

# Reprocessing guidelines for Osscora<sup>™</sup> Surgical Set

## General notes

Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection, and sterilisation.

### CAUTION

- Wear protective clothing, safety glasses, face mask and gloves.
- Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.
- Clean and disinfect the motor with cable and handpiece immediately after every treatment.
- Sterilise the motor with cable and handpiece prior to every use.
- The control unit is not approved for automated cleaning and disinfection.
- Do not immerse the control unit or clean it under running water.

## Cleaning agents, disinfectants, and disinfectors

### CAUTION

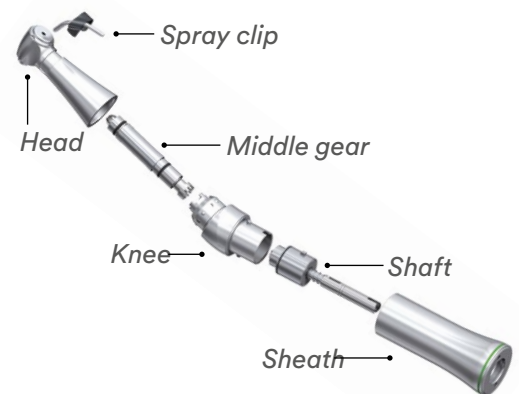
- Read the notes, follow the instructions, and heed the warnings provided by the manufacturers of washer-disinfectors.
- Read the notes, follow the instructions, and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.

Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

### CAUTION

The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

## Contra-angle handpiece



## STEP 1 Pre-disinfection

1. Remove the spray clip (fig. 1).
2. If heavily soiled, clean first with disinfectant cloths (fig. 2).

## STEP 2 Disassembly

### Step 2A (fig. 3)

1. Hold the head firmly with one hand. Push sheath and knee gently together.
2. At the same time, twist the sheath from the knee.
3. Remove the sheath and the shaft.

### Step 2B (fig. 4)

1. Remove the knee.
2. Remove the middle gear from the knee.

## STEP 3 Cleaning & disinfection

### Alternative 1: Automated cleaning and disinfection



Cochlear recommends automated cleaning and disinfection using a washer-disinfector.



Disassemble the contra-angle handpiece before automatic cleaning and disinfection.

The motor with cable must not be twisted, kinked or be coiled too tight.



Before disinfection and cleaning push the motor protective cover onto the motor attachment. (fig. 9)



Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

- Cleaning at 55° C (131° F) – 5 minutes
- Disinfection at 93° C (200° F) – 5 minutes



Make sure that the contra-angle handpiece is completely dry internally and externally after thermo washer disinfection. Remove any liquid residues with compressed air.

Lubricate the dry contra-angle handpiece immediately after thermo washer disinfection.

Sterilise according to instructions in STEP 7



Fig. 1

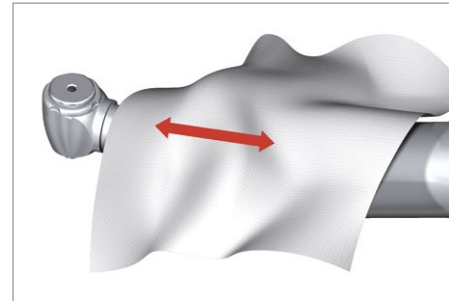


Fig. 2

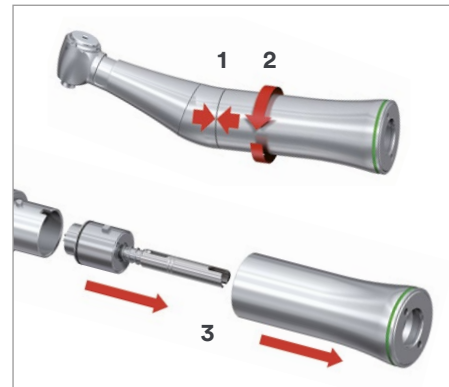


Fig. 3

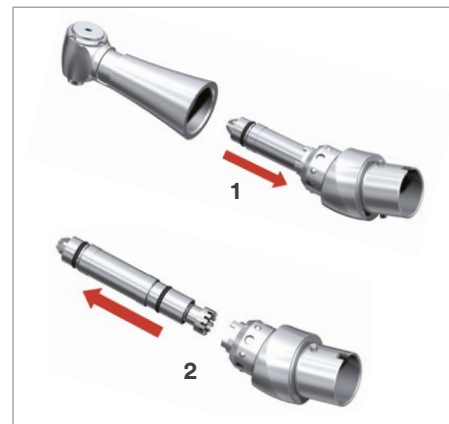


Fig. 4



Fig. 5

## Alternative 2: Manual cleaning and disinfection

### Contra angled handpiece

#### Step 3A (fig. 5)

- Rinse under demineralised water (< 38° C, < 100° F).



