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INFORMATION AND CONSENT DOCUMENT FOR OTOPLASTY

INFORMED CONSENT

General Health Law of 14/1986 of April 25 (BOE 102), article 10, section 6
Law 41/2002 of November 14, Basic Regulatory of Patient Autonomy and Rights and
Obligations in the Matter of Clinical Information and Documentation, chapter IV, articles 8,
9 and 10 Organic Law 3/2018 of December 5, Protection of Personal Data and guarantee of
digital rights - LOPDGDD

INFORMED CONSENT FOR OTOPLASTY · EAR SURGERY – Dr. JOAQUIM SUÑOL

INFORMATION AND CONSENT DOCUMENT FOR OTOPLASTY · EAR SURGERY

This document is used for you or whoever represents you to give your consent for this intervention. Can you withdraw this consent at any time. Signing it does not obligate you to have the intervention. No adverse consequences will arise from your refusal regarding the quality of the rest of the medical care you receive.

Before signing, it is important that you read the following information slowly. Signing this consent implies full understanding of what is contained therein. Tell us if you have questions or need more information.

You must sign at the bottom of each page, indicating that you have read it, and also the consent on page 5.

INTRODUCTION

Otoplasty is a surgical procedure designed to improve the shape, position, size or projection of the ears for various reasons:

- Helix valgus (protruding ears or separated from the head).
- Ear lobes rotated or too visible in frontal view
- Congenital malformations: macrotias (large ears), contracted ears, microtias (small ears).
- Acquired malformations: sequelae of previous surgeries (secondary otoplasties), burns, trauma.

There are different otoplasty techniques and their indication varies depending on the type of deformity. In general, they consist of carving and modeling the auricular cartilage, recreating its natural folds and correcting the implantation that is excessively separated from the skull. It is usually made with incisions on the back of the ear. In some malformations it is necessary to use cartilage grafts from the healthy ear or ribs.

Otoplasty is the surgical intervention that allows you to modify the shape and size of the ears that are altered, and achieve a natural appearance. Each patient and each of their ears are treated individually and specifically, depending on the alterations they present and the surgical indication that is performed in each particular case, after an exhaustive preoperative study and analysis.

EFFECTS AND BENEFITS

This surgery is intended to improve the appearance of the ear pinnae, not the hearing.

ALTERNATIVE TREATMENTS

Protruding ears and other small malformations can be treated with support molds, but this technique is only effective in the first months of life. In large deformities, an alternative to surgery is the placement of an epithesis (artificial external prosthesis). Otoplasty is an elective surgical intervention. Treatment could consist of not carrying out the intervention.

RISKS OF OTOPLASTY

Any surgical procedure carries a certain degree of risk and it is important that you understand the risks associated with otoplasty. The individual decision to undergo surgery is based on the comparison of risk with potential benefit. Although most patients do not experience the following complications, you should discuss each of them with your plastic surgeon to ensure that you understand the risks, potential complications and consequences of otoplasty.

Ear hematoma or edema. It is accentuated in the first days after surgery. It is usually due to the anesthetic infiltration technique. There may be a feeling of tension in the ears, which subsides in a few days. It does not usually require surgical treatment.

Persistent deformity. In large malformations it is never possible to reconstruct a “normal” ear. In the most severe cases, several operations are often required to obtain a satisfactory result. Minor deformities may also require “touch-ups.”

Bleeding. It is possible, although rare, for a bleeding episode to occur after surgery. If postoperative bleeding develops, you may require emergency treatment to remove accumulated blood. You should not take aspirin, anti-inflammatories, ginkgo biloba or excess garlic for 10 days before surgery, since they alter blood clotting and can increase the risk of bleeding problems. Bruising may occur that resolves on its own, but accumulations of blood under the skin can delay healing for a few days or weeks and cause excessive scarring.

