CI422

Cochlear™ Nucleus® CI422 cochlear implant with Slim straight electrode

Surgeon's Guide

United States of America

Hear now. And always

Cochlear®

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.

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 circumstance(s) or factor(s) 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.

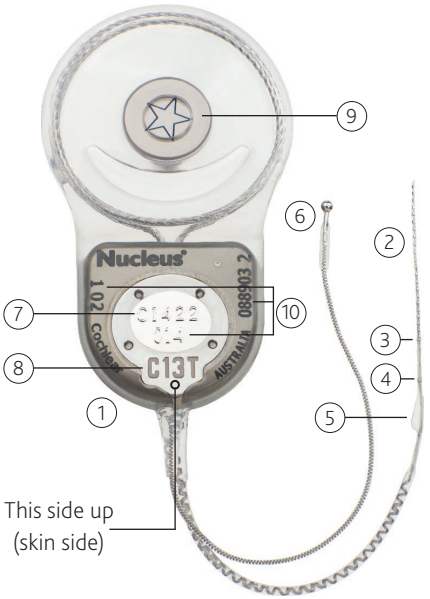
Caution

- Surgeons implanting this device should be experienced in cochlear implant surgery.
- Please ensure you are thoroughly familiar with all product labelling.
- When using sharp instruments near the device, take great care to avoid nicking or damaging the case, insulation, or electrode lead.

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.

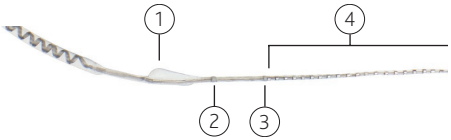
The CI422 implant

The CI422 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.



1. Receiver/stimulator
2. Intracochlear electrode array
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 and later)
9. Magnet (star on skin side)
10. Serial no. (e.g. 102 014 0889032)

Figure 1: CI422 implant (skin side)



1. Handle
2. White marker indicating 25 mm (max) insertion depth
3. White marker indicating 20 mm active array
4. Intracochlear electrode array

Figure 2: CI422 implant electrode array

Surgical Instruments

Surgical Instruments for the CI422 Implant

The CI24RE Series Surgical Instruments Kit (Z60523) is appropriate for use with the CI422 implant. All instruments are stainless steel and sterilisable (according to your institution's policies).

BTE Template (Z33011)

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

Figure 3: BTE Template

CI24RE Series Implant Template (Z33019)

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

Figure 4: CI24RE Series implant Template

CI24RE Series Bone Recess Template (Z60479)

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

Figure 5: CI24RE Series Bone Recess Template

CI24RE Series Array Exit Marking Template (Z33017)

Used to check the size of the well excavation, select the final position of the implant by rotating the instrument in the well, and mark the exit position and width of the channel for the electrode array and extracochlear lead.

Figure 6: CI24RE Series Array Exit Marking Template

CI24RE Series Recess Gauge (Z60480)

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

Figure 7: CI24RE Series Recess Gauge

Electrode Claw (Z30090)

Aids insertion of the electrode array into the cochlea.

Figure 8: Electrode Claw

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

CI24RE Series Non-Sterile Silicone Implant Template (Z33020)

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

Caution

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

Figure 10: Non-sterile Silicone Implant Template

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

Aids insertion of the electrode array into the cochlea. With curved tip ends that gently cup the array, improve stability and minimise rotation.

Figure 11: AOS Forceps

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 in which 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 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 coil and an ear level speech processor so that the speech processor will not rest on the receiver/stimulator.
2. Place the Silicone Implant Template on the skin so that the antero-inferior edge is at least 10 mm behind the edge of the pinna 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.
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 well for the implant bed with a drop of methylene blue on the bone. To do this, insert an 18-gauge needle through the hole in the template and through the skin.
5. Prior to incision, the incision line may be infiltrated with 1:100 000 or 1:200 000 adrenaline/epinephrine unless contraindicated.

2. 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, and form a flap (a monopolar cutting current may be used). Stabilise the flap using retraction as necessary.
2. Use the Implant Template to check the position of the implant.
3. Incise the underlying periosteum and lower portion of the temporalis fascia muscle creating an anteriorly-based large palva flap.
4. Elevate a large periosteal pocket for 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.

