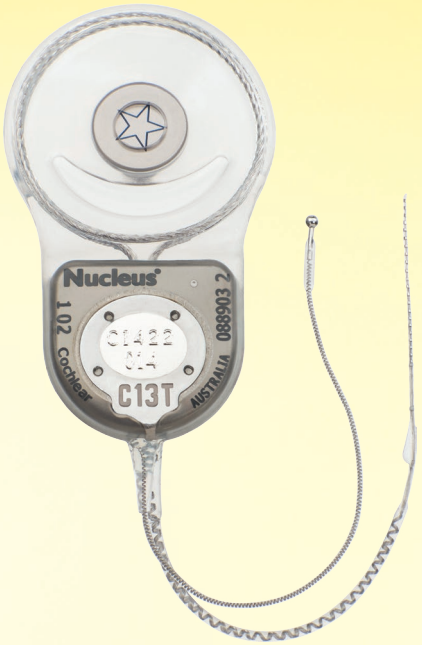
CI422

Cochlear™

Nucleus® CI422 cochlear implant with Straight electrode

Physician's Guide



Hear now. And always

Cochlear®

About this guide

This guide applies to the Cochlear™ Nucleus® CI422 cochlear implant, which is a CI24RE 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 guide

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 this entire 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.*

* 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 CI422 implant is MR Conditional. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 54.

Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, or electrode lead.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 use and indications

Intended use

Cochlear Nucleus CI24RE Series implants are single use devices intended for long term implantation under the skin in the mastoid region of either side of the head. They are for professional use only.

Indications

A cochlear implant provides auditory sensation and sound perception by electrically stimulating the auditory nerve of a hearing-impaired ear.

Degree of hearing loss and compromised hearing with hearing aids must be established and verified clinically using age-appropriate measures before recommending unilateral or bilateral cochlear implants.

Prospective implant recipients and their families 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

Individuals aged up to 17 years who have clinically established bilateral or unilateral sensorineural hearing loss, and who have compromised functional hearing with hearing aids or would receive no benefit with hearing aids. Typical preoperative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately severe to profound degree[*,†].

Group B

Individuals aged 18 years and older who have clinically established postlinguistic bilateral or unilateral sensorineural hearing loss, and who have compromised functional hearing with hearing aids or would receive no benefit with hearing aids. Typical preoperative threshold levels in the impaired ears 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 have compromised hearing with hearing aids.

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* Pure-tone average loss can be defined as the average threshold calculated for 4 frequencies at 500, 1000, 2000 and 3000 or 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.

† ANSI standards for defining hearing impairment quoted by ASHA. Available from www.asha.org/public/hearing/Degree-of-Hearing-Loss (Feb 2012).

Benefits

Bilateral hearing loss

Group A, B or C

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

- detection of medium to loud environmental sounds at comfortable listening levels
- detection of conversational speech at comfortable listening levels.

Group A or B

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

- improved speech recognition and communication ability with lip reading
- improved speech recognition without lip reading.

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

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

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 require considerably more listening experience, therapeutic and educational support than adults to achieve the benefits described above with their cochlear implants.

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.

Contraindications

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

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

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

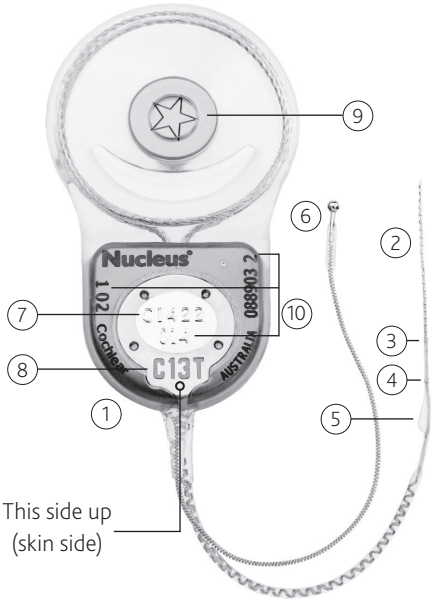
The external components include a sound processor, and associated accessories and cables.