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Infection. Infection after this type of surgery is very rare. If an infection occurs, additional treatment, including antibiotics or surgery, may be necessary. It is possible, although extremely rare, that a serious infection called necrotizing soft tissue infection (necrotizing fasciitis) may develop. Necrotizing fasciitis is a soft tissue infection that can reach the fascia of the muscles. It is a very rare infection in plastic surgery, but it is life-threatening and is an emergency. If present: intense pain that does not improve with analgesia, fever, blisters in the operated area or purplish discoloration of the skin; You should contact Dr. Joaquim Suñol immediately.

Pain. After the intervention, before the effect of the local anesthesia wears off, you can take mild analgesics such as Paracetamol, which will relieve the discomfort. The elastic band to hold the sterile gauze pads that will be placed as a postoperative bandage should NOT put too much pressure on your ears. If the band is too tight on your ears, you will feel pain. If you notice a lot of pain, you can tell Dr. Joaquim Suñol, who will tell you what you should do to relieve it, possibly including removing or changing the elastic band for another one that is not so tight.

Asymmetry. If you are looking for perfection, you should NOT have surgery. The two ears are not and will never be exactly the same: the ears usually have slightly different shapes and measurements from each other and are usually implanted in the skull at different heights. Otoplasty does not alter or improve these slight asymmetries, which are totally normal. Factors such as scarring and cartilage stiffness can contribute to a normal asymmetry in body features and may contribute to not achieving a completely symmetrical appearance between the two ears after an Otoplasty.

Suture material. There are some patients who suffer from intolerance to certain types of suture material. It may also happen that one or more of the permanent sutures that are placed during Otoplasty to form the auricular cartilage become externalized or extruded through the thin skin behind the ear and may cause discomfort, making it necessary to remove them; In rare cases it may then be possible for the shape of the ear to change slightly and even additional treatments including surgery may be needed for correction. Blows, trauma, and exaggerated mobilization of the ears during the immediate postoperative period can cause the sutures placed to modify the auricular cartilage to tear the cartilage tissue, which is soft, and the desired effect and shape changes obtained with otoplasty may be lost. ; In these rare cases additional surgery may be necessary.

Grafts: In some cases, it may be necessary to graft the patient's own tissues (skin, cartilage, fascia grafts, etc.) to modify or restore the shape of the ear or to shape and reinforce the cartilage folds. The viability or survival of these grafts cannot be 100% assured, and they may be totally or partially reabsorbed (and therefore the desired effect may disappear) or necrotize (forming a wound in the skin that may require healing and care for weeks). until it is resolved by healing by secondary intention). Complications in the donor area: When it is necessary to take cartilage grafts, complications may occur in the place where they are taken, whether from the contralateral ear, the inguinal area, the nose or the costal cartilage.

Changes in skin sensitivity. Temporary changes in skin sensitivity may occur after otoplasty, which usually resolve within a variable time (6-12 months). Decreased or complete loss of skin sensitivity can occur, but is extremely rare.

Wound and Scar Healing. Although good healing is expected after the surgical procedure, abnormal scarring may occur on the skin. In rare cases, abnormal scars and keloids may occur. Additional treatments may be needed including intralesional corticosteroid infiltration or surgery to treat abnormal scarring.

Skin loss. Skin loss is very rare after otoplasty. In secondary otoplasties there are usually previous scars that can reduce the skin's blood supply and increase the risk of skin loss and skin necrosis. Some surgeons apply pressure bandages after otoplasty, and tissue compression carries an increased risk of skin necrosis. Dr. Joaquim Suñol does not recommend this type of compressive bandages for the postoperative period of otoplasty. If skin loss occurs, additional treatments, including surgery, may be needed.

Delayed healing. Wound opening or delayed healing is rare but possible. Some areas of skin may be lost, which may require frequent bandage changes, or subsequent surgery to remove scar tissue.

