Cochlear™ Baha®
and Vistafix®

Osscora Surgical Set

INSTRUCTIONS FOR USE
MODEL NO. 91053

Cochlear®

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.

Symbols

Symbols on the control unit


Follow instructions for use


Consult instructions for use


Class II equipment


Date of manufacture


Electric fuse


Not suitable for intracardiac application – Type B appliance


Do not dispose of with domestic waste


Foot switch


On / Off


Data matrix code for product identification e.g. for hygiene / maintenance processes

Medical – General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with UL60601–1; CAN/CSA C22.2 No. 601.1; IEC60601–1; ANSI/AAMI ES60601–1.
25UX (Control No.)

REF	Catalogue number
SN	Serial number
V	Supply voltage of the unit
AC	Alternating current
VA	Electric power input of the unit
A	Supply current
Hz	Frequency of the alternating current
rpm	Revolutions per minute (rpm = min.-1)

Symbols

Symbols on the packaging

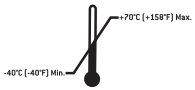
This way up

Fragile, handle with care

Keep away from rain

Der Grüne Punkt
Identification mark of Duales System Deutschland AG

General symbol for recovery/ recyclable



Temperature limit

Humidity limitation

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner.

Symbols

Symbols on the irrigation tubing

Sterilisation with ethylene oxide

Consult instructions for use

Not for re-use

Manufacturer:
ASSAmed GmbH
Münchweiser Str.4
D-66450 Bexbach
Germany

Latex-free

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner.

Use by date

Batch ID

Contents

1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your Cochlear product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients is of paramount importance to us.

It is therefore essential to read the safety notes on pages 8 to 11.

Intended use
Osscora surgical set with contra-angle handpiece is intended to be used for Baha® and/or Vistafix® surgery including:

- Dermatome use
- Drilling
- Thread cutting
- Implant placement and removal

Qualification of the user
Osscora surgical set with contra-angle handpiece is intended to be used in operating rooms and to be used by trained surgeons and operating room staff.
Only suitable qualified medical, technical and specialist trained staff may use the surgical unit.We have based our development and design of the Osscora surgial set on the “physician” target group.

Responsibility of the manufacturer
Cochlear Bone Anchored Solutions AB can only accept responsibility for the safety, reliability and performance of the Osscora surgical set when there is compliance with the following directions:

- The Osscora surgical set must be used in accordance with these Instructions for Use.
- The Osscora surgical set has no components which can be repaired by the user. Assembly, modifications or repairs must be undertaken by authorised personnel only.
- The electrical installation at the premises must comply with the regulations applicable in your country.
- Unauthorised opening of the equipment invalidates all claims under warranty and any other claims.

2. Safety notes

Please ensure that you carry out the following instructions:

- Before using the Osscora surgical set for the first time, store it at room temperature for 24 hours.
- Only fit the contra-angle handpiece when the motor is at a complete standstill.
- Never touch rotary instruments that are still rotating.
- Never touch the chuck mechanism of the contra-angle handpiece while it is still running.
- Always ensure correct operating conditions and that adequate cooling is delivered.
- Avoid overheating at the treatment site.
- Check the Osscora surgical set, the contra-angle handpiece and the motor with cable for damage and loose parts each time before use. Correct any faults or refer to your local Cochlear office. Do not operate the Osscora surgical set if it is damaged.
- When changing the fuse, disconnect the unit from the power supply and only use original fuses.
- Perform a test run prior to each treatment.
- Never touch the patient and the connection for the foot control simultaneously.
- Check the parameter settings every time the device is restarted.

Use only suitable and serviceable tools
Ensure that you comply with the manufacturer's instructions for surgical contra-angle handpieces with respect to maximum speed, maximum torque, forward and reverse movement.

Inappropriate use
Improper use, in addition to incorrect assembly, installation, modification or repairs of the Osscora surgical set or non-compliance with our instructions invalidates all claims under warranty and any other claims.

2. Safety notes

Risks due to electromagnetic fields
The functionality of implantable systems, such as cardiac pacemakers and ICD (implantable cardioverter defibrillator) can be affected by electric, magnetic and electromagnetic fields.

- Find out if patients and users have an implanted device before using the product and consider the applications.
- Weigh the risks and benefits.
- Keep the product away from implanted devices.
- Make appropriate emergency provisions and take immediate action on any signs of ill-health.
- Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).

Danger zones M and G
In accordance with IEC 60601-1 /ANSI/AAMI ES 60601-1, the control unit and the motor with cable are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

Control unit
The control unit is classed as “conventional equipment” (closed equipment without protection against the ingress of water).

The Osscora surgical set control unit is designed only to be used with the Osscora contra-angle handpiece. Use of other contra-angle handpieces may result in deviation from the indicated torques and is the user’s responsibility.

The motor, motorcable and contra-angle handpiece are applied parts.

Foot control
The foot control is approved for use in zone M (AP).

Please note that at low speeds, it is more difficult to determine that the motor is running.

2. Safety notes

Electromagnetic compatibility (EMC)
Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

Cochlear guarantees the compliance of the device with the EMC requirements only when used with original Cochlear accessories and spare parts. The use of other accessories/spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

You can find the current EMC manufacturer's declaration on our website at http://www.cochlear.com/files/assets/baha/pdf/OsscoraEMC.pdf

HF communication equipment
Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.

2. Safety notes

Mains cable
Only use the mains cable supplied.
Only connect to an earthed socket outlet.
Set up the device so that the power switch is easily accessible. In dangerous situations, the device can be disconnected from the power supply using the power switch or power cable. The power switch can also be used to safely stop the device.

Power failure
In the event of a power failure, if the control unit is switched off, or when alternating between programs, the last values set are saved and reactivated on power-up.

System failure
A total system failure of the Osscora surgical set does not constitute a critical fault. Simply switch the unit off and then on again.

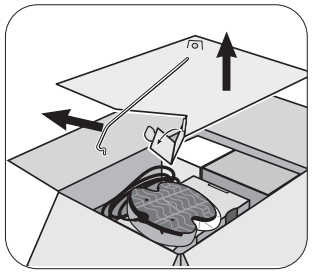
Intermittent operating mode S3 (3min/10min)
If the operating mode specified is observed no overheating of the system and therefore no injury to the patient, user or third persons arises.
The responsibility for the use and timely shutdown of the system lies with the user.

Coolant
The Osscora surgical set is designed for use with physiological saline solution. Use only suitable irrigation fluids and comply with the medical data and instructions from the manufacturer. Use the supplied irrigation tubing set or accessories supplied by Cochlear. Coolant bottle or coolant bag can be obtained from a pharmacist.

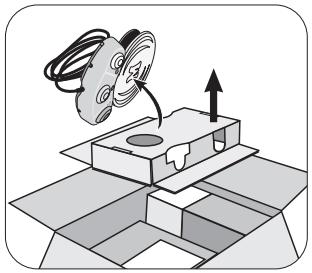
Sterility of irrigation tubing set
Sterile irrigation tubing sets are supplied with the equipment. These irrigation tubings are disposable articles and must be thrown away after each treatment! Please note the expiry date and the relevant regulations for disposal of irrigation tubing. Only use disposable irrigation tubing with undamaged packaging.

Rotational energy
Fast deceleration of the bur can, at times, cause the selected torque to be overloaded as a result of the rotational energy stored in the drive system.
Perform a test run prior to thread cutting and implant placement to check if motor stops correctly after releasing the foot control.

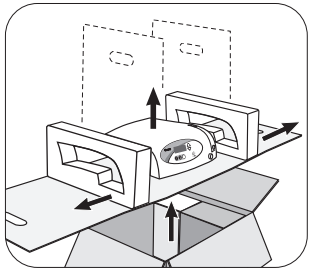
3. Unpacking



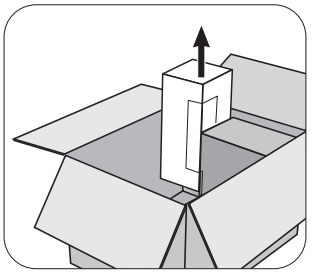
❶ Lift out insert with stand.