The system is programmed by a Cochlear proprietary programming system.

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

The Cochlear™ Nucleus® CI422 cochlear implant with Straight electrode

The CI422 implant is a CI24RE Series implant.

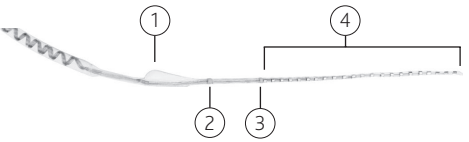


1 Receiver/stimulator (skin side)
2 Intracochlear electrode
3 White marker indicating 20 mm insertion depth
4 White marker indicating 25 mm (max) insertion depth
5 Handle
6 Extracochlear electrode
7 Model (CI422)
8 Radiopaque characters
Manufacturer (C = Cochlear)
Model (13 = CI422)
Year made (T = 2004 or later)
9 Magnet (star on skin side)
10 Serial no. (in three parts e.g. 102 014 0889032)

Figure 1: CI422 cochlear implant with Straight electrode (skin side)

1 Magnet (blank on bone side)
2 Pedestal (bone side)

Figure 2: CI422 cochlear implant (bone side)



1 Handle
2 White marker indicating 25 mm (max) insertion depth
3 White marker indicating 20 mm active array
4 Intracochlear electrode with 22 half-band contacts

Figure 3: Straight electrode

Surgical instruments

Instruments for use during surgery are available in a Surgical Instrument Kit and can also be ordered individually.

Surgical Instrument Kit

The Surgical Instrument Kit is appropriate for use with CI24RE Series implants (including CI422). All instruments in the kit are stainless steel and can be cleaned and resterilised as instructed in the *Surgical Instrument Sterilisation Reprocessing Guide*.

BTE Template

Used to ensure the implant is positioned with sufficient space for a behind-the-ear sound processor.

Figure 4: BTE Template

CI24RE Series Bone Recess Template

Used to mark the bone recess on the skull, and measure the bone recess depth after drilling.

Figure 5: CI24RE Series Bone Recess Template

CI24RE Series Array Exit Marking Template

Used to check the size of the bone recess, select the final position of the implant by rotating the instrument in the bone recess, and mark the exit position and width of the channel for the intracochlear and extracochlear electrodes.

Figure 6: CI24RE Series Array Exit Marking Template

CI24RE Series Implant Template

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

Figure 7: CI24RE Series implant Template

CI24RE Series Recess Gauge

Used to mark the bone recess on the skull, and measure the depth of the bone recess after drilling.

Figure 8: CI24RE Series Recess Gauge

Contour® Electrode Claw

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

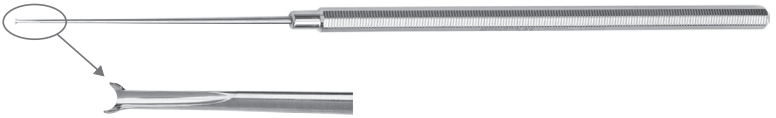


Figure 9: Contour Electrode Claw

Electrode Claw (Straight)

Aids insertion of the Straight electrode into the cochlea.

Figure 10: Electrode Claw

Other instruments

Surgical instruments that can be ordered individually are described below.

AOS™ (Advance Off-Stylet®) Forceps

Used to grasp or hold the electrode during insertion of the intracochlear electrode into the cochlea. Curved tip ends gently cup the array, improve stability and minimise rotation.

Figure 11: AOS Forceps

Spacer for Intraoperative Testing

Used to check there is a minimum space of 2 mm between the processor coil and implant coil, when the processor coil is placed directly over the implant coil.

The Spacer is non-sterile.

Caution

Do not sterilise. A sterile sheath is required for use.

Figure 12: Spacer

CI24RE Series Non-sterile Silicone Implant Template

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

⚠ Caution

Do not sterilise. Do not use in the sterile field. Single-use item.

