

Cochlear[™] Nucleus[®] CI612 cochlear implant with Contour Advance[®] electrode

Physician's Guide

Asia Pacific



Hear now. And always

About this document

This guide applies to the Cochlear™ Nucleus® CI612 cochlear implant, which is a CI600 Series implant.

This guide is intended for surgical staff involved in implanting the device.

Surgeons implanting the device should be experienced in cochlear implant surgery.

Before surgery, ensure you are thoroughly familiar with the information in this guide and the product labelling. The guide includes important information on MRI, indications, contraindications, adverse effects, warnings and precautions. A surgical procedure for implanting the device is also explained.

This guide does not take account of any particular circumstances or factors relevant to an individual patient or case. Other surgical approaches and variations are practised and may be more appropriate in certain circumstances. After considering all relevant circumstances, factors and information in each case, the appropriate surgical procedure is determined by the relevant physician exercising independent medical judgment.

Symbols used in this document



Note

Important information or advice.



Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.



Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

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Warnings and Cautions for device use

This section does not contain all the important information required to use and implant the device, only critical information to implant the device safely and effectively. Read the full *Physician's Guide* before implanting the device.



Warnings

Preoperative

- **Meningitis** is a known risk of inner ear surgery. You should counsel candidates of this risk and determine their immunisation status for micro-organisms that cause meningitis.
- **Wound infection** after cochlear implant surgery or explantation may be prevented by administering broad-spectrum antibiotic before and during surgery.
- The implant is sterilised using **ethylene oxide (EtO)**. After the sterilisation process, residual EtO is less than 0.4 mg per device. This residual level is suitable for a recipient with a body weight of 7 kg or greater.*
- Cochlear Nucleus implants contain magnets, which should be kept away from neurostimulation devices (for example, deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at 2.5 cm (1 in) from the edge of the implant, with or without external sound processor magnet coupled to it, in any direction is less than 300 Gauss.

* Calculated with guidance from EN ISO 10993-7.

Medical treatments generating induced currents, heat and vibration

- **Electrosurgical instruments** can induce radio frequency currents that could flow through the electrode.

When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in) from the electrodes.

- **High currents** induced into the electrode lead can cause damage to cochlea and neural tissues, and the implant.

Do not use:

- **monopolar electrosurgical instruments** on the head or neck of an implant patient
- **therapeutic or medical diathermy** (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave)
- **neurostimulation** directly over the implant.
- **Ultrasound fields** can be inadvertently concentrated at the implant and cause tissue damage or damage to the implant.

Do not use:

- **therapeutic levels of ultrasound energy** directly over the implant
- **medical diathermy using ultrasound** on the head and neck of an implant patient.
- **Electroconvulsive therapy** can cause tissue damage or damage to the implant. Do not use electroconvulsive therapy on an implant patient under any circumstances.

Magnetic Resonance Imaging (MRI)



The Cochlear Nucleus CI612 cochlear implant is **MR Conditional**. MRI is contraindicated except under specific circumstances. Refer to *MRI safety information* on page 54.



Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, or exposed magnet cassette cover or non-magnetic cassette cover.
- **Ionising radiation therapy** can cause damage to the implant. Do not use ionising radiation therapy directly over the implant.



Note

Facial nerve monitor use is advised, particularly for cases where the facial nerve may be at greater risk such as congenital temporal bone anomalies and revision surgeries.

Intended purpose

Intended purpose

The CI612 cochlear implant is intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.

Indications

The degree of hearing loss and lack of benefit from hearing aids must be established and verified clinically using age-appropriate measures before recommending unilateral or bilateral cochlear implants.

Prospective implant recipients should be medically suitable to undergo cochlear implantation, taking into account their age, medical condition, contraindications and surgical risks. They and their families or carers should be well motivated, willing to undergo hearing rehabilitation as needed and have appropriate expectations of the potential benefits of unilateral or bilateral implants.

Cochlear Nucleus cochlear implants are intended for the following individuals:

Group A

Children aged up to 17 years (with no minimum age limit) who, following a clinically established diagnosis:

- have sensorineural hearing loss in one or both ears. Typical preoperative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately-severe to profound degree^{*,†}
- receive or would receive little or no benefit with hearing aids[‡]
- have families or carers who support and are committed to the child's ongoing participation in hearing rehabilitation
- weigh 7 kg or more, due to the potential presence of residual ethylene oxide after sterilisation of the device (refer to *Warnings and Cautions for device use* on page 6).

Group B

Individuals aged 18 years and older who have clinically established postlinguistic bilateral or unilateral sensorineural hearing loss and who receive or would receive little or no benefit with a hearing aid. Typical preoperative threshold levels in the impaired ear demonstrate a pure-tone average loss of moderately severe to profound degree^{*,†}.

Group C

Prelinguistically or perilinguistically deafened individuals aged 18 years and older who have profound bilateral sensorineural hearing loss and who receive or would receive little or no benefit with hearing aids.

* Pure-tone average loss can be defined as the average threshold calculated for four frequencies at 500, 1000, 2000, 3000 and 4000 Hz as available. Reference: American Speech-Language-Hearing Association. (1981). On the Definition of Hearing Handicap [Relevant Paper]. Available from www.asha.org/policy.

† Definition of hearing impairment as quoted by ASHA. Available from www.asha.org/public/hearing/Degree-of-Hearing-Loss (March 2023).

‡ American Academy of Audiology Clinical Practice Guidelines on Pediatric Amplification (June 2013). Available from <https://apps.asha.org/EvidenceMaps/Articles/ArticleSummary/ecbfe2a5-c85d-4836-a629-f4454e43844b>

Contraindications

A Cochlear Nucleus cochlear implant is not suitable for individuals having the following conditions:

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlea development
- tympanic membrane perforation in the presence of active middle ear disease
- ossification of the cochlea that prevents electrode insertion.

Intended users

The intended users who have direct interaction with the Cochlear Nucleus cochlear implant include qualified medical professionals such as surgeons and surgical nurses. The intended users of the Cochlear Nucleus cochlear implant who have indirect use of the device include the recipient into whom the device is implanted, and their carer where appropriate. Additionally, qualified medical professionals such as radiologists and audiologists are also intended users who have indirect interaction with the device.

Benefits

Potential benefits of receiving a Cochlear Nucleus cochlear implant relate to the following:

- better understanding of speech in quiet
- better understanding of speech in noise
- increased satisfaction based on hearing capabilities.

Bilateral hearing loss

Group A, B or C

Most Cochlear Nucleus cochlear implant recipients from group A, B or C with bilateral hearing loss will experience:

- detection of medium to loud environmental sounds
- detection of conversational speech.

The listening level perceived by the recipient is determined by the programming of the sound processor.

Some Cochlear Nucleus cochlear implant recipients from group A, B or C with bilateral hearing loss will experience:

- limited improvement in the recognition of environmental sounds
- limited ability to use the telephone.

