



CONSENT FORM FOR COCHLEAR IMPLANT

Med Rec. No.....

Surname:.....

Forename:

DOB:.....

AFFIX LABEL HERE

PROPOSED TREATMENT

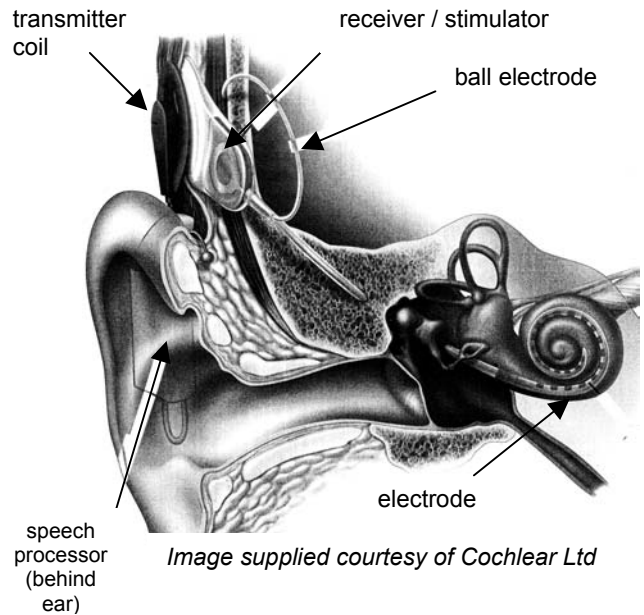
The doctor has explained that I, (*name of patient*), haveand that a **cochlear implant** on theside/s is proposed:

This means implanting a small device behind the ear that bypasses damaged inner ear structures and sends electrical signals directly to the auditory nerve to be sent to brain and interpreted as sound. There are several different varieties of implant; your surgeon will advise which is best for you.

This is a quality of life, elective, procedure. You do not need it to live a normal life span.

Under a general anaesthetic, a cut is made behind the ear and a small area of the mastoid bone hollowed out to lodge the receiver/stimulator part of the device. An array of electrodes is inserted through the skull into the cochlea (inner ear). Any bleeding is stopped and the skin wound closed over the device.

The external part of the device will be fitted when the wound has healed.



RISKS

These are the commoner risks. There may be other unusual risks that have not been listed here. Please ask your ENT surgeon if you have any general or specific concerns.

I understand there are risks associated with any **anaesthetic** (see separate *Anaesthetic Consent Form*).

I may have side effects from any of the drugs used. The commoner side effects include light-headedness, nausea, skin rash and constipation.

I understand the procedure has the following **specific risks and limitations**:

- The device will not cure my deafness nor will it completely restore my hearing. I am likely to need some 'listening' training to be able to benefit as much as possible.
- I will need to have regular follow-up and the device will need regular maintenance
- I may have some dizziness, dryness in my mouth and/or ringing in my ear(s) after the operation as a result of the surgery to the skull. This resolves in most people.
- My wound may become infected and I may need antibiotics for this. Rarely the skin wound may fail to heal and the device may have to be removed.
- Very rarely, I may have some bleeding after the operation, which may require local treatment or occasionally a return to the operating theatre.
- I may notice some numbness or stiffness around the ear, which in most cases will improve gradually with time.
- I may have some loss of taste on the side of the operation, which may be temporary or permanent.
- Very rarely, I may have some temporary weakness of my face muscles if there is some swelling near the facial nerve, which runs close to the operation site. This usually resolves over the course of some weeks, but permanent paralysis may rarely occur.
- I may have some pain in the area of the coil, which should improve over time.
- My body may 'reject' the implant, which may be extruded.
- Placement of the implant may stimulate new bone growth, which may damage surviving nerves and make replacement of my device difficult.

RISKS CONTINUED OVERLEAF →

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RISKS CONTINUED

- The implants have been in use for over 30 years without any reports of consequences from electrical stimulation. If problems should develop in future, the implant can be easily removed.
- The external equipment may fail and require remapping. The internal device may fail eg after a blow to the head. I will need to avoid sports where there is a potential to damage the device, and must warn medical staff that I have one, as some procedures or investigations can damage the device.

I understand some of the above risks are more likely if I smoke, on overweight, diabetic, have high blood pressure or other medical conditions.

INDIVIDUAL RISKS

I understand the following are possible significant **risks and complications specific to my individual circumstances**, that I have considered in deciding to have this operation:

.....
.....

DECLARATION BY PATIENT

- I acknowledge the ENT surgeon has informed me about the procedure, alternative treatments and answered my specific queries and concerns about this matter.
- I acknowledge that I have discussed with the ENT surgeon any significant risks and complications **specific to my individual circumstances** that I have considered in deciding to have this operation.
- I agree to **any other additional procedures** considered necessary in the judgement of my ENT surgeon during this operation.
- I agree to the disposal by the hospital authorities of any tissues that may be removed during the procedure. I understand that some tissues or samples may be kept as part of my hospital records.
- I understand that a doctor other than the specialist ENT surgeon may perform the procedure.
- I have received a copy of this form to take home with me.
- If a needlestick/sharps injury occurs to staff during any operation I give my permission for blood to be taken and tested for HIV and other blood borne disorders. I understand I will be advised and counselled as soon as practicable after the operation if this has been necessary.

Signature of patient **Date**

If the patient is an adult and unable to give consent, a proxy form must be completed and attached

DECLARATION BY DOCTOR

- I declare that I have explained the nature and consequences of the operation to be performed, and discussed the risks that particularly concern the patient
- I have given the patient an opportunity to ask questions and I have answered these.

Doctor's signature

Doctor's name **Date**
(please print)

INTERPRETER'S DECLARATION - I confirm I have accurately interpreted the contents of this form and the related conversations between the patient and the doctor

Interpreter's signature **Date**

Interpreter's name