

Instructions for use



CE
0297



Surgical

Saw handpieces
S-8R, S-8S, S-80

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Symbole



WARNING!
(risk of injury)



ATTENTION!
(to prevent
damage occurring)



General explanations,
without risk to
persons or objects



Do not dispose of with
domestic waste

R_x_{only}












Caution!

According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.



Manufacturer

Symbols

| | | | | | |
|--|--|---|--|---|--|
|  | CE marking with identification number of the Notified Body |  | DataMatrix Code for product information including UDI (Unique Device Identification) |  | Data structure in accordance with Health Industry Bar Code |
|  | Catalogue number |  | Thermo washer disinfectable |  | Sterilizable up to the stated temperature |
|  | Serial number |  | UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements |  | Medical device |
|  | Date of manufacture | | |  | Consult Instructions for Use |

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Instructions for Use. These explain how to use your medical device and guarantee a smooth and efficient operation.



Observe the safety notes.

Intended use

Saw handpieces for cutting and separating bone substances mechanically in cranio-maxillo-facial surgery (CMF).



Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.



Qualifications of the user

We have based our development and design of the medical device on the physician target group.

Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

- > The medical device must be used in accordance with these Instructions for Use.
- > The medical device has no components that can be repaired by the user.
- > Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 47).



Skilled application

The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.



Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Safety notes



- > Before using the medical device for the first time, store it at room temperature for 24 hours.
- > The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- > In case of coolant supply failure, the medical device must be stopped immediately.
- > Check the medical device for damage and loose parts each time before using.
- > Do not operate the medical device if it is damaged.
- > Only attach the medical device onto the motor when the motor is at a complete standstill.
- > Perform a test run each time before using.
- > Avoid overheating at the treatment site.
- > The maximum permitted drive speed of 40,000 rpm must not be exceeded.
- > Tighten the clamping screw fully only when you have inserted a saw blade (risk of breakage).



- > Only use saw blades that are in perfect condition and be careful when the saw blade is moving.
- > Follow the operating instructions of the manufacturer.
- > Use only saw blades approved by W&H.
- > Change the saw blades after every treatment.
- > Insert the saw blade only when the medical device is stationary.
- > Do not interfere with the running or slowing down saw blade.
- > Contact between the tissue and the saw blade may result in injury.

Hygiene and maintenance prior to initial use

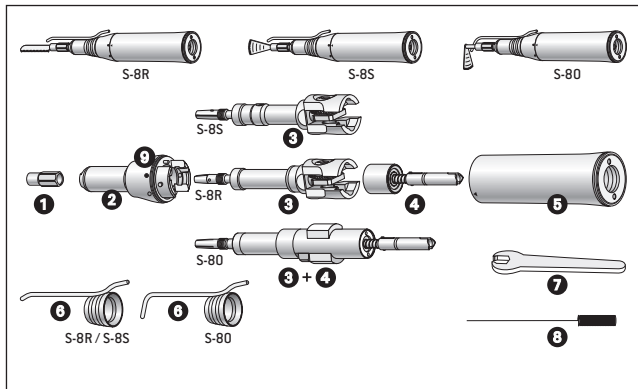


- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.

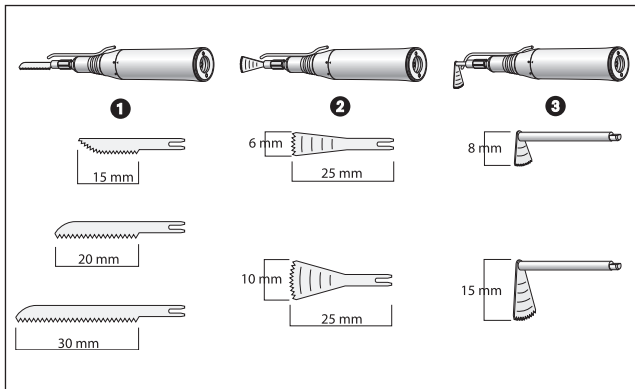


- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device, the saw blades, the coolant tube, the spanner and the nozzle cleaner.

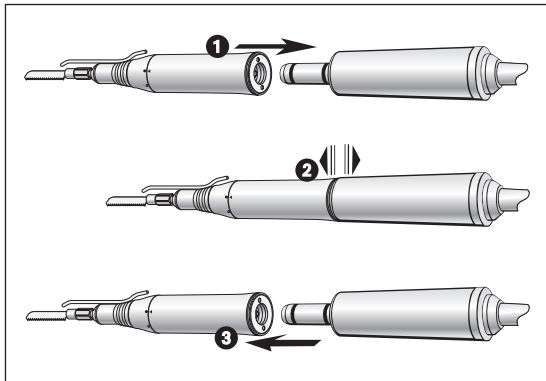
3. Product description



- 1 Clamping screw
 - 2 Handpiece tip
 - 3 Drive shaft
 - 4 Shaft
 - 5 Sheath
 - 6 External coolant tube
 - 7 Spanner
 - 8 Nozzle cleaner
 - 9 Symbol description
- Sheath open
● Sheath locked



- 1** Reciprocating
R-15, R-20, R-30
- 2** Sagittal
S-6, S-10
- 3** Oscillating
O-8, O-15



Do not assemble or remove the medical device during operation!

