CI512

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

Surgeon's Guide

United States of America

Hear now. And always

Cochlear®

Contents

Introduction

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

Symbols

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

Note

- Surgeons implanting this device should be experienced in cochlear implant surgery.
- Please ensure you are thoroughly familiar with all product labelling.

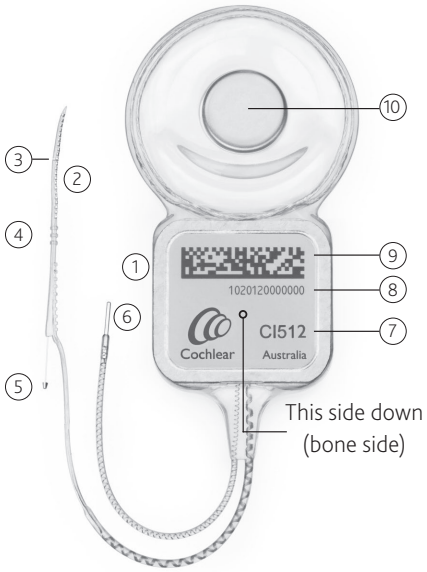
Caution

- When using sharp instruments near the device, take great care to avoid nicking or damaging the case, insulation, or electrode lead.
- US law restricts this device to sale by, or on the order of, a physician.

Please read the Physician's Package Insert and the Important Information booklet. They contain important information on MRI, indications, contraindications, adverse effects, warnings and precautions.

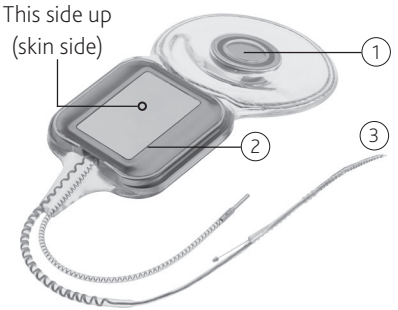
The Cochlear™ Nucleus® CI512 cochlear implant with Contour Advance® electrode

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



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

Figure 1: CI512 cochlear implant (bone side)



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

Figure 2: CI512 cochlear implant (skin side)

1 Ribs indicating array insertion depth
2 White marker indicating array insertion depth

Figure 3: Contour Advance perimodiolar electrode array with stylet removed

Surgical instruments

The following surgical instruments are appropriate for use with the CI500 Series of cochlear implants. All instruments are stainless steel and can be cleaned and resterilised as instructed in the ***Surgical Instrument Kit Reprocessing Guide***. A CI500 Series upgrade kit is also available.

BTE Template (Z33011)

Used to ensure the implant is positioned with sufficient space for an ear level sound processor.

Figure 4: BTE Template

CI500 Series Implant Template (Z139273)

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

Figure 5: CI500 Series Implant Template

CI500 Series Recess Gauge (Z139274)

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

Figure 6: CI500 Series Recess Gauge

Contour® Electrode Claw (Z33021)

Aids insertion of the electrode array into the cochlea. Gold coloured handle.

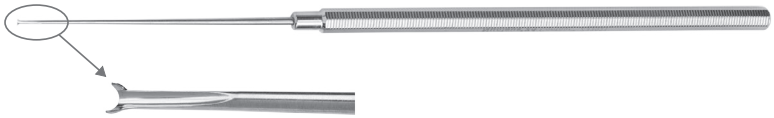


Figure 7: Contour Electrode Claw

AOS (Advance Off-Stylet®) Forceps (Z60770)

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

Figure 8: AOS Forceps

Other instruments

Spacer for Intraoperative Testing (Z33012)

Order from Cochlear as an individual item.

Used to check that there is at least 2 mm between the transmitting coil and implant antenna when the coil is placed directly over the antenna.

Non-sterile. A sterile sheath is required for use.

Figure 9: Spacer

CI500 Series Non-sterile Silicone Implant Template (Z179609)

Used to determine/check the optimum implant position and mark it onto the skin prior to incision.

Warning

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

Figure 10: CI500 Series Non-sterile Silicone Implant Template

CI500 Series Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. See *2. The Sterile Silicone Implant Template* on page 14 and the warnings below for more information.

Used in the sterile field to check the size of the periosteal pocket, the shape and depth of the implant well and appropriate positions for tie-down holes.

Figure 11: CI500 Series Sterile Silicone Implant Template

Warning

- For temporary use only. Not for implantation.
- Supplied sterile. Do not re-sterilise.
- Single-use item. Do not use more than once.
- Do not use if the sterile packaging is damaged.
- It is advised to dispose of the Sterile Silicone Implant Template after surgery, even if not used.
- Dispose of used template according to your institution's policy for the disposal of biohazardous waste.

