

Cochlear™ Non-Magnetic Plugs and Replacement Magnets Important Information

Europe / Middle East / Africa

For Recipients

Hear now. And always



Contents

About this document.....	4
Read this document carefully.....	4
Symbols used in this document	5
Non-magnetic plugs and replacement magnets	6
Intended purpose.....	7
Intended purpose.....	7
Indications.....	8
Contraindications	10
Intended patient population	10
Intended users.....	10
Benefits.....	11
Troubleshooting	11
MRI safety information	12
Materials and substances.....	13
Product component measurements	13
Privacy and the collection of personal information	14
Summary of safety and clinical performance.....	15
Serious incidents.....	16
What is a serious incident?	16
Reporting a serious incident.....	16
Expected device lifetime	17
Trademark legal notice	18

About this document

This document applies to:

- Cochlear™ CI500 Series Sterile Non-Magnetic Plugs
- Cochlear CI24RE Series Sterile Non-Magnetic Plugs
- Cochlear Sterile Non-Magnetic Plugs
- Cochlear CI500 Series Sterile Replacement Magnets
- Cochlear CI24RE Series Sterile Replacement Magnets and
- Cochlear Sterile Replacement Magnets.

It is intended for Cochlear implant recipients and their carers.

Read this document carefully

This document contains information relating to the non-magnetic plugs and replacement magnets, including.

- device compatibility, and
- device specifications.

Please refer to your *Important Information* document for warnings, cautions and essential advice that applies to Cochlear implant systems. For additional warnings and precautions for cochlear implants, refer to the Physician's Guide for the implant, or visit: www.cochlear.com/warnings

Symbols used in this document



Note

Important information or advice.



Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.



Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

Non-magnetic plugs and replacement magnets



Cochlear CI500 Series Sterile Non-Magnetic Plug (Z146624)



Cochlear CI500 Series Sterile Replacement Magnet (Z179608)



Note

Some CI500 Series implant recipients may have a magnet with a Cochlear logo.



Cochlear CI24RE Series Non-Magnetic Plug (Z50100)



Cochlear CI24RE Series Replacement Magnet (Z50101)



Cochlear Sterile Non-Magnetic Plug (P1620901)



Cochlear Sterile Replacement Magnet (P1620873)

Intended purpose

Intended purpose

Non-magnetic plug

The non-magnetic plug is intended to be used temporarily in place of the magnet of a hearing implant after the implant magnet is removed.

Replacement magnet

The replacement magnet is intended to be used to replace the magnet of the hearing implant that has been removed to facilitate a medical procedure. The magnet enables an external coil to be retained in place and correctly aligned with the implant coil.

Indications

Non-magnetic plug

The non-magnetic plug is indicated for use when MRI scans are conducted with a hearing implant recipient, when the implant magnet is removed. It helps to minimise the growth of fibrous tissue and prevents debris entering the implant recess. It is indicated for use when the implant magnet is removed for MRI scans performed over multiple days.

Cochlear CI24RE Series Sterile Non-Magnetic Plug

The Cochlear CI24RE Series Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI24R and CI24M Series Implants: CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI11+11+2M
- CI22M with removable magnet.

Cochlear CI500 Series Sterile Non-Magnetic Plug

The Cochlear CI500 Series Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI500 Series Implants: CI512, CI522, CI532, ABI541.

Cochlear Sterile Non-Magnetic Plug

The Cochlear Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible Cochlear implants:

- OSI200.

Replacement magnet

The replacement magnet is indicated for use when the hearing implant requires a new magnet due to removal of the original magnet, to restore the medical functionality of the implant.

Cochlear CI500 Series Sterile Replacement Magnet

The Cochlear CI500 Series Sterile Replacement Magnet is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI500 Series Implants: CI512, CI522, CI532, ABI541.

Cochlear CI24RE Series Sterile Replacement Magnet

The Cochlear CI24RE Series Sterile Replacement Magnet is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI24R and CI24M Series Implants: CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI11+11+2M
- CI22M with removable magnet.

Cochlear Sterile Replacement Magnet

The Cochlear Sterile Replacement Magnet is indicated for a recipient with a compatible Cochlear OSI200 implant.

Contraindications

The non-magnetic plug is not indicated for use in the hearing implant unless required for MRI imaging purposes. The non-magnetic plug is not indicated when MRI scans are conducted on the same day as the magnet removal and replacement.

The non-magnetic plugs are not indicated for a recipient with any implant except those identified in the Indications.

The replacement magnet is not indicated for a recipient with any implant except those identified in the Indications.

Intended patient population

The intended patient population are recipients of compatible Cochlear hearing implants who require replacement of the existing implant magnet. There are no additional restrictions for the intended patient population of these devices in terms of age, weight, health or other condition.

