



**Queensland
Government**

Cochlear Implant Consent

Child/Young Person (under 18 years)

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 Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure/treatment/investigation/examination and the consequences of non-treatment – ‘Gillick competence’ (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)

→ **GO TO section B**

No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form

→ **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person* → Documentation verified

Name of parent/legal guardian/other person*:

Relationship to child/young person:

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/parent/legal guardian/other person* 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/parent/legal guardian/other person*.

I have explained to the patient/parent/legal guardian/other person* 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

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SW9504

COCHLEAR IMPLANT CONSENT



Cochlear Implant Consent

Child/Young Person (under 18 years)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

H. Patient/parent/legal guardian/other person* consent

I acknowledge that the doctor/clinician has explained:

- the "Cochlear implant" patient information sheet
- my/the child's 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 an immediate life-threatening event happens during the procedure/treatment/investigation/examination, health care will be provided in accordance with good clinical practice and in my/the child's best interests
- 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/the child will be asked to sign a separate consent form. If I/the child choose not to consent, it will not adversely affect my/the child's access, outcome or rights to medical treatment in any way.

I/the child 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/parent/legal guardian/other person* have received the following consent and patient information sheet(s):

- "Cochlear implant"
- "About your child's anaesthetic"
- "Fresh and/or manufactured blood products transfusion"

On the basis of the above statements,

I/parent/legal guardian/other person* consent to having a cochlear implant.

Name of patient/parent/legal guardian/other person*:

Signature:

Date:

- I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this treatment (*not applicable if the child/young person is Gillick competent and signs this form*).

Cochlear implant

Child/Young Person (under 18 years) | Informed consent: patient information

A copy of this form should be given to the patient/parent/legal guardian/other person* 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 can provide access to sound for children with severe-to-profound hearing loss or who cannot hear well enough with hearing aids.

There can be a wide range of outcomes for children after receiving a cochlear implant. Many children can learn to listen and speak using cochlear implants. However, others may only be able to hear environmental sounds with their cochlear implant(s). Some children and young people with cochlear implants may still need to use sign language as their main means of communication.

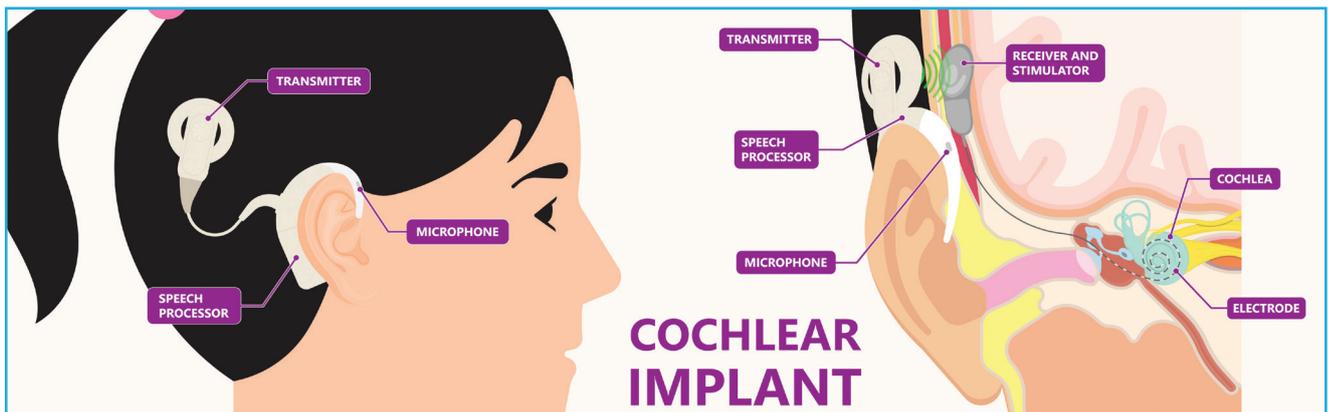


Image: Cochlear implant. ID: 1793297512. www.shutterstock.com

It is not possible to guarantee specific outcomes with a cochlear implant. However, the cochlear implant candidacy criteria are set so that children and young people who meet the criteria should do better with a cochlear implant than they do with their hearing aid(s) providing they wear their devices all the time and attend therapy.

The decision to proceed with a cochlear implant is an important one. It is made only after comprehensive assessment and consultation between 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
- anatomical abnormalities and/or ossification of the cochlea may prevent full insertion of, or an inability to insert, the cochlear implant which may affect subsequent hearing outcomes

- 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
- some diseases and medicines, including complementary medicines, may affect blood clotting. A list of commonly affected medicines is found here www.health.qld.gov.au/consent/bloodthinner.
- 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?

When you see your child after theatre, they will be wearing a head bandage. This stabilises the implant and should be left in place for 1 week. Once back in the ward, your child should rest in bed, keep their head movement to a minimum and remain quiet and calm to minimise dizziness or nausea. Your child will have an intravenous (IV) drip in the back of one hand. Your child may require medication through the IV once they've returned to the ward. Nosebleeds are common after the operation and are of no need for concern. Do not allow your child to blow their nose, however, if they need to cough or sneeze, do not try to stop them.

Your child may have mild to moderate pain in and around their ear and have a headache for a few days. They may have some popping or clicking in their ear(s) and feel dizzy. This usually goes away within 1 week. The area behind their 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 usually happens about 2 to 6 weeks after surgery but can be earlier.

Before discharge, your child will have a Stenver x-ray performed. This x-ray shows the position of the cochlear implant.

Care at home

Medication:

Your child will generally be on oral antibiotics for the week following surgery. The whole course of antibiotics must be taken.

Pain relief:

Pain is usually only mild. Paracetamol may be given. Check with your child's doctor/clinician before giving any other medicines.

Bathing:

Use a shower cap to keep your child's bandage and hair dry while bathing.

When the bandage has been removed, you may wash the area daily with warm soapy water and pat it dry.

Activity:

Your child should keep to quiet activities for approximately one week after the operation.

Bandage care:

If your child's bandage comes off at home it needs to be replaced to minimise the risk of infection. If this occurs bring your child to the emergency department and ask to have the bandage replaced by an ENT registrar.

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
- if weakness of the muscles of the face occurs.

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:

Cochlear implantation is a long-term commitment. You will need to attend regular audiology and speech pathology appointments to obtain maximum benefit from the cochlear implant(s). 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.