1

Push the medical device onto the motor.



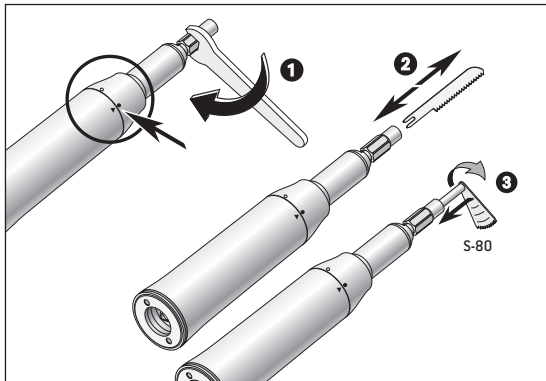
When using a locking pin between motor and medical device: See Instructions for use of the control unit.



2 Verify full engagement.

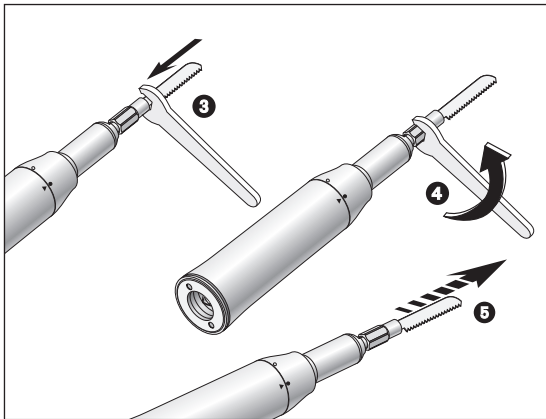
3

Remove the medical device.



To change saw blade

- 1** Undo the clamping screw with the spanner or by hand. Ensure that the sheath remains closed.
- 2** Insert the blade up to the limit stop or remove it.
Only for S-80: Press the saw blade and turn it until it engages audibly.



- 3** Guide the spanner to the clamping screw.
Use the spanner to tighten the clamping screw.



- 4** Verify full engagement.

Test run



Do not hold the medical device at eye level!

- > Insert saw blade.
- > Operate the medical device.



In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) **stop the medical device immediately** and contact an authorized W&H service partner.



- > Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



- > 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.

Cleaning agents and disinfectants



- > 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, for example 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.



The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

- > Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.

Processing cycles



- > We recommend a regular service for the W&H medical device after 500 processing cycles or one year.



Clean the medical device immediately after every treatment, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

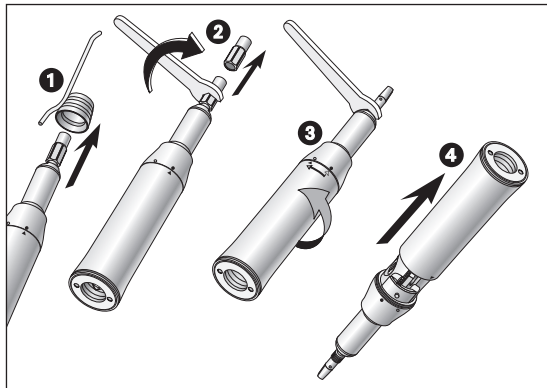
- > Operate the medical device for at least 10 seconds at idle speed.
- > Ensure that all outlets are rinsed out.



- > Wipe the entire surface of the medical device with disinfectant.
- > Remove the saw blade.
- > Remove the medical device.

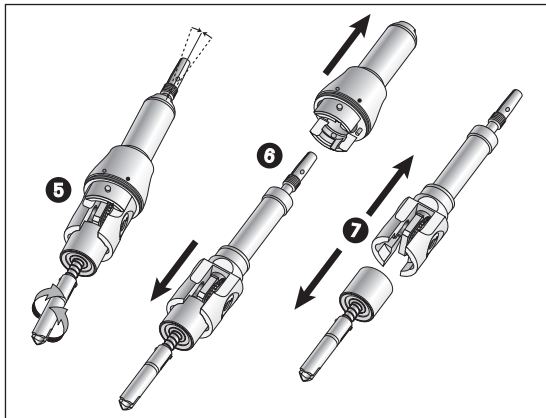


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.



