EN-US English

Cochlear®

Reprocessing Guide

For reusable instruments and Instrument Case

For professionals

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 guideline is intended for staff involved in reprocessing of reusable instruments and Instrument Case from Cochlear. The instruments listed in the table below are intended for Cochlear™ implant surgery. For information on instruments used during surgery, refer to the respective Cochlear surgical manual.

Item no	Description
90381	Machine Screwdriver 25 mm UniGrip
90397	Machine Screwdriver abutment
90453	Screwdriver for internal hexagon 20 mm
90456	Screwdriver for hexagon 17 mm
90459	Screwdriver UniGrip 20 mm
90469	Screwdriver UniGrip 95 mm
90478	Connection to handpiece
91116	Drill Indicator for WS-75 and Osscora
93183	Counter torque wrench for Vistafix® VXA300
94071	Implant magnet template
95070	Soft tissue gauge 6 mm
P1578046	Bone Bed Indicator 14 mm
P1469690	Bone Bed Indicator 17 mm
P1582203	Baha Indicator
P1582229	Abutment inserter
P1582230	Implant inserter
P1582231	Counter Torque Wrench
P1593725	Raspatorium/ Probe
P1340904	Instrument case

P1340904 Instrument Case has been validated for sterilization of the above listed reusable instruments from Cochlear and the following instruments distributed by Cochlear:

C9866 Multi Wrench with ISO Adapter

C10110 Square Adapter for Multi Wrench.

C10086 ISO Adapter for Multi Wrench

Some instrument cases may not include etchings or part numbers for the multi wrench and adapters.

Note

The following reusable instruments must be reprocessed using the manufacturer's instructions provided with the instrument:
C9866 Multi wrench with ISO Adapter
C10110 Square Adapter for Multi wrench
C10086 ISO Adapter for Multi wrench

The sterilization department or reprocessing center at your hospital or clinic is responsible for reusable instrument sterility. They should:

- Use device and product-specific validated procedures for cleaning, disinfecting and sterilization.
- Use washer-disinfectors and sterilizers that are maintained and checked regularly.
- Make sure recommended parameters are applied for each cycle.

Cochlear has validated the instructions in this guide for preparing reusable instruments and Instrument Case for re-use. Staff at the hospital or the clinic are responsible for ensuring that reprocessing achieves the desired result – as performed using equipment, materials and staff in the reprocessing center or sterilization 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 for use

The Instrument Case is intended for staff involved in reprocessing of reusable instruments, and for surgical teams.

The product shall only be used:

- in a controlled surgical environment under sterile conditions such as a hospital,
- in reprocessing environment at sterilization departments or reprocessing centers,
- and for transport of surgical instruments.

Sterilization parameters:

In US: Pre-Vacuum Steam at 132 °C (270 °F) for 4 minutes with a 20 minutes dry time.

Outside US: See the Reprocessing Guide for reusable instruments and Instrument Case available in your country.

The worse-case validated load for the Instrument Case, including instruments, is 1700 g.

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 oxidizing 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 (288 °F).

Limitations on reprocessing

Repeated processing has a minimal effect on these instruments. End-of-life is normally determined by visible manifestation of wear and damage. See “Inspection and maintenance” on page 12.

Warnings

- Cochlear reusable instruments and Instrument Case are supplied non-sterile and must be cleaned, disinfected and sterilized before use.
- Damaged instruments must not be used.
- Do not use:
  - Metal brushes or steel wool for cleaning.
  - Combined cleaning-disinfection solutions.
  - Dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilization.
  - Instrument oils for instrument maintenance.
- Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

⚠ Caution

- Instruments must not contact other instruments during cleaning and disinfection.
- 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 and Instrument Case to temperatures higher than 142 °C (288 °F).
- Do not use a manual procedure, even in conjunction with an ultrasonic bath.
- The Instrument Case is not designed to hold reusable instruments during cleaning and disinfection. Cleaning and disinfection of the instruments must be carried out separately.

Reprocessing instructions

The reprocessing should be performed by suitably trained staff using well maintained equipment in a facility that meets the requirements of ISO 17665-1, for equipment validation and routine control.

