ERCİYES UNİVERSITY
FACULTY OF DENTISTRY
ORAL AND MAXILLOFACIAL SURGERY HOSPITAL

INFORMATION CONSENT FORM
CLEFT LIP SURGICAL TREATMENT

This form is intended to inform you about cleft lip and palate surgeries and the possible risks and complications (undesirable consequences) of such surgeries. Please read the form carefully. If you have questions or do not understand anything, please ask your doctor for help. Your doctor will give you additional written and verbal explanation upon your request.

GENERAL İNFORMATİON

Long before the child is born, in the first weeks of development, the left and right edges of the lip and the palate come together after developing separately. However, in approximately one in every 1000 babies, normal fusion does not occur and the lip and palate remain cleft. Cleft lip can vary widely, from a small notch in the upper lip to a complete cleft extending to the base of the nose. The cleft may be unilateral or may be located on both sides of the lip. Many children with cleft lip also have a cleft palate. The problems of the baby with this condition are much more than those of babies with only cleft lip. In addition, cleft lip may accompany other congenital diseases and problems related to these diseases may be encountered.

Surgery for cleft lip is usually performed until the child is 3 months old. Although parents want the cleft to be repaired immediately after birth and before the child goes home, surgery on a newborn is difficult, as it is dangerous and the results are often below average. That's why many cleft palate and lip treatment centers prefer to wait until the child is approximately 3 months old to perform the first lip repair. There are many reasons for this delay. First of all, when the child reaches a weight of 10-12 kilos, he becomes healthier and stronger and will be less affected by anesthesia and surgery. Secondly, this waiting period gives sufficient time to diagnose the extent of the disease and the characteristics of the problem and to determine the presence of other associated problems, as well as to plan immediate and long-term treatment. Thirdly, a 3-month-old child is much older than a newborn in terms of meeting the technical requirements of surgery and is suitable for obtaining better results in terms of aesthetic and functional results.

To repair a cleft lip, muscle repair will be performed following an incision on both sides of the cleft. Additionally, if it is necessary to remove bone or tissue from another location, it may be necessary to make an incision from another location. The cleft will be closed by repairing the oral mucosa and skin. In this way, the muscle will be able to function and a normal lip shape will be created. Deformity in the nose will also benefit from this intervention. Your child may have an uneasy time after cleft lip surgery. Various medications will be recommended to you by your doctor to get through this period. It may be necessary to use bandages that prevent bending of the elbows for a while to keep your child's hands away from the surgery area. If a dressing is used, it will be removed after 1-2 days. There are absorbable stitches inside the nose. These will fall off on their own. Depending on the procedure performed, there will be stitches outside the nose or around the lips. In order to avoid any crust remaining, these areas should be cleaned with half diluted oxygen and water using an ear pick (cotton swab).