3. Mastoidectomy and well

The mastoidectomy is described next. Some surgeons prefer to drill the well 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 complete mastoidectomy be performed.

The well

The blue dye dot on the bone indicates the position for the well.

To drill the well:

1. Mark the well using the circular Bone Recess Template and/or the Implant Recess Template.
2. Drill the well bed. The round drill bed allows for some rotation of the receiver/stimulator, to achieve optimal placement.
3. Use the Bone Recess Template to check the well's final dimensions.
4. Place the Array Exit Marking Template in the well and rotate it to the optimum position.
5. Mark the exit of the electrode array.
6. Drill a channel to connect the well and cavity. The channel will help to protect the electrode array against trauma.
7. Use the Recess Gauge to check the position of the array exit.

4. Tie-down holes

1. Determine the longitudinal axis for the receiver/stimulator, then 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 diameter 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.

5. 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.

6. Preparing the Round Window or Cochleostomy

The CI422 implant electrode is compatible with both the round window (method 1) and cochleostomy (method 2) approaches. This section describes the preparation of the site for both approaches. See later section for details on inserting the electrode array.

Method 1 – 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.

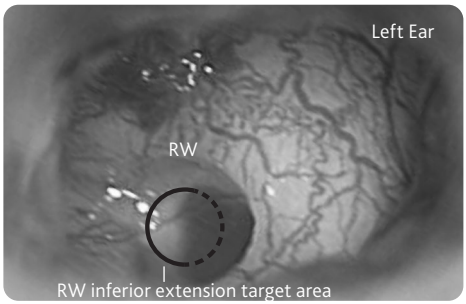


Figure 12: Round window target area

2. Remove the false membrane.
3. Immediately prior to inserting the electrode, a straight incision can be made with a 22-gauge hypodermic needle.

Note

The diameter of the incision must be at least equal to the diameter of the electrode at the proximal end i.e. 0.6 mm diameter. A 22-gauge hypodermic needle has a diameter of 0.711 mm.

Method 2 – 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. It may be necessary to 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 diameter 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 and blood from the cochleostomy.

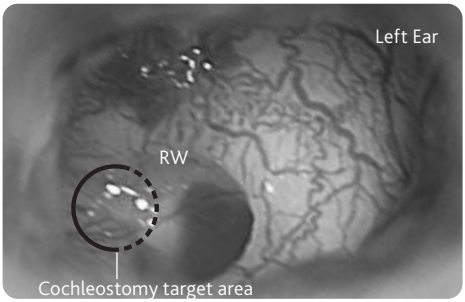


Figure 13: Cochleostomy target area

3. Drill sufficient bone with the 1.4 mm or 1.0 mm diameter diamond burr to expose at least 0.65–0.75 mm of endosteum. A 0.5 mm diameter diamond burr or a small foot plate hook (0.2 mm diameter) may be used to remove the final layer of bone.

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

1. Open the endosteum with a hook or needle and visualise the undersurface of the basilar membrane and the modiolar wall.
2. Using stapes footplate instruments, remove any sharp edge of bone which might snag the electrode.

Note

Try not to suction the perilymph.

7. Inspecting the implant and electrodes

1. Remove the implant's outer packaging.
2. Break the seal on the outer tray, and without touching the device, confirm the inner packaging is not damaged, and that exposure to ethylene oxide processing is indicated.
3. Remove the sterile tray and confirm the implant is not damaged.
4. Lift the implant from the sterile packaging tray.

Note

Leave the protective tube on the array until just prior to insertion.

Caution

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 electrodes must not contact the implant and should be kept more than 1 cm from the extracochlear electrodes.

8. Securing the device

Place the pedestal of the receiver/stimulator in the well, and place the electrode lead in the centre of the channel with the implant between the electrode tie-down holes. If desired, the antenna coil may be placed in a pericranial/temporalis pocket.

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 pedestal.

If desired, secure the package with a suture using a non-absorbable synthetic material. Move the knot to the edge of the implant.

Caution

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

9. Securing the extracochlear electrode

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

10. Inserting the electrode array

Note

If inserting via the round window – immediately prior to inserting the electrode, a straight incision can be made with a 22-gauge hypodermic needle.