For instruments used with patients who represent a definite or potential risk of TSE transmission, contaminated instruments should be placed immediately into the correct clinical waste container for disposal. Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

Point of use

Throughout the surgical procedure, wipe blood and debris from instruments to prevent drying. Do not allow contaminated devices to dry before reprocessing.

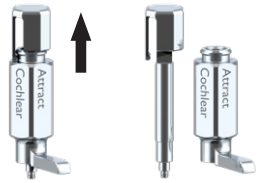
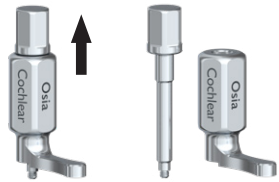
Directly after use, remove coarse impurities from the instruments by wiping the articles using lint-free cloths dampened with distilled water and soak in distilled water until they are reprocessed.

Instruments should be reprocessed within one hour after use.

Containment and transportation

Follow the validated containment and transportation instructions of your hospital or clinic.

Instruments to be disassembled before cleaning and disinfection

Item no	Description	Product image
P1578046 Bone Bed Indicator 14 mm	The Bone Bed Indicator (BBI) 14 mm for Attract consists of a body and a pin. Disassemble it by pulling the body and pin apart.	 *BBI* *Pin* *Body*
P1469690 Bone Bed Indicator 17 mm	The Bone Bed Indicator (BBI) 17 mm for Osia consists of a body and a pin. Disassemble it by pulling the body and pin apart.	 *BBI* *Pin* *Body*

Instructions for thorough cleaning

Thoroughly clean the instruments by manual pre-cleaning according to Step 1 followed by automated cleaning and disinfection according to Step 2 below. After the automated cleaning, inspect the instrument according to the instructions in the Inspection and maintenance section below, to ensure that the cleaning is properly executed. Otherwise repeat Step 1 and 2.

Step 1: Manual pre-cleaning

- Rinse under cold water, not warmer than 45 °C (113 °F) while brushing thoroughly for a minimum of 1 minute.
- Do not use metal brushes or steel wool. For manual removal of impurities, use a soft brush only. For holes, use suitable interdental brushes.

Step 2: Automated cleaning and disinfection

PREREQUISITES

Do not use a manual procedure, even in conjunction with an ultrasonic bath.

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 (see "Instrument material compatibility" on page 6).
- Always follow the instructions from the detergent manufacturer regarding the concentration.

Note

Cleaning validation as shown in "Appendix 1 – Validation information" on page 15, was undertaken using minimum detergent concentration levels. Always follow the detergent manufacturer instructions regarding concentration levels when reprocessing instruments.

PROCEDURE FOR AUTOMATED CLEANING AND DISINFECTION

1. Transfer instruments into the washer-disinfector in a small parts basket. Position instruments to allow for drainage of water.
2. Start the validated program as described in Table 1 on page 11.
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, pressurized 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 OR alkaline detergent
Wash	5 minutes	Set point 55 °C (131 °F)	Neutral/non-enzymatic detergent
Rinse	2 minutes	Heated 50 °C – 60 °C (122 °F – 140 °F)	Critical water†
Thermal disinfection	5 minutes	Heated 93 °C (200 °F)	Critical water†
Dry‡	10 minutes	Heated 110 °C (230 °F)	Not applicable

Table 1: Automated cycle parameters

† *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 (maximum 10 germs/ml, maximum 0.25 endotoxin units/ml).*

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

Note

For validation information, see "Appendix 1 – Validation information" on page 15.

Drying

Inspect instruments to ensure no residual moisture is present. If moisture is present, use filtered, pressurized 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.

Inspection and maintenance

Inspect all instruments after cleaning/disinfection for corrosion, surface damage, flaking, contamination or discoloration, and set aside damaged instruments.

- Do not use damaged or worn instruments.
- Instruments that remain dirty must be cleaned and disinfected again. Failure to properly clean the instruments could lead to inadequate sterilization.
- Do not use instrument oils for instrument maintenance

For specific critical control points see Table 2 below.