Figure 13: CI24RE Series Non-sterile Silicone Implant Template

Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the Cochlear Nucleus cochlear implant. The relevant physician may determine that other more appropriate approaches and variations should be performed.

The surgical procedure includes the following:

1. Pre-incision: non sterile field (page 28).
2. Incision (page 29).
3. Mastoidectomy and preparing the bone recess (page 30).
4. Drilling tie down holes (page 33).
5. Opening the facial recess (page 34).
6. Preparing the round window or cochleostomy (page 35).
7. Inspecting the cochlear implant and electrodes (page 38).
8. Positioning and securing the device (page 39).
9. Securing the extracochlear electrode (page 40).
10. Inserting the intracochlear electrode (page 41).
11. Securing and sealing the intracochlear electrode (page 43).
12. Performing intraoperative measurements (page 45).
13. Closure (page 46).

Where a surgical instrument is mentioned in the procedure, see *Surgical instruments* 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.
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 centre of 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. 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.

3. 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. The round drill bed allows for some rotation of the receiver/stimulator to achieve optimal placement.

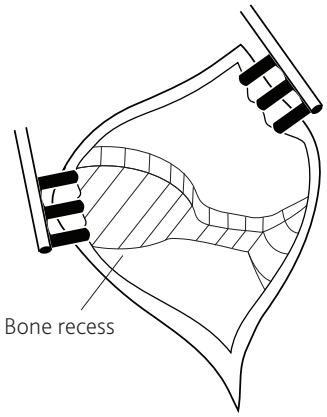
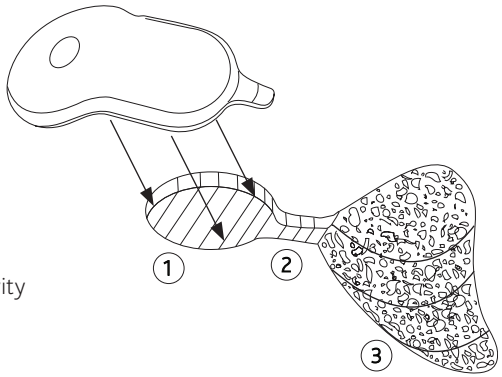


Figure 14: Bone recess

3. Check the final dimensions of the bone recess using the Recess Gauge, Bone Recess Template, Implant Template or the Sterile Silicone Implant Template.



1 Bone recess
2 Channel
3 Mastoidectomy cavity

Figure 15: Bone recess, electrode channel and mastoidectomy

4. Place the Implant Template, Array Exit Marking 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 (see Figure 15). The channel will help protect the electrode against trauma.
6. Use the Recess Gauge to check the position and depth of the electrode exit.

4. Drilling tie-down holes

1. Using the implant seat for orientation (see *The bone recess* on page 30), 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 16: Tie-down holes for CI24RE Series implants

Warning

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

5. 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.

6. Preparing the cochleostomy or round window

The CI422 cochlear implant with Straight electrode is compatible with both round window and cochleostomy approaches.

This section describes site preparation for both approaches. For details on inserting the electrode see *10. Inserting the intracochlear electrode* on page 41.

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.

   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.

2. Perform a cochleostomy into the scala tympani using a 1.4 mm or 1.0 mm diamond burr at low speed.

   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.

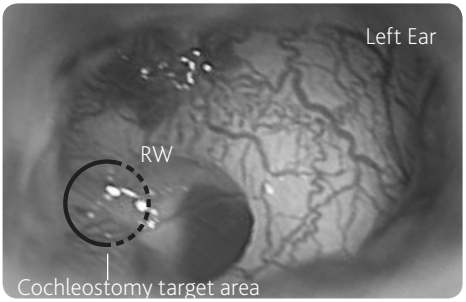


Figure 17: Cochleostomy target area

3. Drill sufficient bone with the 1.4 mm or 1.0 mm diamond burr to expose at least 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 *10. Inserting the intracochlear electrode* on page 41.

