Cochlear™ Reusable Surgical Instruments

User Guide

United States of America and Canada

For Professionals

Hear now. And always

Cochlear®

Symbols used in this guide

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 is intended for staff involved in the sterilisation reprocessing of the following metal surgical instruments and for medical professionals who use these instruments in the surgical procedure:

Instruments	Product code
Cochlear™ AOS™ Forceps 	Z60770
Cochlear™ BTE Template 	Z33011
Nucleus® CI24RE Series Implant Template 	Z33019
Cochlear™ CI500 Series Implant Template 	Z139273

Instruments	Product code
Cochlear™ Contour® Electrode Claw 	Z33021
Cochlear™ Straight Electrode Claw 	Z30090
Nucleus® CI24RE Series Bone Recess Template 	Z60479
Nucleus® CI24RE Series Array Exit Marking Template 	Z33017
Nucleus® CI24RE Series Recess Gauge 	Z60480

Instruments	Product code
Cochlear™ CI500 Series Recess Gauge	Z139274

For information on the use of the instruments in the surgical procedure, refer to the guide for the appropriate implant.

The instruments listed above are supplied non-sterile and must be cleaned, disinfected and sterilised before use.

The instruments are stainless steel and can be cleaned and resterilised as instructed in the ***Reprocessing instructions*** on page 15.

The sterilisation department or reprocessing centre at your hospital or clinic is responsible for surgical instrument sterility. They should:

- use device and product-specific validated procedures for cleaning, disinfecting and sterilisation
- use washer-disinfectors and sterilisers that are maintained and checked regularly
- make sure validated parameters are applied for each cycle.

Cochlear has validated the instructions in this guide for preparing a surgical instrument for re-use.

Staff at the hospital or clinic are responsible for ensuring that reprocessing achieves the desired result—as performed using equipment, materials and staff in the reprocessing centre or sterilisation department. This requires validation and routine monitoring of the process. Any deviation from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Indications

Cochlear AOS Forceps

The AOS Forceps can be used to grasp or hold the electrode during insertion of the electrode array into the cochlea during a hearing implant surgical procedure. The curved tip ends gently cup the array, improving stability and minimising rotation.

The AOS Forceps are indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI500 Series Implants: CI512, CI522, CI532
- CI600 Series Implants: CI612, CI622, CI624, CI632, CI632P
- CI1000 Series Implants: CI1012, CI1022, CI1024, CI1032.

Cochlear BTE Template

The BTE Template can be used with a non-sterile silicone template to ensure the implant will be positioned to allow sufficient space for a behind the ear sound processor prior to a hearing implant surgical procedure. This ensures the sound processor will not overlap the implant.

The BTE Template is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI500 Series Implants: CI512, CI522, CI532, ABI541
- CI600 Series Implants: CI612, CI622, CI624, CI632, CI632P
- CI1000 Series Implants: CI1012, CI1022, CI1024, CI1032.

Nucleus CI24RE Series Implant Template

The Implant Template can be used to determine, or check, the shape of the implant bone recess and the position of the implant during a hearing implant surgical procedure.

The Nucleus Implant Template is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST), CI24RE (CS).

Cochlear CI500 Series Implant Template

The Implant Template can be used to determine, or check, the shape of the implant bone recess and the position of the implant during a hearing implant surgical procedure.

The CI500 Series Implant Template is indicated for the following implants:

- CI500 Series Implants: CI512, CI522, CI532, ABI541
- CI600 Series Implants: CI612, CI622, CI624, CI632, CI632P
- CI1000 Series Implants: CI1012, CI1022, CI1024, CI1032.

Cochlear Contour Electrode Claw

The Contour Electrode Claw can be used to help guide the electrode tip towards the cochleostomy/round window and into the scala tympani. It can also help to orientate the electrode array (with half electrode contacts facing towards modiolus of cochlea) during a hearing implant surgical procedure.

The Contour Electrode Claw is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI500 Series Implants: CI512, CI522
- CI600 Series Implants: CI612, CI622, CI624
- CI1000 Series Implants: CI1012, CI1022, CI1024.