Surgical procedure

General surgical issues

The routine use of a facial nerve monitor is advised, and is particularly important for cases of congenital temporal bone anomalies, revision surgeries, and other cases where the facial nerve may be at greater risk.

Meningitis is a known risk of inner ear surgery. Candidates should be appropriately counselled of this risk and the vaccination status against micro-organisms that cause meningitis. Broad-spectrum antibiotic coverage for the operation is important. Coverage should be determined by the surgeon, to be consistent with best practice.

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 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. At least 15 mm must be allowed between the implant and the incision.

   The incision must be large enough to accommodate the implant. The flap may be inferiorly- or anteriorly-based, but must allow the surgeon to secure the implant to the bone.
4. Mark the centre of the proposed seat for the implant bed with a drop of methylene blue on the bone. To do this, insert a 21 gauge needle through the hole in the template and through the skin.
5. Prior to incision, the incision line may be infiltrated with local anaesthetic and 1:100 000 or 1:200 000 adrenaline/epinephrine unless contraindicated.

2. The Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. See *CI500 Series Sterile Silicone Implant Template* on page 11 for warnings and more information. To open the template tray:

1. Remove the cardboard box (outer packaging).
2. Break the seal on the outer tray, and confirm that the two inner trays are not damaged, and that exposure to ethylene oxide processing is indicated.
3. Notice that the tray containing the template has a blue seal. The tray containing the implant has a white seal.
4. Lift out the template tray (blue seal) and break the seal.

   Note

   Keep the implant tray (white seal) to one side, within the sterile field, with the seal intact until later in the surgery.
5. Lift the Sterile Silicone Implant Template from the tray.

3. Incision

Warning

If the patient has an implant in the other ear, monopolar electrosurgical instruments must not be used (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 antenna.
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 implant seat

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

The mastoidectomy

Create an adequate mastoidectomy cavity, allowing an overhang both superiorly and posteriorly to accommodate any redundant proximal electrode lead. For children, it is recommended that a mastoidectomy be performed.

The implant seat

The blue dye dot on the bone indicates the position of the front edge of the stimulator. Use the Recess Gauge, Implant Template or the Sterile Silicone Implant Template to determine the angular orientation of the implant. This is usually placed at 30–45 degrees above the temporal line.

To drill the implant seat:

1. Mark the seat using a surgical marker with the aid of the Recess Gauge, Implant Template or the Sterile Silicone Implant Template.
2. Drill the seat. 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.

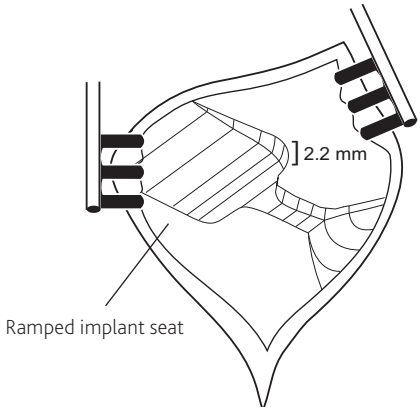


Figure 12: Ramped implant seat

3. Check the seat's final dimensions using the Recess Gauge, Implant Template or the Sterile Silicone Implant Template.

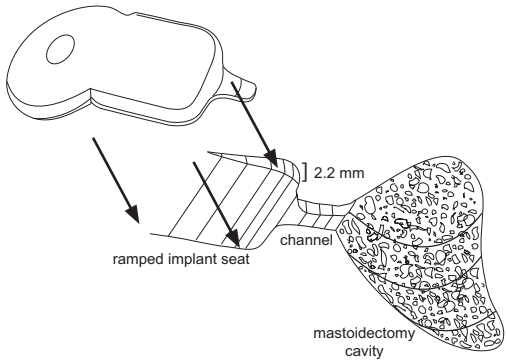


Figure 13: Ramped implant seat, channel and mastoidectomy

4. Place the Implant Template or Recess Gauge in the seat and use it to mark the exit of the electrode array.
5. Drill a channel to connect the seat and mastoid cavity (see ***Figure 13***). The channel will help protect the electrode array against trauma.
6. Use the Recess Gauge to check the position of the array exit.

5. Tie-down holes

1. Using the implant seat for orientation (see *The implant seat* on page 16), 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. For children, an elevator may be used to protect the dura.

