Queensland Government

Cochlear Implant Consent

Adult (18 years and over)

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

A. Does the patient have capacity?

☐ Yes ➔ ***GO TO** section B*

☐ No ➔ ***COMPLETE** section A*

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

B. Is an interpreter required?

If *yes*, the interpreter has:

☐ provided a sight translation of the informed consent form in person

☐ translated the informed consent form over the telephone

Name of interpreter:

Interpreter code: Language:

C. Patient/substitute decision-maker requests the following procedure(s)

Cochlear implant

Site/side of procedure:

D. Risks specific to the patient in having a cochlear implant

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in *not* having a cochlear implant

(Doctor/clinician to document specific risks in not having a cochlear implant):

F. Alternative treatment options

(Doctor/clinician to document alternative treatment not included in the patient information sheet):

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient/substitute decision-maker.

I have explained to the patient/substitute decision-maker the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature: Date:

DO NOT WRITE IN THIS BINDING MARGIN

COCHLEAR IMPLANT CONSENT

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H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the "Cochlear implant" patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- the specific risks and benefits of the procedure
- the prognosis, and risks of not having the procedure
- alternative treatment options
- that there is no guarantee the procedure will improve the medical condition
- that the procedure may involve a blood transfusion
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if a life-threatening event occurs during surgery, I will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure/treatment/investigation/examination; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form *(this should be in consultation with the doctor/clinician)*.

I/substitute decision-maker have received the following consent and patient information sheet(s):

☐ "Cochlear implant"

☐ "About your anaesthetic"

☐ "Blood and/or manufactured blood products transfusion"

On the basis of the above statements,

1) I/substitute decision-maker consent to having a cochlear implant.

Name of patient/substitute decision-maker:

Signature: Date:

DO NOT WRITE IN THIS BINDING MARGIN

Cochlear implant

Adult (18 years and over) | Informed consent: patient information

A copy of this form should be given to the patient/substitute decision-maker to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

1. What is a cochlear implant and how will it help me/the patient?

A cochlear implant is a surgically implanted device that provides a sense of sound to someone who has severe to profound hearing loss. A cochlear implant may improve hearing at comfortable listening levels, allow the patient to detect individual sounds, understand others more accurately and use the telephone.

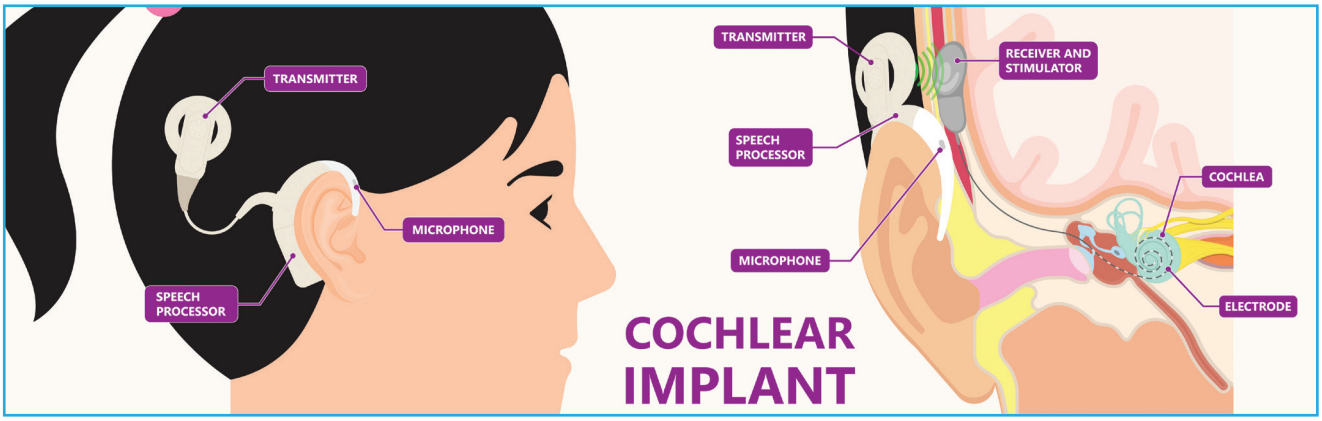

Image: Cochlear implant. ID: 1793297512. www.shutterstock.com

The decision to proceed with a cochlear implant is an important one that is made in consultation with the patient, their family and the medical team.

The surgery itself takes between 2 to 4 hours depending on complexity, and if one or both ears require a cochlear implant. Sometimes an area of hair will be shaved behind the ear before a small incision (cut) is made. During the procedure, the surgeon makes a cut behind the ear and opens the mastoid bone. The facial nerve is identified and an opening to access the cochlea is created and the electrodes of the implant are inserted into the cochlea. The receiver is placed under the skin on top of the bone behind the ear. The skin incision is then closed, and dressings and head bandage applied. The doctor/clinician may perform tests to measure response to the implant.