Round window

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.

   The round window membrane may be obscured by the overhang of the lateral margin of the niche. It may be necessary to drill away the overhang to see the round window membrane.

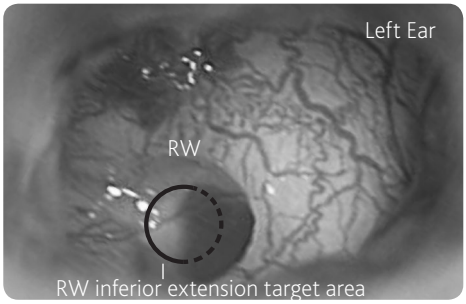


Figure 18: Round window target area

2. Remove the false membrane.

Warning

Do not open the round window membrane until immediately before insertion of the electrode as described in *10. Inserting the intracochlear electrode* on page 41.

7. Inspecting the cochlear implant and electrodes

Non-sterile field

1. Remove the cardboard box (outer packaging).
2. Break the seal on the outer tray, and confirm that:
   - exposure to ethylene oxide processing is indicated by a green dot on the outer tray
   - the inner packaging is not damaged.

Warning

If the sterile pack is damaged, do not use the cochlear implant.

Sterile field

3. Remove the sterile tray and confirm the cochlear implant is not damaged.
4. Remove the cochlear implant from the sterile packaging tray.

Warning

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, leave the protective tube on the electrode until just before insertion.

8. 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 see *Device description* on page 18.

2. Place the electrode lead in the centre of the channel.

   Caution

   If rotating the implant in the bone recess, take care not to pinch the electrode lead between the edge of the bone channel and the casing.

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.

9. Securing the extracochlear electrode

1. Grasp the protective tube (in the end section) and carefully remove the tube from the extracochlear electrode. Do not squeeze the electrode or stretch the electrode lead.
2. 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.

10. Inserting the intracochlear electrode

Warning

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.

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

Do not suction the perilymph.

Inserting via the round window

Make a straight incision the width of the round window.

Insertion

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode. Do not squeeze or stretch the electrode.

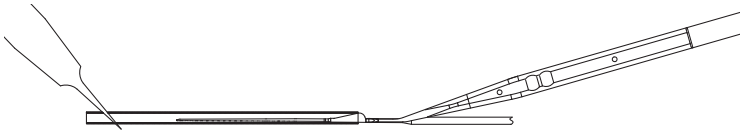


Figure 19: Removing the tube

2. Guide the tip of the array toward the cochleostomy or round window using AOS forceps to hold the electrode by the handle. The Electrode Claw can also be used to help guide the electrode.
3. Begin slowly inserting the electrode, ensuring that the half-band electrode contacts remain oriented toward the modiolus. The handle can be used to identify electrode orientation, as it is located on the opposite side of the electrode contacts.

Warning

Do not force if resistance is felt before full insertion.

4. Continue inserting the electrode to a suitable depth using the white markers located at 20 mm and 25 mm on the electrode as a guide.

   The maximum recommended insertion depth is 25 mm. It is not necessary to insert the electrode to the maximum depth of 25 mm. Partial insertion is better than forcing the electrode beyond the point of first resistance.
5. Stabilise the lead to prevent movement of the electrode in the cochlea.

11. Securing and sealing the intracochlear electrode

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 continuously by the handle.

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

1. Pack completely around the electrode in the cochleostomy or round window with an autograft consisting of strips of fascia or pericranium to ensure there are no gaps in the seal.

   Note

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

2. Coil the excess redundant proximal electrode lead inside the mastoid cavity under the bony overhangs.
3. Place any excess loop of the extracochlear electrode in the mastoid cavity.

   Note

   If the electrodes 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 see Xu J, Xu SA, Cohen LT, Clark GM. Cochlear View: Post-operative Radiography for Cochlear Implantation. Am J Otol, 21(1):49-56, 2000.

12. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sheath.