For additional support, posterior tie-down holes may be drilled, or the antenna portion can be placed under a pericranium pocket.

6. Facial recess

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.

Identify the facial nerve, but do not expose it.

The chorda tympani nerve can almost always be preserved.

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

7. 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. 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.

   Drilling too far anteriorly or superiorly will result in the endosteum appearing white and the scala media or vestibuli may be entered. Drilling too far inferiorly will miss the cochlea entirely and a hypotympanic air cell may be entered, leading to incorrect electrode placement.

   Take care to remove bone dust, blood and other fluids from the cochleostomy.

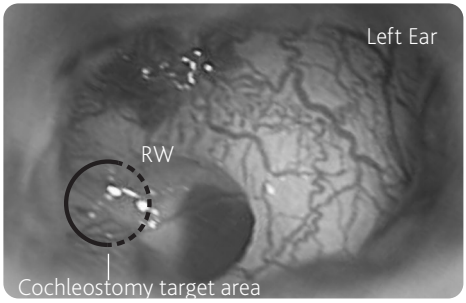


Figure 14: Cochleostomy target area

3. Drill sufficient bone with the 1.4 mm or 1.0 mm diamond burr to expose at least 1.5 mm of endosteum.

Note

Do not open the endosteum until immediately prior to insertion of the electrode as described in ***11. Inserting the electrode array*** on page 25.

8. Inspecting the implant and electrodes

If the Sterile Silicone Implant Template has already been unpacked, go to step 4.

1. Remove the cardboard box (outer packaging).
2. Break the seal on the outer tray, and confirm that the two inner trays are not damaged, and that exposure to ethylene oxide processing is indicated.
3. Notice that tray containing the template has a blue seal. The tray containing the implant has a white seal.
4. Lift out the implant tray (white seal) and break the seal.
5. Remove the implant tray and confirm the implant is not damaged.

Caution

- Do not bend the array as the stylet is malleable and will deform.
- Leave the protective tube on the array until just prior to insertion.

Warning

Monopolar electrosurgical instruments must not be used on the neck and head of a cochlear implant patient from this point. Bipolar electrosurgical instruments may be used; however, the cautery electrode tips must not contact the implant and should be kept more than 1 cm from the extracochlear electrodes.

9. Securing the device

Place the receiver/stimulator in the seat with the antenna coil in the subperiosteal/pericranial pocket. Place the electrode lead in the centre of the channel with the implant between the tie-down holes.

Caution

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

Secure the receiver/stimulator with a single suture, using a non-absorbable synthetic material. Move the knot to the edge of the implant.

Note

Do not suture directly over the magnet in case the magnet requires removal at a later date.

10. Securing the extracochlear electrode

Carefully place the extracochlear electrode against the bone under the temporalis muscle to avoid mechanical stress on the electrode lead. Do not place it in the temporalis muscle.

11. Inserting the electrode array

Note

- The AOS method, as described, is highly recommended by Cochlear. The AOS method was developed specifically for implants with the Contour Advance Electrode.
- Use minimal force, and do not rush the insertion.
- During the insertion, ensure the half-band electrodes remain oriented towards the modiolus and that the array does not kink.
- At the end of the insertion, the most proximal rib is usually just outside the cochleostomy. Do not try to force the array into the cochlea should the most proximal rib not be exactly at the cochleostomy.

Warning

- Do not reinsert the stylet whilst the array is either partially or fully inserted, as this may cause damage to the array and the cochlea.
- In the event of suboptimal placement, it is recommended to remove the array and use the backup implant instead. Do not reinsert the stylet in order to reinsert or reposition the array.

The following should be performed immediately prior to insertion of the electrode:

1. Open the endosteum with a sharp pick and ensure that the cochleostomy is wide enough to accommodate the 0.8 mm electrode and the 1.2 mm marker rib.
2. Remove any sharp edge of bone which might snag the electrode with stapes footplate instruments or a 0.8 mm or 0.6 mm diamond burr.

Warning

Try not to suction the perilymph.

AOS insertion

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode array. Do not squeeze or stretch the array.
2. Orientate the array so that its curve will follow the cochlea's spiral.
3. Guide the tip toward the cochleostomy, using the claw or other blunt tip surgical tool. Angle the array toward the floor of the scala tympani. Ensure the half-band electrodes remain oriented toward the modiolus.
4. Insert the electrode until the white marker is at the cochleostomy (see ***Figure 15*** on page 27).
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 (see ***Figure 15*** B, C and D).
6. Remove the remainder of the stylet.

