



# **Cochlear**<sup>™</sup> **Slim Modiolar Electrode Sheath**

**User Guide**

United States of America and Canada

For Professionals



# Contents

About this guide .....	2
Symbols used in this guide.....	2
Cochlear Slim Modiolar Electrode Sheath .....	3
Indications.....	4
Loss of residual hearing.....	4
Using the replacement sheath.....	5
Opening the replacement sheath .....	5
Reloading the electrode into the sheath .....	7
How is it supplied.....	10
Transport and handling.....	10
Storage.....	10
Specifications .....	11
Disposal .....	11
Labelling symbols .....	12
Serious incidents.....	14
What is a serious incident?.....	14
Reporting a serious incident .....	14
Trademark legal notice .....	15

# About this guide

This guide is for healthcare professionals using the Cochlear™ Slim Modiolar Electrode Sheath.



## Note

- The sheath is a single-use, sterile surgical instrument.
- Refer to the relevant sections for cautions and warnings relating to the use of the Slim Modiolar Electrode Sheath.

## Symbols used in this guide



Note

Important information or advice.



Tip

Time saving hint.



Caution (no harm)

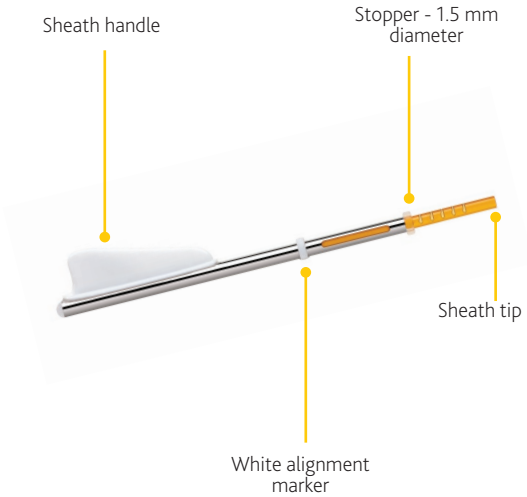
Special care to be taken to ensure safety and effectiveness.  
Could cause damage to equipment.



Warning (harmful)

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

# Cochlear Slim Modiolar Electrode Sheath (P1291522)



## Indications

The Cochlear Slim Modiolar Electrode Sheath is a replacement in the event the primary sheath supplied with the cochlear implant with Slim Modiolar electrode is either damaged or has been removed from the sterile field.

The Cochlear Slim Modiolar Electrode Sheath can be used to position the electrode on the following implants\*:

- CI500 Series Implants: CI532
- CI600 Series Implants: CI632, CI632P
- CI1000 Series Implants: CI1032.

## Loss of residual hearing

Inserting the depth gauge into the cochlea may result in complete loss of residual hearing in the ear to be implanted.

---

\* Not all products are available in all countries. Please contact your local Cochlear representative for product information.

## Using the replacement sheath

If the original sheath is damaged during surgery, a Slim Modiolar Electrode Sheath should be used as a replacement.



### **Warning**

Single-use item. Do not use more than once. Re-use could cause infection.



### **Warning**

Do not reload if the electrode is damaged – use a backup implant.

## Opening the replacement sheath

To open the sheath tray:

### **Non-sterile field**

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



### **Warning**

If the sterile pack is damaged or opened unintentionally, do not use the sheath.

## Sterile field

4. Remove the inner tray, break the seal and remove the tray insert.
5. Lift the sheath from the tray.



### Caution

To avoid damaging the sheath, do not hold it by the orange tip – hold the metal section or handle.

6. Confirm the sheath is not damaged.



### Caution

If the sheath is damaged, use another replacement sheath.

# Reloading the electrode into the sheath



## Warning

Do not use surgical instruments or accessories supplied or intended to be sterile if they become non-sterile, e.g. if dropped or mishandled in theatre.

1. Hold the sheath handle with forceps. Gently hold the electrode lead with AOS™ Forceps below the white alignment mark, as shown below.
2. Gently guide the electrode into the sheath tip, as shown below.
3. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further.