Non-absorbable stitches will be removed within 5-7 days under anesthesia in the operating room or under sedation in the outpatient clinic. After the stitches are removed, you will need to tape the incision lines all day for a few weeks. After the surgery, you need to massage the scar on the lip for 5-10 minutes, 3-5 times a day, for at least three months. This prevents knots from forming under the skin and the scar from pulling up on the lip.
The surgery scar will become redder and wider in the first few weeks. This appearance will decrease over time, but the scar will never completely disappear. In some children, this scar may be barely visible due to shadowing in the nose and lip area.
While cleft palate is a small notch affecting the uvula in some children, in others it extends from the uvula to the lip area. Cleft palate repair can be performed between 3 and 12 months depending on the condition of the surgeon, anesthesiologist and patient. In this way, it becomes easier for the child to endure the surgical procedure. During surgical repair, incisions are made on both sides of the cleft, the tissues on the edge are brought closer to the midline and the integrity of the palate is ensured. During this repair, the soft palate muscles are also repaired, thus providing the necessary basis for the child to speak and feed correctly. Additionally, if it is necessary to remove bone or tissue from another location, it may be necessary to make an incision from another location.
In the first day or two after cleft palate surgery, there may be discomfort and pain complaints that can be easily controlled with medications. During this period, although the child is started to be fed orally, the necessary support is provided by giving fluids intravenously, as the child cannot be fed in normal amounts. In the first days, bandages that prevent bending of the elbows are necessary to prevent the child from bringing his hands to his mouth. Your doctor will give you the necessary recommendations for your child's nutrition in the first few weeks after the surgery. Compliance with these recommendations is necessary for the smooth healing of the palate. It takes several months for the palate to reshape. However, during the 3-week repair period when the palate becomes strong enough, the baby's fingers or food utensils (fork, spoon, straw) may damage the palate. Inserting fingers or anything else into the mouth should be avoided during the initial phase of healing.
Feeding your baby requires special care after surgery. You must keep your baby's diet away from breastfeeding for 2 to 2.5 weeks after surgery. A list of food and drinks will be given to you. You should carefully give food and drinks into his mouth drop by drop using a cup or syringe. It can be given to children as liquid food by pouring it from a glass. If the mixture is too thick, it can be diluted with warm water. Following each meal, the palate area is cleaned with water. Since milk and dairy foods stick to the stitches, it is generally appropriate to give them after 3-4 days.
The baby stays in the hospital until he drinks well and has no fever. We usually send your baby home 1-2 days after surgery. The stitches used in palate repair do not need to be removed because they are dissolvable. After surgery, it is important to see the baby at 3 days to 7 days and then at 2.5 to 3 weeks.
Complications of cleft lip or palate (unfavorable outcome) include recurrent ear infections, hearing loss, an excessive area of dental space, and dislocation of teeth requiring orthodontic correction. Although the scars and deformities left from the surgery are generally highlighted by the child's family, eliminating the speech disorder is one of the most important goals. In some children, speech defects may persist even after surgery due to inadequate functioning of the muscle in the palate. Apart from this, there are many additional reasons that may cause speech defects (insufficient hearing, improper mouth closing, gap between teeth, insufficient tongue movement, intelligence level, psychological state, etc.). All these reasons

should be reviewed by a team and a treatment plan should be made in order of importance. Even if all the negativities have been resolved, it would be beneficial to apply speech therapy to every child whose cleft palate has been repaired.

RISKS ASSOCIATED WITH ANAESTHESIA

1. Difficulty in intubation and need for tracheostomy: If the tube that must be inserted into the windpipe through the mouth for anaesthesia cannot be inserted, it may be necessary to insert this tube (tracheostomy) through an incision made in the front of the throat. This tube may need to remain in place for some time after the operation and some problems with this tube may develop over time.
2. Some areas of the lung may deflate, and infection (microbial diseases) may occur. This may require antibiotics and physiotherapy.
3. Depending on the procedure, death may occur.

POSSIBLE RISKS OF "CLEFT LIP AND PALATE" SURGERY

It is important to understand the risks associated with any surgical intervention. The decision to undergo a surgical procedure is based on a careful assessment of the potential benefits and risks. While most patients do not experience these side effects, it is essential to discuss each one with your plastic surgeon, who will perform your surgery. This will ensure that you have a clear understanding of the risks, side effects and consequences of the surgery.

1. Bleeding: It is possible that bleeding may occur during or after surgery, and the patient may require a blood transfusion.
2. Infection: Infection is a rare occurrence following this type of surgery. Should infection develop, antibiotic treatment and surgical intervention may be required.
3. Respiratory problems: Following cleft palate surgery, there is a risk of slight leaks occurring from the surgical area into the mouth. In rare cases, this may result in leakage into the trachea, which could potentially lead to breathing difficulties. In such instances, emergency surgical intervention may be required. In some cases, it may be necessary to place a tube into the windpipe (tracheostomy) through an incision made in the front of the throat. It is possible that the tube may need to remain in place for some time after surgery, and that some problems may develop over time.
4. Pulmonary complications (unfavourable outcome): It is possible for pulmonary complications to develop as a result of general anaesthesia. These complications can be caused by blood clots blocking the vessels of the lung (pulmonary embolism) or by partial collapse of the lung (part of the lung cannot be ventilated). If any of these complications occur, the child may require hospitalisation and additional treatment. In some cases, pulmonary embolism can be life-threatening or fatal.
5. Scarring: It is inevitable that scarring will occur following lip repair. This is usually acceptable, although in some cases, abnormal scars may develop. These scars may be unattractive and may have a different colour to the surrounding tissue. In such cases, treatment may be required, including surgery.

