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),

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 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.**

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

החברה לניהול סיכונים ברפואה