Cochlear Straight Electrode Claw

The Straight Electrode Claw can be used to help guide the electrode tip towards the cochleostomy/round window and into the scala tympani. It can also help to orientate the electrode array (with half electrode contacts facing towards modiolus of cochlea) during a hearing implant surgical procedure.

The Straight Electrode Claw is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (ST)
- CI500 Series Implants: CI522
- CI600 Series Implants: CI622, CI624
- CI1000 Series Implants: CI1022, CI1024.

Nucleus CI24RE Series Bone Recess Template

The Bone Recess Template can be used to mark the outline of the bone recess on the skull and gauge the bone recess depth after drilling during a hearing implant surgical procedure.

The template is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST), CI24RE (CS).

Nucleus CI24RE Series Array Exit Marking Template

The Nucleus CI24RE Series Array Exit Marking Template can be used to check the size of the bone recess, select the final position of the implant in the bone recess, and mark the exit position and width of the channel for the intra-cochlear and extra-cochlear electrodes during a hearing implant surgical procedure.

The template is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST).

Nucleus CI24RE Series Recess Gauge

The Recess Gauge can be used to outline the shape of the implant seat on the skull during a hearing implant surgical procedure. It is also used to check the depth of the ramped implant seat after drilling.

The Nucleus CI24RE Series Recess Gauge is indicated for the following implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST), CI24RE (CS).

Cochlear CI500 Series Recess Gauge

The Recess Gauge can be used to outline the shape of the implant seat on the skull during a hearing implant surgical procedure. It is also used to check the depth of the ramped implant seat after drilling.

The CI500 Series Recess Gauge is indicated for the following implants:

- CI500 Series Implants: CI512, CI522, CI532, ABI541
- CI600 Series Implants: CI612, CI622, CI624, CI632, CI632P
- CI1000 Series Implants: CI1012, CI1022, CI1024, CI1032.

Cochlear Surgical Instrument Kit and Cochlear Surgical Instrument Upgrade Kit

The intended medical indications of the Surgical Instrument Kit and Surgical Instrument Upgrade Kit are the same as those of the individual instruments in the kit.

Nucleus CI24RE Series Surgical Instrument Kit and Nucleus CI24RE Series Surgical Instrument Upgrade Kit

The intended medical indications of the Surgical Instrument Kit and Surgical Instrument Upgrade Kit are the same as those of the individual instruments in the kit.

Specifications

Materials (hardness)

Item	Material
Cochlear AOS Forceps	Stainless steel EN 1.4021
Cochlear Contour Electrode Claw	Stainless steel AISI Grade 316L Gold-plated (98% Au min)
Cochlear BTE Template	Stainless steel AISI Grade 316L
Nucleus CI24RE Series Implant Template	
Cochlear CI500 Series Implant Template	
Cochlear Straight Electrode Claw	
Nucleus CI24RE Series Bone Recess Template	
Nucleus CI24RE Series Array Exit Marking Template	
Nucleus CI24RE Series Recess Gauge	
Cochlear CI500 Series Recess Gauge	

Measurements

Item	Dimensions/edges
Cochlear AOS Forceps	151 mm – length Forceps tip: 0.45 mm grooved tip ends Rounded edges
Cochlear BTE Template	Earhook width 26 mm Rounded edges

Item	Dimensions/edges
Nucleus CI24RE Series Implant Template	50 mm – length 30 mm – width Mimic radius of implant: min R0.2 mm
Cochlear CI500 Series Implant Template	58.15 mm – length 23.9 mm – width Mimic radius of implant: R0.5 mm Rounded edges
Cochlear Contour Electrode Claw	Handle: 99 mm – length Claw tip: 0.8 mm – width Rounded edges
Cochlear Straight Electrode Claw	Handle: 99.5 mm – length Claw tip: 0.75 mm – width Rounded edges
Nucleus CI24RE Series Bone Recess Template	Handle length – 143 mm Head diameter – 16 mm Mimic radius of implant: min R0.2 mm
Nucleus CI24RE Series Array Exit Marking Template	50 mm – length 30 mm – width Mimic radius of implant: min R0.2 mm
Nucleus CI24RE Series Recess Gauge	Handle length – 143 mm Head diameter – 16 mm Head recess length – 10.5 mm Mimic radius of implant: min R0.2 mm