Group A or B

Most Cochlear Nucleus cochlear implant recipients from group A or B with bilateral hearing loss will experience:

- improvement in speech recognition in a quiet environment in the implanted ear
- improvement in speech recognition in a noisy environment
- improvement in overall sound quality
- reduced tinnitus
- reduced fatigue when listening.

Unilateral hearing loss

Group A or B

Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience no change to the hearing status of the non-implanted ear.

Most Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience:

- improved identification of environmental sounds in the implanted ear
- improved speech recognition in a quiet environment in the implanted ear.

Some Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience:

- improvement in identifying the direction of environmental sounds and speech
- improvement in speech recognition in a noisy environment
- improvement in overall sound quality
- reduced tinnitus
- reduced fatigue when listening.

Children

Generally, children with bilateral hearing loss require considerably more listening experience, therapeutic and educational support than adults to achieve the benefits described above.

All implant recipients

In cases where the intracochlear array is partially inserted into the cochlea, recipients may not experience some of the benefits described above.

Adverse effects

Prospective Cochlear Nucleus cochlear implant recipients should be advised of the following possible effects of receiving an implant:

- Normal risks associated with surgery and general anaesthesia.
- Increased surgical and anaesthetic risks for certain populations.
- Complications most frequently associated with this surgical procedure—stimulation of the facial nerve, taste disturbance and tinnitus.
- Complications that may require additional medical treatment, surgery and/or removal of the device, such as:
 - Acute Otitis Media (AOM)
 - facial nerve injury leading to temporary facial nerve weakness
 - perilymph fistula
 - concurrent Cerebrospinal Fluid (CSF) leakage
 - vestibular dysfunction
 - subdural injury
 - subcutaneous haematoma
 - irritation, inflammation or breakdown of the skin flap, infection, and in some cases, extrusion of the device caused by the presence of a foreign body under the skin
 - decreased hearing ability caused by the electrode array migrating partially or completely out of the cochlea
 - perforation of external ear structures, such as the tympanic membrane or canal wall, by the electrode lead
 - perception of non-auditory sensations and poorer performance than expected from misplacement of the electrode array.

- Electrical stimulation may result in increased tinnitus, temporary facial nerve stimulation, temporary dizziness, or temporary pain.
- The long term effects of electrode insertion trauma or chronic electrical stimulation are unknown. Such effects may include new bone growth in the cochlea or deterioration of the nerve cells. These effects may preclude replacement of the electrode array or may lead to eventual deterioration of cochlear response.
- Failure of component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Failure of various component parts of the implanted device could require removal or replacement of the implant, or a reduction in the number of electrodes used.

Meningitis

Before implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against micro-organisms that cause meningitis.

Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. Certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- CSF shunts or drains
- recurrent episodes of bacterial meningitis before implantation
- perilymph fistulas and skull fracture/defect with CSF communication.

Loss of residual hearing

Inserting the electrode into the cochlea may result in complete loss of residual hearing in the implanted ear.

Device description

Cochlear Nucleus cochlear implant systems are designed to provide useful hearing. The system works by converting sound in the environment into electric pulses that stimulate the auditory nerve, allowing the brain to perceive sound.

The Cochlear Nucleus cochlear implant system has implanted and external components.

Implanted component

The cochlear implant is surgically implanted under the skin behind the ear. It includes a receiver/stimulator to receive and decode the electrical signals from the sound processor and an electrode to deliver these signals to the cochlea.

External components

The external components include a sound processor, and associated accessories and cables.

The system is programmed by a Cochlear proprietary programming system.

For information on compatibility between implants and sound processors, refer to the *Custom Sound® User Guide*.

Magnet cassette

CI600 Series implants have implant coil plates either side of a magnet pocket which contains a removable magnet cassette. This design allows for magnet removal and replacement from the distal end of the implant coil, if required.



Figure 1: CI600 Series implant with magnet cassette partially removed from pocket

The Cochlear Nucleus CI612 cochlear implant with Contour Advance electrode

The CI612 cochlear implant with Contour Advance® electrode has a receiver/stimulator which receives and decodes the electrical signal from the sound processor, and an electrode array which delivers the signal to the cochlea.

The CI612 cochlear implant is a CI600 Series implant.

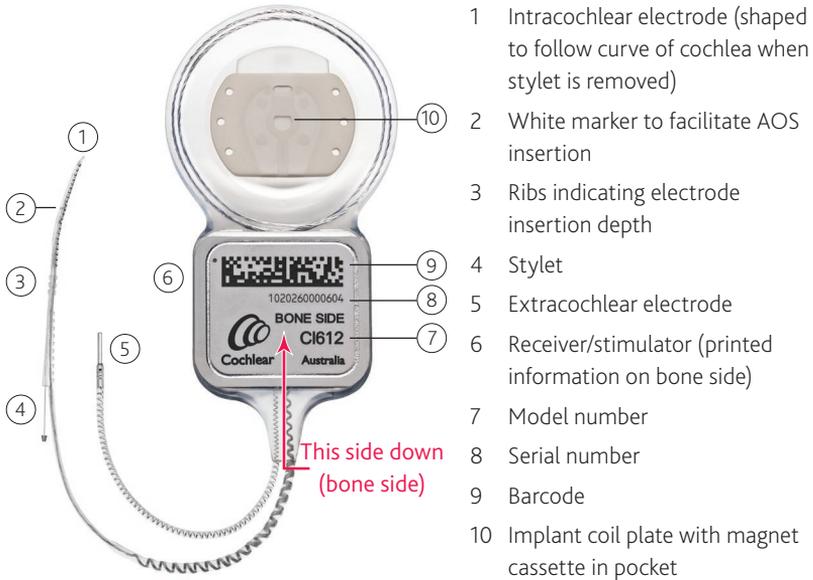


Figure 2: CI612 cochlear implant with Contour Advance electrode (bone side)

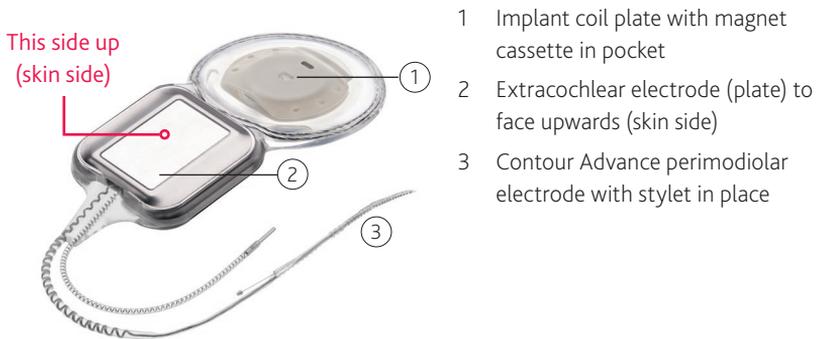


Figure 3: CI612 cochlear implant with Contour Advance electrode (skin side)