Item no and description	Give attention to the following:
P1578046 Bone Bed Indicator 14 mm	Body: Internal surface of hole; Laser marking (UDI) Pin: Outer threads; Laser marking (UDI)
P1469690 Bone Bed Indicator 17 mm	Body: Internal surface of hole; Laser marking (UDI) Pin: Outer threads; Laser marking (UDI)
90478 Connection to handpiece	Dead end chamber at the tip of the instrument
90397 Machine Screwdriver abutment	Dead end chamber at the tip of the instrument
P1582229 Abutment inserter	Dead end chamber at the tip of the instrument
90456 Screwdriver for hexagon 17 mm	Dead end chamber at the tip of the instrument

Table 2: Critical control points for surgical instrument inspection

Packaging

Pack the cleaned and disinfected instruments in sterilization packaging that meets the following requirements:

- Compliant with EN ISO/ANSI AAMI ISO 11607.
- 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.
- Sealed using a validated thermo-sealing process.

If the Instrument case is used for sterilization, place the cleaned and disinfected instruments in the Instrument case. Pack the Instrument case in FDA approved sterilization packaging.

For more information see “Appendix 1 – Validation information” on page 15.

Note

Keep the Bone Bed Indicators (14 mm and 17 mm) unassembled if they are to be sterilized in the Instrument case. Place the head of the Multi Wrench in the component tray.

Sterilization

Cochlear has developed and validated the sterilization instructions in this guide for preparing a reusable instrument for re-use to comply with the requirements of ISO 17665-1.

Use steam sterilization as described:

- Dynamic air removal steam sterilization cycle (prevacuum).
- Validated parameters for temperature and time:

Minimum temperature	Minimum exposure time	Minimum drying time
132 °C (270 °F)	4 minutes	20 minutes

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

Storage

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

Appendix 1 – Validation information

Test items

Samples of Cochlear's reusable instruments and Instrument Case with the most challenging features to clean, disinfect and sterilize were used in the validation tests. The instruments and Instrument Case were tested for 25 cycles of reprocessing as instructed in this guide.

Note

P1469690 Bone Bed Indicator 17 mm belongs to another family of Cochlear's resuable instruments. For validation information related to this instrument, refer to Cochlear Osia Surgical Instruments Sterilization Reprocessing Guide.

Automated cleaning

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

For device contamination, a blood soil containing serum, skim milk powder and bone meal was used.

The test soil was distributed on all exterior surfaces of the devices and allowed to dry for a minimum of 2 hour before cleaning. Any pre-cleaning involved wiping the instrument for 30 seconds with a non-linting cloth dampened with critical water (15–25 °C) and soaking for 55 seconds in tap water at 40 °C. Whilst immersed the instruments were brushed with a SUBEM/50 brush for 30 seconds.

After cleaning, test samples were visually inspected for any sign of remaining blood soil. Extractions were used to determine the 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	Sterilizer
Type	N/A	Steam
Manufacturer	Miele	GETINGE/MMM Group
Serial Number	74397892	2105318-010-01/B210220
Model	PG8536	HS5510EM-2/ Vakulab PL 669-2-CL

Table 3: Cleaning equipment used for cleaning validations using both enzymatic and alkaline detergents

Automated cleaning validations			
Cycle	**Time**	**Temperature**	**Detergent/water type**
Pre-cleaning	2 minutes	Cold <45 °C (<113 °F)	Tap water
Detergent wash	2 minutes	Heated 50–60 °C (122–140 °F)	1. Valsure Enzymatic Detergent (ph 7–9) 2 ml/L or 2. Neodisher Septoclean (ph 11.3–12.3) 1 ml/L
Wash	5 minutes	Heated 50 °C–60 °C (122 °F–140 °F)	Valsure Neutral (ph 6–8) 2 ml/L
Rinse	2 minutes	Cold <45 °C (<113 °F)	Critical water
Dry	10 minutes	Heated 70 °C (158 °F)	Not applicable

Table 4: Validation for automated cleaning cycles using enzymatic or alkaline detergent in two separate validations

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, 90 °C (194 °F) using critical water) were validated to demonstrate that Cochlear's reusable surgical instruments and Instrument Case and selected worst-case thermocouple/temperature probe locations demonstrate successful thermal disinfection.

See "Table 3: Cleaning equipment used for cleaning validations using both enzymatic and alkaline detergents" on page 16 for details of the Washer/Disinfector used for thermal disinfection validation.