Disassembly of the medical device

- 1 Pull off the external coolant tube.
- 2 Remove the clamping screw from the drive shaft with the spanner or by hand.
- 3 Position the spanner on the upper part of the handpiece tip. Loosen the handpiece tip from the sheath by simply turning it from ● to ○.
- 4 Remove the sheath from the handpiece tip.

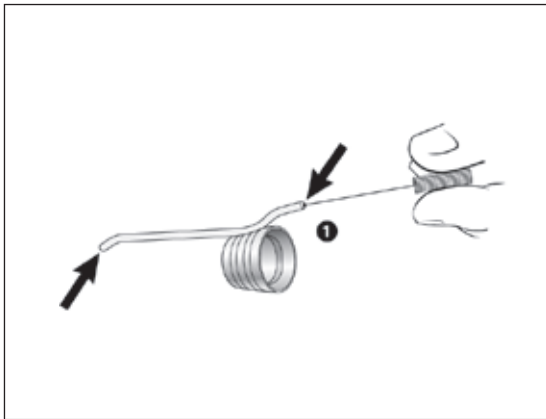


- 5 Ensure that the drive shaft is positioned exactly in the centre. If necessary, correct the position by turning the shaft to the left or right.
- 6 Remove the lower shaft and drive shaft from the handpiece tip.
- 7 Pull the lower shaft and drive shaft apart.




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

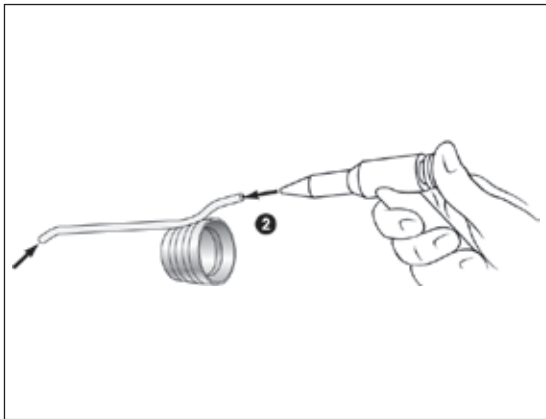
- > Clean the medical device under running tap water (< 35°C / < 95°F).
- > Rinse and brush off all internal and external surfaces.
- > Move moving parts back and forth several times.
- > Remove liquid residues using compressed air.



Cleaning of the coolant tube

 The coolant tube and the nozzle cleaner can be cleaned in an ultrasonic bath and/or in the washerdisinfector.

- 1** Clean coolant tube carefully with the nozzle cleaner to remove dirt and deposits.



2 Blow through the coolant tube and coolant outlets using compressed air.



In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner.



> W&H recommends wiping down with disinfectant.



Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the disinfectants "mikrozid® AF wipes" (Schülke & Mayr GmbH, Norderstedt) and "CaviWipes™" (Metrex).



W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).

- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer disinfectors, cleaning agents and/or disinfectants.

External coolant tubes and spray clips

Only use approved and validated adaptors for products with voids for your thermal washer disinfector.



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

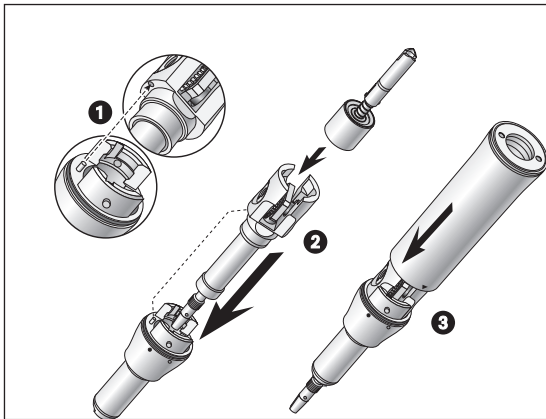


- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove any liquid residues using compressed air.

Inspection



- > Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
- > Reprocess any medical devices that are still soiled.
- > Sterilize the reassembled medical device following cleaning, disinfection and lubrication.



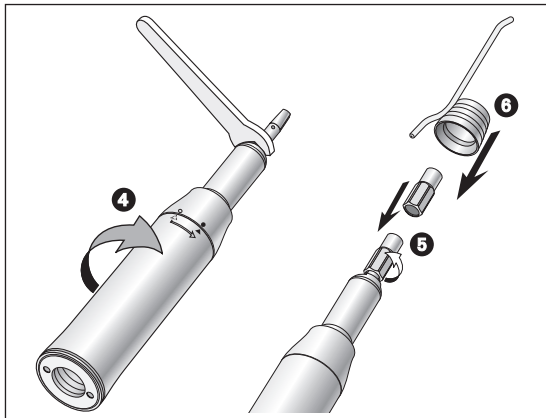
Reassembling the medical device



Reassemble the medical device following manual cleaning and disinfection.