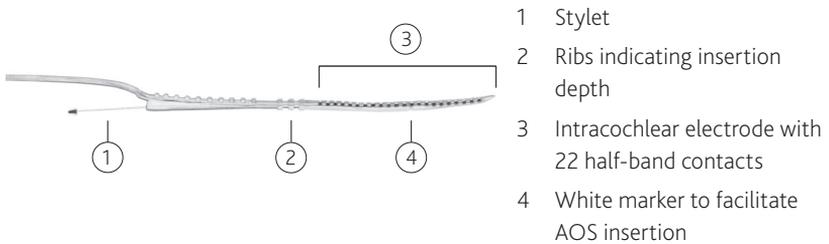


Figure 4: Contour Advance electrode with stylet



Figure 5: Contour Advance electrode with stylet removed

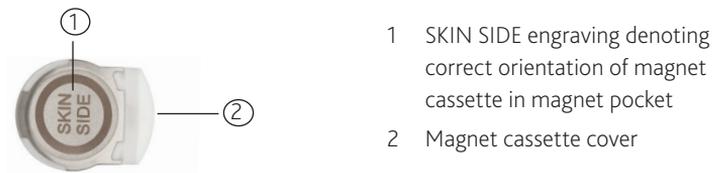


Figure 6: Cochlear Nucleus Magnet Cassette (skin side)

Surgical instruments and accessories

Instruments and accessories in this section are appropriate for use with Cochlear Nucleus CI600 Series implants. For intended use of individual instruments, refer to descriptions on the following pages.

All items except the Sterile Silicone Implant Template are available to be ordered individually. As indicated below, some items are included in the Cochlear Surgical Instrument Kit. A Cochlear Surgical Instrument Upgrade Kit is also available.

Instruments	Product code
Cochlear™ AOS™ Forceps*†	Z60770
Cochlear™ BTE Template*	Z33011
Cochlear™ CI500 Series Recess Gauge**†	Z139274
Cochlear™ CI500 Series Implant Template*†	Z139273
Cochlear™ Contour® Electrode Claw*	Z33021
Cochlear™ Straight Electrode Claw	Z30090
Cochlear™ Contour Advance® Depth Gauge	Z179994
Cochlear™ Straight Depth Gauge	Z60006
Sterile Silicone Implant Template‡	Y119819
Cochlear™ CI500 Series Non-Sterile Silicone Implant Template	Z179609
Accessories	
Cochlear™ Non-Magnetic Cassette	P782484
Cochlear™ Replacement Magnet Cassette	P782485

* Included in the Cochlear Surgical Instrument Kit

† Included in the Cochlear Surgical Instrument Upgrade Kit

‡ Supplied with implant; not available separately

Items used with the CI612 cochlear implant are referenced in the *Surgical procedure* and *MRI safety information* sections of this guide.



Warning

Do not use surgical instruments or accessories supplied or intended to be sterile if they become non-sterile, for example, if dropped or mishandled in theatre.

Disposal

Items that have been in patient contact should be placed into the correct clinical waste container for disposal. Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

Items that have not been in patient contact can be disposed of as normal hospital or household waste, or in accordance with local regulations.

Reusable after reprocessing

These instruments are stainless steel, and can be cleaned and resterilised as instructed in the *Surgical Instrument Sterilisation Reprocessing Guide*.

Cochlear™ AOS™ Forceps

Z60770



Used to grasp or hold the Contour Advance electrode during its insertion into the cochlea. Curved tip ends gently cup the array to improve stability and minimise rotation.



Caution

To avoid damaging the electrode, before each use hold forceps tips closed and ensure they are parallel and aligned. If not, do not use, as it may be difficult to release the electrode after insertion.

Cochlear™ BTE Template

Z33011



Used to ensure the implant position provides space for a behind-the-ear sound processor.

Cochlear™ CI500 Series Recess Gauge

Z139274



Used to mark the bone recess on the skull, measure the depth of the bone recess and check the location of the electrode exit excavation after drilling.

Cochlear™ CI500 Series Implant Template

Z139273



Used to determine, or check, the shape of the implant bone recess excavation and the position of the implant.

Cochlear™ Contour® Electrode Claw

Z33021



Aids insertion of the Contour Advance electrode into the cochlea.
Gold-plated handle.

Cochlear™ Straight Electrode Claw

Z30090



Aids insertion of the Straight electrode into the cochlea.

Single-use sterile

These items are supplied sterile for single-use only.

Warning

- Supplied sterile. Sterilised in ethylene oxide. Do not resterilise.
- Single-use item. Do not use more than once. Re-use could cause infection.
- Do not use if packaging is damaged.
- Do not use if item becomes non-sterile, for example, if dropped or mishandled in theatre after removal from packaging.

Cochlear™ Non-Magnetic Cassette

P782484



If the recipient requires MRI examinations over several days on the head, a non-magnetic cassette is used to replace the magnet cassette.

The non-magnetic cassette is not intended for use unless required for MRI examinations over several days. If magnet removal and replacement will take place on the same day, the magnet recess can remain empty.

For more information refer to *MRI safety information* on page 54.

Cochlear™ Replacement Magnet Cassette

P782485



Used to replace a non-magnetic cassette after MRI examinations are complete.

For more information refer to *MRI safety information* on page 54.



Note

- Non-magnetic cassettes and replacement magnet cassettes are supplied in a silicone carrier, as illustrated below. Remove the cassette from the silicone carrier before use.

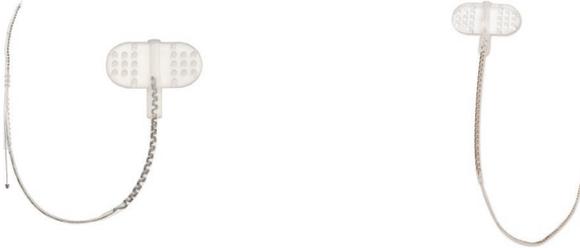


- When marking the incision site, the silicone carrier can be used as a template. For details refer to the *Cochlear™ Non-Magnetic Cassettes and Replacement Magnet Cassettes User Guide* provided with the non-magnetic cassettes and replacement magnet cassettes.

Depth Gauges

Cochlear™ Contour Advance®
Depth Gauge Z179994

Cochlear™ Straight Depth Gauge
Z60006



Depth gauges are typically used in the sterile field when:

- preoperative imaging to assess cochlea patency is inconclusive or unavailable
- it is suspected that cochlear obstruction such as ossification may prevent successful electrode insertion.

Use of depth gauges is not intended for normal cochleae where there is no suspicion of obstruction or malformation.

For more information refer to the appropriate *Depth Gauge User Guide*.