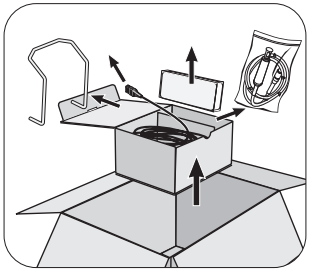
❷ Remove foot control and insert.



❸ Lift out insert with control unit.



❹ Remove irrigation tubing set.



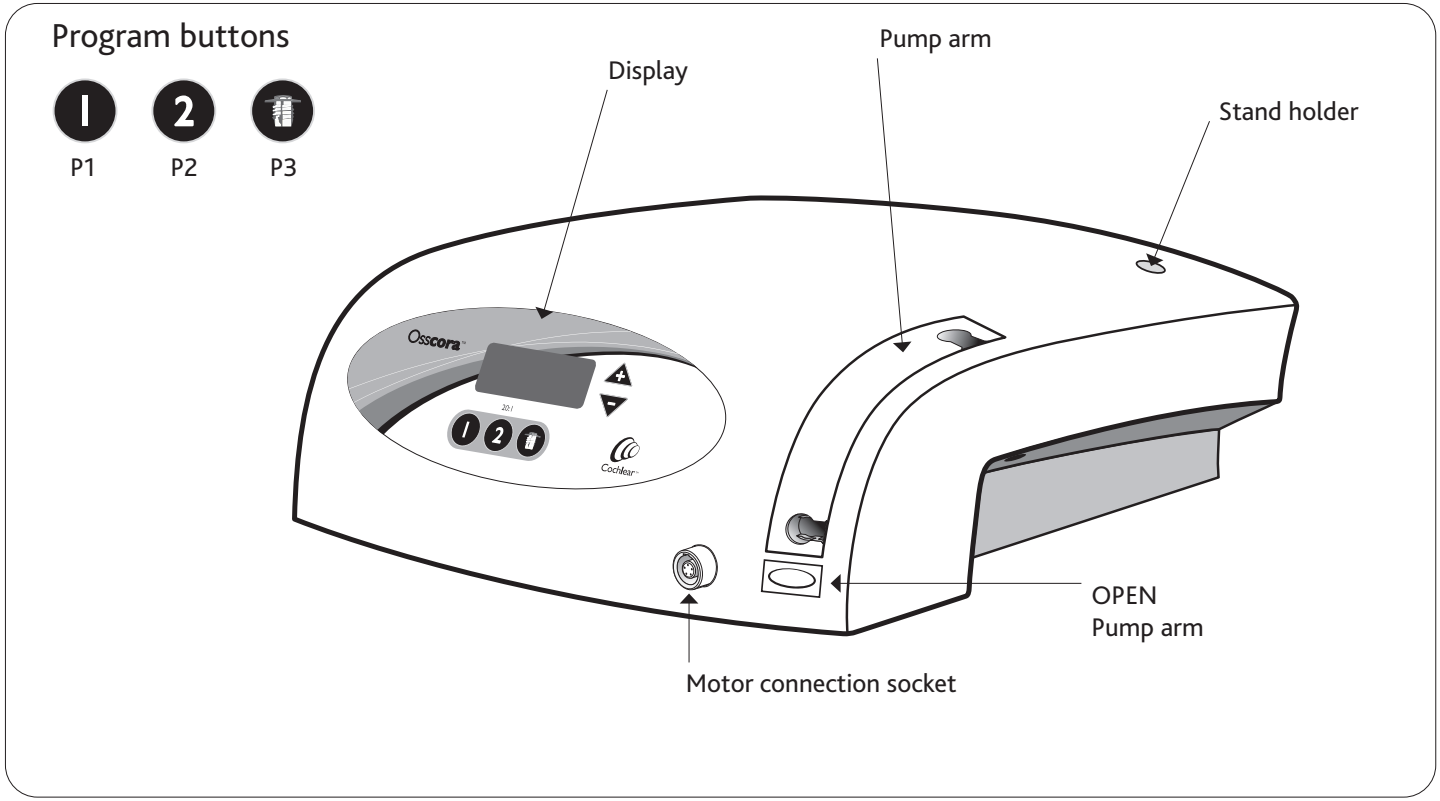
❺ Remove carton containing motor, mains cable, handle and contra-angle handpiece.

The packaging is environmentally friendly and can be disposed of by industrial recycling companies. However, we recommend that you keep the original packaging.

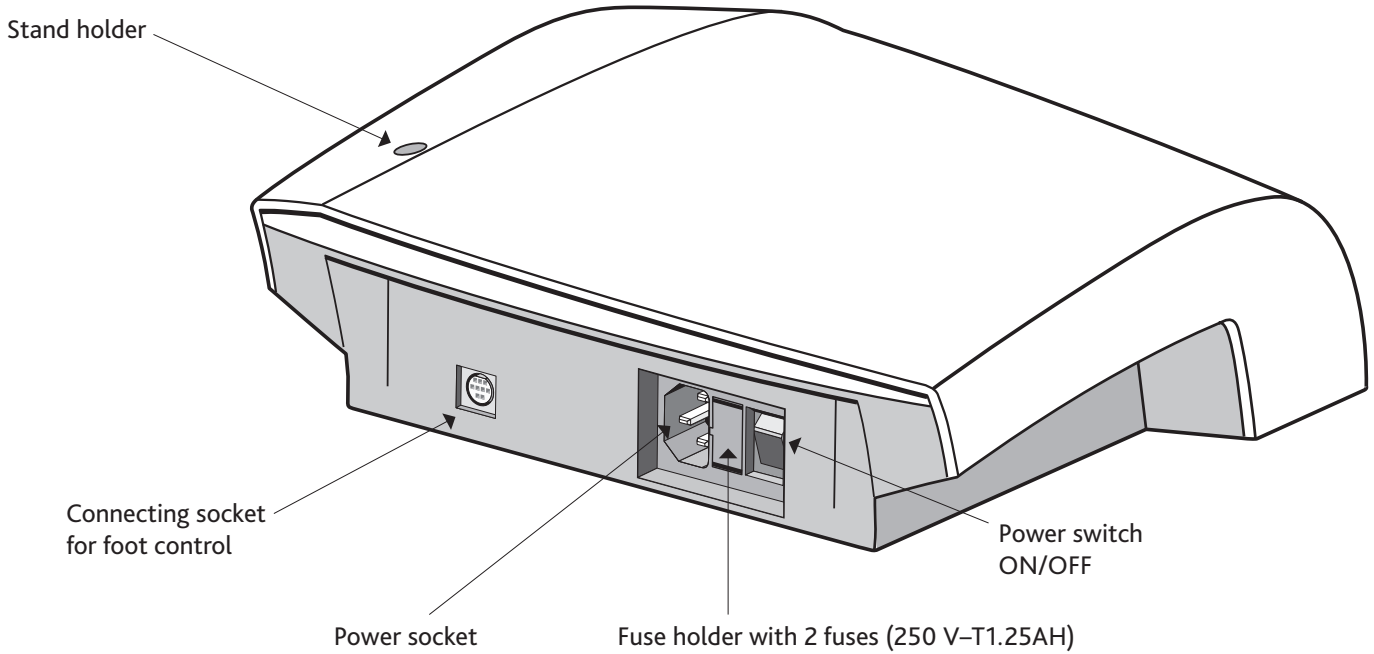
4. Equipment supplied

91053 Osscora surgical set 115 V
Control unit, 115 V
Foot control S-N1
Motor with 3,5 m cable incl. motor protective cover, locking pins (2 pcs) and clips (10 pcs)
Osscora contra-angle handpiece
Irrigation tubing set (6 pcs)
Mains cable (1 pcs) (USA, CAN, JAP)
Stand

