EN-CA ENGLISH

Cochlear®

Cochlear™ Osia®

Surgical Instruments Sterilisation Reprocessing Guide

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.

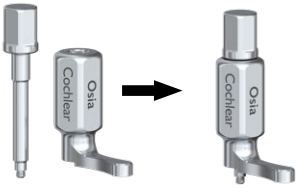
Warning (harmful)
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

Introduction

This guideline is intended for staff involved in sterilisation reprocessing of the Bone bed indicator 17 mm. The Bone bed indicator 17 mm is intended to be used throughout the surgery to correctly position and attach the OSI200 or OSI300 Implant. For information on instruments used during the surgery, refer to the Physician's Guide.

Bone bed indicator 17 mm



Pin Body

P1469690
Bone bed indicator 17 mm

- Delivered in two parts (body and pin) that have to be combined before use.
- Parts do not lock.

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 recommended 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 the 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.

⚠ Warning

- The Cochlear Bone bed indicator 17 mm is 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. This particularly applies to different guidelines regarding the inactivation of prions.

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. See “Inspection and function testing” on page 10.

⚠ Caution

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 (288 °F).

Reprocessing instructions

The following reprocessing instructions are for instruments used with patients who in the general population represent no identified risk of Transmissible Spongiform Encephalopathies (TSEs) transmission and where:

a. The instruments have not been exposed to tissue that are known to have high-infectivity for Creutzfeldt-Jakob disease (CJD) (e.g. dura)

or

b. Where the instruments have been exposed to tissue known to have high-infectivity for CJD (e.g. dura).

⚠ Warning

- 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.

Preparation for cleaning

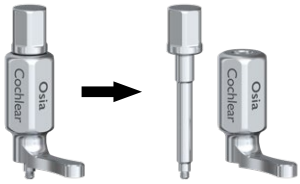
Rinse under water at a temperature that should not exceed 45 °C (113 °F) while brushing for a minimum of 1 minute.

⚠ Caution

Do not use metal brushes or steel wool. For manual removal of impurities, use a soft brush only. For holes, use suitable interdental brushes.

Bone bed indicator 17 mm

- The Bone bed indicator 17 mm consists of a body and a pin
- Disassembling required if assembled



Pin Body

Cleaning and disinfecting

⚠ Warning

Do not use a manual procedure, even in conjunction with an ultrasonic bath. Manual procedures could cause damage to delicate instrument parts, resulting in prolonged surgery time.

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 (A_0 value >3000).
- 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 5).

Note

Cleaning validation as shown in "Appendix 1 – Validation information" on page 14, was undertaken using minimum detergent concentration levels. Always follow the instructions from the detergent manufacturer regarding concentration, temperature and soaking time.

Apply only the parameters that were applied during process validation in the hospital or clinic's reprocessing centre or sterilisation department.

Warning

For instruments in contact with patients with no identified risk of TSE transmission and where the instruments have been exposed to tissue known to have high infectivity for CJD (e.g. dura), 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 9.
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 required, 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 OR Prion inactivating 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)	Hot tap 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

*⚠ **Warning**

Use an alkaline detergent validated for prion inactivation (e.g. Neodisher® MediClean Forte) for instruments in contact with patients with no identified risk of TSE transmission and where the instruments have been exposed to tissue known to have high-infectivity for CJD (e.g. dura).

† 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, pressurised 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 14.

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.

⚠ Warning

Do not use damaged or worn instruments. Instruments that remain dirty must be cleaned and disinfected again.

For specific critical control points see Table 2 below.

Cochlear Osia surgical instruments	Specific critical control points Give particular attention to the following:
P1469690 Bone bed indicator 17 mm	Body: Internal surface of hole; Laser marking (UDI) Pin: Outer threads; Laser marking (UDI)

Table 2: Critical control points for surgical instrument inspection

Packaging

Pack the cleaned and disinfected instruments in sterilisation 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.

For more information see "Appendix 1 – Validation information" on page 14.

Sterilisation

Cochlear has developed and validated the sterilisation instructions in this guide for preparing a surgical instrument for re-use to comply with the requirements of 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 parameters and instructions as specified by the steam steriliser manufacturer and your hospital or clinic, including those related to the quality of water supplied to the steam generator.
- Validated parameters for temperature and time for instruments used with patients with no identified risk of TSE transmission and where the instruments have not been exposed to tissue that are known to have high-infectivity for CJD (e.g. dura):

Minimum temperature	Minimum exposure time	Minimum drying time
132 °C (270 °F)	4 minutes	20 minutes
134 °C (273.2 °F)[†]	3 minutes	16 minutes

- Use the following parameters for instruments used with patients with no identified risk of TSE transmission and where the instruments have been exposed to tissue that are known to have high-infectivity for CJD (e.g. dura):

Minimum temperature	Minimum exposure time	Minimum drying time
134 °C (273.2 °F)†	18 minutes*	16 minutes

* The construction and design of the surgical instruments have been verified to withstand 18 minutes exposure time at 134 °C (273.2 °F)

† The cycles 134 °C (273.2 °F) for 3 minutes and 134 °C (273.2 °F) for 18 minutes are not applicable to U.S. healthcare facilities.

⚠ Warning

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

⚠ Caution

Maximum sterilisation temperature of 138 °C (280 °F).

Storage

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

Symbols

	Consult instructions for use		Catalogue number
	Caution		Batch code
	Date of manufacture		Non-sterile
	Manufacturer	Rx Only	Caution: US law restricts this device to sale by, or on the order of, a physician
	Authorised representative in the European Community		Medical device

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; 120.6 °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 °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 (183.5 °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.

For instruments used with patients with no identified risk of TSE transmission and where the instruments have been exposed to tissue that are known to have high-infectivity for CJD (e.g. dura) the articles were soaked for in a 0.5% (5 mL/L) Neodisher Mediclean Forte solution at 55 °C whilst stirring for 10 minutes prior to the following automated cleaning cycle.

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

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

Automated cleaning validations			
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 ° F)† Tap water	Neodisher Mediclean Forte 2 mL/L‡
Wash 2	4 minutes *	55 °C (131 °F)† Tap water	Valsure Neutral 2 mL/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 an $A_0 \geq 600$.
See "Table 3: Cleaning equipment used for cleaning validations using enzymatic detergent" on page 14 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 1	
Steriliser type	Prevacuum	
Preconditioning pulses	4 (Set point: 10 inHg for 1 minute)	
Temperature	132 °C (270 °F)	134 °C (273.2 °F)
Full cycle time	4 minutes	3 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

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 17.
- Placed into the 'cold' spot of the steam steriliser, typically over the drain.
- Sterilised using validated full cycle set points with drying times in Table 9 below.

Parameter	Setting 1	Setting 2
Drying time	20 minutes	16 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 a Cochlear representative.

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