Sterile Silicone Implant Template

Y119819

Used in the sterile field to check periosteal pocket size, implant bone recess shape and depth, and tie-down hole positions.

Provided with the implant; not available separately.
For more information refer to 2. *Opening the CI500 Series Sterile Silicone Implant Template* on page 32.



Warning

For temporary use only. Not for implantation.



Note

Suitable for use with CI600 Series implants.

Non-sterile

These items are supplied non-sterile and are single use. They should not be sterilised.



Warning

Do not use more than once. Re-use could cause infection.

Cochlear™ CI500 Series Non-Sterile Silicone Implant Template

Z179609

Used to determine or check the optimum implant position and mark it on the skin before incision.



Warning

Do not use in the sterile field. Use in the sterile field could cause infection.



Note

Suitable for use with CI600 Series implants.



Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the Cochlear Nucleus cochlear implant.

The surgical procedure includes the following:

1. Pre-incision: non-sterile field – page 31
2. Opening the Sterile Silicone Implant Template – page 32
3. Incision – page 33
4. Mastoidectomy and preparing the bone recess – page 34
5. Drilling tie-down holes – page 37
6. Opening the facial recess – page 38
7. Preparing the cochleostomy – page 39
8. Inspecting the cochlear implant and electrodes – page 41
9. Positioning and securing the implant – page 42
10. Securing the extracochlear electrode – page 43
11. Inserting the intracochlear electrode – page 44
12. Securing and sealing the intracochlear electrode – page 47
13. Performing intraoperative measurements – page 49
14. Closure – page 50

Where a surgical instrument is mentioned in the procedure, refer to *Surgical instruments and accessories* on page 22.

1. Pre-incision: non-sterile field

1. Place the BTE Template in position on the ear. Ensure there will be sufficient clearance between the receiver/stimulator and an ear level sound processor so that the sound processor will not rest on the receiver/stimulator.
2. Place the Non-sterile Silicone Implant Template on the skin so that the antero-inferior edge is at least 10 mm behind the edge of the BTE Template and above the canthomeatal line. Angle the Non-sterile Silicone Implant Template 30 to 45 degrees postero-superiorly, to lie on a flat portion of the skull. Mark its position on the scalp.



Note

For bilateral patients, position the second receiver/stimulator so that it is symmetrical with the first.

If the recipient has an Osia implant on the contralateral side, make sure to have a distance of at least 10 cm between the coils of the implants to avoid interference between the systems.

3. Mark the incision with a marking pen. Allow at least 15 mm between the implant and the incision.

The incision must be large enough to accommodate the cochlear implant. The flap may be inferiorly-based or anteriorly-based but must allow the surgeon to secure the implant to the bone.

4. The Implant Template can be used to mark the position of the electrode lead exit for the proposed bone excavation for the receiver/stimulator. Mark with a drop of methylene blue on the bone using a 21 gauge needle through the skin.
5. Before incision, the incision line may be infiltrated with local anaesthetic and 1:100 000 or 1:200 000 adrenaline, or epinephrine, unless contraindicated.

2. Opening the Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. For more information on use of the Template refer to *Sterile Silicone Implant Template* on page 28.

Non-sterile field

1. Remove the cardboard box (outer packaging).
2. Visually inspect the outer tray and ensure that:
 - exposure to ethylene oxide processing is indicated by a green dot on the tray
 - the tray is not damaged.
3. Break the seal on the outer tray. Visually inspect the two inner trays. Confirm that both of the inner trays are not damaged.
4. Notice that the tray containing the Sterile Silicone Implant Template has a blue stripe. The tray containing the cochlear implant displays the Cochlear logo.



Warning

To avoid infection, if the sterile package is damaged or opened unintentionally, do not use the template.

Sterile field

5. Remove the template tray (blue stripe) and break the seal.



Note

Keep the cochlear implant tray (white seal) to one side, within the sterile field, with the seal intact, until later in the surgery.

6. Lift the Sterile Silicone Implant Template from the tray.
7. Confirm the Sterile Silicone Implant Template is not damaged.

3. Incision



Warning

If the patient has an implant in the other ear, do not use monopolar electro-surgical instruments. Bipolar electro-surgical instruments may be used.

1. Make the incision down to the avascular plane of the periosteum and temporalis fascia (long enough to provide sufficient access). Stabilise the area using retraction as necessary.
2. Use the Implant Template or the Sterile Silicone Implant Template to check the position of the implant.
3. Incise the underlying periosteum and lower portion of the temporalis fascia creating a fibromuscular/periosteal flap based either anteriorly or posteriorly.
4. Elevate a periosteal pocket to accommodate the implant coil.
5. Elevate a narrow periosteal pocket against the bone under the temporalis muscle. This is to make a place for the extracochlear electrode between the skull and the periosteum, i.e. under the temporalis muscle.

4. Mastoidectomy and preparing the bone recess

The cortical mastoidectomy is described next. Some surgeons prefer to drill the implant recess first.

The cortical mastoidectomy

Create an adequate cortical mastoidectomy cavity, allowing an overhang both superiorly and posteriorly to accommodate any redundant proximal electrode lead.



Note

For children, it is recommended that a mastoidectomy be performed.

The bone recess

The blue dye dot on the bone indicates the position of the channel for the electrode lead exit.

Use the Recess Gauge, Bone Recess Template, Implant Template or the Sterile Silicone Implant Template to determine the angular orientation of the implant. This is usually placed at 30 to 45 degrees above the temporal line.



Warning

When drilling the bone recess, take care to avoid injury to the underlying dura.

To drill the bone recess:

1. Mark the recess using a surgical marker with the aid of the Recess Gauge, Implant Template, or the Sterile Silicone Implant Template.
2. Drill the bone recess. Aim to achieve a flat surface 'ramp', starting deeper on the anterior end of the implant and tapering off posteriorly. The ramp should be approximately 2.2 mm deep at the antero-inferior end of the implant, depending on the thickness of the skull. Providing that the skull is sufficiently thick, drilling deeper will result in a lower profile beneath the skin flap.