5. Description of front panel



6. Description of rear panel



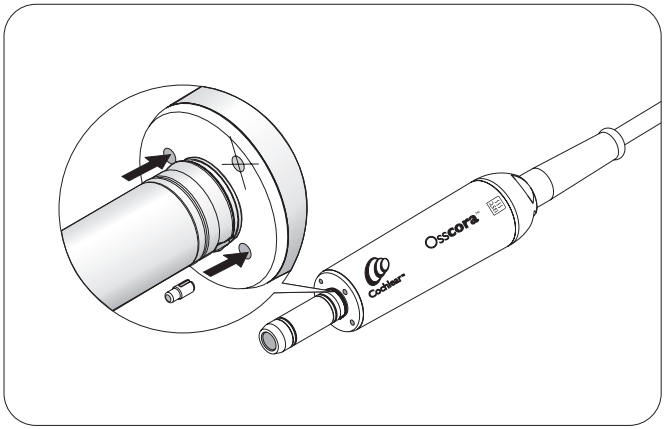
7. Description of motor with cable

The motor may not be dismantled!
The motor bearings are lubricated for life. No oil lubrication or other maintenance is necessary.

To prevent the instrument on the motor attachment from turning during the transmission, the locking pin supplied can be pushed into one of the two holes of the motor (see illustration).

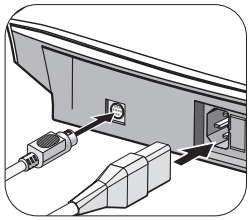
Test run

- Start the motor.
- If you observe dysfunctions (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) stop the motor immediately and contact your service agent. For details, please contact your local Cochlear office.

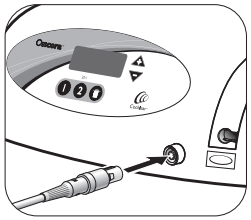


8. Starting operation–General

Always place the Osscora on a flat level surface.
Ensure that the Osscora can be disconnected easily from the power supply.

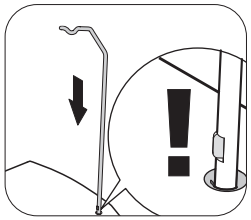


❶ Connect the mains cable and foot control.



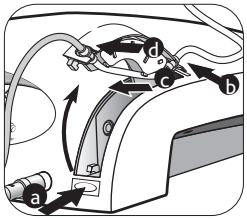
❷ Connect the motor cable.

Note the positioning.

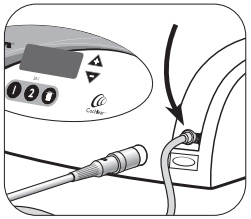


❸ Insert the stand.

Note the positioning. (maximum load capacity 1.5 kg)

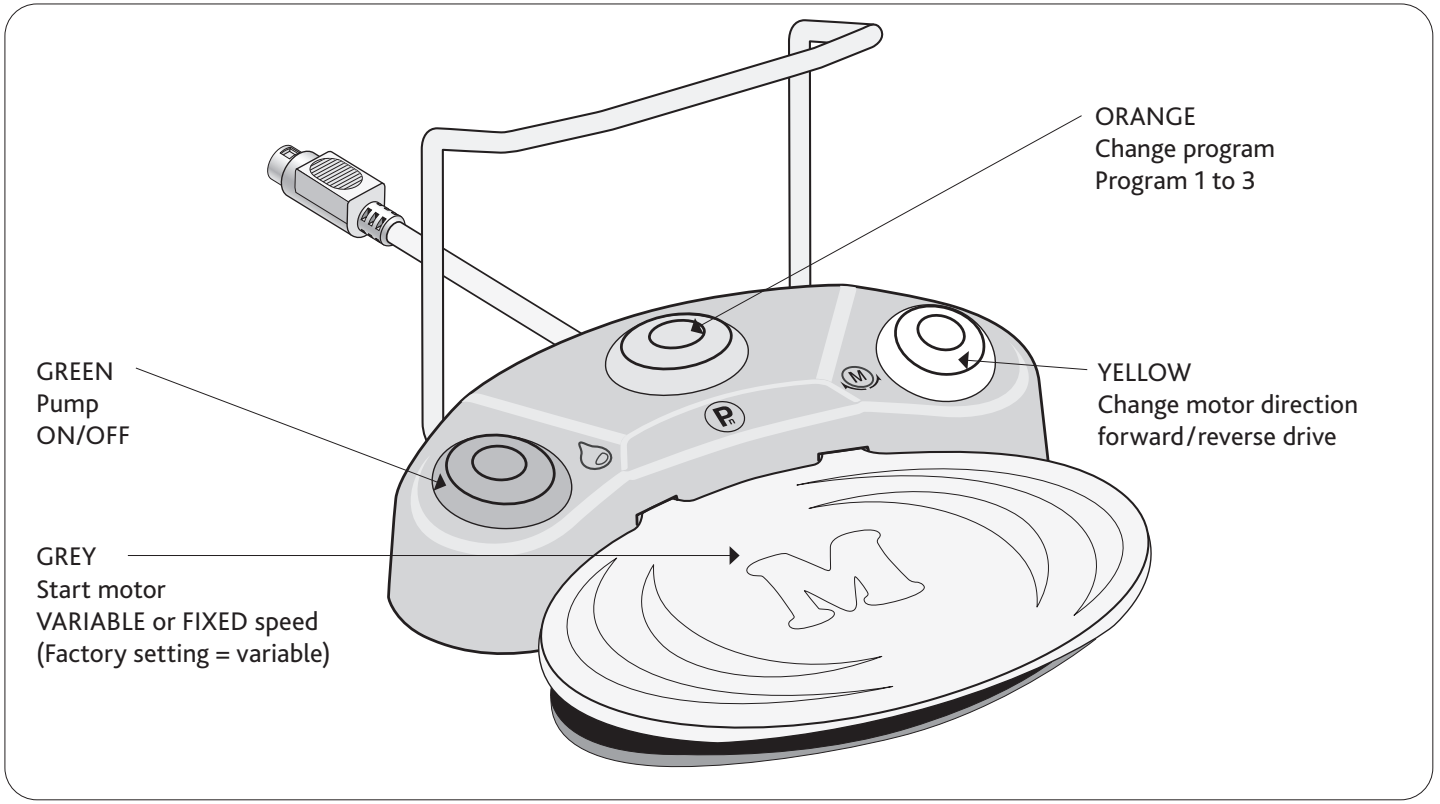


❹ Fit the irrigation tubing set.
a) Open the pump arm
b) Insert the tube in the rear holder. Note the position of the flange on the tube
c) Pull the tube towards the front
d) Insert the tube in the front holder. Note the position of the flange on the tube



❺ Close pump arm.

9. Starting operation–Foot control



9. Starting operation–Foot control

Changing program
The programs 1–3 can be selected in ascending sequence by operating the ORANGE button.

When changing from program 3 to program 1, a longer confirmation signal is heard.

With each program change, the motor direction is automatically set to forward operation.

Pump ON/OFF
Only when the motor is stationary the pump can be switched on or off by operating the GREEN button of the foot control. When pump operation is active, the pump symbol appears on the display.

Reverse operation
You can switch between forward and reverse operation by pressing the YELLOW button. On selecting reverse operation, an audible signal can be heard and the selected program button flashes. Before the motor starts in reverse operation, there is a delay while 3 audible warning signals are given.

9. Starting operation–Foot control

To change motor speed from VARIABLE speed to FIXED speed (variable speed is only available for program 1 and 2.)

Keep program button P3 depressed throughout this procedure!

❶ Press P3 for approx. 4 seconds.

❷ Keep P3 depressed and simultaneously press PLUS and MINUS.

❸ Keep P3 depressed and carry out adjustment.

01 = VARIABLE speed (factory setting) – Press PLUS button.