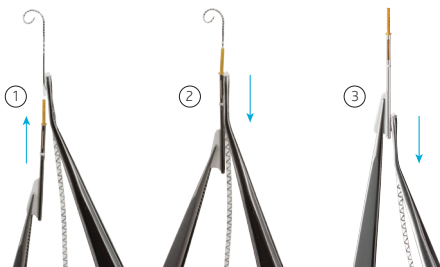


Figure 1: Guiding the electrode into the sheath and retracting the electrode array



## Caution

Check that the electrode is fully contained within the sheath. If not, push the electrode entirely out and repeat from step 1.

4. To check that the electrode and sheath are functioning properly, push the electrode out until the white markers on the electrode array and sheath are aligned.
5. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further, ready for insertion into the cochlea.

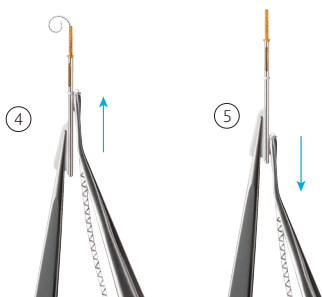


Figure 2: Sliding electrode through sheath and retracting



**Caution**

If the electrode is not fully inside the sheath or they do not function as illustrated above, use a backup implant.

**Caution**

If resistance is felt during insertion, stop immediately, withdraw the sheath and assess the exposure of the round window/cochleostomy opening. You should be able to insert the sheath to the stopper without resistance. Do not use force.

**Warning**

Ensure the sheath is fully removed at the end of the procedure. The sheath needs to be completely removed from the electrode and not left in place after the procedure is complete.

**Warning**

Keep the sheath in the sterile field in case it is needed for a second insertion attempt.

For complete surgical procedure, refer to the *Physician's Guide* for the specific implant.

## How is it supplied

The implant and the sheath are single use items. The sheath is supplied separately. All of the above components are supplied in sterile gas-permeable packaging. Ethylene oxide processing is indicated on the label of each sterile package. Before opening the sterile package, inspect it carefully. Return the device and packaging to Cochlear if:

- the use by date stamped on the outside package has expired
- the sterile pack containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

## Transport and handling

The sheath has been validated for transport and handling temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

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

## Storage

Store the sheath inside its packaging at room temperature. Keep dry.

The product and its packaging have been designed to withstand storage temperatures from +1 °C (+34 °F) to +30 °C (+86 °F) and transient and seasonal excursions beyond this range.

## Specifications

Product component measurements for the sheath.

Weight	Thickness	Width	Length
0.5 g	1.5 mm	4 mm	29 mm

---











## Disposal














A sheath that has been in patient contact should be placed into the correct clinical waste container for disposal. Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

A sheath that has not been in patient contact can be disposed of as normal hospital or household waste, or in accordance with local regulations.

# Labelling symbols

The following symbols may appear on the packaging.

Symbol	Description
	Consult instructions for use
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	MR Conditional
	Manufacturer
	Date of manufacture
	Use by date
	Do not reuse
	Do not resterilise
	Authorised representative in the European Community/ European Union
	Authorised representative in Switzerland

Symbol	Description
	Unique Device Identifier
	Medical Device
	Catalogue number
	Serial number
	Batch code
	CE registration mark with notified body number
	CE registration mark
<b>Rx Only</b>	By prescription
	Sterile barrier
	Sterilised using ethylene oxide
	Recyclable material
	Keep dry
	Fragile
	Do not use if package is damaged and consult instructions for use

## 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 any of the following:

- 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/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](http://www.cochlear.com/intl/contact/global-offices)
- your National Regulator.

## 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

**EC REP DE Cochlear Deutschland GmbH  
& Co. KG** Mailänder Straße 4 a, 30539  
Hannover, Germany  
Tel: +49 511 542 770

**CH REP 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 Fax: +39 051 39 20 62

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

[www.cochlear.com](http://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

**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