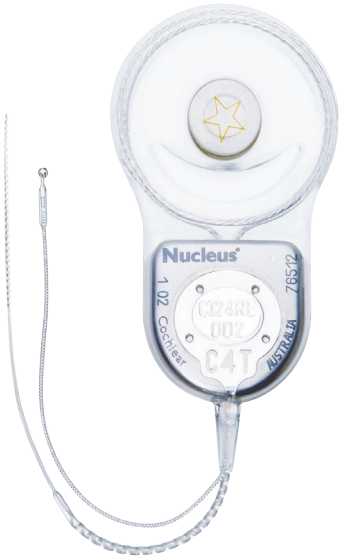
Cochlear™ Nucleus® CI24RE (ST) cochlear implant with Straight electrode

Surgeon's Guide

United States of America



Symbols

Note
Important information or advice.

Caution
Special care to be taken to ensure safety and effectiveness.
Could cause damage to equipment.

Warning
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

Introduction

This guide explains the general surgical procedure for implanting the Nucleus® Freedom® implant with straight electrode, model CI24RE (ST).

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

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.

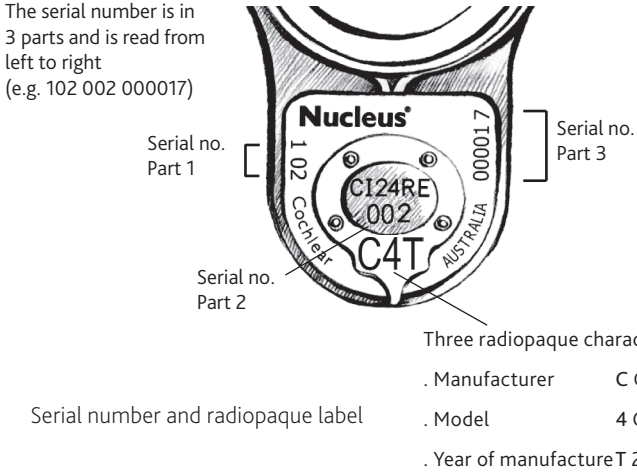
CI24RE (ST) cochlear implant

The CI24RE (ST) has a receiver/stimulator, which receives and decodes the electrical signal, and an electrode array, which delivers the signal to the cochlea.

The electrode array has 22 intracochlear electrodes, and the implant also has two extracochlear electrodes, one on the receiver/stimulator, the other on a lead.

A radiopaque label enables identification by x-ray after implantation.

- The letter on the left shows the manufacturer. “C” indicates “Cochlear”.
- The number in the middle shows the model. “4” indicates CI24RE (ST).
- The letter on the right shows the year of manufacture, up to and including 2004. Implants manufactured after 2004 will show "T " in this position, regardless of their year of manufacture.



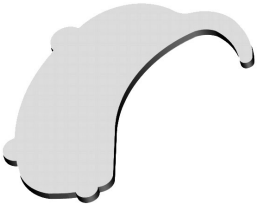
Serial number and radiopaque label

Surgical Instruments

The CI24RE Series Instrument Kit (Z60523) contains the following instruments. 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 speech processor.



CI24RE Series Implant Template (Z33019)

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

CI24RE Series Bone Recess Template (Z60479)

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

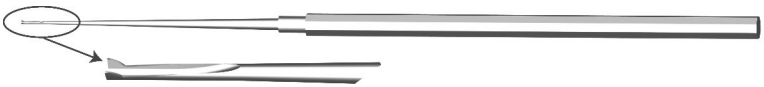
CI24RE Series Array Exit Marking Template (Z33017)

- 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.

CI24RE Series Recess Gauge (Z60480)

Used to check the size and position of the well/array exit excavation.

Contour® Electrode Claw (Z33021)



Aids insertion of the Contour Electrode into the cochlea. Gold.

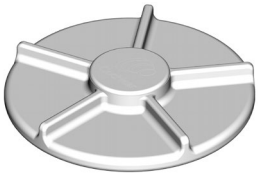
Electrode Claw (Z33090)

Aids insertion of the electrode into the cochlea.

Other Instruments

These instruments can be ordered as separate items from Cochlear.

Spacer for Intraoperative Testing (Z33012)



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.

CI24RE Series Non-Sterile Silicone Implant Template (Z33020)

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

Not for use in the sterile field. Single-use item.

Do not sterilise.

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.

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

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 ball 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 Checking 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 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. 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 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 white spot of endosteum will be seen.

   Drilling too far superiorly will enter the scala media or vestibuli, while too far inferiorly will miss the cochlea entirely and may enter a hypotympanic air cell, leading to incorrect electrode placement.

   Take care to keep bone dust and blood from the cochleostomy.

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

4. Open the endosteum with a sharp pick and visualise the undersurface of the basilar membrane and the modiolar wall.

5. Using stapes footplate instruments, remove any sharp edge of bone which might snag the electrode. Try not to suction the perilymph.

Note

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.

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.

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.

Secure the package with a single mattress suture, using a non-absorbable synthetic material. Move the knot to the edge of the implant. Tie the antenna portion if necessary.