If inserting via a cochleostomy – open the endosteum with a hook or needle and visualise the undersurface of the basilar membrane and the modiolar wall. Using stapes footplate instruments, remove any sharp edge of bone which might snag the electrode. Try not to suction the perilymph.

The forceps should be used to insert the electrode array into the round window or cochleostomy, holding the electrode by the handle. The Electrode Claw can also be used to help guide the electrode.

1. Carefully remove the protective tube from the electrode array. Do not squeeze or stretch the array.
2. Holding the electrode by the handle, guide the tip toward the cochleostomy or round window ensuring that the half-band electrodes 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 array. Advance the electrode slowly so that the first few electrodes are inserted.
3. Continue to insert the electrode slowly using the handle to maintain orientation. The active portion of the array runs 20 mm back from the electrode tip whilst 25 mm is the maximum recommended insertion depth. Use the white markers located at 20 mm and 25 mm on the array to assist in achieving a suitable insertion depth.

Note

Begin inserting the electrode array slowly with the forceps. Do not force if resistance is felt prior to full insertion. If the array is not suitably/sufficiently inserted, back out one or two rings, rotate the electrode lead toward the modiolus (clockwise for the left ear, counter-clockwise for the right) and attempt further insertion. Do not use significant force and do not allow the electrode array to kink. 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.

4. Stabilise the lead to prevent movement of the electrode array in the cochlea.

11. Securing and sealing the intracochlear electrode array

Caution

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 by the handle. Movement of the excess lead could result in the electrode twisting and potentially damaging structures, or possibly freeing itself from the cochlea.

The electrode array may be secured to limit the risk of migration or breaking the 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 or round window 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.

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.

12. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed. Either:

- Put the transmitting coil on top of the Intraoperative Spacer in a sterile sheath, and place this on top of the implant.

Or

- Put the transmitting coil alone in a sterile sheath, replace the flap and place the coil on top.

Note

The implant transmitting range is 2–10 mm. The implant may not function properly if the coil is directly on top of the receiver/stimulator.

13. 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 dressing.

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.

Clinicians and recipients should weigh the benefits and risks of completing an MRI scan at 1.5 T and choose one course of action:

1. Keep the magnet in place and use an MRI Kit.
2. Remove the implant magnet and replace it via surgical procedures.
3. Do not perform the MRI scan.

Full MRI safety information should be reviewed prior to determining the most appropriate course of action. Safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines*
- by visiting www.cochlear.us/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 (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 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 magnet's star symbol (denoting polarity) facing up. See magnet images in ***Replacing the magnet*** on page 25. 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 25.

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. Make a small incision (see *Removing the magnet after implantation* on page 22) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing, without closing the wound.

   The 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, insert a new sterile replacement magnet with the star symbol (denoting polarity) facing up. See *Replacing the magnet* on page 25.

Multiple MRI

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

The patient must wear a retainer disc to hold their external transmitter coil in place when the magnet has been removed.

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

The titanium 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 22) 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 14: 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 25.

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 22 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 15: 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.

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 10th 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).

Identifying the implant

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

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 (Z25017). 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 handle).

Figure 16: Cutting the electrode lead (location marked) for explantation

- If the extracochlear electrode is difficult to remove, cut the extracochlear lead and leave the electrode in place.
- If the intracochlear electrode array is removed from the cochlea, return it in the kit, even if it is damaged.
- 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 her/him. 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.

CI422 implant specifications

Electrodes

- 22 half-banded platinum electrodes, moulded with a silicone elastomer carrier, and spaced over a 20 mm active array.
- A circumferential white marker proximal to the 1st electrode indicates 20 mm insertion depth. A similar marker 5 mm closer to the implant indicates 25 mm maximum insertion depth.
- Diameter of electrodes: 0.6 mm at the basal end, tapering to 0.3 mm at the apical electrode band.
- Two extracochlear electrodes: one platinum plate attached to the receiver/stimulator package, and a separate 1.5 mm (typical) diameter ball electrode on a 80 mm lead.

Receiver/stimulator

- Hermetically sealed titanium case
- Case dimensions: 20.5 mm x 19.3 mm x 6.9 mm
- Coil dimensions: 30.6 mm diameter x 3.6 mm thick
- Weight 9.5 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 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
	Refer to instruction manual
	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
	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
	MR Conditional

Notes

Notes

Hear now. And always

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