Do not place the handpiece in liquid disinfectant or in an ultrasonic bath.

#### Step 3B (fig. 6)

1. Clean coolant outlet carefully with the nozzle cleaner to remove dirt and deposits.
2. Blow through the coolant tube and coolant outlet with the compressed air.

#### Step 3C (fig. 7)

Ensure that the handpiece is completely dry internally and externally after cleaning. Remove any liquid residues by blow-drying with compressed air.

#### Step 3D (fig. 8)

Disinfect with surface disinfectants.

- Use only surface disinfectants which do not contain chlorine, and which are certified by officially recognised institutes.
- Note the manufacturer's specifications for the use of the surface disinfectants.
- For USA: Use EPA registered surface disinfectants.



Ensure that the handpiece is completely dry internally and externally after disinfection. Reassemble and lubricate the dry handpiece immediately after cleaning and disinfection.

### Motor with cable

#### Step 3E (fig. 9)



Before cleaning and disinfection, push the motor protective cover onto the motor attachment. Do not twist and kink the motor cable! Do not coil it too tightly!

- If heavily soiled, clean first with disinfectant cloths.
- Rinse under demineralised water (< 38° C, < 100° F).
- Do not place the motor in liquid disinfectant or in an ultrasonic bath.
- Remove any liquid residues by blow-drying with compressed air or wiping with an absorbent cloth.



Fig. 6



Fig. 7



Fig. 8

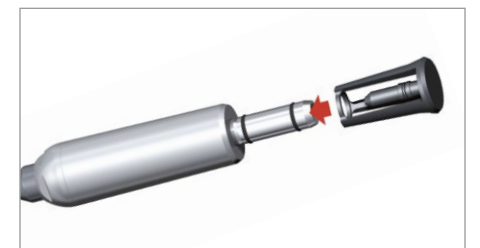


Fig. 9

**Step 3F (fig. 10)**

- Use only surface disinfectants which do not contain chlorine, and which are certified by officially recognised institutes.
- Note the manufacturer’s specifications for the use of the surface disinfectants.
- For USA: Use EPA registered surface disinfectants.

**STEP 4 Assembly**

**Step 4A (fig. 11)**

1. Insert the middle gear into the contra-angle head. Check free running of the chucking system.
2. Insert the knee onto the contra-angle head until it engages.
3. a) Put the shaft in the knee.  
b) Observe the position of the rotational lock.  
c) Check free running rotation.

**Step 4B (fig. 12)**

1. Press the sheath firmly against the knee.
2. Twist until it engages.
3. Attach the spray clip.

**STEP 5 Lubrication**

Lubricate the contra-angle handpiece with W&H service oil F1, MD-400 (fig. 13). Follow the Instructions for Use on the oil spray can.

Always sterilise after lubrication.

**STEP 6 Packaging**

⚠ Pack the cleaned and disinfected motor with cable and handpiece in sterilisation packaging that meets the following requirements:

- Compliant with EN ISO/ANSI AAMI ISO 11607, EN 868-5.
- The sterilisation package must be large enough for the sterilisation goods.
- The loading sterilisation package must not be under tension.