Item	Dimensions/edges
Cochlear CI500 Series Recess Gauge	Well-gauge: 23.9 mm – width 30 mm – length max. 3.9 mm – thickness Handle: 140 mm – length Rounded edges

Surface roughness

Item	Surface roughness
Cochlear AOS Forceps	0 to 0.8 µm Ra
Cochlear BTE Template	
Nucleus CI24RE Series Implant Template	
Cochlear CI500 Series Implant Template	
Cochlear Contour Electrode Claw	
Cochlear Straight Electrode Claw	
Nucleus CI24RE Series Bone Recess Template	
Nucleus CI24RE Series Array Exit Marking Template	
Nucleus CI24RE Series Recess Gauge	
Cochlear CI500 Series Recess Gauge	

⚠ Warnings

- Metal surgical instruments are supplied non-sterile and must be cleaned, disinfected and sterilised before use.
- Instruments must not contact other instruments during cleaning and disinfecting.
- Damaged instruments must not be used.
- Do not use:
  - combined cleaning-disinfection solutions
  - dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilisation
  - instrument oils for instrument maintenance – no maintenance required.
- Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.
- Do not use surgical instruments or accessories intended to be sterile if they become non-sterile, for example, if dropped or mishandled in theatre.

Limitations on reprocessing

Repeated processing has a minimal effect on these instruments. The instruments have been validated for 25 cycles of reprocessing as instructed in this guide. End-of-life is normally determined by visible manifestation of wear and damage. Refer to *Inspection and function testing* on page 19.

⚠ Cautions

Do not use metal brushes or steel wool for cleaning.

Instrument material compatibility

- To avoid corrosion, do not process Cochlear metal instruments with instruments that have aluminium, brass, copper or chrome-plated parts.
- Do not use cleaning detergents with the following ingredients:
  - Organic, mineral, and oxidising acid.
    The minimum allowed pH-value is 5.5.
  - Halogens (for example chlorine, iodine, bromine).
  - Aromatic, halogenated hydrocarbons.
- Do not expose instruments to temperatures higher than 142 °C (287.6 °F).

Reprocessing instructions

Warning

- The reprocessing should be performed by suitably trained staff using well-maintained equipment. We recommend following the requirements of ISO 17665-1, for equipment validation and routine control.
- Instruments used, or suspected of use, with patients who represent a known or potential risk of transmissible spongiform encephalopathy (TSE), such as Creutzfeldt-Jakob Disease (CJD), transmission, should not be reused and should be immediately and safely disposed according to the safe disposal instructions of your hospital or clinic.

Point of use	Open the packaging carefully to avoid damage to the instruments. Throughout the surgical procedure, wipe blood and debris from instruments to prevent drying. Do not allow contaminated devices to dry before reprocessing. Directly after use, remove coarse impurities from the instruments by wiping the articles using lint-free cloths dampened with distilled water and soak in distilled water until they are reprocessed. Instruments should be reprocessed within one hour after use.
Containment and transportation	Follow the validated containment and transportation instructions of your hospital or clinic.

Thoroughly clean the instruments by preparation for cleaning (refer to *Preparation for cleaning* on page 16) followed by automated cleaning and disinfection (refer to *Cleaning and disinfecting* on page 16).

After the automated cleaning, inspect the instrument according to the instructions in *Maintenance* on page 19 and *Inspection and function testing* on page 19, to ensure that the cleaning is properly executed. Otherwise repeat the preparation for cleaning and automated cleaning and disinfection steps.

