CRANIOSYNOSTOSIS SURGERY

Informed Consent Document

Form No: AOF-025	**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 medical / surgical treatments and diagnostic procedures recommended 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 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 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 many circumstances, it should not be considered 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 to accept or not to accept the procedures to be performed. Except in situations of legal and medical necessity, you may refuse to be informed or may 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 all your doubts regarding the procedure in question have been resolved by the physician.

2. General Information About the Disease and Its Treatment

Craniosynostosis is a congenital disease related to the underdevelopment of the joints (sutures) between the skull bones. Because these joints have not developed, the structure of the face and skull will be affected and this will lead to aesthetic or functional disorders. Among these disorders, irreversible conditions related to vision and brain development may be encountered. I understand that this congenital condition, which affects brain development, can be partially—though not definitively—remedied by surgery. I know that the surgery to be performed can only partially provide a solution to this problem. The surgery to be applied can reach the desired goal only over time, and the method carries no guarantee; a second surgery may be required in the future.

Open cranial vault remodeling method: During the surgery, the bones forming the head and face will be exposed through a skin incision or incisions; bones may be removed to create bone gaps; the bones

forming the head and face will be taken out of their positions, corrected and placed in appropriate new positions; and to fix these bones, various materials including plates and screws, wire or suture thread may be used. After the surgery, there may be wide bone gaps between the skull bones. This is a requirement of the surgical technique applied. During the surgery, large bone pieces will be exposed, some will be removed, and severe bleeding may require a blood transfusion. The surgery to be performed has application difficulties and carries no guarantee. After the surgery, blood accumulating under the skin will cause swelling of the face and head for a few days and may require a blood transfusion.

Endoscopic method: In this method, the bones forming the head and face will be exposed through a skin incision or incisions, and with the help of endoscopic surgical instruments the prematurely closing bones will be removed to create bone gaps. After the surgery, there may be bone gaps between the skull bones; this is a requirement of the surgical technique applied. During the surgery, bone pieces will be exposed and removed, and severe bleeding may require a blood transfusion. In the period after the surgery, a helmet therapy process that may extend up to about 1 year will begin. Helmet therapy is a supportive-complementary treatment method of the surgery; with this method, the aim is to support the healthy development of the bone structure while preserving it, in the correction of the patients' postoperative skull deformations. While a gap is left between the surgical area and the helmet, contact is applied on the other parts to support the shaping during bone development. The patient is followed at regular check-up intervals and the helmet contact areas are adjusted; in some cases, the need to use a second new helmet may arise during the process.

Your doctor, after evaluating your child's condition in detail, has decided on the most appropriate surgical treatment method (open cranial vault remodeling or endoscopic method) and has recommended this approach to you.

3. Alternatives to the Surgery, If Any

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

- As explained to me verbally by my doctor, accepting all risks and not having this surgery,
- Accepting all risks and follow-up with computed tomography, magnetic resonance imaging or other examinations,
- Other possible treatment options...

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

4. Expected Benefits of the Surgery

The aim of this surgery is to correct, as much as possible, the developmental disorders present in the skull bones and the skull deformations, to create the space needed for brain development and the appropriate conditions for normal development, and to provide, as much as possible, a cosmetically appropriate appearance. I am aware that there is no absolute guarantee that the results of this procedure will be good, but I accept the intervention.