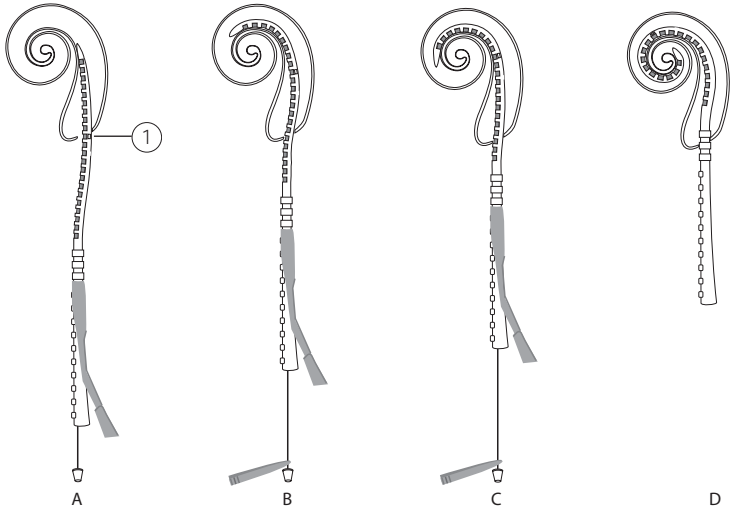


Figure 15: AOS Insertion (white marker (1) at cochleostomy)

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

12. Securing and sealing the intracochlear electrode array

Warning

Immediately after electrode insertion and before arranging the excess proximal electrode lead in the mastoid cavity, it is important to immobilise the electrode by continuously holding it in place. Movement of the excess lead could result in the electrode twisting and potentially damaging structures.

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

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.

Note

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

Coil the excess redundant proximal electrode lead inside the mastoid cavity under the bony overhangs.

Place any excess loop of the extracochlear electrode in the mastoid cavity. If the 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 leads with fine gauge sutures.

Confirmation of electrode placement

Prior to 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.

13. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the transmitting 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 implant transmitting range is 1 mm to 10 mm. The implant may not function properly if the coil is directly on top of the receiver/stimulator.

   Methods to determine that the implantable system is functioning properly include impedance measurement using a Cochlear proprietary programming system.

14. Closure

The facial recess may be packed with soft tissue. Suture the palva flap over the proximal portion of the intracochlear electrode lead. Close the wound in layers. Drainage is not recommended. Apply a large mastoid pressure dressing.

MRI safety information

The Cochlear Nucleus CI512 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 CI500 Series are a different size to magnets for the Nucleus 24 range. Ensure that the correct magnet (Z179608) is used.
- Non-magnetic plugs for the CI500 Series are a different size to non-magnetic plugs for the Nucleus 24 range. Ensure that the correct non-magnetic plug (Z146624) 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 before the device is implanted.

The replacement procedure should take place under sterile conditions.

To replace the magnet prior to implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the cochlear logo or black ring (denoting polarity) on the magnet facing up (see images of magnets in ***Single MRI*** on page 34). 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 antenna of the implant.
3. Remove the sterile non-magnetic plug (available from Cochlear - Z146624) from its packaging and insert it into the recess. Lift the lip of the recess using an elevator and press the non-magnetic plug into position, being careful not to exert undue pressure on the implant.
4. The implant is now ready for implantation.

Replace the magnet when there is no further need for MRI examinations, following the procedures below.

To wear an external transmitter coil while the implant has no magnet in place, the patient must wear a retainer disc.

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 33) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing.

   The magnet recess may remain empty, with sterility maintained, for a period of up to four hours.
3. Take the patient for the MRI examination.
4. After the MRI has been taken, under sterile conditions insert a new sterile replacement CI500 Series Magnet (available from Cochlear - Z179608) with the Cochlear logo or black ring (denoting polarity) facing up (see below).

Figure 16: CI500 Series magnets (facing upwards)

5. Use the elevator to lift the lip of the recess and position the magnet.
6. Close the wound in layers.

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 non-magnetic plug prevents fibrous tissue growing into the recess. Such growth makes later magnet replacement difficult.

The patient must wear a retainer disc (available from Cochlear - S15249) to hold their external transmitter coil in place when the magnet has been removed.

When there is no further need for MRI examinations, the non-magnetic 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 33) and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug (available from Cochlear - Z146624) into position, being careful not to exert undue pressure on the implant.

Figure 17: CI500 Series non-magnetic plug (Z146624)

Caution

Non-magnetic plugs for the CI500 Series are a different size to non-magnetic plugs for the Nucleus 24 range. Ensure that the correct non-magnetic plug (Z146624) is used.

