develop after the surgery as a result.

Injury to the Spinal Cord Membrane: Surgical treatment may lead to tears in the spinal cord membrane or to closure defects (incomplete closure), and as a result cerebrospinal fluid may leak, making repeat surgical repair necessary; an infection may develop in the nerve membrane or tissue, resulting in meningitis or encephalitis.

I have also understood the possibility that, during my surgery, when faced with an unexpected situation such as bleeding, injury to an adjacent tissue or organ, etc., my doctor may perform, in addition to the planned procedure, other procedures required for my health, and I approve this.

Specifically for this surgery, in addition, all the structures located near the needle entry path (the spinal cord, nerve roots, vessels, the esophagus, the lungs and the other intra-abdominal organs) are at risk. During the injection of bone cement, leakage of the cement outside may cause pressure on the spinal cord or nerve roots, and this may cause temporary or permanent nerve damage. A fat / cement clot may travel into the blood vessels and subsequently to the lungs, the heart or the brain. Prolonged bleeding may occur. Air leakage between the lung membranes and respiratory distress may occur. Cerebrospinal fluid leakage and rib fractures may occur. I have understood and accept all the risks written above that may arise 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 course.

8. Important Characteristics of the Medications to Be Used

If you have a previously identified drug allergy, you must be sure to inform your physician and your nurse about this. During your current course of treatment, medications appropriate to the patient's medical condition (painkillers, antibiotics, medications supporting the circulation and the heart, blood products, intravenous fluid (serum) therapies, medications specific to your disease) will be given according to the reason for your hospitalization or to newly developing conditions. During the use of medications, side effects may emerge and cause damage to the heart, the 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 with the aim of reducing the risk of surgical site infection. USE OF BLOOD-THINNING MEDICATIONS: If you are using anticoagulant, blood-thinning medications, you may be given different drug treatments or blood products to counteract the effects of these medications. SPINAL CASES: In the event of severe pain after spinal operations, medications sold under a controlled ("green") prescription, which can be addictive, may be used. After spinal surgeries, in situations where the weakness in the arms and legs does not change, or where new weakness develops, edema-reducing 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 appear 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, the kidneys and other organs. In addition to these, medications related to anesthesia are used. The general anesthetic (narcosis) 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 given my doctor information 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 sedative/narcotic substances. 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 to 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. Anesthesia risks are greater in patients who smoke, and death due to anesthesia occurs 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 program, etc.) and, if one has been requested, 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

*Circumstances specific to the patient 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 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 / to hospitals able to perform 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 was 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 carried out with a view to 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 to the **VERTEBROPLASTY / KYPHOPLASTY SURGERY** and to all different or additional surgical 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 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 the rules of confidentiality are observed.

Photographs/Observers: I consent to the surgery to be performed being photographed or video-recorded for scientific, medical or educational purposes, provided that the images do not reveal my identity.

13. Confirmation of Consent

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 of 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, point by point, 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 making this decision of my own free will.
I had enough time, a reasonable period before the intervention, to obtain a second opinion.
I have read and understood the content of the Informed Consent form.
All the 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 VERTEBROPLASTY / KYPHOPLASTY, 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**		