5. Estimated Duration of the Surgery

The duration of the procedure to be performed may vary according to the condition of the disease and of the patient, and is on average ..... - ..... hours. In addition, the procedures to be performed on patients before and after the surgery by the anesthesia doctors are not included in this duration. The procedure may take longer than the stated duration depending on the condition of the case. 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 the 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 case of bleeding, additional treatment or 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. On the other hand, in this intervention performed by inserting a camera into the brain, there is also a possibility of small-scale brain hemorrhage.
Blood clot formation: Blood clots may form after any type of surgery. Clots forming in the bleeding area 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 the surgery due to problems such as bleeding at the surgical site, brain edema (pressure on the brain as a result of fluid accumulation) or vasospasm (narrowing of the vessels).
Brain injury: Although rare, the procedure to be performed carries a risk of damaging the underlying brain tissue. The symptoms resulting from this damage may vary according to the location of the surgical area.
Risk of cerebrospinal fluid leakage: 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 aimed at repairing 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.
Infection: Infection may occur at the skin incision site as well as in the surgical field, and even in the bone within the surgical field. Risks related to infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (accumulation of pus).
Recurrence (Relapse): After the surgery, some of the complaints may reappear in the early or late period, and in this case additional surgery may be required. As the child grows, the skull deformation may develop again, and a second surgery may be required in later periods.
Respiratory difficulty: Respiratory distress may occur due to brainstem damage during surgery, and after surgery due to the pressure effect of a clot on the brainstem or spinal cord leading to lung infection (pneumonia) and to the effect of a clot on the pulmonary artery (pulmonary embolism). It may require additional treatment.
Seizure (convulsion, epilepsy): Abnormal electrical activity in the brain may cause a seizure/convulsion, and this condition may result from the complications developing in the intracranial part of the surgery.
Wound discharge: Discharge from the surgical wound, seen especially in the first days and, rarely, later. It may require additional surgery.
Pressure sore on the skin due to helmet use (in cases receiving helmet therapy after the endoscopic method).
Failure of the surgery: The surgical intervention to be performed may not ensure the improvement of all or some of the complaints. The surgery to be applied may only partially reach the desired cosmetic and functional goal; the method carries no guarantee.
Death: Although a very rare complication, complications resulting in death reported in the literature may develop. Sudden death may occur, as well as undesired problems resulting in death due to the above-mentioned complications.

The possibility of remaining bedridden and dependent on the constant help of another person after surgery, and, in line with this possibility, problems that may arise such as deep vein thrombosis, pulmonary embolism and bedsores.

Transfusion of blood and blood products: I have understood that during this hospitalization the transfusion of blood and blood products may become necessary; that, although all blood products are screened for infectious diseases such as Hepatitis B, C and HIV and have been shown to be free of these agents, these products may in reality be infected, and that, even with a very low probability, I could acquire an infection from this transfusion procedure. I am also aware that an allergic reaction may develop during the transfusion and that this may create problems that may extend to death.

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

I have understood that, although I may benefit from the planned procedure, every medical and surgical intervention carries a risk, that my doctors cannot completely eliminate these risks but will perform all necessary medical interventions to minimize them. These general risks may also include the following possible situations: allergic reactions, bleeding, blood clotting, embolism, brain damage, loss of sensation, and even the loss of all bodily functions or of life.

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; there may be a worsening. The aesthetic or functional disorders in the face and skull structure due to the underdevelopment of the joints may progress; irreversible conditions related to vision and brain development may be encountered.

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, 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 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 protective antibiotic therapy is applied with the aim of reducing the risk of surgical site infection. USE OF BLOOD-THINNING MEDICATION: If you are using anticoagulant, blood-thinning medications, different medication therapies or blood products may be given to you to counteract the effects of these medications. ANTIEPILEPTIC MEDICATION: After brain surgeries, seizure-preventing medications called antiepileptics are used to prevent epileptic seizures. INTENSIVE CARE-DELIRIUM: During prolonged intensive care stays, for psychological symptoms that may emerge in patients, mental health-regulating medications recommended by a psychiatrist may be used. These medications may damage the heart, kidneys and other organs. SHUNT INFECTION, EVD: As a result of a CSF infection, it will be necessary to start appropriate antibiotics recommended by infectious diseases. Among these treatments, the method in which medications are applied into the brain ventricles by means of an EVD, expressed as intraventricular treatment, may also be used. In addition to these, medications related to anesthesia are used. The general anesthetic medications given during the 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 narcotics/intoxicants. The effects of the use of these substances before and after the surgery have been explained to me by my doctor and

recommendations have been made. During my stay in the hospital, I have 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 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. Anesthesia risks are higher in patients who smoke; death due to anesthesia is seen more frequently. If you smoke, you should know that the success of the 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 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 restriction status).

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 Assistance on the Same Matter When Needed

Not accepting the application of 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/hospitals capable of performing the treatment/surgery in question.

I have received information about how to access medical assistance 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 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 **CRANIOSYNOSTOSIS SURGERY** and for all different or additional surgeries and additional 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 doctor training, provided that confidentiality rules are observed.

Photography/Observers: I consent to the photographing or video recording of the surgery to be performed for scientific, medical or educational purposes, provided 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 not carry a guarantee of cure.
I have understood everything that has been told to me.
My doctor has answered all my questions.
My doctor has explained to me what is written here, item by item, in a clear, understandable and explanatory manner that I can comprehend.
I know the meaning of the Informed Consent form.
I have been informed about the approximate cost of the treatment.
I am making my decision 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 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 CRANIOSYNOSTOSIS 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: .....)			
Head of Surgical Team, Responsible Specialist	**Dr. Özgür Akşan**		