In all Otoplasties (but especially Reduction and Secondary ones) it is necessary NOT to smoke and avoid NICOTINE replacement therapies (gum, patches, pills, inhalers and nasal sprays) for at least 15 days before the intervention and until 15 days later. Smokers have a higher risk of skin loss or complications of delayed healing and necrosis.

Allergic reactions. In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may occur to medications used during surgery or prescribed afterward. Allergic reactions may require additional treatment.

Others. You may be dissatisfied with the results of the surgery. Infrequently, additional surgery may be necessary to try to improve results.

Anesthesia. Normally otoplasty is performed under local anesthesia. Dr. Joaquim Suñol will apply local anesthesia, which will be painless. The effect of anesthesia usually lasts about 4-5 hours. Both local and general anesthesia carry a risk. There is the possibility of complications, injuries, and even death, from any form of anesthesia or surgical sedation.

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PATIENT COMPLIANCE

Follow Dr. Joaquim Suñol's instructions carefully; This is essential for the success of the result. It is important that the surgical incisions are not exposed to excessive pressure or force, inflammation, abrasion, or movement during the healing period. Personal and professional activity must be restricted. Protective bandages and drains should not be removed unless instructed to do so. Successful postoperative function depends on both the surgery and aftercare. Physical activity that increases the pulse or heart rate can cause bruising, swelling, fluid buildup, and the need for further surgery. It is wise to refrain from intimate physical activities for a couple of weeks after surgery. It is important that you participate in follow-up care and that you remain in contact with Dr. Joaquim Suñol to resolve any doubts or questions you may have, that you return for subsequent consultations/check-ups, and that you promote your recovery after surgery. until final medical discharge (approximately 1 year).

NEED FOR ADDITIONAL SURGERY

There are many variable conditions in addition to potential surgical risks and complications that can influence the long-term results of otoplasty. Although risks and complications are rare, the risks cited are particularly associated with otoplasty.

Other risks and complications can occur, but are even rarer. If complications occur, additional surgery or other treatments may be necessary. The practice of Medicine and Surgery is not an exact science, and although good results are expected, there is no explicit or implicit guarantee about the results that can be obtained.

ECONOMIC RESPONSIBILITIES

The cost of surgery results from various charges for services provided. The total includes the fees of the surgeon and his assistants, the cost of surgical supplies, anesthesia, laboratory tests, and possible hospital charges, depending on where the surgery is performed. The possible additional costs (prolongation of hospital stay, admission to the ICU, blood transfusions, etc.) if complications arise from the surgery and the costs for secondary surgery or day hospital surgery related to the surgical revision will also be borne by you. position and are not included in the initial indicative budget that has been provided to you.

LEGAL RESPONSABILITY

Operative consent documents are used to inform about the proposed surgical treatment for a disease or condition in addition to the statement of risks and alternative forms of treatment or treatments. The operative informed consent process is intended to define risk disclosure principles that should generally meet the needs of most patients in most circumstances. However, surgical consent documents should not be considered absolute to define other methods of care or the risks encountered. Your plastic surgeon may give you additional or different information based on all the facts of your particular case as well as the state of your medical knowledge.

Operational consent documents are not intended to define and serve as a standard of medical care. Standards of medical care are determined based on all factors involved in an individual case and are subject to change as scientific knowledge and technology advance and as patterns of medical practice evolve.

**IT IS IMPORTANT THAT YOU READ THE ABOVE INFORMATION CAREFULLY AND
HAVE ALL YOUR QUESTIONS ANSWERED BEFORE SIGNING THE CONSENT FOR INTERVENTION OR
TREATMENT FOUND ON THE NEXT PAGE.**

Date and Signature of Patient or Guardian _____ Informed Consent for OTOPLASTY. (Page 4 of 7)

Dr. JOAQUIM SUÑOL · Medical Reg. N° 080824075 · Spanish Board Certified in Plastic, Reconstructive and Aesthetic

CONSENT FOR SURGERY/PROCEDURE OR TREATMENT

1. I hereby authorize Dr. Joaquim Suñol and the assistants who are selected to perform the following procedure or treatment: OTOPLASTY.....