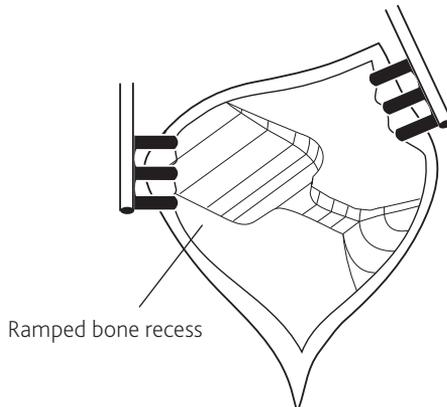


Figure 7: Ramped bone recess

3. Check the final dimensions of the bone recess using the Recess Gauge or Implant Template.

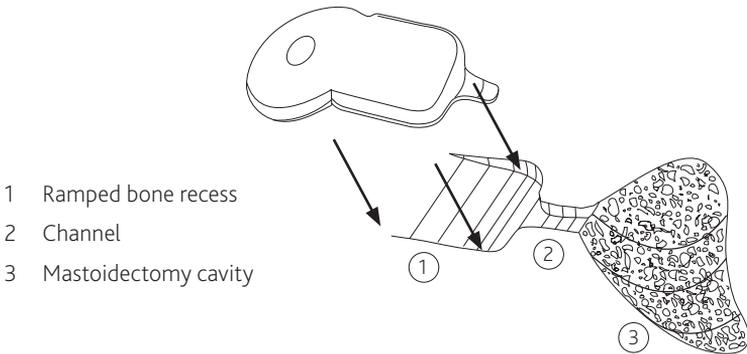


Figure 8: Ramped bone recess, electrode channel and mastoidectomy

4. Place the Implant Template or Recess Gauge in the bone recess and use it to mark the exit of the electrode.
5. Drill a channel to connect the bone recess and mastoid cavity, refer to *Figure 8*. The channel will help protect the electrode against trauma.
6. Use the Recess Gauge to check the position and depth of the electrode exit.

5. Drilling tie-down holes

1. Using the implant seat for orientation (refer to *The bone recess* on page 34), mark tie-down holes above and below the anterior portion of the receiver/stimulator to ensure the implant can be secured.
2. Drill these holes with a 2 mm diamond burr.



Note

- For children, an elevator may be used to protect the dura.
- For additional support, posterior tie-down holes may be drilled or the implant coil can be placed under a pericranium pocket.



Figure 9: Tie-down holes for CI600 Series implants



Warning

When drilling the tie-down holes, take care to avoid injury to the underlying dura.

6. Opening the facial recess

1. Open the facial recess ensuring it gives as much visibility and access as possible. The horizontal canal and short process of the incus should be clearly visualised.
2. Identify the facial nerve and chorda tympani nerve, but do not expose them.

The posterior portion of the middle ear, including the stapedius tendon, promontory and round window niche, should be clearly visualised.

In some instances of poor round window visualisation, the chorda tympani nerve is unavoidably cut to perform an extended facial recess approach.

7. Preparing the cochleostomy

This section describes site preparation. For details on inserting the electrode refer to *11. Inserting the intracochlear electrode* on page 44.

Cochleostomy

1. Visualise the stapes to confirm the site of the round window, and visualise the round window membrane. It is approximately 2 mm inferior and slightly posterior to the oval window.
2. The round window membrane may be obscured by the overhang of the lateral margin of the niche and a mucosal false membrane. It may be necessary to gently drill away the overhang to see the round window membrane.
3. Perform a cochleostomy into the scala tympani using a diamond burr at low speed.
4. Position the cochleostomy inferior and slightly anterior to the round window membrane. It should be close to, or incorporating, the round window niche. A slight blue line of endosteum should become visible as the bone is being thinned for the cochleostomy. This indicates the location of the scala tympani.



Warning

Damage to the cochlea or vestibular system may be caused by drilling too far anteriorly or superiorly. This will result in the endosteum appearing white and the scala media or vestibuli may be entered.



Caution

Incorrect electrode placement may result from drilling too far inferiorly. This will miss the cochlea entirely and a hypotympanic air cell may be entered. Take care to remove bone dust, blood and other fluids from the cochleostomy.

5. Drill sufficient bone to expose approximately 1.5 mm of endosteum.



Warning

To avoid risk of contamination do not open the endosteum until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 44.

8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked refer to 2. *Opening the Sterile Silicone Implant Template* on page 32.

Sterile field

1. Remove the cochlear implant from the sterile packaging tray.
2. Confirm the cochlear implant is not damaged.



Warning

- To avoid infection or revision surgery, do not use the implant if the sterile package or the implant are damaged.
- To avoid damage to tissues or the implant, from this point, do not use monopolar electrosurgical instruments on the neck and head of the patient. Bipolar electrosurgical instruments may be used; however the cautery electrode tips must not contact the cochlear implant and should be kept more than 1 cm (½ in) from the electrodes.



Caution

To avoid damage to the cochlear implant:

- minimise handling of the electrode
- do not bend the electrode as the stylet is malleable and will deform
- leave the protective tube on the electrode until just before insertion.

9. Positioning and securing the implant

1. Place the receiver/stimulator skin side up in the bone recess, with the implant coil in the subperiosteal/pericranial pocket between the tie-down holes.

For information on correct implant orientation refer to *Device description* on page 18.



Caution

To avoid damage, do not bend the implant coil.

2. Place the electrode lead in the centre of the channel.
3. Secure the receiver/stimulator with a single suture, using a non-absorbable synthetic material.

Move the knot to the edge of the cochlear implant.



Note

Do not suture directly over the magnet cassette cover as this may obstruct potential cassette removal – refer to *Figure 12* on page 57.

10. Securing the extracochlear electrode

Carefully place the extracochlear electrode against the bone under the temporalis muscle.



Caution

To avoid mechanical stress on the electrode lead, do not place the extracochlear electrode in the temporalis muscle.

11. Inserting the intracochlear electrode



Warning

- Damage to the electrode and the cochlea may be caused if the stylet is reinserted. Do not reinsert the stylet in order to reinsert or reposition the electrode.
- In the event of suboptimal placement, it is recommended to remove the electrode and use the backup implant instead.



Caution

- Use minimal force. Do not rush the insertion.
- During insertion, ensure the array does not kink and the half-band electrode contacts remain oriented towards the modiolus.
- At the end of the insertion, the most proximal rib is usually just outside the cochleostomy. Do not force the electrode into the cochlea.

Before insertion

The following should be performed immediately before insertion of the electrode:

Inserting via a cochleostomy

1. Open the endosteum with an otologic hook and ensure that the cochleostomy is wide enough to accommodate the electrode.
2. Remove any sharp edge of bone which might snag the electrode.



Warning

To avoid residual hearing loss or vestibular issues, do not suction the perilymph.

Advance Off-Stylet (AOS) insertion

The Advance Off-Stylet® (AOS™) method, as described, is highly recommended by Cochlear. The AOS method was developed specifically for implants with the Contour Advance Electrode.

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode. Do not squeeze, stretch or bend the electrode.
2. Orientate the electrode so that its curve will follow the cochlear spiral.
3. Guide the tip toward the cochleostomy, using the claw or other blunt tip surgical instrument. Angle the electrode toward the floor of the scala tympani. Ensure the half-band electrode contacts remain oriented toward the modiolus.
4. Insert the electrode until the white marker (7.6 mm from tip) is at the cochleostomy. Refer to *Figure 10* on page 46.
5. Hold the stylet stationary with jeweller's forceps and hold the electrode at the ribs with AOS forceps. Advance the electrode off the stylet and into the cochlea until the third (most proximal) rib is at the cochleostomy (B, C and D) in *Figure 10* on page 46.
6. Remove the remainder of the stylet. Then pass the stylet out of the surgical field.

