AMERICAN SOCIETY OF PLASTIC SURGEONS®

Informed Consent

Congenital Reconstruction Cleft Lip – Cleft Palate

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INSTRUCTIONS

This document will help you learn about cleft lip and cleft palate surgery. It will also outline the risks and other treatments.

It is important that you read the whole document carefully. Please initial each page. Doing so means you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Cleft lip and cleft palate are defects of the face and mouth that occur during fetal development. In such cases, the upper lip (cleft lip) or roof of the mouth (cleft palate) may not develop fully. These defects can occur separately or together. The severity of the case can vary and may involve one or both sides of the face. Reconstructive surgery can correct this abnormal development. Surgery can restore both function and appearance. Cleft lip repair can be done when a child is at least 10 weeks old, weighs 10 pounds, and has a blood count of at least 10. Cleft palate surgery can be done when a child is 9 to 18 months of age. Other procedures may be needed to restore function or to refine appearance. Nasal defects can also be fixed during cleft lip surgery.

OTHER TREATMENTS

Other forms of treatment include not having surgery. However, not treating these defects may lead to more risks and problems. There may be visible and obvious malformations. There may also be developmental and functional problems with breathing, eating, hearing, and talking.

RISKS OF SURGERY

Every surgery has risks. It is important that you understand these risks and the possible problems that can result from them. All procedures have limits. Choosing to have a surgery means comparing the risks and benefits. Most patients do not face problems, but you must talk about them with your plastic surgeon. Make sure you understand all possible outcomes of congenital reconstruction cleft lip and/or cleft palate surgery.

SPECIFIC RISKS OF CLEFT LIP – CLEFT PALATE SURGERY

Cleft Lip:

Issues with cleft lip surgery are rare. More common are problems with healing, which may lead to scars or other deformities. This may need more surgery. Most patients with cleft lip repairs benefit from more surgery later in life.

Dehiscence (Separation):

Sometimes, a wound may open or separate. This may be due to infection or normal movements of the lip during crying, sucking, eating, etc. This may require emergent re-repair or a later surgery based on the severity.

Asymmetry of the Nose or Lip:

Asymmetry of the nose and lip can occur. This can happen because of scarring or growth changes due to the cleft lip and nose deformity. Surgery after a child is fully grown can fix this.

Scars:

Scars are a normal part of healing. Some scars can widen or change color after surgery. This may need to be fixed. Some scars can distort the lip and nose. This can lead to problems like difficulty breathing through one or both nostrils.

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Cleft Palate:

Breathing Problems:
You may have breathing problems. This is most likely in the hours soon after surgery. A few patients may need to be kept in an intensive care unit to monitor breathing. They may need more oxygen or other breathing treatments. In rare cases, a child may need ventilator support for breathing until the airway swelling has reduced.

Fistula:
A fistula is a hole between the mouth and nose or lip. It is most common in the mid path along the palate. This is where major repair is needed. A fistula may become symptomatic when the upper jaw widens during orthodontic treatment. In some cases, you may have a speech problem (nasal air loss) or there may be fluid reuptake in the nose. You may need more surgery to fix this.

Speech Problems:
Even with cleft palate surgery, speech development may not be ideal. You may also have difficulty speaking or swallowing. About 20% of patients have speech problems. Speech therapy is the first line of treatment, but more surgery may be needed.

Maxillary Growth:
Cleft palate surgery can impact growth of the maxilla (the upper jaw). About 10–40% of patients with a non-genetic cleft palate may need orthognathic surgery in their teens. LeFort I maxillary advancement or upper jaw surgery may need to be done. Most children with clefts need orthodontic treatment as they grow.

Damage to Deeper Structures:
Surgery may damage the nerves, blood vessels, muscles, teeth, or tear ducts. This may or may not happen depending on the type and area of surgery. These injuries may not be permanent. You may need more surgery to fix these problems.

DISCLAIMER
Informed consent documents give you information about a surgery you are considering. These documents explain the risks of that surgery. They also discuss other treatment options, including not having surgery. However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the way doctors practice medicine.

It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

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CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby and the doctor's assistants to do the procedure **Congenital Reconstruction Cleft Lip – Cleft Palate.**
2. I got the information sheet on Congenital Reconstruction Cleft Lip – Cleft Palate.
3. I understand that, during the surgery, an unexpected situation may require a different medical procedure than the surgery listed above. I permit the doctor listed above, the assistants and/or designees to provide any treatment that my doctor thinks is needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the surgery.
4. I understand what my surgeon can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the surgery. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the surgery's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the surgery.
5. I agree to the anesthetics that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and even death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after surgery. I also agree to any additional surgeries or treatment that is needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the surgery for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this surgery. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the surgery is an option and that I can opt-out of having the surgery.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE SURGERY TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE SURGERY

I CONSENT TO THE SURGERY AND THE ITEMS THAT ARE LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____

Patient or Person Authorized to Sign for Patient Date/Time

_____

Witness Date/Time

_____ Patient Initials

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