00 = FIXED speed – Press MINUS button.

After changeover the program button P3 illuminates and is active!

10. Factory settings

Factory settings P1– P3	P1 	P2 	P3 Forward 	P3 Reverse 
Factory setting rpm	2000	2000	15	30
Adjustable range rpm	15–2000	15–2000	–	–
Motor direction	Forward	Forward	Forward	Reverse
Pump	Off	On	Off	Off
Factory setting Ncm	Max.	Max.	20	20
Adjustable range Ncm	–	–	5–50	5–50
Intermediate stage Ncm	–	–	32	32

10. Factory settings

Reset factory settings

Factory setting always starts with program 1 (P1).

❶ Switch off the control unit.

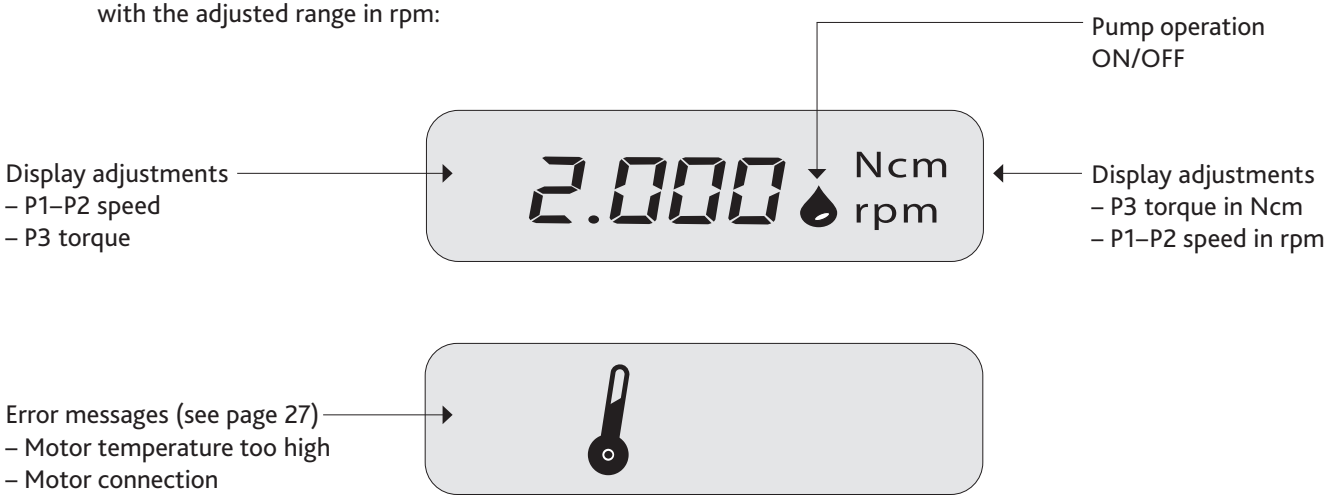
❷ Keep P1 depressed and simultaneously switch on the control unit.

❸ Keep P1 depressed as long as “DE FAU” appears on the display.

11. Control unit operation

Changing the program (P1–P3)

Activate the required program (P1–P3) by pressing the corresponding program button. During selection an audible signal can be heard and the program button is illuminated. On the display the selected program appears with the adjusted range in rpm:



When switching on the Osscora surgical set ensure that the LED displays on the buttons and the display itself are all on.

11. Control unit operation

Changing the speed (P1–P2)

Keeping PLUS/MINUS depressed activates the repeat function and the values are continuously increased/decreased.

Press program button (P1–P2).

Increase speed

Decrease speed

The accuracy of the set speed in the range 300 – 40,000 (at the motor) rpm is ± 10%.

11. Control unit operation

Changing the torque (P3)

Adjustable range from 5 up to 50 Ncm, intermediate stage 32 Ncm. Keeping PLUS/MINUS depressed activates the repeat function and the values are continuously increased/decreased.

When changing from 5 to 50 Ncm and 50 to 5 Ncm, a longer confirmation signal is heard.

When the adjustable torque in the forward/reverse drive mode is reached, the motor switches off automatically.

Press P3.

Increase torque in 5-Ncm-steps

Decrease torque in 5-Ncm-steps

The accuracy of the set torque at 50 Ncm is ± 10% with the Osscora contra-angle handpiece. Greater deviations are possible with other instruments.

11. Control unit operation

Changing the coolant flow (P1–P3)

Factory setting 80% of maximum flowrate (max flowrate: approx. 100 ml/min). Adjustable range 65%, 80% and 100%. Depressing PLUS/MINUS the values are continuously increased/decreased.

Keep program button P2 depressed throughout this procedure!

Keep P2 depressed for approximately 4 seconds (the adjusted coolant flow rate appears).

Keep P2 depressed and press PLUS button to increase flow rate.

Keep P2 depressed and press MINUS button to decrease flow rate.

After adjustment, the program button P2 illuminates and is active!

12. Error messages

Error No.	Description	Remedy
00	Electronics overheating–safety shutdown	Switch off the equipment, allow to cool for at least 10 minutes, then restart
01	Electronics overloaded	Switch off the equipment, allow to cool for at least 10 minutes, then restart
07	Foot control error–initialising	Switch off the equipment, restart, do not actuate foot control when switching on
09	Foot control error	Switch off the equipment, check connection of the foot control, then restart
19	Run limiting control	Switch off the equipment and restart
99	System failure	Switch off the equipment, allow to cool for at least 10 minutes, then restart
	Motor temperature too high Motor connection – safety shutdown	Switch off the equipment, check motor connection, allow motor to cool for at least 10 minutes, then restart

12. Error messages

If one of the error messages described above cannot be rectified by switching off the Osscora surgical set and then switching it on again, the equipment must be checked by a service agent. For contact details, please contact your local Cochlear office.

If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.

13. Reprocessing guidelines

General notes

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

- 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 disinfector

- 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).

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

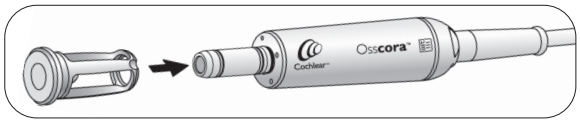
13. Reprocessing guidelines

Automated cleaning and disinfection of Osscora motor with cable and contra angle handpiece

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

Disassemble the contra-angle handpiece before automatic cleaning and disinfection (see page 43). 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.



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.
Assemble and lubricate the dry contra-angle handpiece immediately after thermo washer disinfection. See page 44 and 45 on how to assemble and lubricate the handpiece.

Manual cleaning and disinfection of the control unit and foot control

Pre-disinfection

- If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects.

13. Reprocessing guidelines

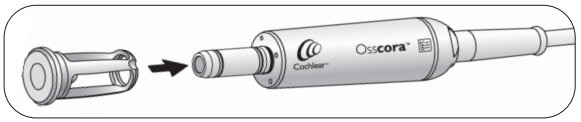
The front panel of the control unit and the foot control are sealed and may be wiped clean.

- Disinfection with surface disinfectants, wiping disinfection is recommended.
- Use only surface disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
  For USA: Use EPA registered surface disinfectants.
- Note the manufacturer's specifications for the use of the surface disinfectants.
- Clean the ESD spring contact of the foot control regularly.

Manual cleaning and disinfection of the motor with cable

Do not twist and kink the motor cable! Do not coil it too tightly!

Before disinfection and cleaning push the motor protective cover onto the motor attachment!



Pre-disinfection

– If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects.

Manual cleaning

- Rinse under demineralised water (< 38 °C) with the aid of a brush (brush is not recommended in U.K.)
- Then remove any liquid residues (absorbent cloth, blow dry with compressed air).

