

Consent Form: Cochlear Implant

The operation is intended to generate hearing in children born without hearing, or rehabilitate hearing in adults with severe hearing disorder, bordering on deafness. Indication for surgery is a hearing defect that prevents communication with the environment despite the use of a hearing aid. The operation is carried out through making a section behind the ear, in which the bone behind the ear is drilled in order to plant an electrode into the cochlea and an electronic processor under the skin behind the ear. In some cases, a combined implant may be recommended (cochlear implant plus hearing aid). In most cases, the hair above and behind the ear must be shaved off.

Following surgery, an adaptation period is required, as well as cooperation of the implant recipient and his family in the rehabilitation process.

The surgery is usually carried out under general anesthesia.

I hereby declare and confirm having received a detailed oral explanation from Dr. _____
Last name First name

About the need for cochlear implant on the _____ side/ both sides, due to _____
_____ (hereinafter: "the
procedure")

I was informed some cases require a repeated operation due to lack of success in positioning the implant or the implant's faulty operation. Failure to insert the electrode may occur. Sometimes, after several years, the implant may undergo technical or electronic malfunction. Furthermore, the implant may have to be replaced due to infiltration of liquid into the envelope or chronic infection.

I hereby declare and confirm I received an explanation about the side effects of the procedure including hemorrhaging, infection, pain in the area of the surgery, decline in sensation in the area of the surgery, pains when chewing, possible change in sense of taste.

Furthermore, I received an explanation about the possible risks and complications of the procedure, including: paralysis of the facial nerve, temporary or lengthy impairment of balance (dizziness), loss of residual hearing (if any) in the operated ear, necrosis of the skin covering the electronic processor, electric stimulation of the facial nerve or electric stimulation causing pains, tinnitus (buzzing in the ear), leakage of brain liquids, inflammation or infection of the meninges or brain tissues, massive hemorrhaging due to injury to a major blood vessel. I was told that in any case I would have a scar behind the ear. The shape of the scar depends on my skin type and its healing qualities and in some cases keloid scars (thick, prominent scars) may develop.

I was informed that following the procedure, I will have to guard against injury to the implant area, refrain from exposure to electromagnetic radiation (at the entrance to airports and public buildings),

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static electricity (slides). Furthermore, I will not be able to undergo MRI tests and must warn surgeons against using electric scalpels in any future surgery.

I hereby declare and confirm that I have received an explanation and am aware of the possibility that in the course of the procedure the need may arise to extend its scope, modify it or use other or additional procedures to save life or prevent physical damage, including additional surgical procedures that cannot be foreseen certainly or fully at this stage, but their significance has been explained to me. I therefore also consent to said extension, modification or other or additional procedures, including surgical actions institution physicians believe to be vital or required during the course of the 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.

I was informed that the procedure will be performed under general anesthesia, and the anesthetist will give me a relevant explanation about it.

I am aware that and consent to the procedure and all other procedures to be carried out by the person to whom it was allocated according to the institution's procedures and instructions, and I have not received any assurance that the procedure or a part thereof will be carried out by a particular person, provided it is carried out within the responsibility accepted by the institution and subject to the law.

| | | |
|------|------|---------------------|
| Date | Hour | Patient's signature |
|------|------|---------------------|

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

I hereby confirm that I provided the patient/the patient's guardian* with an oral explanation of all of the above in required details and s/he signed the consent before me after I was convinced s/he fully comprehended my explanation.

Physician's name

Physician's signature

License no.

* Strike out the irrelevant item

Israeli Medical Association

Medical Risk Management Company Ltd.

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