Intended users

The intended users who have direct interaction with these devices include qualified medical professionals such as surgeons and surgical nurses. The intended users of these devices who have indirect use of the device include the recipient into whom the device is implanted, and their carer where appropriate. Additionally, qualified medical professionals such as radiologists and audiologists are also intended users who have indirect interaction with the device.

Benefits

The use of non-magnetic plugs minimise the risk of infection and fibrous tissue growing into the implant recess of the respective hearing implant and ensures the recess is kept clear of debris to allow for the successful replacement of the magnet.

The replacement magnets operate in conjunction with a compatible Cochlear implant system. Potential benefits of receiving a Cochlear implant system include:

- better understanding of speech in quiet
- better understanding of speech in noise
- increased satisfaction based on hearing capabilities.

Troubleshooting

Please contact your clinician if the coil does not attach to your head or you experience sound quality issues.

MRI safety information



The non-magnetic plugs and the replacement magnets are 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.

The replacement magnets are identical to the magnet assemblies originally incorporated into the implants with which they are compatible. Accordingly, the MR conditions of the implants incorporating replacement magnets are identical to the MR conditions of the implants with their original magnet.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines* or *Cochlear Osia MRI Guidelines*
- by visiting www.cochlear.com/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.



All external components of the Cochlear implant system (for example, sound processors, remote assistants and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

Materials and substances

The following table lists the materials and substances used in the Cochlear Nucleus implants that come in direct contact with body tissues.

Item	Material
Cochlear CI500 Series Sterile Non-Magnetic Plug and Cochlear Sterile Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI500 Series Sterile Replacement Magnet and Cochlear Sterile Replacement Magnet	Titanium (grade 2)
Cochlear CI24RE Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI24RE Replacement Magnet	Titanium (grade 1)

In accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, the following materials present in the devices are considered carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, but are not expected to be in direct contact with body tissue:

Item	Material
Cochlear CI24RE Replacement Magnet	Cobalt

Product component measurements

Item	Weight	Diameter	Thickness
Cochlear CI500 Series Sterile Non-Magnetic Plug and Cochlear Sterile Non-Magnetic Plug	1.1 g	11.84 mm	2.2 mm
Cochlear CI500 Series Sterile Replacement Magnet and Cochlear Sterile Replacement Magnet	1.4 g	11.95 mm	2.2 mm
Cochlear CI24RE Non-Magnetic Plug	1.0 g	10.9 mm	2.5 mm
Cochlear CI24RE Replacement Magnet	1.6 g	10.9 mm	2.5 mm

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user or recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you.

Summary of safety and clinical performance

A summary of the safety and clinical performance of the Cochlear Non-Magnetic Plugs and Cochlear Replacement Magnets can be found at: <https://ec.europa.eu/tools/eudamed>.

Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

What is a serious incident?

A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat.

Reporting a serious incident

There is no definitive list of events or incidents that constitute a serious incident, however, all serious incidents should be reported to:

- your local Cochlear office
www.cochlear.com/intl/contact/global-offices
- your National Competent Authority
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

Expected device lifetime

Cochlear™ Nucleus® implants and the Cochlear Osia® OSI200 Implant do not have a specified end of life date and are designed to remain operational for a period exceeding the warranty period of 10 years. Statistical analysis of historical reliability data including accelerated life testing results for Cochlear™ Nucleus® Implants and the Cochlear Osia® OSI200 Implant indicates the expected lifetime of the majority of devices is over 75 years*.

However actual implant life may differ from this and can be related to the recipient's individual circumstances.

* This forward looking statement is based on a number of assumptions which may prove to be incorrect due to significant uncertainties, risks and contingencies, many of which are outside the control of, and/or are unknown to Cochlear Limited.

Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

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

ECREP DE Cochlear Deutschland GmbH & Co. KG

Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770

CHREP CH Cochlear AG

Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204

US Cochlear Americas

10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 (800) 523 5798

CA Cochlear Canada Inc

2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 523 5798

GB Cochlear Europe Ltd

6 Dashwood Lang Road, Bourne Business Park, Addlestone,
Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400

BE Cochlear Benelux NV

Schaliënhoevdreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11

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)

IT Cochlear Italia S.r.l.

Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11

SE Cochlear Nordic AB

Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel: +46 31 335 14 61

www.cochlear.com

TR Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.

Küçükkalkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900

HK Cochlear (HK) Limited

Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773

KR Cochlear Korea Ltd

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

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

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

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

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

PA Cochlear Latinoamérica S.A.

International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220

NZ Cochlear NZ Limited

Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983

CE 0123

© Cochlear Limited 2024

P1897378 D1828600-V8 2024-10


Cochlear®