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

Disinfection

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

13. Reprocessing guidelines

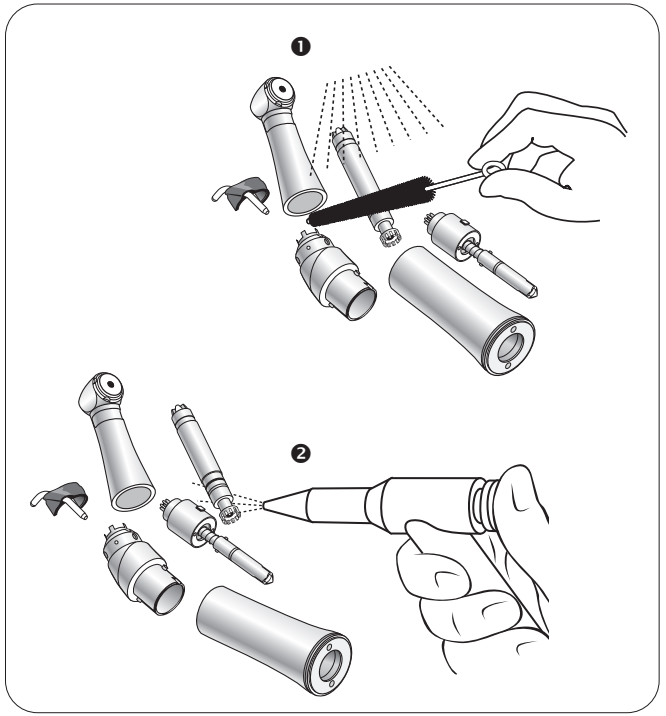
Manual cleaning and disinfection of the contra-angled handpiece

– Remove the rotary instrument.
– Remove the contra-angle handpiece from the motor.

Pre-disinfection
If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects. Clean and disinfect the disassembled contra-angle handpiece **immediately after every treatment**, to flush out any liquid residues (such as blood, etc.) and to prevent settling on the internal parts.

See page 39 on how to disassemble the handpiece.

❶ Rinse under demineralised water (< 38 °C) with the aid of a brush (not recommended in U.K.).
❷ Then remove any liquid residues (absorbent cloth, blow dry with compressed air).



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

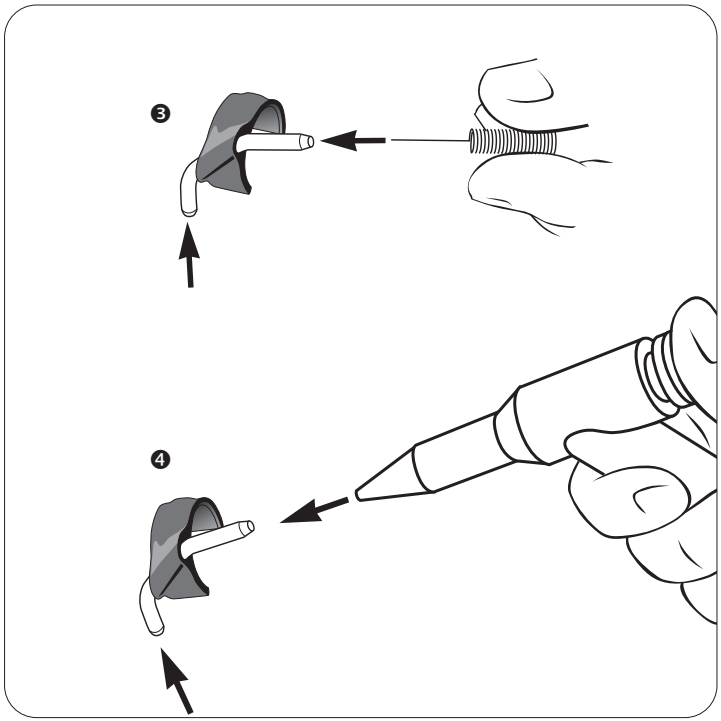
13. Reprocessing guidelines

Manual cleaning (continued) Clean external coolant tubes

❸ Clean coolant outlet carefully with the nozzle cleaner to remove dirt and deposits.
❹ Blow through the coolant tube and coolant outlet with the air syringe.

In the case of a clogged up spray nozzle or coolant tube contact your service agent. For details, please contact your local Cochlear office.

The removable spray clip can be cleaned in an ultrasonic bath.



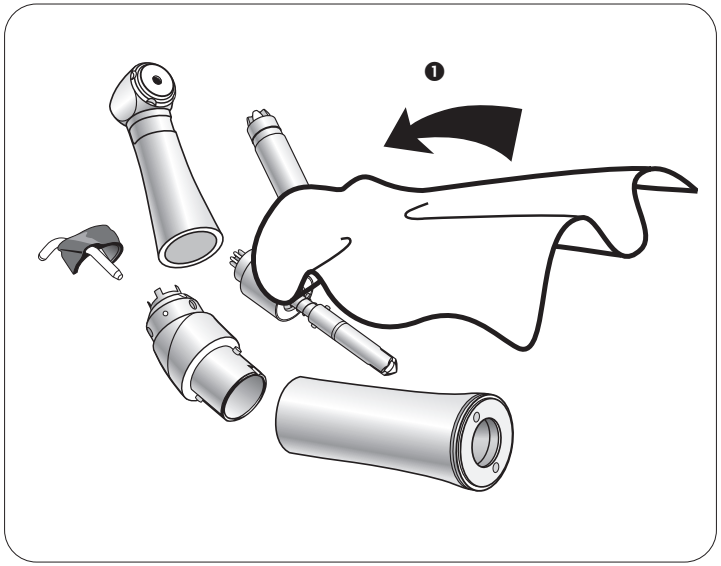
13. Reprocessing guidelines

Manual disinfection

– Disinfect with surface disinfectants. ❶ Wiping disinfection is recommended.
– Use only surface disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
For USA: Use EPA registered surface disinfectants.
– Note the manufacturer's specifications for the use of the surface disinfectants.

Reassemble and lubricate the handpiece immediately after cleaning and disinfection.

See page 44 and 45 on how to assemble and lubricate the handpiece.



13. Reprocessing guidelines

Drying

- Ensure that the motor with cable and handpiece is completely dry internally and externally after cleaning and disinfection.
- Remove any liquid residues using compressed air.

Packaging

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

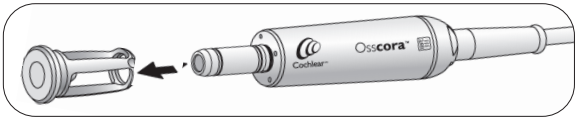
- The sterilisation package must meet the applicable standards in respect of quality and use and must be suitable for the sterilisation method.
- The sterilisation package must be large enough for the sterilisation goods.
- The loading sterilisation package must not be under tension.

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.

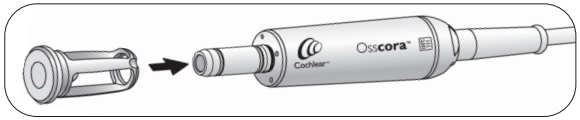
The program selected must be suitable for the medical device. Read the notes, follow the instructions, and heed the warnings provided by the manufacturers of steam sterilisers.

For sterilisation in sterilisers WITH a drying program we recommend removing the motor protective cover.



For sterilisation in sterilisers WITHOUT a drying program we recommend using the motor protective cover.

13. Reprocessing guidelines



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 Sterilisation 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.