Steam sterilization

Instruments:

Prevacuum sterilization cycles were used for validation. Test articles were individually double-pouched in an inner pouch (Crosstex Ref nr: SCS2 510(k) 941327) and an outer pouch (Crosstex Ref nr: SCL2 510(k) 941327) and placed on the bottom shelf of the autoclave near the door.

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 spores*, ATCC #7953 Crosstex SUS-07 were used.

Sterilization parameters	
Parameter	Setting 1
Sterilizer type	Prevacuum
Temperature	132 °C (270 °F)
Full cycle time	4 minutes

Table 5: Validation for sterilization

Instrument Case:

Sterilization validation was performed on an Instrument case fully loaded with instruments (total weight for Instrument case including instruments is 1700 grams).

Prevacuum sterilization cycles were used for validation. The fully loaded Instrument case was double-wrapped with sterilization wraps (Crosstex Ref nr: SW24 510(k): K082554; Crosstex LTA Medical Ref nr: 4569057060060 510(k): K800123) and sterilization packaging tape (Crosstex Ref Nr: STLF18MM 510(k): K191741) and placed inside the autoclave chamber near the drain.

Instruments contained in the Instrument case were evaluated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using half-cycle studies and the biological indicator overkill method. *Geobacillus stearothermophilus spores*, ATCC #7953 Crosstex SUS-07 were used.

See "Table 3: Cleaning equipment used for cleaning validations using both enzymatic and alkaline detergents" for details of the sterilizer used for Steam sterilization validation.

Drying

Any residual moisture after drying in the cleaning/disinfection cycle was removed by using a non-linting wipe before being prepared for sterilization.

For validation of drying time each test article was:

- Prepared as described in "Steam sterilization" on page 17 and 18.
- Placed into the 'cold' spot of the steam sterilizer, typically on the bottom shelf of the autoclave near the door or inside the autoclave chamber near the drain.
- Sterilized using validated full cycle set points with drying times in Table 6 below.

Parameter	Setting 1
Drying time	20 minutes

Table 6: Validation for drying

All surfaces of test articles were inspected for visible moisture. Any visible moisture on pouch or wrap surfaces was noted.

Repeat reprocessing

The instruments and Instrument Case have been validated for 25 cycles of reprocessing using Neodisher Septoclean as instructed in this guide. Neodisher Septoclean was regarded as worst case conditions for the wear and damage of the instruments.

Standards

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

Document Title	Number
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff	Document issued on March 17, 2015
Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	AAMI TIR12:2010 AAMI TIR12:2020
Technical information report: a compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	AAMI TIR 30:2011/(R)2016
Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	ISO 17664:2017
Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices	ISO 17664-1:2021

SE **Cochlear Bone Anchored Solutions AB,** Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden. Tel:+46 31 792 44 00

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

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

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

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

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

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

BE **Cochlear Benelux NV,** Schaliënhoevedreef 20 I, 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), Tel: 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

TR **Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Sti.,** Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3 Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye. Tel:+90 216 538 59 00

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

CA **Cochlear Canada Inc,** 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada. Tel:+1 800 483 3123

JP **Nihon Cochlear Co Ltd,** Ochanomizu-Motomachi Bldg 2-3-7 Hongo, Bunkyo-Ku, Tokyo 113-0033, Japan. Tel:+81 3 3817 0241

SG **Cochlear Limited (Singapore Branch),** 238A Thomson Road #25-06, Novena Square Office Tower A, Singapore 307684, Singapore. Phone: +65 65533814

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

HK **Cochlear (HK) Ltd,** Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong. Tel:+852 2530 5773

IN **Cochlear Medical Device Company India PVT Ltd,** Platina Bldg, Ground Floor, Plot No. C 59, G Block, BKC, Bandra East, Mumbai 400051 India. Tel:+91 22 6112 1111

CO **Cochlear Colombia,** Avenida Carrera 9 #115-06 Of. 1201 Edificio Tierra Firme, Bogota D.C., Colombia. Tel:+57 315 339 7169 / +57 315 332 5483

MX **Cochlear México S.A. de C.V**, Av. Tamaulipas 150 Torre A piso 9, Col. Hipódromo Condesa, 06170 Cuauhtémoc, Ciudad de México, México. Tel:+52 0155 5256 2199

www.cochlear.com

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