Caution

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

9. Securing the extracochlear ball electrode

Place the extracochlear ball electrode against the bone under the temporalis muscle. Do not place it in the temporalis muscle.

10. Inserting the electrode array

This description assumes the surgeon is using the Electrode Claw. Some surgeons prefer to use jeweller's forceps.

1. Carefully remove the protective tube from the electrode array. Do not squeeze or stretch the array.
2. Guide the tip toward the cochleostomy, using the claw or side of a fine suction tip. By advancing both hands, the first few electrodes can usually be inserted.
3. Use the Electrode Claw to stroke the array into the scala tympani, using minimal force, and attempting to insert only a few electrodes at a time.
4. If resistance is encountered, 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.

Remember it is not necessary to insert all rings, and that a partial insertion is better than a damaged array.

11. Securing and sealing the intracochlear electrode array

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 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 ball 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.

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 CI24RE (ST) 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 CI24RE (ST) 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 titanium 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 star symbol on the magnet facing up. Do not remove the electrode array protective tube.
2. Using an elevator, or similar instrument, lift the tip 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 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 cochlear implant is now ready for implantation.

Replace the magnet when there is no further need for MRI examinations, following the steps in *Removing the magnet after implantation* on page 18.

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 18) 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 *20*.

Multiple MRI

For implant users 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. Make a small incision (see *Removing the magnet after implantation* on page 18) and remove the magnet.
2. 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.

Figure 1: 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 20.

Replacing the magnet

When MRI is no longer a necessity:

1. Make a small incision (see *Removing the magnet after implantation* on page *18*) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a sterile replacement magnet with the star symbol (denoting polarity) facing up. Use an elevator to lift the lip of the recess and position the magnet.

Figure 2: CI24RE Series magnet facing upwards

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 at about the tenth day.

The initial fitting procedure for the speech 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).

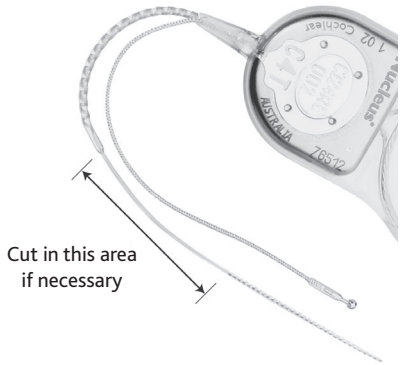
Identifying the implant

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 your Cochlear representative to order an Explant 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 Explant 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 straight portion of the electrode lead, as shown (between the helix and the electrode contacts).
- If the intracochlear electrode array is removed from the cochlea, return it in the Explant Kit, even if it is damaged.
- If necessary, leave the distal end of the extracochlear electrode lead (with the ball electrode) in place.
- Return the Explant 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.

CI24RE (ST) specifications

Electrodes

- Number of platinum rings: 32 (22 active electrodes and 10 inactive stiffening rings) moulded with a silicone elastomer carrier.
- 22 platinum electrodes spaced over a 16.4 mm active array.
- Diameter of electrodes: 0.6 mm at the basal end, tapering to 0.4 mm at the apical end of the array.
- The 10 stiffening rings (of 0.6 mm diameter) are inactive and help stiffen the carrier during insertion.
- The electrode array may be rotated during insertion.
- Two extracochlear electrodes: one platinum plate attached to the receiver/stimulator, and a separate 1.5 mm (typical) diameter ball electrode on an 80 mm lead.

Receiver/stimulator

- Hermetically sealed titanium case
- Case dimensions: 20.3 x 19.3 x 6.9 mm
- Coil dimensions: 30.9 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 speech 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

Caution

Do not re-use

Do not resterilise

Date of manufacture

Manufacturer

Use-by date

Temperature limits

Keep dry

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	MR Conditional

Notes

Notes

Notes

Hear now. And always

AU **Cochlear Ltd** (ABN 96 002 618 073)
1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352

EC REP DE **Cochlear Deutschland GmbH & Co. KG**
Karl-Wiechert-Allee 76A, 30625 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770

CH REP CH **Cochlear AG**
Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205

US **Cochlear Americas**
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010

CA **Cochlear Canada Inc**
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 483 3123 Fax: +1 416 972 5083

GB **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

BE **Cochlear Benelux NV**
Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70

FR **Cochlear France S.A.S.**
135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)
Fax: +33 5 34 63 85 80

IT **Cochlear Italia S.r.l.**
Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

SE **Cochlear Nordic AB**
Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60

www.cochlear.com

TR **Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.**
Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900 Fax: +90 216 538 5919

HK **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

KR **Cochlear Korea Ltd**
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450 Fax: +82 2 533 8408

CN **Cochlear Medical Device (Beijing) Co., Ltd**
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900

IN **Cochlear Medical Device Company India Pvt. Ltd.**
Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100

JP **株式会社日本コクレア(Nihon Cochlear Co Ltd)**
〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245

AE **Cochlear Middle East FZ-LLC**
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925

PA **Cochlear Latinoamérica S.A.**
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218

NZ **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

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