Preparation for cleaning	Rinse under water up to 50 °C (122 °F) while brushing for a minimum of 1 minute. ⚠ Caution • Do not disassemble instruments – no disassembly required. • Do not use metal brushes or steel wool. For manual removal of impurities, use a soft brush only. For holes, use suitable interdental brushes.
Cleaning and disinfecting	⚠ Caution Do not use a manual procedure, even in conjunction with an ultrasonic bath. Manual procedures could cause damage to delicate instrument parts. Equipment: Washer-disinfector and cleaning detergent. The washer-disinfector must have these properties: • Approved efficiency (CE mark in Europe, FDA registration/ clearance for USA). • Validated for EN ISO 15883. • Approved program for thermal disinfection. • Suitable program for the instruments with sufficient rinsing steps. The cleaning detergent must have the following properties: • Suitable for cleaning stainless steel instruments. • Compatible with the instruments (refer to *Instrument material compatibility* on page 14).

Cleaning and disinfecting

Note

Cleaning validation as shown in *Appendix 1 – Validation information* on page 25, was undertaken using minimum detergent concentration levels. Always follow the instructions from the detergent manufacturer regarding concentration, temperature and soaking time.

Warning

Where instruments have been exposed to brain or dura mater tissue, fully immerse the instruments in a 1% solution of neodisher® MediClean forte at 55°C (131°F) and stir for 10 minutes prior to automated cleaning/ disinfecting.

Automated cleaning and disinfecting procedure

1. Transfer instruments into the washer-disinfector in a small parts basket. Position instruments to allow for drainage of water.

Warning

Instruments must not contact other instruments during cleaning and disinfecting.

2. Start the validated program as described in *Table 1* on page 18.
3. Execute the cycle release by checking that the process parameters were correctly applied.
4. Inspect instruments to ensure no residual moisture is present.
5. If residual moisture is present, use filtered, pressurised air to complete the drying process.

Cycle	Time	Minimum temperature	Detergent/water type
Pre-cleaning	2 minutes	Cold <40 °C (<104 °F)	Tap water
Detergent wash	2 minutes	Heated 40 °C – 55 °C (104 °F – 131 °F)	Enzymatic detergent (for example, Valsure Enzymatic Detergent)[1] OR alkaline detergent[2] (for example, neodisher® MediClean forte)[1]
Wash	5 minutes	Set point 55 °C (131 °F)	Neutral/non-enzymatic detergent (for example, Valsure Neutral Detergent)[1]
Rinse	2 minutes	Heated 50 °C – 60 °C (122 °F – 140 °F)	Hot tap water
Thermal disinfection	5 minutes	Heated 93 °C (199.4 °F)	Critical water[3]
Dry[4]	10 minutes	Heated 110 °C (230 °F)	Not applicable

Table 1: Automated cycle parameters

1 Refer to the cleaning agent labelling for preparation and usage instructions.

2 ⚠ Warning: Use the alkaline detergent neodisher® MediClean forte for instruments exposed to brain or dura mater tissue.

3 Water extensively treated to ensure removal of the microorganisms and the inorganic and organic material. Treatment is usually a multistep process that may include a carbon bed, softening, DI, and RO or distillation (bacteria measurement of <10 colony forming units (CFU)/mL and endotoxin measurement of <10 endotoxin units (EU)/mL).

4 If instruments are not dry after automated cleaning / disinfection cycle, filtered, pressurised air is recommended to complete the drying process. Follow the instructions of your hospital or clinic.

Note

For validation information, refer to *Appendix 1 – Validation information* on page 25.

Drying	Inspect instruments to ensure no residual moisture is present. If required, use filtered, pressurised air to complete the drying process. Hot air drying is not recommended, except for drying that is part of the above-mentioned validated automatic washing-disinfecting cycle.
Maintenance	**Warning** Do not use instrument oils for instrument maintenance–no maintenance required.
Inspection and function testing	Check all instruments after cleaning-disinfecting for corrosion, damaged surfaces and impurities. Particular attention should be given to ensure: • correct parallel closure and absence of deformations on the clamping ends of forceps, and • absence of sharp edges on the instruments' surfaces. **Warning** Do not use damaged or worn instruments. Instruments that remain dirty must be cleaned and disinfected again. For specific critical control points refer to *Table 2: Critical control points for surgical instrument inspection* on page 20.