Types of implants

You will be given information regarding the available implants and speech processors and their advantages and disadvantages. Implants vary in the type of magnet they contain. This can have an effect on the ability of the person to undergo Magnetic Resonance Imaging (MRI) scans and use particular models of speech processors, such as off-the-ear processors. Although every effort will be made to implant a device that aligns with your preference, technical or other issues at the time of surgery may mean that this is not possible.

2. What are the risks?

There are risks and potential complications with this procedure. There may also be risks specific to a person's individual condition and circumstances. Please discuss these with the doctor/clinician and ensure they are written on the consent form before you sign it. Risks include but are not limited to the following:

Specific risks

- the ear may be numb after the surgery
- nerve damage may cause the following:
  – changes in taste
  – weakness and paralysis of the face
- balance may be affected, this may be long-term
- rarely, balance upset may be permanent and life changing
- tinnitus (ringing in ears)
- infection of the fluid around the brain (meningitis)
- poor hearing result
- loss of residual hearing
- leakage of fluid from the cochlea, perhaps requiring another operation
- device movement and/or malfunction
- possible implant removal (under extraordinary circumstances)
- electrode misplacement or tip rollover
- implants may malfunction, although this is rare
- it may be necessary to remove the magnet if Magnetic Resonance Imaging (MRI) is required in the future.

General risks

- excessive bleeding may occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- infection may occur, requiring antibiotics and further treatment
- small areas of the lung may collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy
- heart attack or stroke may occur due to the strain on the heart
- blood clot in the leg (deep vein thrombosis or DVT) causing pain and swelling. In rare cases part of the clot may break off and travel to the lungs
- death as a result of this procedure is possible.

This procedure will require an anaesthetic.

For more information about the anaesthetic and the risks involved, please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with the doctor/clinician.

If you have not been given an anaesthetic information sheet, please ask for one.

What are the risks of not having a cochlear implant?

There may be consequences if you choose not to have the proposed procedure/ treatment/investigation/examination. Please discuss these with the doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure/treatment/ investigation/examination. Please contact the doctor/clinician to discuss.

3. Are there alternatives?

- Assistive devices.
- Other types of implants and hearing aids.
- Alternative forms of communication such as sign language.

4. What should I expect after the procedure?

You may have mild to moderate pain in and around your ear and have a headache for a few days. You may have some popping or clicking in your ear(s) and feel dizzy. This usually goes away within 1 week. The area behind your ear will be swollen for about 3 to 5 weeks. The incision will leave a scar that will fade with time.

The doctor/clinician will not turn on, or activate, the implant until the incision has healed. This is in about 2 to 6 weeks but can be earlier. Most adults are able to return to work 1 to 2 weeks after surgery.

- Avoid strenuous activities, such as bike riding, jogging, weight-lifting, or aerobic exercise, for about 4 to 6 weeks or until your doctor/clinician says it is okay to do so. Avoid lifting anything that would make you strain.
- You may shower and wash your hair about 1 week after the surgery. Keep water out of your ear by using an ear plug or shower cap. Do not put your head underwater until your doctor/clinician tells you it is okay to do so.
- You may have a bandage over the incision. This may be able to be removed 2 or 3 days after surgery or when your doctor/clinician says it is okay to do so.
- After you remove the bandage, wash the area daily with warm, soapy water, and pat it dry. Don't use hydrogen peroxide or alcohol-based products, which may slow healing.
- Do not blow your nose. If you need to sneeze or cough, do not try to stop it. Open your mouth and do not pinch your nose.

When to contact your doctor/clinician or hospital

If any of the following occurs, call the hospital and ask for the ear, nose and throat (ENT) registrar or the emergency department:

- increased pain (some pain is common but should be relieved by paracetamol)
- bleeding or discharge from the bandaged ear
- distress, dizziness or vomiting
- signs of infection (e.g. temperature over 38.5°C)
- redness or swelling around the bandaged ear
- weakness of the muscles of the face.

Precautions following cochlear implant surgery

MRI:
MRI is not recommended for those with a cochlear implant. Some low strength and lower body MRI scans can be done with a cochlear implant in place. Magnet removal is possible if required.

Radiographers/radiologists must be advised about the presence of a cochlear implant.

Air travel:
Cochlear implants will activate metal detectors. An identification card must be carried. X-ray equipment will not damage cochlear implants or speech processors.

Sport:
Direct impact on the implant site can damage the implant. Full contact sports, sky diving, hockey and lacrosse are not recommended. Protective head gear is recommended for bat and ball sports.

Long-term commitment:
Post-operatively it may take months for the brain to learn to use the implant information. During that time, and every year thereafter, it is necessary to attend audiology appointments for adjustment of the implant parameters ('mapping').

You will also need to attend regular speech pathology and audiology/auditory training appointments to obtain maximum benefit from the cochlear implant(s). It is usual after a cochlear implant to lose any residual hearing. The audiology appointments will be lifelong.

5. Who will be performing the procedure?

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could be a doctor/clinician undergoing further training, all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss with the doctor/clinician.

6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss with your doctor/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.

7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your/the patient's medical condition, treatment options and proposed procedure.

8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.