6. Separation of sutures: Following surgery, the sutures in the lip or mouth may separate due to tissue quality, excessive tension, infection or the baby's hands separating the sutures. In such a case, further surgical intervention may be required.
7. Fistula formation: It is possible that the palate may not heal completely in the late postoperative period. In the future, a hole may form between the nasal cavity and the oral cavity in these areas, allowing liquid foods to pass from the mouth to the nasal cavity. In the event of fistula development, a second surgical procedure may be necessary.
8. Surgical anaesthesia: Both local and general anaesthesia have inherent risks. All forms of surgical anaesthesia or sedation (calming the patient without making them fully asleep) can have the potential for complications, injury and even death.
9. Allergy: In rare cases, localised allergies to tapes, suture material or topical (externally applied) medications have been reported. More serious systemic allergies are caused by drugs used during surgery and prescribed medications. Allergic reactions require additional treatment.

ADDITIONAL SURGICAL PROCEDURES THAT MAY BE REQUIRED

In addition to the risks and complications (unfavourable outcomes), there are other conditions that may affect the long-term outcome of cleft lip and palate. Although they are rare, these risks are particularly relevant for cleft lip and palate. Although other risks and complications may also occur, they are even rarer. If complications develop, additional treatments or surgical intervention may be required. There is no certainty in medicine and surgery. While we can expect good results, we cannot guarantee or assure you of the results that can be achieved. Additional surgical procedures may include repair of the lip and palate, correction of nasal deformities, ensuring bone continuity of the tooth arch, correction of speech impairment, and closure of the mouth after puberty, jaw surgery (orthognathic surgery) and aesthetic nose surgery (rhinoplasty) to give the nose its final shape. To ensure the timely and accurate performance of these procedures, it is essential to maintain regular communication with your doctor.

DESCRIPTION
The purpose of informed consent documents is to provide information about the surgical treatment of the disease or condition concerned and to explain the risks and alternative treatment methods. The informed consent process aims to provide information about risks in a way that most patients can benefit from in most situations. However, informed consent forms do not cover all risks and other methods of care. Informed consent forms are not organised as a standard of medical care and cannot be used as such. The standards of medical care are determined on the basis of all the facts about the individual's condition and are open to change in line with scientific developments.

It is important that you read the above information carefully and that all your questions are answered before you sign the consent form on the next page.

CONSENT FORM FOR "CLEFT LIP AND PALATE" SURGERY

 My doctor explained my child's medical condition and the proposed surgical procedure. I understood the risks of the operation, the risks specific to my child and the possible favourable and unfavourable consequences (complications).
 My doctor explained other treatment options, the associated risks, the possible medical prognosis and the risks of not receiving treatment.
 I was given an anaesthetic information sheet. I was given a patient information sheet.
 My doctor provided a detailed explanation of my child's medical condition and the proposed surgical procedure. I was informed of the potential risks associated with the operation, including those specific to my child, as well as the possible favourable and unfavourable consequences (complications).
 My doctor presented the available treatment options, outlining the associated risks, the potential medical prognosis, and the risks of not receiving treatment.
 I was provided with an anaesthetic information sheet and a patient information sheet.
I was given the opportunity to discuss any questions I had about my child's medical condition, treatment and risks, as well as alternative treatments. I was satisfied with the answers I received to my questions and opinions.
I agree that my child may be given blood during the operation if necessary.
 My doctor informed me that there is a possibility of life-threatening events occurring during the operation. I understand that photographs and video footage may be taken during the operation, which can then be used for training healthcare professionals.
 I understand that there is no guarantee that the operation will improve or worsen my child's condition.
 I am aware that in the event of unforeseen circumstances arising during or after the operation or during anaesthesia, procedures other than those described above may be necessary. I agree that the doctor mentioned above will decide on and carry out the necessary procedures, and that specialists in the relevant disciplines will be involved in the surgical intervention.
I have read all of the above information and have been given many other verbal information.

I CONFIRM THAT I AM SATISFIED WITH THE ORAL AND WRITTEN EXPLANATIONS PROVIDED TO ME. I CONSENT TO THE PROPOSED TREATMENT OR OPERATION, TO ANY SUBSEQUENT TREATMENT IN THE EVENT OF COMPLICATIONS, TO THE ITEMS LISTED ABOVE, AS WELL AS TO THE ORAL EXPLANATIONS GIVEN TO ME. FURTHERMORE, I CONSENT TO THE TREATMENT BEING PERFORMED ON MY CHILD.

Patient's name **Signature** **Date**
Deputy and degree of proximity

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1. Doctor’s name **Signature** **Date**

2. Doctor's name **Signature** **Date**