

CONSENT FOR COCHLEAR IMPLANT

Name:

Age / Sex:

Date of Birth: Proposed Date of Surgery:

Hospital Registration No: _____

Type of Implant:

Address:

PROPOSED TREATMENT

The doctor has explained that I/my _____ have /has
(Condition /diagnosis) _____ and that a cochlear implant on
the _____ side/s is proposed.

OPTIONAL: I have chosen to get _____ model of _____ Company
Implanted on myself / my _____

COCHLEAR IMPLANTATION

The cochlear implant is an electronic device that is implanted inside the cochlea (inner ear), which bypasses damaged or absent hair cell and provides electrical stimulation directly to the hearing nerve fibres.

Under a general anaesthetic, an opening 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 into the cochlea (inner ear). Any bleeding is stopped and the skin wound close over the device. The external part of the device will be programme and fitted when the wound has healed. The Programming is usually done after two or three weeks.

BENEFITS OF COCHLEAR IMPLANTATION

Cochlear implantation is designed for people with severe to profound hearing loss who derive limited benefits from hearing aids. The speech / language / hearing skill will improve following cochlear implantation. The improvement depends upon many factors which have been explained to me by the cochlear implant team, audiologist and therapist.

RISK

These are the more common risks. There may be other unusual risks that have not listed here.

I understand that there are risks associated with any anaesthesia.

I / my _____ may have side effects from any of the drugs used. The Common 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 / my _____ deafness nor will it completely restore by hearing. I am likely to need some ‘listening’ training to be able to benefit as much as possible.
- There may be circumstances where it may not be possible to insert the implant completely and this may sometimes affect eventual outcomes.
- The ability of the implant to improve speech perception will depend on the ability of the auditory nerve to conduct the electrical stimulus and the functional integrity of the auditory cortex. This may not be possible to detect with current investigative methods accurately and so if the auditory cortex and the nerve are defective the outcomes may be poor.
- Static electricity may damage the electronic components of the device or the program.
- I / my _____ will need to have regular follow- up for ENT consultation; programming and auditory verbal therapy and the device will need regular maintenance.
- I / my _____ 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 ear.
- I / 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. In post operative period, there may be leakage of fluid from the cochlea perhaps requiring a further operation.
- Very rarely I may have 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.
- Rarely, I may have 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.
- Very rarely, my body would '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.
- The implants have been used for over thirty 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 re-mapping. Should there be a need for the patient to undergo Magnetic Resonance Imaging, the magnet in the cochlear implant would need to be surgically removed.
- The internal implant may fail and need a second surgery to replace the damaged device. I / my relative will need to avoid sports where there is a potential to damage the device, and must warn medical staff and I / my relative have one, as some procedures or investigations can be damage the device. Hence we should contact the implant surgeon for advice.
- I understand some of the above risks are more likely if I / my relative smoke/ s become overweight, diabetic, 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 / RELATIVE

- I acknowledge that the ENT surgeon & Audiologist have informed me about the procedure, alternative treatments & answered my specific queries & concerns about this matter.
- I understand the need for continuous follow up care & therapy for adequate benefit.
- I acknowledge that I have discussed with the ENT surgeon regarding any significant risks & complications specific to my / our 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 / our ENT surgeon during this operation.

- I understand that a doctor other than the specialist ENT surgeon may perform the procedure, when necessary.
- I have received a copy of this form to take home with me.
- If a needle stick / sharp injury occur to staff during any procedure I give my permission for blood to be taken & tested for HIV & other blood borne disorders. I understand that I will be advised & counselled as soon as practicable after the operation if this has been necessary.
- I understand that the recordings from my surgery / programming may be used at presentations / promotions if necessary without revealing my identity.

OPTIONAL:

We, _____ of _____ have agreed to use _____ cochlear implant system.

We have been informed of the specifications / functioning.

We have been informed of the various warranty associated with the cochlear implant system.

We have been informed the costs associated with post operative maintenance of the device.

Signature of patient / relative: _____

Relationship to patient: _____

Signature of Witness: _____

Name of Witness: _____

Date: _____

DECLARATION BY DOCTOR

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

Surgeon's signature: _____ Anaesthetist's signature: _____

Surgeon's Name: _____ Anaesthetist's Name: _____

Date: _____