

Instructions for use



CE
0297

PEOPLE HAVE PRIORITY



Surgical

Contra-angle handpieces
WS-56 L, WS-75 L, WS-91 L, WS-92 L
with mini LED+

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Symbols in the Instructions for use



WARNING!
(risk of injury)



ATTENTION!
(to prevent
damage occurring)



General explanations,
without risk to
persons or objects



Do not dispose of
with domestic waste

Caution!

According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices, and who intends to use or order the use of this medical device.

Symbols on the medical device / packaging



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



Date of manufacture

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.

Intended use

Surgical treatment of dental hard tissue.



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

Qualifications of the user

The medical device is intended for use by suitably qualified, medical, technical and specialist staff only.
We have based our development and design of the medical device on the physician target group.



Production according to EU Directive

The medical device meets the requirements of Directive 93/42/EEC.



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 55).

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.

Service

In the event of operating malfunctions immediately contact an authorized W&H service partner (see page 55). Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

2. Safety notes



- > Operation of the medical device is permitted only on dental units which correspond to the Medical Device Directive.
- > 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 (e.g., push-button).
- > 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.
- > Never touch the push-button of the medical device during operation or while it is still running down.
- > Never touch the rotary instrument while it is still rotating.
- > Perform a test run each time before using.
- > Avoid overheating at the treatment site.



- > Do not touch the soft tissue with the contra-angle head (risk of burning due to the push-button heating up)!
- > Avoid contact between LED and soft tissue (risk of burning due to the LED heating up).
- > Do not use the medical device as a light sensor.
- > Do not look directly into the LED.



Danger zones M and G

In accordance with IEC 60601-1 / ANSI/AAMI ES 60601-1, the medical device is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



The medical device is not suitable for use in oxygen enriched atmospheres.



Zone M is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary.

Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.



Risks due to electromagnetic fields

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

- > Find out if patient and user have implanted systems before using the medical device and consider the application.
- > Weigh the risks and benefits.
- > Keep the medical device away from implanted systems.
- > 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.

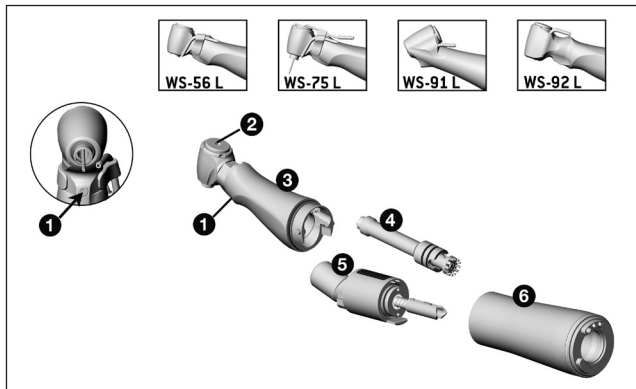
Hygiene and maintenance prior to initial use



The medical device is in a clean condition and sealed in PE-film when delivered.

- > Lubricate the medical device.
- > Sterilize the medical device, the nozzle cleaner, the Y-manifold, the spray clips and the coolant tube for internal bur cooling.
- > Oil service page 37, 40
- > Sterilization page 44

3. Product description



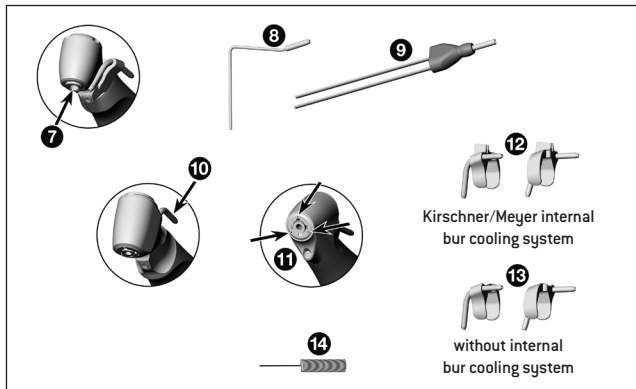
WS-56 L, WS-75 L, WS-91 L, WS-92 L

- ①** LED
- ②** Push-button
- ③** Contra-angle head*
- ④** Middle gear
- ⑤** Knee
- ⑥** Sheath*

*** Symbols on parts ③ and ⑥**

- ▲ Sheath open
- ↔ Direction of rotation
- ▲ Sheath locked

3. Product description – Continuation



WS-75 L

- ⑦ Hexagon chucking system
- ⑧ Coolant tube for internal bur cooling
- ⑨ Y-manifold