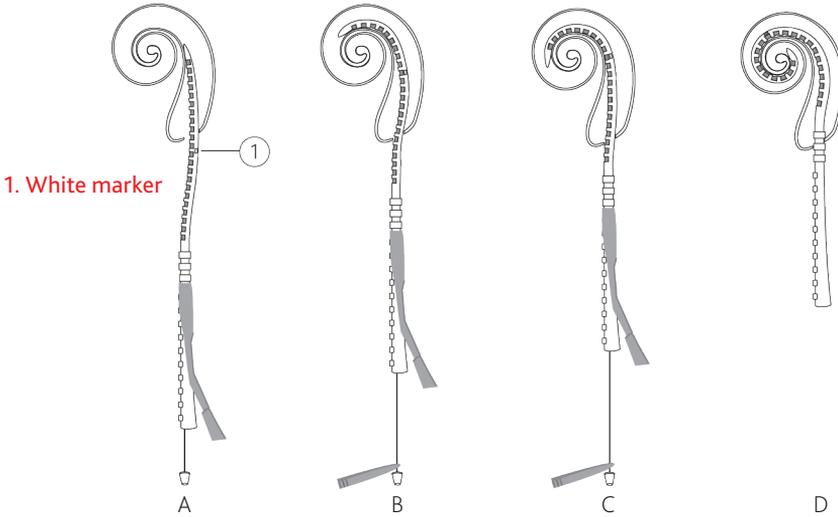


Figure 10: AOS insertion — white marker 7.6 mm from tip, at cochleostomy

7. If necessary, retract the electrode slightly, so the third (most proximal) rib is just outside the cochleostomy. This ensures the electrode is close to the modiolus at the back of the basal turn.



Warning

Movement of the excess electrode lead could result in the electrode twisting and potentially damaging cochlear structures. Immediately after inserting the electrode and before arranging the excess proximal electrode lead in the mastoid cavity, the electrode must be immobilised. Ensure the electrode is held in place continuously by the handle.

12. Securing and sealing the intracochlear electrode

1. Whilst continuing to hold the electrode in place, stabilise the electrode array to minimise movement inside the cochlea.

To limit the risk of migration, the electrode should be further secured. The method of fixation, and choice of fixation points, will depend on surgical access and the surgeon's discretion.

2. Coil the excess proximal electrode lead inside the mastoid cavity under the bony overhangs. Pack completely around the electrode in the cochleostomy with an autograft consisting of strips of fascia or pericranium to ensure there are no gaps in the seal.



Warning

Seal the round window or cochleostomy to avoid an open pathway to the inner ear.



Note

If there is a perilymph leak, extra tissue may be needed to ensure that the seal is tight.

3. Place any excess loop of the extracochlear electrode in the mastoid cavity.



Note

If the electrode leads are able to migrate into subcutaneous tissue they may be subject to excessive movement and fatigue. To avoid this, ensure the leads are secure within the cavity, but do not suture over the electrode leads with fine gauge sutures.

Confirmation of electrode placement

Before closure, an X-ray may be obtained (preferably a lateral or modified Stenver's view), to confirm proper electrode placement.

For information on Stenver's view, contact Cochlear or refer to *Xu J, Xu SA, Cohen LT, Clark GM. Cochlear View: Post-operative Radiography for Cochlear Implantation. Am J Otol, 21(1):49-56, 2000.*

13. Performing intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sleeve.
3. Place the external coil over the implant magnet.



Note

- The transmitting range of the cochlear implant is 1 mm to 10 mm. However, maximum skin flap thicknesses of 6 mm for off-the-ear (OTE) sound processors and 10 mm for behind-the-ear (BTE) sound processors are required for good magnet retention.
- The cochlear implant may not function properly if the processor coil is placed directly on top of the receiver/stimulator.
- Methods to determine that the cochlear implant is functioning properly include impedance measurement using a Cochlear proprietary programming system.

14. Closure

1. Pack the facial recess with soft tissue.
2. Suture the palva flap over the proximal portion of the intracochlear electrode lead.
3. Close the wound in layers. Drainage is not recommended.
4. Apply a large mastoid pressure dressing.

Postoperative management

Monitor the patient as for all procedures involving general anaesthesia. Keep the pressure dressing on for one day, then inspect the wound and apply another dressing for five days.

Fitting the sound processor

The initial fitting procedure for the sound processor should be scheduled three to four weeks after the operation. Fitting should be checked at three months, six months and one year postoperatively, then at yearly intervals (or more frequently if required by the condition of the patient).

Registering the implant

Registration form

Complete the registration form. Send the completed form to Cochlear within 30 days of receiving the product.

Patient Implant Card and Important Information document

Fill out patient details on the Patient Implant Card. Give the card and the Important Information document to the patient or their carer. The patient or their carer should carry the Patient Implant Card with them at all times.

Identifying the implant

For information on identifying Cochlear Nucleus implants without surgical intervention, refer to the *Cochlear Nucleus Implants MRI Guidelines*.

Explanting the implant

In rare circumstances, it may be necessary to explant a cochlear implant. Please follow the steps below.

1. Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged. To assist in removing the device undamaged you can cut the intracochlear electrode lead. Refer to *Cutting the intracochlear electrode lead* on page 53.
5. If the intracochlear electrode lead is removed from the cochlea, place it in the kit, even if it is damaged.
6. Return the kit containing the explanted device to the Cochlear address nearest you.

Cutting the intracochlear electrode lead

Cut the intracochlear electrode lead if it will assist you to remove the device without damaging it. The cut should be in the region of the electrode lead shown below.

If required to remove the device without damage, cut the electrode lead before the ribbed portion of the array:



Figure 11: Contour Advance electrode lead cut location for explanation

If necessary, leave the distal end of the extracochlear electrode lead in place.

Reporting incidents

Legislation on medical devices requires the manufacturer to report serious adverse events or incidents to the appropriate authorities. All serious incidents should be reported to:

- your local Cochlear office
www.cochlear.com/intl/contact/global-offices
- Therapeutic Goods Administration
<https://www.tga.gov.au>
- only if the serious incident has taken place in Australia or involves an Australian resident.

MRI safety information



The Cochlear Nucleus CI612 cochlear implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines*
- by visiting www.cochlear.com/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.



All external components of the Cochlear implant system (for example, sound processors, remote assistants and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

MRI examinations

Cochlear Nucleus CI600 Series implants are designed to withstand MRI at static magnetic field strengths described in the *Cochlear Nucleus Implants MRI Guidelines*.