2. I have read, understood and signed the pages of the attached information leaflet: "Informed Consent for Otoplasty".

3. I attest that I have not omitted or altered data when presenting my history and clinical-surgical history, especially those referring to previous interventions, allergies and illnesses or personal risks, including taking medications, toxins or any other type of substances.

4. I am aware that, during the course of the operation and medical treatment or anesthesia, unforeseen conditions may arise that require procedures other than those proposed. I hereby authorize the named surgeon and his assistants to perform these other procedures in the exercise of their necessary and desirable professional judgment. The authorization granted by this paragraph will include any condition requiring treatment that was not known to the surgeon at the time the procedure was initiated.

5. I give consent for the administration of anesthetics that are considered necessary or advisable. I understand that any form of anesthesia carries risk and the possibility of complications, injuries, and even death.

6. I agree that no guarantee has been given to me by anyone as to the result that may be obtained. Photographic simulations of ear size reductions allow us to assess the maximum degree of reduction that could be achieved while maintaining normal aesthetic proportions, but they do not have any guarantee of results.

7. I agree that the two ears may not be completely symmetrical and I accept that the final result presents a slight asymmetry (even of several millimeters), which is totally normal for the vast majority of people.

8. I give consent for the photographing or filming of the operation to be performed, for medical, scientific or educational purposes at in-person Plastic Surgery congresses and on the internet, since my identity will remain protected and cannot be revealed in the images.

9. For the purpose of advancing medical education, I give consent for the entry of observing surgeons into the operating room.

10. I undertake to faithfully follow, to the best of my ability, the instructions of Dr. Joaquim Suñol before, during and after the aforementioned operation and until final discharge. I understand, understand and accept that postoperative visits are essential and fundamental to achieving a good final result. I undertake to faithfully follow them, as well as all postoperative recommendations until final medical discharge.

11. I accept that Dr. Joaquim Suñol delays or suspends the operation if he believes it is necessary.

12. I understand that the purpose of the operation is to improve my appearance, with the possibility that some imperfection persists and that the result may not be what I expected. I know that Medicine is not an exact science and that no one can guarantee absolute perfection. I acknowledge that no such guarantee has been given to me at all. I also understand and it has been duly explained to me that a second or even successive surgical times may be necessary in the future for small corrections, in order to achieve a good final result.

THE FOLLOWING HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- a. THE ABOVE-MENTIONED TREATMENT OR OPERATION TO WHICH I WILL SUBJECT.
- b. THERE MAY BE ALTERNATIVE OPERATIONS OR METHODS TO THE TREATMENT.
- c. THAT THERE ARE RISKS IN THE PROPOSED OPERATION OR TREATMENT
- d. THE LOCATION OF THE SCARS: In folds, grooves and areas close to the defect to be corrected.

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I **CONFIRM** that the aforementioned operation has been thoroughly explained to me by the surgeon in words understandable to me, with the risks involved, other alternative treatment solutions (when they exist), as well as the discomfort or, sometimes, pain that I may feel, having a normal postoperative period. I have understood the explanations that have been provided to me in clear and simple language, and the doctor who has treated me has allowed me to make all the observations and has clarified all the doubts that I have raised.

I **EXPRESSLY CONSENT** to the processing of my personal data that, in accordance with Organic Law 3/2018, will be collected for the purpose of adequately managing the intervention and peri- and postoperative process, and incorporated into the files for which Dr. Joaquim Suñol is responsible. I declare that all the data provided by me is true and correct, and I undertake to communicate any changes that may occur therein. Likewise, in order to successfully carry out said intervention and treatment, I expressly consent to the transfer of my data to as many professionals as necessary to carry out the relevant professional consultations.