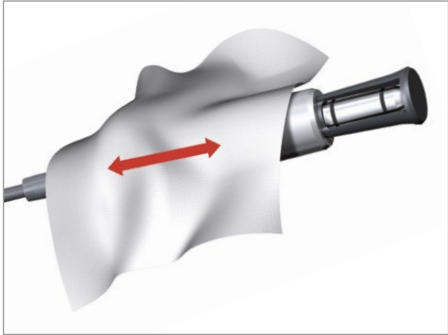


Fig. 10

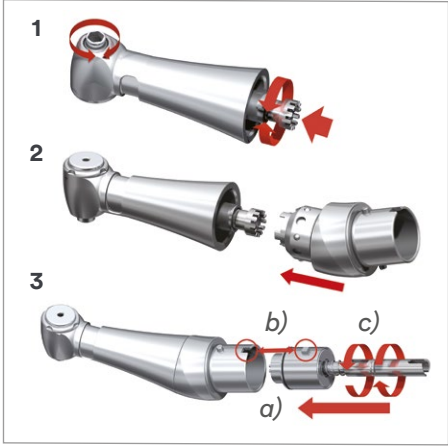


Fig. 11

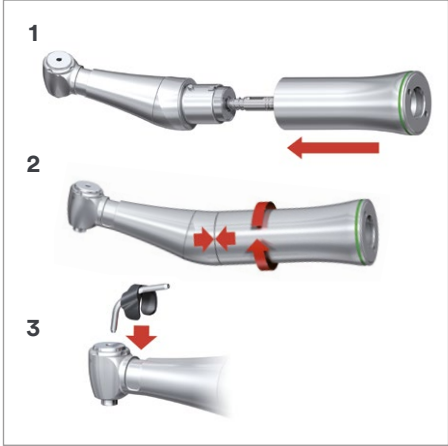


Fig. 12



Fig. 13

**STEP 7 Sterilisation**

👉 Cochlear recommends sterilisation according to EN 13060, EN 285 or ANSI/AAMI ST79.

Follow your country-specific directives, and guidelines based on the standards related to sterilisation of medical devices.

⚠ The program selected must be suitable for the medical device. Read the notes, follow the instructions, and heed the warnings provided by the manufacturers of steam sterilisers.

👉 For sterilisation in sterilisers WITH a drying program we recommend that you remove the motor protective cover. (fig. 14)

For sterilisation in sterilisers WITHOUT a drying program we recommend that you use the motor protective cover (fig. 15).

**Recommended sterilisation cycles**

**Steam sterilisation**

- Sterilisation time at least 3 minutes at 134° C (273° F), 4 minutes at 132° C (270° F), 30 minutes at 121° C (250° F)
- Maximum sterilisation temperature 135° C (275° F)

Evidence of the medical device’s basic suitability for effective sterilisation was provided by an independent test laboratory using the LISA 517 B 17L\* steam steriliser (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150\* steam steriliser (Systec) and the CertoClav MultiControl MC2-S09S273\*\* steam steriliser (CertoClav GmbH, Traun).

“Dynamic-air-removal prevacuum cycle” (type B) / “Steam-flush pressure-pulse cycle” (type S)\*/\*\*

- 134° C (273° F) for at least 3 minutes
- 132° C (270° F) for at least 4 minutes

“Gravity-displacement cycle” (type N)\*\*

- 121° C (250° F) for at least 30 minutes

\*EN 13060, EN 285, ISO 17665

\*\*ANSI/AAMI ST55, ANSI/AAMI ST79

**NOTE**

All other sterilisation methods are not approved and must not be used.

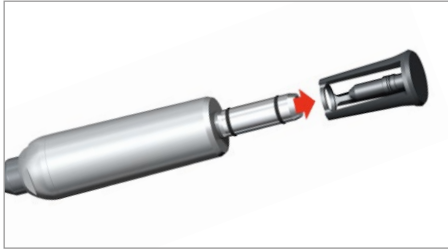


Fig. 14

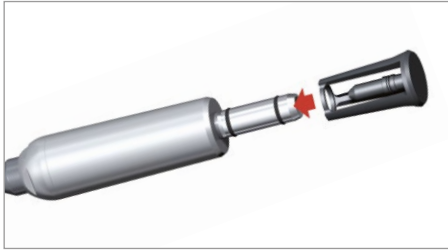


Fig. 15

Storage



- Store sterile goods in dust-free and dry conditions.
- The shelf life of the sterile goods depends on the storage conditions and type of packaging.

Before starting operation again, wait until the motor and cable are completely dry. Moisture in the motor or plug can lead to malfunction. (Risk of short circuit).

Symbols



Warning

Risk of injury.



Attention

Important notes to prevent damage occurring.



General explanations

Without risk to persons or objects.



Thermo washer

Disinfectable.



Sterilisable


Up to the stated temperature.

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