Before an MRI examination, in some instances the magnet cassette must be removed in a sterile surgical environment.



Warning

To minimise the risk of infection or fibrous tissue growing into the implant recess, do not leave the magnet pocket empty for MRI examinations taking place over several days. When removing a magnet cassette, replace with a non-magnetic cassette.

If the MRI examination, magnet cassette removal and replacement will be completed on the same day, the magnet recess can remain empty. For MRI examinations taking place over several days, the magnet cassette is removed and replaced with a sterile non-magnetic cassette.

While the magnet cassette is removed, the recipient may wear a Cochlear Disk Retainer to hold their external transmitter coil in place. Disk retainers are available from Cochlear.



Caution

When removing or inserting a magnet cassette:

- take care not to damage the implant silicone or coil wires
- minimise force applied to the implant and electrodes
- minimise pressure applied to the implant coil.

Removing the magnet cassette before implantation

If an MRI examination is scheduled in the near future, it may be appropriate to replace the magnet cassette with a non-magnetic cassette before the device is implanted.

If the MRI examination, magnet cassette removal and replacement will be completed on the same day, the magnet recess can remain empty.

If MRI examinations are needed over a period of time on the head with the magnet removed, the magnet cassette must be replaced in a sterile surgical environment with a non-magnetic cassette.

Refer to the *Cochlear™ Non-Magnetic Cassette and Replacement Magnet Cassette User Guide* provided with the non-magnetic cassette for step-by-step instructions.

The replacement procedure should take place under sterile conditions.

Refer to the following instructions on how to remove the magnet cassette.

Removing the magnet cassette before implantation

1. In sterile conditions, remove the implant from its sterile packaging and place it on a flat and stable surface with the bone side (engraved side) facing down.



Figure 12: CI600 Series implant with magnet cassette



Warning

To avoid infection, if the sterile package or implant are damaged do not use the implant.

2. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the centre of the magnet cassette cover.

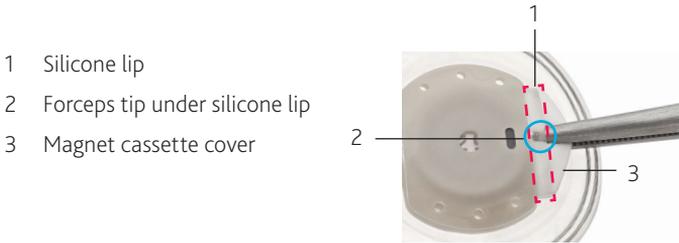


Figure 13: CI600 Series implant - forceps position on magnet cassette cover



Caution

When holding the magnet cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

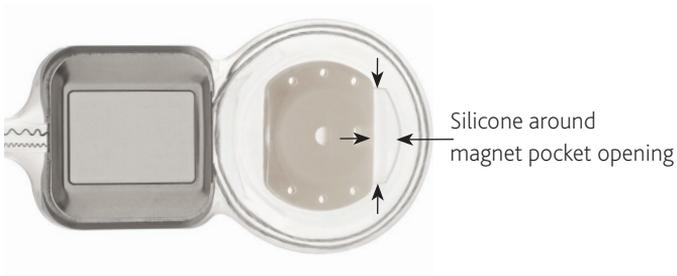


Figure 14: CI600 Series implant with magnet cassette removed

- Using constant traction, remove the magnet cassette from the magnet pocket. The magnet cassette cover is designed to stretch under the constant traction applied during removal.

The removal direction is in the same plane as the implant coil, towards the distal end of the implant – refer to arrow in *Figure 15*.

⚠ Caution

To avoid damaging the magnet pocket, do not apply vertical pulling force to the implant coil.



Figure 15: CI600 Series implant with magnet cassette partially removed

📌 Note

If the magnet cassette cover pulls away, use forceps to hold the metal tab and continue removal.



Figure 16: CI600 Series implant - metal tab on magnet cassette



Figure 17: CI600 Series implant - magnet cassette removal using metal tab

4. Dispose of the removed magnet cassette. It is not re-usable.

The implant is now ready for implantation.

After the MRI examination is completed, under sterile conditions insert a new sterile replacement magnet cassette. Refer to the *Cochlear™ Non-Magnetic Cassette and Replacement Magnet Cassette User Guide* provided with the replacement magnet cassette for step-by-step instructions.

Removing the magnet cassette after implantation

If the MRI examination will take place over several days, the magnet cassette must be replaced with a non-magnetic cassette. Refer to the *Cochlear™ Non-Magnetic Cassette and Replacement Magnet Cassette User Guide* provided with the non-magnetic cassette for step-by-step instructions.

If the MRI examination, magnet cassette removal and replacement will be completed on the same day, the magnet recess can remain empty.

Refer to the following instructions on how to remove the magnet cassette.



Warning

- Do not use vertical force. Take care not to displace the implant.
- Use of excessive or vertical force could lead to implant or electrode migration, causing the implant to malfunction and require removal, replacement or revision surgery.



Caution

- Take care not to damage the implant silicone or coil wires.
- When holding the magnet cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.



Note

The magnet cassette can be safely removed and replaced with a new sterile magnet cassette up to eight times without any adverse effect to the implant.

Remove the magnet cassette in sterile conditions, using either general or local anaesthetic.

1. Make an incision beyond the distal end of the implant coil.

 **Note**

You may use the cassette's silicone carrier to mark the incision:

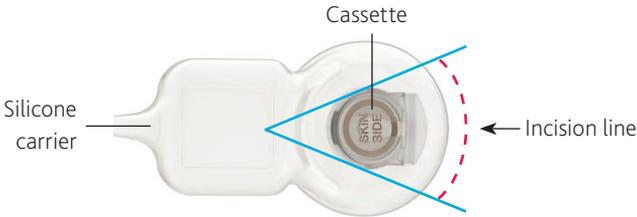


Figure 18: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the cassette cover. Ensure there is good visibility and access to the cassette cover.
3. Stabilise the implant, taking care to minimise force applied to the implant coil.

4. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the centre of the magnet cassette cover.



Figure 19: CI600 Series implant - forceps position on magnet cassette cover

5. Using constant traction, remove the magnet cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – refer to arrow in *Figure 20*.



Note

The magnet cassette has been designed to remain in place and not move during an MRI examination. Therefore, additional force may be required to remove the magnet cassette. In such cases, ensure the implant is sufficiently stabilised during removal.



Figure 20: CI600 Series implant with magnet cassette partially removed



Note

If the magnet cassette cover pulls away, use forceps to hold the metal tab and continue removal.



Figure 21: CI600 Series implant - metal tab on magnet cassette



Figure 22: CI600 Series implant - magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette. It is not re-usable.
7. If the MRI examination, magnet cassette removal and replacement will be completed on the same day, leave the magnet recess empty. Apply a dry sterile dressing.