3. Close the wound in layers.

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 33) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a new sterile replacement magnet (available from Cochlear - Z179608) with the Cochlear logo or black ring (denoting polarity) facing up (see images of magnets in ***Single MRI*** on page 34).

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

   Caution

   Magnets for the CI500 Series are a different size to magnets for the Nucleus 24 range. Ensure that the correct magnet (Z179608) 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.

General information

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.

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).

Explantation

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

- Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
- Before explanting the device, examine it for any defects, and note these on the form provided with the kit.
- Try to keep the explanted device intact and undamaged.
- Cut the intracochlear electrode lead if this will make it easier to remove the device without damaging it. The cut should be in the region of the electrode lead as shown below (before the ribbed portion of the array).

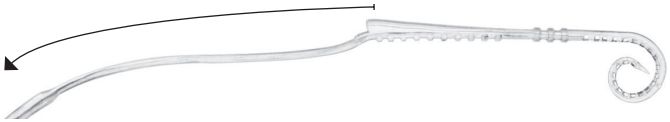


Figure 18: Cutting the electrode lead for explantation

- If the intracochlear electrode array is removed from the cochlea, return it in the kit, even if it is damaged.
- If necessary, leave the distal end of the extracochlear electrode lead in place.
- Return the kit containing the explanted device to Cochlear.

Problem reporting

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.

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.

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.

CI512 implant specifications

Electrodes

- 22 platinum electrodes, moulded with a silicone elastomer carrier, and spaced over a 14.25 mm active array.
- Diameter of electrodes: 0.8 mm at the basal end, tapering to 0.4 mm at the apical electrode band.
- Two extracochlear electrodes: one titanium plate at the receiver/stimulator package, and a separate 0.6 mm (typical) diameter cylindrical electrode with hemispherical tip on a 60 mm lead.
- A marker in the middle of the active part of the array, indicates insertion depth when the tip is near to the lateral wall of the otic capsule at the back of the basal turn.
- Platinum stylet holds electrode straight for insertion.

Receiver/stimulator

- Hermetically sealed titanium case
- Case dimensions: 24 mm x 23 mm x 3.9 mm
- Coil dimensions: 31 mm diameter x 3.7 mm thick
- Weight: 8.6 g including electrode array.

Operating characteristics

- Power and data received by a 5 MHz inductive link from the sound processor headset coil
- Delivers biphasic current pulses
- Delivers monopolar, bipolar or common ground stimulation
- Delivers stimulus amplitudes from 0 mA to 1.75 mA
- Delivers stimulus duration from 9.6 µs to 400 µs per phase.

Symbols

The following symbols may appear on your implant packaging:

Fragile, handle with care

Do not use if package is damaged

Consult instructions for use

Refer to instruction manual

Caution

Do not re-use

Do not resterilise

Date of manufacture

Manufacturer

	Use-by date
	Temperature limits
	Keep dry
STERILE EO	Sterilised using ethylene oxide
Rx Only	Caution: US law restricts this device to sale by, or on the order of, a physician
REF	Catalogue number
SN	Serial number
LOT	Batch code
EC REP	Authorised representative in the European Community
CE 0123	CE registration mark with notified body number
	MR Conditional

Notes

Hear now. And always

Cochlear Ltd (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove, NSW 2066, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
EC REP **Cochlear Deutschland GmbH & Co. KG** Karl-Wiechert-Allee 76A, 30625 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770
Cochlear Americas 10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 416 972 5082 Fax: +1 416 972 5083
Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205
Cochlear Europe Ltd 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400 Fax: +44 1932 26 3426
Cochlear Benelux NV Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70
Cochlear France S.A.S. 135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National) Fax: +33 5 34 63 85 80
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62
Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacık, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919
Cochlear (HK) Limited Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183
Cochlear Korea Ltd 1st floor, Cheongwon Building 33, Teheran-ro 8 gil, Gangnam-gu, Seoul, Korea
Tel: +82 2 533 4450 Fax: +82 2 533 8408
Cochlear Medical Device (Beijing) Co., Ltd
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road, Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900
Cochlear Medical Device Company India Pvt. Ltd.
Ground Floor, Platina Building, Plot No C-59, G-Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100
株式会社日本コクレア（**Nihon Cochlear Co Ltd**）〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245
Cochlear Middle East FZ-LLC
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor, Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925
Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403, Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218
Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna, Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036

www.cochlear.com

N491859-491694 V6 2021-06

Cochlear®