CI512

Cochlear™ Nucleus® CI512 cochlear implant with Contour Advance® electrode

Physician's Guide

Asia Pacific

Hear now. And always

Cochlear®

About this document

This guide applies to the Cochlear™ Nucleus® CI512 cochlear implant, which is a CI500 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.

Contents

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

Pre-operative

- **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 CI512 cochlear implant is MR Conditional. MRI is contraindicated except under specific circumstances. Refer to *MRI safety information* on page 53.

Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, or electrode lead.
- **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 CI512 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.

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.

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* 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.

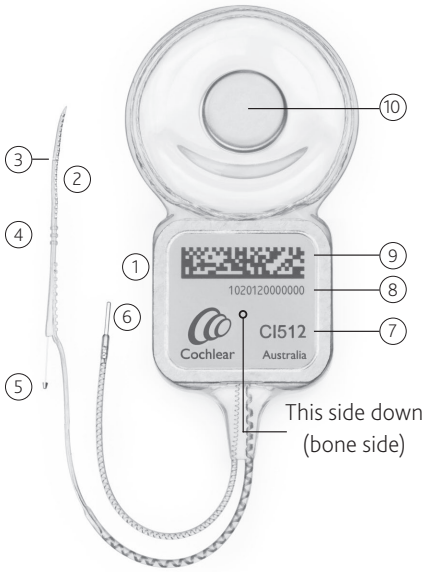
The system is programmed by a Cochlear proprietary programming system.

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

The Cochlear Nucleus CI512 cochlear implant with Contour Advance electrode

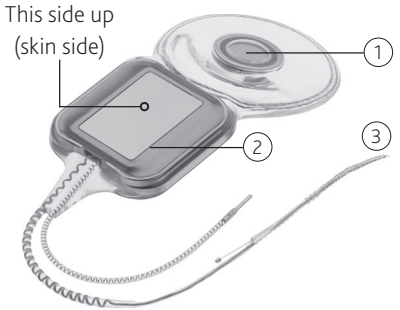
The CI512 cochlear implant has a receiver/stimulator, which receives and decodes the electrical signal from the sound processor, and an electrode array, which delivers the signal to the cochlea.

The CI512 cochlear implant is a CI500 Series implant.



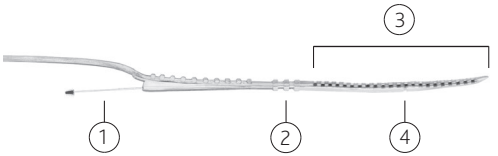
1 Receiver/stimulator (printed information on bone side)
2 Intracochlear electrode (shaped to follow curve of cochlea when stylet is removed)
3 White marker to facilitate AOS insertion
4 Ribs indicating electrode insertion depth
5 Stylet
6 Extracochlear electrode
7 Model number
8 Serial number
9 Barcode
10 Magnet (blank on bone side)

Figure 1: CI512 cochlear implant with Contour Advance electrode (bone side)



1 Magnet (grey ring on skin side)
2 Extracochlear electrode (plate) to face upwards/skin side
3 Contour Advance perimodiolar electrode with stylet in place

Figure 2: CI512 cochlear implant with Contour Advance electrode (skin side)



1 Stylet
2 Ribs indicating insertion depth
3 Intracochlear electrode with 22 half-band contacts
4 White marker to facilitate AOS insertion

Figure 3: Contour Advance electrode with stylet

1 Ribs indicating insertion depth
2 White marker to facilitate AOS insertion

Figure 4: Contour Advance electrode with stylet removed

Surgical instruments and accessories

Instruments and accessories in this section are appropriate for use with Cochlear Nucleus CI500 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
CI500 Series Sterile Silicone Implant Template‡	Y119819
Cochlear™ CI500 Series Non-Sterile Silicone Implant Template	Z179609
Accessories	
Cochlear™ CI500 Series Non-Magnetic Plug	Z146624
Cochlear™ CI500 Series Sterile Replacement Magnet	Z179608

* 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 Cochlear Nucleus CI512 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™ CI500 Series Non-Magnetic Plug	Z146624

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

The non-magnetic plug is not intended for use unless required for MRI examination 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 53.

Cochlear™ CI500 Series Sterile Replacement Magnet	Z179608

Used to replace a non-magnetic plug or fill an empty magnet recess after MRI examinations are complete.

For more information refer to *MRI safety information* on page 53.

Depth Gauges	
Cochlear™ Contour Advance Depth Gauge Z179994	Cochlear™ Straight Depth Gauge Z60006
	
Depth gauges are typically used in the sterile field when: • pre-operative imaging to assess cochlea patency is inconclusive or unavailable, and • 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*.	

CI500 Series 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 warnings below and *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 31.

Warning

For temporary use only. Not for implantation.

Non-sterile

These items are supplied non-sterile for single-use only. 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 sterilise. Do not use in the sterile field. Use in the sterile field could cause infection.

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:

Where a surgical instrument is mentioned in the procedure, refer to *Surgical instruments and accessories* on page 21.

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- 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 CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the Template refer to *CI500 Series Sterile Silicone Implant Template* on page 27.

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 electrosurgical instruments. Bipolar electrosurgical 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.