If the MRI examinations are needed over a period of time on the head with the magnet removed, insert the non-magnetic cassette. Refer to the *Cochlear™ Non-Magnetic Cassette and Replacement Magnet Cassette User Guide* for step-by-step instructions.

8. Take the patient for the MRI examination.
9. After the MRI examination is completed, under sterile conditions insert a new sterile replacement magnet cassette. Refer to the *Cochlear™ Non-Magnetic Cassette and Replacement Magnet Cassette User Guide* provided with the replacement magnet cassette for step-by-step instructions.

How the implant is supplied

The implant, non-magnetic cassette and replacement magnet cassette are single-use items.



Warning

Do not resterilise. Do not use more than once. Re-use could cause infection.

Non-magnetic cassettes and replacement magnet cassettes are supplied separately.

All of the above components are supplied in sterile gas-permeable packaging. Ethylene oxide processing is indicated on the label of each sterile package.

Before opening the sterile package, inspect it carefully. Return the device and packaging to Cochlear if:

- the 'use by' date stamped on the outside package has expired
- the sterile package containing the implant is ruptured or opened unintentionally
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

Transport and handling

Cochlear Nucleus cochlear implants inside their sterile packaging within the implant box have been validated for transport and handling temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

Handle with care. Severe impact may rupture the sterile package inside.

Storage

Store Cochlear Nucleus cochlear implants inside their sterile packaging within the implant box at room temperature. Keep dry.

The product and its packaging have been designed to withstand storage temperatures from +1 °C (+34 °F) to +30 °C (+86 °F) and transient and seasonal excursions beyond this range.

CI612 implant specifications

Intracochlear electrodes	
Number of electrodes	22 electrodes
Distance between centre of electrode contacts	0.8 mm at proximal end of array graduating to 0.4 mm at distal end of array when curled
Diameter of electrodes (cross-sectional dimension)	0.8 mm at proximal end, tapering to 0.5 mm at distal end
Contact surface area	0.21 mm ² to 0.23 mm ²
Active array length when straightened	14.25 mm
Nominal electrode length when straightened	19 mm from tip to proximal rib
Lead length	99 mm from receiver/stimulator to array tip
Marker for insertion depth	White marker in middle of active part of array (lateral side) when tip is near lateral wall of otic capsule at back of basal turn

Extracochlear electrodes	
<ul style="list-style-type: none">• Plate on receiver/stimulator• Cylindrical electrode 0.6 mm (typical) diameter with hemispherical tip, on a lead 60 mm in length	

Receiver/Stimulator	
Dimensions	Case: 24 mm x 23 mm x 3.9 mm Coil: 31 mm diameter x 3.9 mm thick
Volume	4.2 cm ³ without lead
Mass	9.2 g including electrode array
Operating characteristics	
Power and data	Received by 5 MHz inductive link from sound processor headset coil
Current	Biphasic pulses
Stimulation mode	Monopolar, bipolar or common ground
Stimulus amplitudes	Programmable from 0 μ A to 1750 μ A nominal at 37 °C
Maximum stimulus amplitude	Median: 1750 μ A Range: 1575 μ A to 1925 μ A for a 1 k Ω load resistor at 37 °C
Stimulus duration	Programmable from 9.6 μ s to 400 μ s per phase
Maximum stimulus pulse width	Median: 400 μ s Range: 398 μ s to 410 μ s for a 1 k Ω load resistor at 37 °C
Transmitting range	1 mm to 10 mm Maximum skin flap thickness required for good magnet retention: <ul style="list-style-type: none"> • 6 mm for OTE sound processors • 10 mm for BTE sound processors

Measurement functions	
Compliance	Displays compliance limits using Cochlear proprietary programming software
Neural response telemetry	Measure of electrically evoked compound action potential (ECAP)
Impedance	Measure of electrode impedances in monopolar and common ground modes
Impedance measurement accuracy	>80% when measured for a 10 k Ω load resistor at 37 °C
Implant ID and type check	Enables the sound processor to confirm whether it is coupled to the nominated implant

Materials and substances

The following table lists the materials and substances used in the Cochlear Nucleus cochlear implants that come in direct contact with body tissues.

Materials	Quantity (mm ³)	Location
Silicone elastomer	2834	Lead and receiver/stimulator protective coating and insulation
Titanium (grade 2)	231	Receiver/stimulator case Magnet case
Platinum 99.95%	28	Electrode contacts

For CI600 Series implants, no compounds or elements of toxicological concern were identified.

General information

Warranty

To the purchaser: the law in some countries requires that the written warranty for this cochlear implant must be made available for the patient's review before it is sold to them. The Cochlear terms and conditions of warranty should therefore be given to the patient before implantation of the cochlear implant. The warranty is included in the document pack.

Labelling symbols

The following symbols may appear on your implant or implant packaging:



Fragile, handle with care



Do not use if package is damaged and consult instructions for use



Consult instructions for use



Specific warnings or precautions associated with the device, which are not otherwise found on the label



Do not re-use



Do not resterilise



Date of manufacture



Manufacturer



Use-by date



Keep dry



Single sterile barrier system with protective packaging inside



Sterilised using ethylene oxide

Rx Only	Caution: US law restricts this device to sale by, or on the order of, a physician
UDI	Unique Device Identifier
REF	Catalogue number
SN	Serial number
CH REP	Authorised representative in Switzerland
LOT	Batch code
#	Model number
ECREP	Authorised representative in the European Community/ European Union
CE ₀₁₂₃	CE registration mark with notified body number
	MR Conditional
MD	Medical Device
BONE SIDE	Bone side of implant, to be implanted with this side facing down
SKIN SIDE	Skin side of magnet cassette and replacement magnet cassette

Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you. Contact addresses and phone numbers are available on the back cover of this guide.

Hear now. And always

AU Cochlear Ltd (ABN 96 002 618 073)
1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555

DE Cochlear Deutschland GmbH & Co. KG
Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770

CH Cochlear AG
Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204

US Cochlear Americas
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 (800) 523 5798

CA Cochlear Canada Inc
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 523 5798

GB Cochlear Europe Ltd
6 Dashwood Lang Road, Bourne Business Park, Addlestone,
Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400

BE Cochlear Benelux NV
Schaliënhoevredreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11

FR Cochlear France S.A.S.
135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)

IT Cochlear Italia S.r.l.
Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11

SE Cochlear Nordic AB
Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61

www.cochlear.com

TR Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900

HK Cochlear (HK) Limited
Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773

KR Cochlear Korea Ltd
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450

CN Cochlear Medical Device (Beijing) Co., Ltd
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800

IN Cochlear Medical Device Company India Pvt. Ltd.
Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111

JP 株式会社日本コクレア(Nihon Cochlear Co Ltd)
〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241

AE Cochlear Middle East FZ-LLC
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400

PA Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220

NZ Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983