> Types and serial numbers must be identical

- 1 Push the pin of the handpiece tip into the hole in the drive shaft.
- 2 Push the shaft into the drive shaft.
- 3 Position the sheath onto the front of the handpiece tip and turn until it engages.



! Do not tighten the clamping screw fully
(risk of breakage)

- 1 Position the spanner on the upper part of the handpiece tip. Fix the handpiece tip with the sheath by simply turning it from ○ to ●.
- 2 Screw the clamping screw onto the drive shaft.
- 3 Attach coolant tube.

Lubrication



- > Lubricate the dry medical device immediately after cleaning and disinfection.

Recommended lubrication cycles

- > Essential after every internal cleaning
- > Before each sterilization

With W&H Service Oil F1, MD-400

- > Follow the instructions on the oil spray can and on the packaging.
- or

With W&H Assistina

- > Follow the instructions in the Assistina Instructions for Use.

Test after lubrication



- > Direct the medical device downwards.
- > Operate the medical device so that excess oil can escape.
- > Remove any oil that has escaped.
- > Excess oil may result in the medical device overheating.



Pack the medical device and the accessories in sterilization packages that meet the following requirements:

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



W&H recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST55.



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



- > Sterilize the medical device, the saw blades, the coolant tube, the spanner and the nozzle cleaner.

Recommended sterilization procedures

- > “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
- > Maximum sterilization temperature 135°C (275°F)



Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

| | |
|---|--|
| “Dynamic-air-removal prevacuum cycle” (type B): | 134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/** |
| “Steam-flush pressure-pulse cycle” (type S): | 134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/** |
| “Gravity-displacement cycle” (type N): | 121°C (250°F) – 30 minutes** |
| Drying times: | |
| “Dynamic-air-removal prevacuum cycle” (type B): | 132°C (270°F) – 30 minutes** |
| “Steam-flush pressure-pulse cycle” (type S): | 132°C (270°F) – 30 minutes** |
| “Gravity-displacement cycle” (type N): | 121°C (250°F) – 30 minutes** |

* EN 13060, EN 285, ISO 17665

** ANSI/AAMI ST55, ANSI/AAMI ST79



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

6. Servicing

Repairs and returns

In the event of operating malfunctions immediately contact an authorized W&H service partner.

Repairs and maintenance work must only be undertaken by an authorized W&H service partner.



- > Ensure that the medical device has been completely processed before returning it.

7. Accessories, consumables, spare parts and other recommended medical devices by W&H



Use only original W&H accessories and spare parts or accessories approved by W&H.

Supplier: W&H partners

04580000 Clamping screw

04740200 Spanner

00636901 Nozzle cleaner

Scan the QR code to find accessories, consumables and spare parts for this medical device.



8. Technical data

| | | S-8R | S-8S | S-80 |
|--------------------------------------|----------------------|----------|------------|-------------|
| Transmission ratio | | 3.25:1 | 3.25:1 | 3.4:1 |
| Motor coupling according to standard | | ISO 3964 | ISO 3964 | ISO 3964 |
| Maximum rated speed* | [min ⁻¹] | 40,000 | 40,000 | 40,000 |
| Saw frequency at maximum rated speed | [min ⁻¹] | 12,300 | 12,300 | 11,800 |
| Blade movement | | 1.8 mm | approx. 3° | approx. 12° |

min⁻¹ (Revolutions per minute)



* For safe use, follow the respective manufacturer's instructions regarding maximum rated speed.

Temperature information



| | |
|---|------------------------|
| Temperature of the medical device on the operator side: | maximum 55°C (131°F) |
| Temperature of the medical device on the patient side: | maximum 50°C (122°F) |
| Temperature of the working part (saw blade): | maximum 41°C (105.8°F) |

Ambient conditions

| | |
|--|---|
| Temperature during storage and transport: | -40°C to +70°C (-40°F to +158°F) |
| Air Humidity during storage and transport: | 8 % to 80 % (relative), non-condensing |
| Temperature during operation: | +10°C to +35°C (+50°F bis +95°F) |
| Air Humidity during operation: | 15 % to 80 % (relative), non-condensing |

9. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.

- > Medical device
- > Packaging

Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for use have been followed.

As the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase. Accessories and consumables are excluded from the warranty.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty accompanied by proof of purchase must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 months warranty

Authorized W&H service partners

Find your nearest authorized W&H service partner at <http://wh.com>
Simply go to the menu option »Service« for full details.

Or simply scan the QR code.





W&H Dentalwerk Bürmoos GmbH

Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria

t + 43 6274 6236-0,

office@wh.com

f + 43 6274 6236-55

wh.com

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