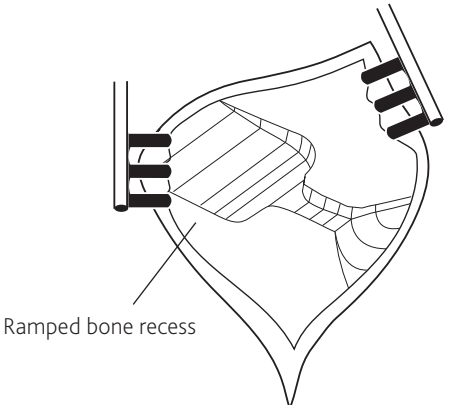
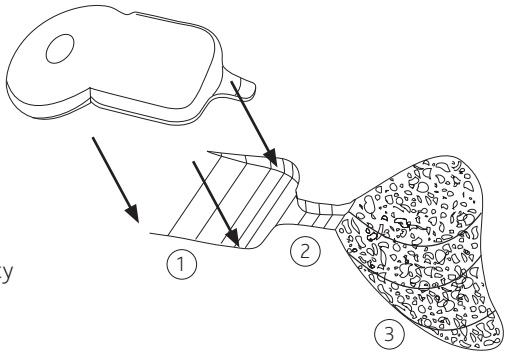


Figure 5: Ramped bone recess

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



1 Ramped bone recess
2 Channel
3 Mastoidectomy cavity

Figure 6: 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 6***. 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 33), 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 7: Tie-down holes for CI500 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 (RWN), 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 43.

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 (RWN). 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 43.

8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked refer to *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 31.

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.

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

   In case the magnet requires removal at a later date, do not suture directly over the magnet.

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 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 8*** on page 45.
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 8*** on page 45.
6. Remove the remainder of the stylet. Then pass the stylet out of the surgical field.

Figure 8: AOS Insertion (white marker (1) 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 cochleostomy or round window 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.
- 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.

Post-operative 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 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 52).
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:

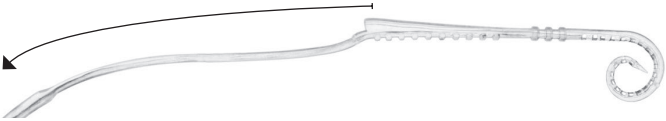


Figure 9: Contour Advance electrode lead cut location for explantation

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 CI512 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

For cochlear implant recipients requiring MRI examinations over several days, the implant magnet is removed and replaced with a non-magnetic plug. If magnet removal and replacement will take place on the same day, the magnet recess can remain empty.

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

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, replace with a non-magnetic plug.

Removing the magnet before implantation

If a new recipient has a condition that will require future MRI examinations, it may be appropriate to replace the magnet with a non-magnetic plug (available from Cochlear) before the device is implanted.

To remove the magnet before implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the magnet's grey ring (denoting polarity) facing up. Do not remove the electrode array protective tube.
2. Using an elevator or similar instrument, lift the lip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimise the pressure applied to the implant coil.

The surgical technique then differs according to whether the patient requires MRI examination on the same day as magnet removal or over several days.

Same day MRI examination and magnet replacement

The implant is now ready for implantation.

When the MRI examination is complete, under sterile conditions insert a new sterile replacement magnet. Refer to the ***Cochlear™ Non-Magnetic Plugs and Replacement Magnets User Guide*** provided with the replacement magnet for step-by-step instructions.

MRI examination over several days

Remove the sterile non-magnetic plug from its packaging and insert it into the recess. Lift the lip of the recess using an elevator and press the plug into position, being careful not to exert undue pressure on the implant.

The implant is now ready for implantation.

When there is no further need for MRI examinations, replace the magnet. Refer to the ***Cochlear™ Non-Magnetic Plugs and Replacement Magnets User Guide*** provided with the replacement magnet for step-by-step instructions.

Removing the magnet after implantation

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

If magnet removal and replacement will take place on the same day, the magnet recess can remain empty. Refer to instructions below on how to remove the magnet.

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

1. Make a small incision ensuring there is good access to the magnet.
2. Cut through any fibrous growth around the implant and expose the magnet.
3. Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the magnet. If a retaining suture runs across the magnet, move the suture out of the way.
4. Leave the magnet recess empty and apply a dry sterile dressing.
5. Take the patient for the MRI examination.
6. When the MRI examination is complete, under sterile conditions insert a new sterile replacement magnet. Refer to the ***Cochlear***™ ***Non-Magnetic Plugs and Replacement Magnets User Guide*** provided with the replacement magnet for step-by-step instructions.

How the implant is supplied

The implant, non-magnetic plugs and replacement magnets are single-use items.

Warning

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

Non-magnetic plugs and replacement magnets 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 pack 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.

CI512 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	• 15 mm from tip to basal electrode • 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
• Plate on receiver/stimulator • Cylindrical electrode 0.6 mm (typical) diameter with lead length 60 mm

Receiver/Stimulator	
Dimensions	Case: 24 mm x 23 mm x 3.9 mm Coil: 31 mm diameter x 3.7 mm thick
Volume	3.9 cm^3 without lead
Mass	8.6 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 µA to 1750 µA nominal at 37 °C
Maximum stimulus amplitude	Median: 1750 µA Range: 1575 µA to 1925 µA for a 1 kΩ load resistor at 37 °C
Stimulus duration	Programmable from 9.6 µs to 400 µs per phase
Maximum stimulus pulse width	Median: 400 µs Range: 398 µs to 410 µs for a 1 kΩ load resistor at 37 °C
Transmitting range	1 mm to 10 mm

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 kΩ 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 implants that come in direct contact with body tissues.

Materials	Quantity (mm^3)	Location
Silicone elastomer	2878	Lead and receiver/stimulator protective coating and insulation
Titanium (grade 2)	231	Receiver/stimulator case Magnet case
Platinum 99.95%	29	Electrode contacts

For the CI500 Series Implant, 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.

Symbols

The following symbols may appear on your 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
EC REP	Authorised representative in the European Community/ European Union
CE 0123	CE registration mark with notified body number
MR	MR Conditional
MD	Medical Device

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.

Notes

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Hear now. And always

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