Warning

If using the Intraoperative Spacer, place the coil on top of the Intraoperative Spacer in the sterile sheath.

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.

13. 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.

Notes

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.

Remove sutures on approximately the tenth day.

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

Complete the registration form. Send the completed form to Cochlear within 30 days of receiving the product. Fill out the implant model number and ear details on the patient identification card and give it to the patient or their carer.

The patient or their carer should carry the patient identification card with them at all times.

Identifying the implant

If required, the implant type and model can be identified without the need of surgical intervention, using X-ray or Cochlear programming software.

Cochlear Nucleus CI24RE Series implant

Using an X-ray, Cochlear Nucleus CI24RE Series implants can be identified by the radiopaque characters printed on them.

The characters at the base ('C13T' in Figure 20 below) indicate the following.

- Manufacturer – 'C' indicates 'Cochlear Ltd'.
- Model
  - '4' indicates CI24RE (ST)
  - '5' indicates CI24RE (CA)
  - '13' indicates CI422, as illustrated below.
- Year of manufacture – 'T ' indicates 2004 or later.

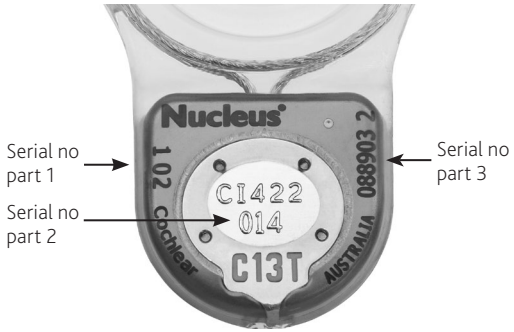


Figure 20: CI422 radiopaque label and serial number

The serial number is in three parts, as labelled in Figure 20, and is read from left to right.

Serial number part 1	Serial number part 2	Serial number part 3
102	014	0889032

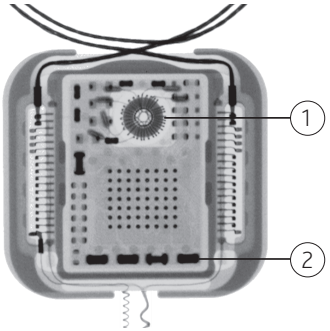
Cochlear Nucleus CI500 Series implant

This information is to assist with identifying differences between Cochlear Nucleus CI500 Series and CI24RE Series implants. Other implant models may have other identifying features.

When interpreting a sagittal X-ray image of a Cochlear Nucleus CI500 Series implant, the device series can be identified by the electronic assembly layout.

Cochlear CI500 Series implants have:

- a round shape at the coil exit end
- four large components at the electrode exit end.



1 Round shape at coil exit end

2 Four large components at electrode exit end

Figure 21: Plain X-ray of CI500 Series implant

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 (see *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 electrode lead without damage, cut the electrode lead before the handle:

Figure 22: Straight electrode lead cut location for explantation

If the extracochlear electrode is difficult to remove, cut the extracochlear lead and leave the electrode in place.

Reporting problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

Notes

MRI safety information

The Cochlear Nucleus CI422 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/warnings
- 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 (e.g. 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.

Removing the magnet

Caution

- Take care when removing or inserting the magnet or non-magnetic plug, so as not to damage the implant silicone. Exerting minimal force, always use a blunt instrument – such as an elevator – to lift the lip of the silicone elastomer recess. Minimise the pressure applied to the antenna of the implant.
- Magnets for the Cochlear Nucleus CI24RE Series implants are a different size to magnets for the Cochlear Nucleus CI500 Series implants. Ensure that the correct magnet is used.
- Non-magnetic plugs for the Cochlear Nucleus CI24RE Series implants are a different size to non-magnetic plugs for the Cochlear Nucleus CI500 Series implants. Ensure that the correct non-magnetic plug is used.

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.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

The replacement procedure should take place under sterile conditions.