Cochlear surgical instruments	Specific critical control points Give particular attention to the following:
AOS Forceps	Forceps crevice Spacer studs Delicate, grooved tips.
BTE Template	Surface only.
CI24RE Series Implant Template CI24RE Series Array Exit Marking Template CI500 Series Implant Template	Internal surfaces of cut-out sections.
CI24RE Series Recess Gauge CI24RE Series Bone Recess Template CI500 Series Recess Gauge	High gradient area at the handle/gauge junction.
Contour Electrode Claw Straight Electrode Claw	Claw groove Handle grip features.

Table 2: Critical control points for surgical instrument inspection

Packaging	Pack the cleaned and disinfected instruments in sterilisation packaging that meets the following requirements: • Pack the instruments using sterilisation accessories that were used in the validation testing (for example, wrap, pouch) and are FDA-cleared for the recommended sterilisation parameters. • Sufficiently protects the instruments against physical damage. • Maintains sterility of the instruments during handling and storage prior to use. • Ensures the instruments are not in excessive contact with each other. • Allows sufficient inner volume to avoid strain on the instruments. For more information refer to *Appendix 1 – Validation information* on page 25.
Sterilisation	Cochlear has developed and validated the sterilisation instructions in this guide for preparing a surgical instrument for re-use as described in ISO 17665-1. • Transfer instruments into the steriliser avoiding known 'cold' locations, typically over the drain. Use steam sterilisation as described: • Dynamic air removal steam sterilisation cycle (prevacuum).

Sterilisation

Validated parameters for temperature and time:

Minimum temperature	Minimum exposure time	Minimum drying time
132 °C (269.6 °F)	4 minutes	20 minutes

Warning

Do not use dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilisation.

Caution

Maximum sterilisation temperature of 138 °C (280.4 °F).

Storage

After sterilisation, store the instruments in sterilisation packaging in a dry and dust-free environment.

Disposal

Reusable surgical instruments that have 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.

Reusable surgical instruments that have 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 packaging:

	Consult instructions for use
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
MD	Medical device
	Manufacturer
Rx Only	Caution: US law restricts this device to sale by, or on the order of, a physician
REF	Catalogue number
EC REP	Authorised representative in the European Community/ European Union
CH REP	Authorised representative in Switzerland
CE 0123	CE registration mark with notified body number
CE	CE registration mark

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 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 Regulator.

Appendix 1 – Validation information

Test items

Samples of Cochlear's reusable surgical instruments with the most challenging features to clean, disinfect and sterilise were used in the validation tests.

Automated cleaning

Critical cleaning parameters were determined by rigorous automated cleaning methods developed using spore logarithmic reduction, total protein, haemoglobin and visual inspection criteria.

For device contamination, a blood soil containing 2M calcium chloride (for coagulation purposes) and bone meal (1 g/100 mL of test soil) was inoculated with a minimum population of 10^4 CFU/mL of *G. stearothermophilus* and *E. faecium*.

The instruments were exposed to the test soil for a minimum of 15 minutes and allowed to dry for a minimum of 1 hour before cleaning and disinfecting. Any pre-cleaning involved rinsing the instrument under water 49 °C (120.2 °F) while brushing with a Spectrum M-16 brush for a minimum of 1 minute.

After cleaning, test samples were visually inspected for any sign of remaining blood soil. Bioburden extractions were used to determine the number of spores, total protein and haemoglobin remaining on test samples. Comparison of data to positive controls and test protocol requirements determined if acceptance criteria were met.

Cleaning equipment		
Equipment	Washer/Disinfector	Steriliser
Type	N/A	Steam; SG-120; AMSCO
Manufacturer	Steris	AMSCO
Serial Number	3603513001	0117594-02
Model	GEN FH07-1XX	SG-120

Table 3: Cleaning equipment used for cleaning validations using enzymatic detergent

Automated cleaning validations			
Cycle	Time	Validated settings	Detergent/water type
Pre-cleaning	2 minutes*	Cold <40 °C (<104 °F)†	Tap water
Detergent wash*	2 minutes*	Heated 48 °C (118.4 °F)†	Valsure® Enzymatic Detergent 2mL/L
Wash	5 minutes*	Set point 55 °C (131 °F)†	Valsure Neutral 2mL/L†
Rinse	2 minutes*	Heated 50 °C – 60 °C (122 °F – 140 °F)†	Hot tap water
Dry	10 minutes*	Heated <84.2 °C (<183.56 °F)	Not applicable

Table 4: Validation for automated cycles using enzymatic detergent

* Validated exposure time required to achieve >3 log bioload reduction.