Storage

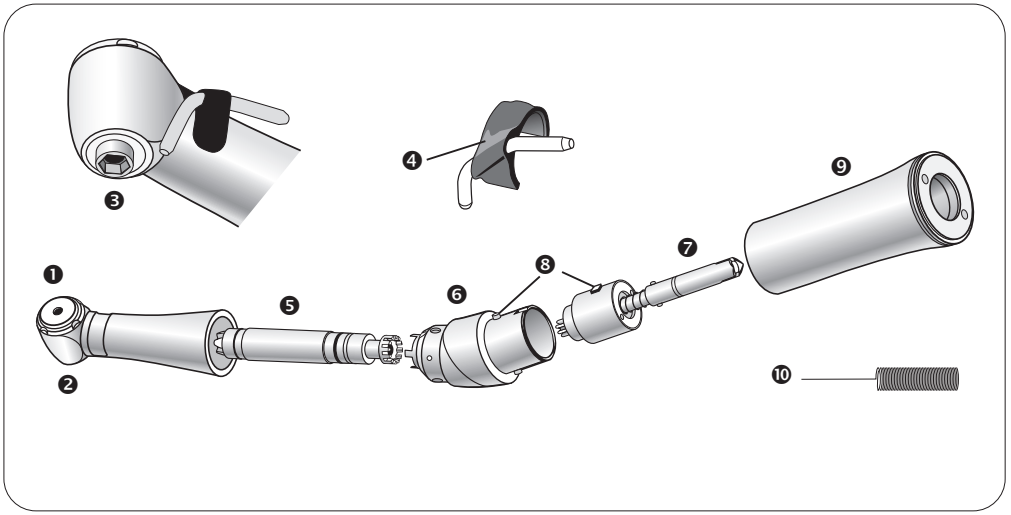
Store sterile goods dust-free and dry.
The shelf life of the sterile goods depends on the storage conditions and type of packaging.

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)

14. Osscora contra-angle handpiece

Product description
Osscora contra-angle handpiece. For disassembly, see page 43.

❶ press-button
❷ head
❸ hexagon chucking system
❹ spray clip
❺ middle gear
❻ knee
❼ lower shaft
❽ locking pin
❾ sheath
❿ nozzle cleaner



14. Osscora contra-angle handpiece

Before use–safety notes

CAUTION:

- If using a Dermatome, please note the Osscora contra-angle handpiece is designed for use with the Baha Dermatome for Osscora only. It must not be used with any other Dermatome model.
- This contra-angle handpiece is only intended for use with Osscora surgical set for Baha and Vistafix surgery.

Prior to initial use:

- Please read the sections on hygienic and maintenance, page 29-46.
- Lubricate the contra-angle handpiece.
- Sterilise the contra-angle handpiece, nozzle cleaner and spray clip.
- Check contra-angle handpiece for damage and loose parts prior to use.
- Always ensure correct operating conditions and cooling function prior to use.

Only assemble components with corresponding type and serial number. Exception: components may be changed at service or repair–these may have a new serial number.

14. Osscora contra-angle handpiece

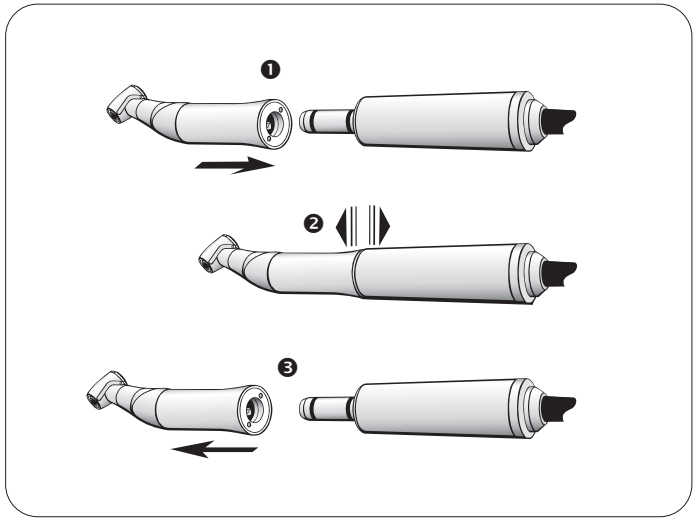
Operation

Assembly and removal
Do not assemble/remove the contra-angle handpiece during the operation!

❶ Push the contra-angle handpiece onto the motor.
– Use a rotational lock between motor and contra-angle handpiece: see page 16.

❷ Check that the motor and handpiece are securely attached.

❸ Remove the contra-angle handpiece from the motor by pulling in an axial direction.



14. Osscora contra-angle handpiece

Operation

Rotary instruments

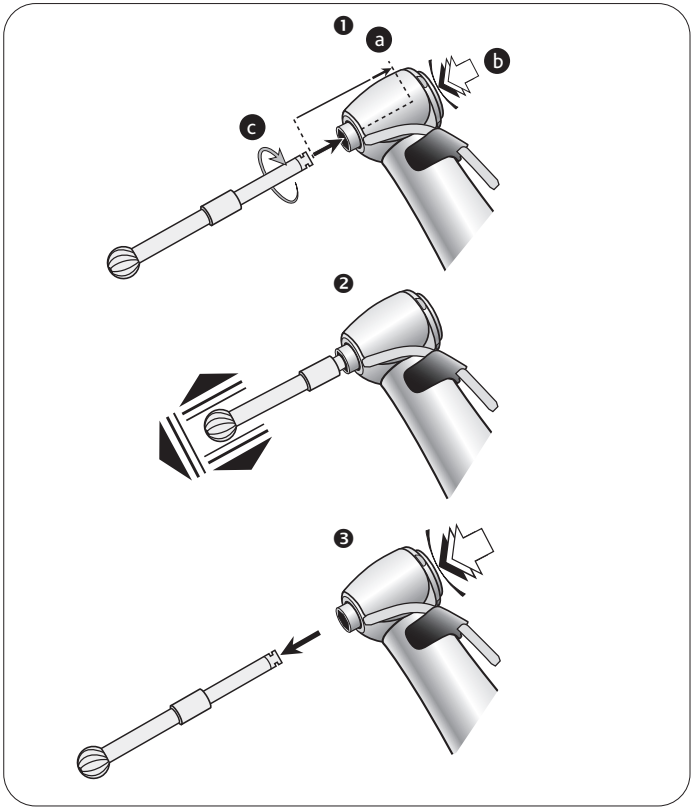
– Use only rotary instruments that are in perfect condition and be careful when the rotary instrument is rotating.
– Insert rotary instruments only when the contra-angle handpiece is stationary.
– Do not activate the press-button of the contra angle handpiece during operation. This leads to detachment of the rotary instrument and makes the head of the contra-angle handpiece hot.

To change rotary instrument in the Osscora contra-angle handpiece:

❶ Insert the instrument into the contra-angle handpiece until back stop (a). Activate press-button (b) and turn the instrument until it engages (c).

❷ Check secure location by applying slight axial tension.

❸ Remove the instrument by pushing the press-button.



14. Osscora contra-angle handpiece

Operation

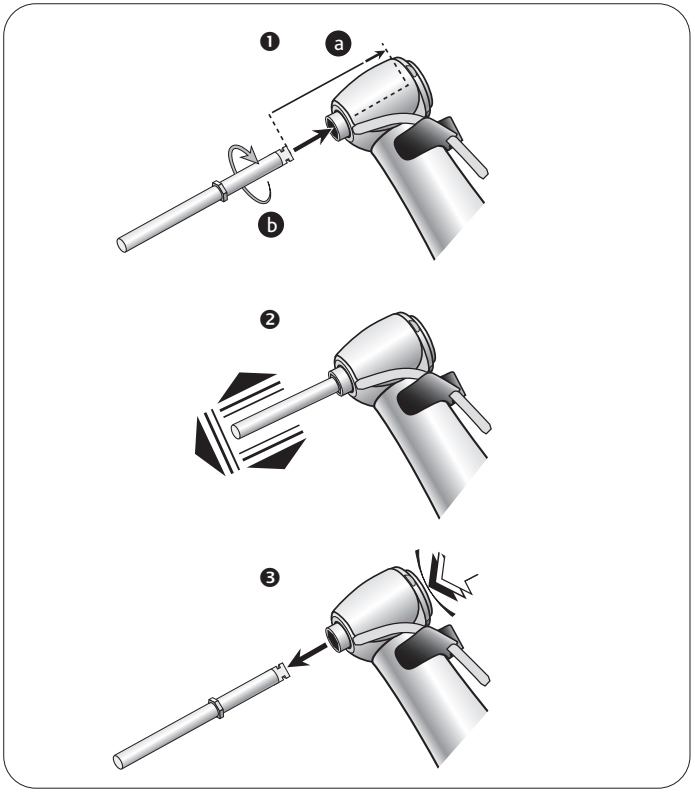
To change rotary instrument with hexagon in the Osscora contra-angle handpiece:

❶ Insert the instrument into the contra-angle handpiece until back stop (a) and turn until it engages (b).

