מדבקת המטופל

Consent form: procedure for closing a hole in the tympanic membrane (tympanoplasty) and/or for ossicular reconstruction (ossiculoplasty)

The purpose of this procedure is to close a hole in the tympanic membrane in order to prevent inflammation, improve the patient's hearing and prevent long term complications, and/or reconstruct the auditory conduction mechanism. It is done by access through the ear and/or an incision behind the ear. Sometimes shaving the hair over and behind the ear may be necessary. The transplant used for closing the hole in the tympanic membrane is normally taken from the tissue covering the temple muscle, and sometimes from ear cartilage or the fat in the earlobe. In such cases, an additional incision may be necessary. The success rate in implanting tympanic membrane is over 90% in adults and around 80% in children. In order to correct any injury to the ossicles, an artificial prosthesis can be implanted, or cartilage or one of the patient's ossicles may be used. The procedure is administered under general or local anesthesia.

Patient's name: _____
Last name First name Father's name ID

I hereby declare and confirm I have been provided with a detailed oral explanation by

Dr. _____ about the need to perform a tympanoplasty or
Last name First name

ossiculoplasty on the _____ side as a result of _____
(hereinafter "The Main Procedure").

It has been explained to me that there are cases requiring a repeat procedure as a result of the implant's failure to absorb or unsuccessful recovery of the patient's sense of hearing. In some cases more than one procedure may be planned to begin with. It is possible that months and even years after a successful procedure to recover the patient's hearing, the prosthesis may dislocate or be expelled, and as a result the patient's sense of hearing may deteriorate, requiring an additional procedure.

It has been explained to me that in the event of an external incision a scar will remain, and that the scar's shape depends on my skin type and its healing properties, with keloid scars developing in some cases (thick, conspicuous scars).

I hereby declare and confirm that the Main Procedure's side effects have been explained to me, including pain in the ear, numbness in the area of the operation, pain during chewing, and an alteration of the sense of taste.

Additionally, the Main Procedure's possible risks and complications have been explained to me, including: bleeding, infection, tinnitus (ringing in the ear), and an injury to the inner ear that may lead to dizziness. In rare cases (about 1%) deterioration of the patient's hearing may occur, to the point of deafness. An injury to the facial nerve is very rare and mostly temporary, but permanent injury is also possible.

I hereby provide my consent to performance ofthe Main Procedure.

I hereby declare and confirm that I have been provided with an explanation and understand that it is possible to discover in the course of the Main Procedure that its scope must be extended or altered, or that other or additional procedures need to be performed in order to save the patient's life or prevent physical damage, including additional surgical procedures that cannot at this time be foreseen with any certainty or completeness but the significance of which has been explained to me. Therefore, I additionally agree to such alteration / extension of the procedure or to the administration of other or additional procedures, including surgical procedures that in the opinion of the institution's physicians will be essential or necessary in the course of the Main Procedure.

I am aware that a transfusion of blood or blood products, such as concentrated red blood cells, fresh plasma, concentrated platelets or cryoprecipitate is given to patients in need of such a transfusion, via an intravenous drip, during surgery or other medical procedures – in light of illness, blood loss, or a lack of blood or one of its components. The administration of blood or blood products is intended to save the life of the patient and to improve his/her chances of recovery and recuperation.

Collection and testing of blood and/or blood products for a transfusion is performed in strict compliance with the guidelines outlined by the Ministry of Health. In addition, the compatibility of the blood units and the blood products with the recipient patient is verified. Nevertheless, there is a very small risk that there may not be full compatibility between the blood and/or blood products and the patient's body, and that, as a result, the patient may suffer an allergic reaction, which will be manifested by fever, rash or chills. These reactions can be successfully treated. In rare cases, a hemolytic reaction (destruction of red blood cells) may occur, which in extreme cases can impair kidney function and even be fatal. In addition, despite the fact that the blood units and the blood products for transfusion are prepared at the Blood Bank, using the most up-to-date methods for detection of possible contamination, there is a small chance of patient infection. This infection may not be detected for a period of months or even years. The risk of becoming infected with viral hepatitis or AIDS (the human immunodeficiency virus) exists, but is extremely rare.

However, the risk to the health of the patient as a result of not receiving the blood or blood-product transfusion during surgery or medical treatment is much greater than the risks inherent in receiving the transfusion. The risks in not receiving blood or blood products include increased length of hospitalization, failure of the medical treatment provided, medical complications, and in certain cases, even death.

In view of the above, I consent to receive a blood transfusion, as justified by my medical condition.

My consent is also hereby provided to the administration of local anesthetics with or without intravenous injection of sedatives, after having been provided with an explanation about the risks and complications of local anesthesia including varying degrees of allergic reactions to the anesthetics, and the possible complications of using sedatives that in rare cases may lead to respiratory impairments and cardiac function impairments, particularly in cardiac patients and in patients with respiratory disorders.

It has been explained to me that if the procedure is performed under general anesthesia, an explanation about the anesthesia will be provided to me by an anesthetist.

I am aware and agree that the Main Procedure and any other main procedure will be performed by the person assigned to do so according to the institutions policies and instructions, and that there is no guarantee that all or any of the procedures will be performed by a particular person, so long as they are responsibly administered as is customary in the institution and subject to the law.

_____

Date Hour Patient's signature

_____

Guardian's name (relationship) Guardian's signature (in case of incompetent, minor or mental patient)

I confirm that I have explained to the patient / the patient's guardian* all of the above in appropriate detail and that he/she has signed this consent form before me after I have become satisfied that he/she fully understands my explanations.

_____

Physician's name Physician's signature License no.

* Strike out the irrelevant item

Israeli Medical Association **Medical Risk Management Company Ltd.**

ההסתדרות הרפואית בישראל
איגוד רופאי אף-אוזן-גרון וכירורגיה של ראש צוואר

החברה לניהול סיכונים ברפואה בע"מ