To replace 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 star symbol (denoting polarity) facing up (see magnet images in ***Replacing the magnet*** on page 60). 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.
3. 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 following the steps in ***Replacing the magnet*** on page 60.

Removing the magnet after implantation

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.

   The surgical technique then differs according to whether the patient requires a single MRI examination or multiple examinations over a period of time.

Single MRI

For a single MRI examination:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 57) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing.
3. The magnet recess may remain empty, with sterility maintained, for a period of up to four hours.
4. Take the patient for the MRI examination.
5. After the MRI has been taken, under sterile conditions insert a new sterile replacement magnet following the steps in ***Replacing the magnet*** on page 60.

Multiple MRI

For cochlear implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the plug prevents fibrous tissue growing into the recess. Such growth would make magnet replacement difficult.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the plug is removed and replaced by a magnet.

The non-magnetic plug and replacement magnet are supplied separately in sterile packs. Both are single-use items.

Inserting a non-magnetic plug

To insert a sterile non-magnetic plug in the recess:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 57) and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug available from Cochlear into position, being careful not to exert undue pressure on the implant.

Figure 23: CI24RE Series non-magnetic plug

Caution

Non-magnetic plugs for CI24RE Series implants are a different size to non-magnetic plugs for CI500 Series implants. Ensure the correct plug is used.

3. Close the wound in layers.
4. When MRI is no longer a regular necessity, insert a replacement magnet by following the steps in ***Replacing the magnet*** on page 60.

Replacing the magnet

When MRI is no longer a regular necessity:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 57) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a new sterile replacement magnet, available from Cochlear, with the star symbol (denoting polarity) facing up, as shown below.

Figure 24: CI24RE Series magnet facing upwards

Use the elevator to lift the lip of the recess and position the magnet.

Caution

Magnets for CI24RE Series implants are a different size to magnets for CI500 Series implants. Ensure the correct magnet is used.

Note

As with the original magnet, the silicone lip retains the replacement magnet.

4. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.

How the implant is supplied

The implant, non-magnetic plugs and replacement magnets are single-use items. 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
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

Storage and handling

Transport and store Nucleus cochlear implants at temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

For long term storage, store at room temperature. Keep dry.

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

CI422 implant specifications

Intracochlear electrodes	
Number of electrodes	22 electrodes
Distance between centre of electrode contacts	0.85 mm to 0.95 mm when straight
Diameter of electrodes (cross-sectional dimension)	0.6 mm x 0.5 mm at proximal end, tapering to 0.35 mm x 0.25 mm at distal end
Contact surface area	0.19 mm^2 to 0.14 mm^2
Active array length when straightened	19.1 mm
Nominal electrode length when straightened	• 20 mm from tip to distal marker • 25 mm from tip to proximal marker
Lead length from receiver/stimulator to array tip	89 mm

Extracochlear electrodes
• Plate on receiver/stimulator • Ball electrode 1.5 mm (typical) diameter with lead length 80 mm

Receiver/Stimulator	
Dimensions	Case: 20.8 mm x 22.4 mm x 6.9 mm Coil: 30.6 mm diameter x 3.6 mm thick
Volume	4.4 cm^3 without lead
Weight	9.5 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 as measured according to EN 45502-2-3
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 as measured according to EN 45502-2-3
Transmitting range	1 to 10 mm

Measurement function	
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, bipolar and common ground modes
Impedance measurement accuracy	80% measured according to EN 45502-2-3
Implant ID and type check	Enables the sound processor to confirm whether it is coupled to the nominated implant

Materials in contact with body tissues	
Silicone elastomer	Lead and receiver/stimulator protective coating and insulation
Titanium	Magnet case
Platinum	Electrode contacts

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
	Refer to instruction manual
	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
	Temperature limits
	Keep dry
	Sterilised using ethylene oxide
	Caution: US law restricts this device to sale by, or on the order of, a physician
	Catalogue number
	Serial number

LOT	Batch code
EC REP	Authorised representative in the European Community
MR	MR Conditional
CE	CE registration mark

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.

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