† Validated exposure temperature required to achieve >3 log bioload reduction.

Cleaning equipment		
Equipment	Washer/Disinfector	Steriliser
Type	N/A	Steam; SG-120; AMSCO
Manufacturer	Belimed	AMSCO
Serial Number	2005453	0117594-02
Model	WD 290	SG-120

Table 5: Cleaning equipment used for cleaning validations using alkaline detergent

Phase	Recirculation time	Temperature	Detergent type and concentration (if applicable)
Pre-wash	2 minutes*	Cold tap water	N/A
Wash 1	2 minutes*	43 °C (109.4 °F) Tap water	neodisher Mediclean forte 2mL/L‡
Wash 2	4 minutes*	55 °C (131 °F) Tap water	Valsure Neutral 2mL/L†
Rinse	1 minute*	50 °C (122 °F) Tap water	N/A

Table 6: Validation for automated cycles using alkaline detergent

* Validated exposure time required to achieve >3 log bioload reduction.

† Validated exposure temperature required to achieve >3 log bioload reduction.

‡ neodisher MediClean forte has been validated by the manufacturer for prion inactivation.

Note

Testing validation was undertaken using minimum detergent concentration levels. Always follow the detergent manufacturer instructions regarding concentration levels when reprocessing instruments.

Thermal disinfection

Thermal disinfection parameters (5 minutes, 93 °C (199.4 °F) using critical water) were validated to demonstrate that Cochlear's reusable surgical instruments and selected worst-case thermocouple/temperature probe locations demonstrate successful thermal disinfection.

Refer to ***Table 3: Cleaning equipment used for cleaning validations using enzymatic detergent*** on page 25 for details of the Washer/Disinfector used for thermal disinfection validation.

Steam sterilisation

Prevacuum (pressure pulse) sterilisation cycles were used for validation.

Test articles were individually single-pouched in a 5.5 x 10 in. pouch (Cardinal Health self-sealed pouch CAT #92510 - 510(k) K153540) and placed on the edge in the steriliser.

Instruments were evaluated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using half-cycle studies and the biological indicator overkill method. *Geobacillus stearothermophilus*, ATCC #7953, was the indicator organism.

Sterilisation parameters	
Parameter	Setting
Steriliser type	Prevacuum
Preconditioning pulses	4 (Set point: 10 inHg for 1 minute)
Temperature	132 °C (269.6 °F)
Full cycle time	4 minutes

Table 7: Validation for sterilisation

Sterilisation equipment					
Manufacturer		Steris			Primus
Model		LV-250			PSS8-A-MSSD
Serial number		0305312-14	0305312-15	0305412-25	17730
Validation item	AOS Forceps	✓	✓	✓	—
	Contour Electrode Claw	✓	—	✓	✓

Table 8: Steam sterilisation validation equipment

Quality of steam was >97%.

Drying

Test articles were weighed pre-sterilisation and post-sterilisation to detect any residual moisture. Any residual moisture after drying in the cleaning/disinfecting cycle was removed by using pressurised filtered air before being prepared for sterilisation. All surfaces of test articles were inspected for visible moisture. Any visible moisture on pouch surfaces was noted.

Each test article was:

- prepared as described in ***Steam sterilisation*** on page 28
- placed into the 'cold' spot of the steam steriliser, typically over the drain
- sterilised using validated full cycle set points with the drying time in ***Table 9*** below.

Parameter	Setting
Drying time	20 minutes

Table 9: Validation for drying

Repeat reprocessing

The instruments have been validated for 25 cycles of reprocessing as instructed in this guide.

Standards

Validation testing was performed using applicable standards.
For details please contact Cochlear.

Trademark legal notice

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

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 **UK Responsible Person: 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**
Schaliënhoevedreef 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.**
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

P2149850 D2047398-V4 2025-06

Cochlear®