The privacy policy of Dr. Joaquim Suñol guarantees the Patient in all cases the possibility of exercising their right of access, rectification, cancellation and opposition of their data, notifying Dr. Joaquim Suñol by writing to Dr. Joaquim Suñol, street Cister 2 · 08022 Barcelona, or by email to: consulta@drsunol.com

THIS DOCUMENT MUST BE DELIVERED AND SIGNED AT THE CONSULTATION, AT LEAST 24 HOURS PRIOR TO THE INTERVENTION. FAILURE, THE ABSOLUTE AND FULL CONFORMITY OF THE PATIENT WITH WHAT IS STATED HERE IS ASSUMED.

I CONSENT TO THE TREATMENT OR OPERATION AND TO THE ABOVE-MENTIONED POINTS, HAVING READ AND UNDERSTOOD IN CLEAR LANGUAGE THE INFORMATION DETAILED IN THE 7 PAGES OF THIS CONSENT. I HAVE BEEN ASKED IF I WANT A MORE DETAILED EXPLANATION, BUT I AM SATISFIED WITH THE EXPLANATION AND DO NOT WANT MORE INFORMATION.

Accordingly, I freely and voluntarily give my consent to the treatment or procedure.

Name and Surname:.....	
Passport Number:.....	
As I authorize the carrying out of the aforementioned procedure.	
Signature of legal representative or patient	Signature of Dr. Joaquim Suñol

(In the case of PATIENT INCAPACITY, the consent of the legal representative will be necessary).

(In the case of MINORS, the minor will always be informed according to his or her level of understanding and, if he or she is over 12 years old, his or her opinion will be heard. If the patient is emancipated or is over 16 years old, he or she will be the one to grant consent. However, in case of serious risk action, according to the physician's criteria, the legal representatives will also be informed and their opinion taken into account for the decision).

Informed Consent prepared according to the bases of the Spanish Society of Plastic, Reconstructive and Aesthetic Surgery (SECPRE)
Version 2024 – www.drsunol.com

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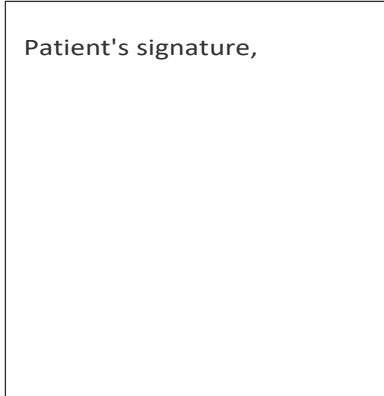
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DENIAL OF CONSENT

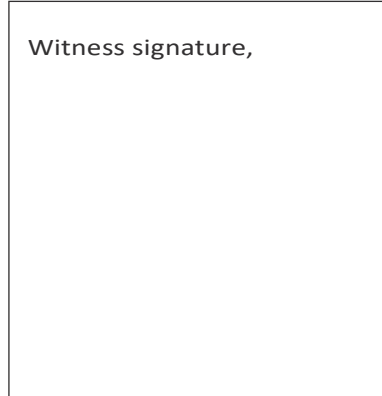
After being informed of the nature and risks of the proposed procedure, I freely and consciously express my refusal of consent for its performance, taking responsibility for the consequences that may arise from this decision.

Reason:

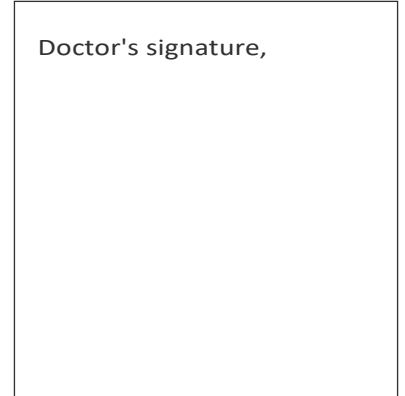
Patient's signature,



Witness signature,



Doctor's signature,



EXPLANATORY IMAGES

(Space for optional insertion, by the surgeon, of images, anatomical diagrams, pictograms, etc.).