❷ Check secure location by applying slight axial tension.

❸ Remove the instrument by pushing the press-button.

☞ Please contact your local Cochlear office for how to get an applicable rotary instrument with hexagon.



14. Osscora contra-angle handpiece

Operation

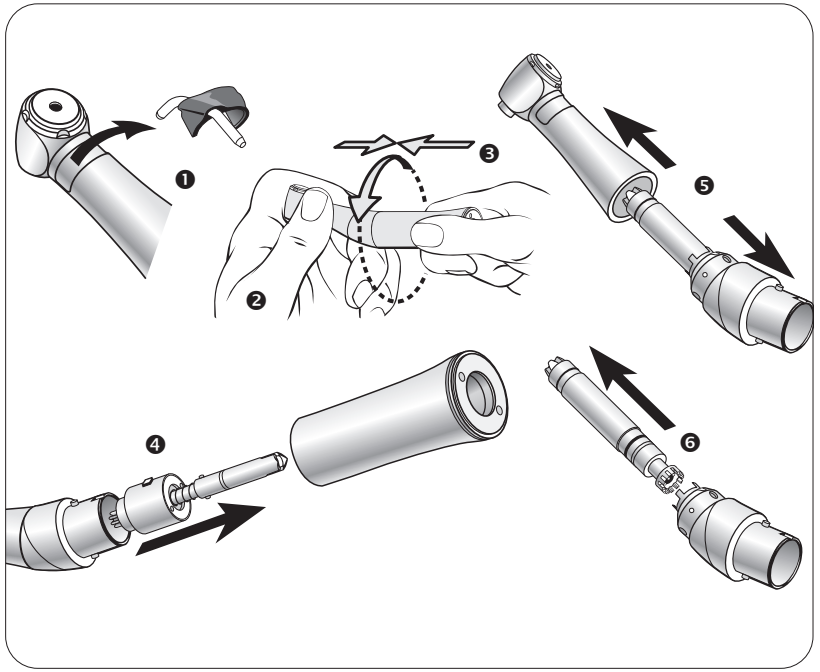
Test run

– Insert the rotary instrument.
– Start the contra-angle handpiece.
– If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) stop the motor immediately and contact your service agent. For contact details, please contact your local Cochlear office.

14. Osscora contra-angle handpiece

Disassemble Osscora contra-angle handpiece

❶ Remove the spray clip.
❷ Hold the contra-angle head firmly with one hand.
❸ Press sheath gently against the contra-angle knee. At the same time turn off the sheath from the knee.
❹ Remove the shaft.
❺ Remove the knee.
❻ Remove the middle gear from the knee.



14. Osscora contra-angle handpiece

Reassemble Osscora contra-angle handpiece

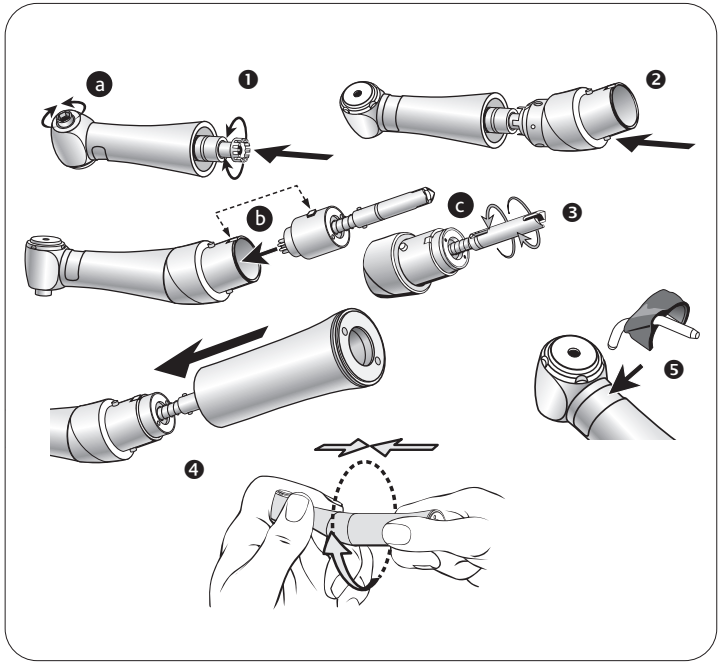
❶ Insert the middle gear into the contra-angle head. Check free running of the chucking system (a).

❷ Insert the knee (4 positions are possible) onto the contra-angle head until it engages.

❸ Put the shaft in the knee and mind the position of the rotational lock (b). Check free running rotation (c).

❹ Press the sheath firmly against the knee and turn until it engages.

❺ Attach the spray clip.



Only assemble components with corresponding type and serial number. Exception: components may be changed at service or repair - these may have a new serial number.

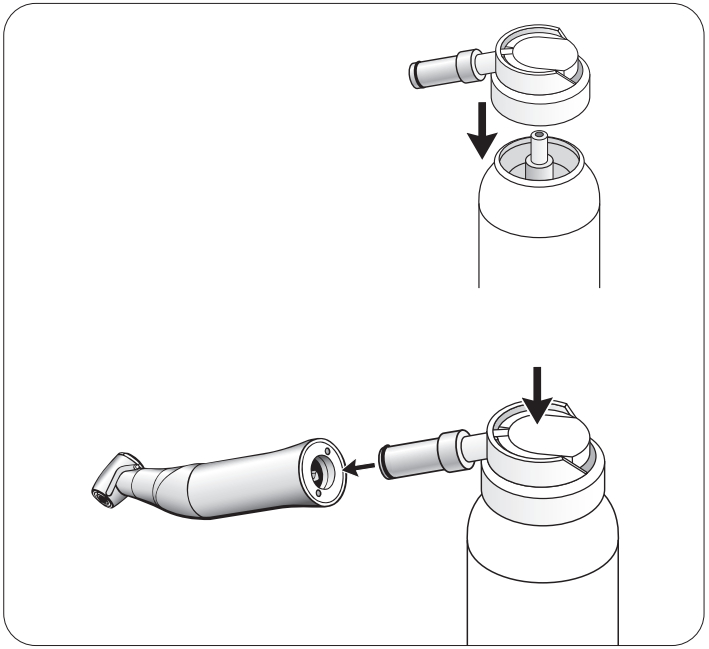
14. Osscora contra-angle handpiece

Oil service only with W&H Service Oil F1, MD-400.

For oil service, W&H Service Oil F1, MD-400 is recommended. For details on how to purchase this, contact your local Cochlear office.

– Follow the Instructions for Use of the oil spray can.

Recommended lubrication cycles
– Essential after every internal cleaning.
– Before each sterilisation.



14. Osscora contra-angle handpiece

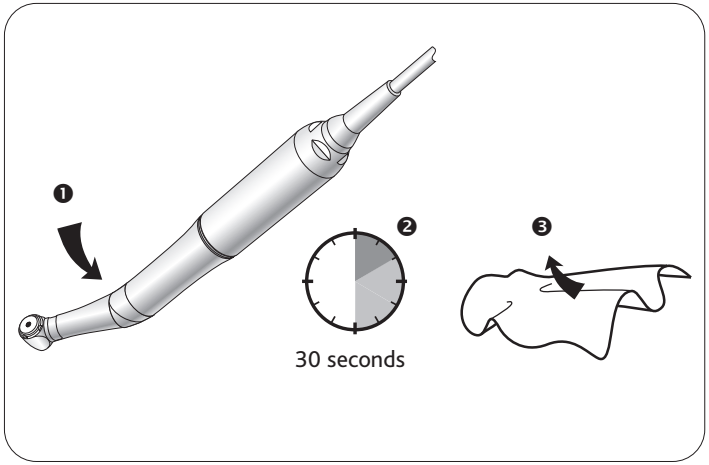
Test run following oil service

❶ Place the contra-angle handpiece with the head, downwards.

❷ Start the contra-angle handpiece for 30 seconds to remove excess oil. Start at the minimum speed and increase to the maximum speed within 5 to 10 seconds.

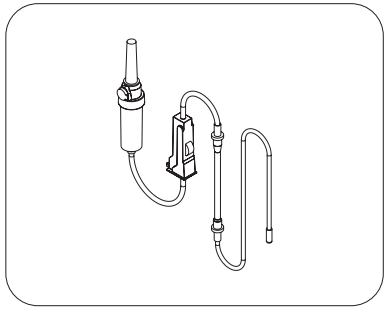
– Repeat the complete hygiene and maintenance process at any sign of dirt re-emerging.

❸ Wipe contra-angle handpiece with gauze or soft cloth.

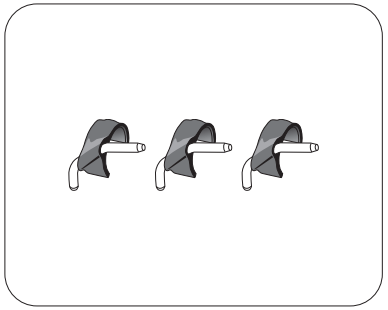


15. Osscora accessories

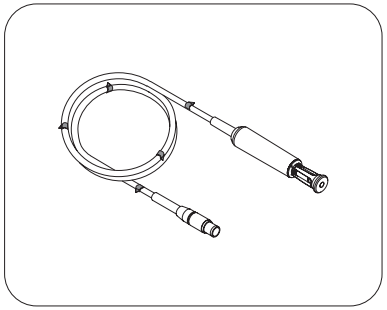
Use only original Cochlear accessories/spare parts
or accessories approved by Cochlear



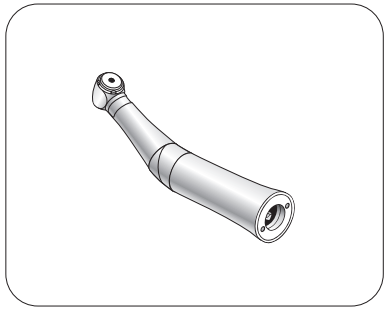
91061 Irrigation tubing set 3,8 m (6 pcs).



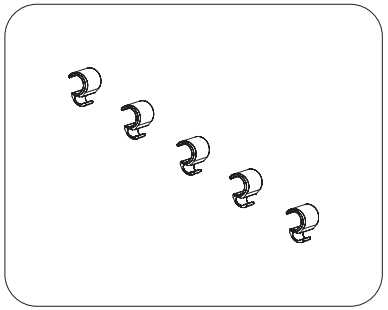
91891 Spray clip (for Osscora handpiece), (3 pcs).



91054 Osscora motor with 3,5 m cable.



91050 Osscora contra-angle handpiece.



92106 Clips for Osscora motor cable (5 pcs).

16. Servicing

Regular checking of Osscora surgical set and accessories
Regular servicing of function and safety of the Osscora surgical set including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organisation and needs to include the following procedures:

– Visual inspection for outside damage.
– Measurement of device leakage current.
– Measurement of patient leakage current.
– Visual inspection of internal components and electronic boards on suspicion of safety interference, e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components.

Regular checking of the foot control
– Visual inspection for outside damage.
– Measurement of enclosure leakage current.
– Functional test with check if the maximum speed can be reached.
- Measurement of ESD conductivity of the foot control (electro-static discharge)

We recommend that only authorised personnel undertake this servicing and checking. For details, please contact your local Cochlear office.

16. Servicing

Motor and cable
The standard ISO 11498 stipulates a durability of at least 250 sterilisation cycles. In the case of the motor with cable from Cochlear we recommend that you carry out a regular servicing after 500 sterilisation cycles, or one year.

Repairs
If a defect occurs, always return all the equipment, due to the fact that with motor malfunctions, an inspection of the electronic controls is also necessary!

Returns
– Refer all questions to your local Cochlear office.
– Always return equipment in the original packaging!

– Do not coil the cable around the motor and do not twist or kink the motor cable! (Risk of damage).

17. Technical data

	91053
Supply voltage:	100 – 130 V
Permitted voltage fluctuation:	± 10 %
Nominal current:	0.2 – 1.7 A
Frequency:	50 – 60 Hz
Mains fuse:	2x 250 V – T1.25AH
Max. power consumption:	170 VA
Max. mechanical output power:	70 W
Max. torque on the motor:	5.5 Ncm
Motor speed range in the nominal voltage range:	300 – 40,000 min.-1
Max. coolant in ml:	approx. 100 ml/min
Operating mode:	S3 (3min / 10min)
Dimensions in mm (WxDxH):	252 x 254 x 90
Set weight in kg:	4.10

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/UL 60601-1:

Equipment of Protective Class II (type of protection against electric shock).

Type B appliance (not suitable for intracardiac application).
Foot control conforms to Class AP according to IEC 60601-1/UL 60601-1 in danger zone M.

The foot control is watertight according to IPX8, 1m depth of immersion, 1 hour (water-tight according to IEC 60529).

Pollution degree: 2
Overvoltage category: II
Altitude: up to 3,000 m above sea level

17. Technical data

Physical characteristics

Temperature in storage and transport:	–40 °C (–40 °F) to +70 °C (+158 °F)
Air humidity in storage and transport:	8 % to 80 % (relative) non-condensing at +40 °C (+104 °F)
Temperature in operation:	+10 °C (+50 °F) to +40 °C (+104 °F)
Air humidity in operation:	15 % to 80 % (relative) non-condensing at +40 °C (+104 °F)

Technical data Osscora contra-angle handpiece

Transmission ratio	20:1
Colour coding	green
Motor coupling according to standard	ISO 3964
Rotary instruments, EN ISO 1797-1 (Ø mm)	2,35*
Length (of rotary instr.) approved by Cochlear (mm)	max. 45**

Disposal of the Osscora surgical set equipment
The equipment contains many valuable materials. Therefore return your equipment for material recycling via the relevant public collection system.
Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.
Ensure that the parts are not contaminated on disposal.

Disposal of the foot control
When the foot control is to be scrapped, it must be disposed of in accordance with local regulations.

Warranty
As manufacturer, Cochlear Bone Anchored Solutions AB is liable for material or manufacturing defects within a warranty period of one year from the date of purchase. Only Cochlear products and accessories, or products and accessories approved by Cochlear, should be used with each other in order to ensure that the warranty is maintained.

* When having a torque higher that 30 Ncm on the rotary instrument you have to use hardened shafts (>50 HRC, > 520 HV) (risk of deformation).
** When using a longer rotary instrument the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

Copy for the user/customer

Certification of training

Essential for EU user/customer

The user has been trained in all functions of the Osscora surgical set in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfection, cleaning, sterilisation and Servicing.

Osscora surgical set .....

Type .....

Serial Number.....

Name of the user/customer .....

Clinic, Department.....

Address.....

Signature .....

Name of the instructor.....

Address.....

Date .....

Signature .....

Cochlear®

Copy for the Medical Device Consultant

Certification of training

Essential for EU user/customer

The user has been trained in all functions of the Osscora surgical set in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfection, cleaning, sterilisation and Servicing.

Osscora surgical set .....

Type .....

Serial Number.....

Name of the user/customer .....

Clinic, Department.....

Address.....

Signature .....

Name of the instructor.....

Address.....

Date .....

Signature .....

Cochlear®

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