WS-91 L, WS-92 L

- ⑩ External coolant tube
- ⑪ Spray nozzles

WS-56 L, WS-75 L

- ⑫ ⑬ Spray clips for the left and right

WS-56 L, WS-75 L, WS-91 L, WS-92 L

- ⑭ Nozzle cleaner

4. Operation – Assembly/Removal



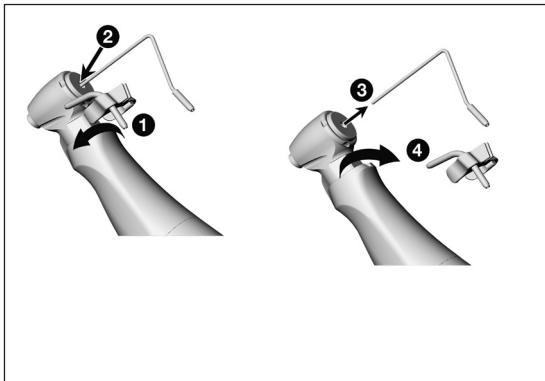
Do not assemble or remove the medical device during operation!



The medical device is matched to W&H electric motor EM-19 LC / EM-19 and to W&H Implantmed SI-10xx. You can only make full use of all the medical device's advantages in this combination (e.g., constant illumination at every speed).



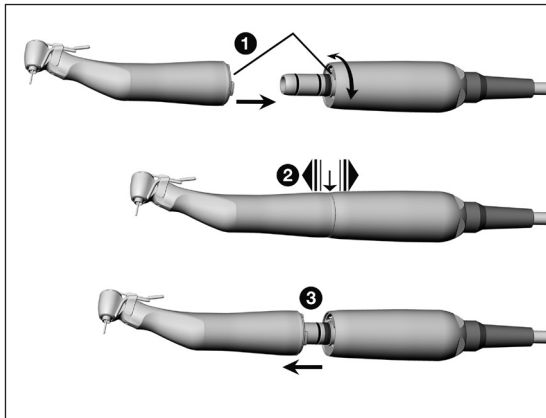
The medical device may only be used with W&H electric motor EM-19 LC / EM-19.
The user accepts sole responsibility if the medical device is used on other electric motors.
The manufacturer accepts no liability.



WS-56 L
Spray clip

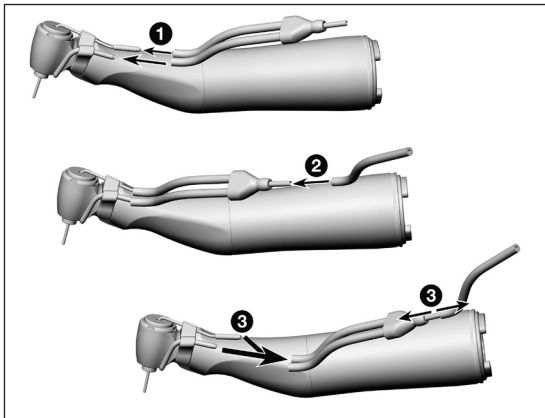
WS-75 L
Spray clip
Coolant tube for internal bur cooling

- ① Attach the spray clip.
- ② Insert the coolant tube for internal bur cooling.
- or
- ③ Remove the coolant tube for internal bur cooling.
- ④ Remove the spray clip.



Medical device

- ➊ Push the medical device onto the motor and turn until it engages audibly.
 - ➋ Check the secure hold on the motor.
- or
- ➌ Remove the medical device from the motor by pulling in an axial direction.



WS-75 L

Y-manifold



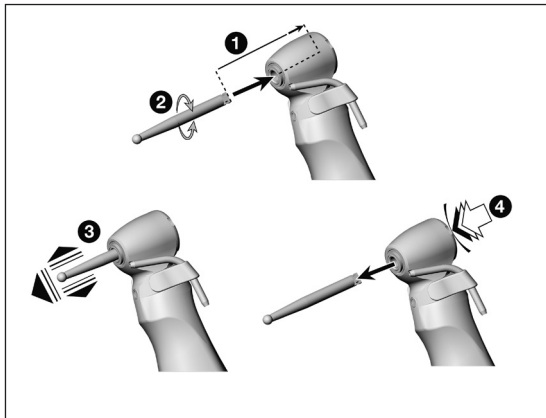
Only when using the coolant tube for internal bur cooling.

- ❶ Insert the coolant hose of the Y-manifold onto the coolant tube of the spray clip and onto the coolant tube for internal bur cooling.
- ❷ Insert the Y-manifold into the irrigation tubing.
or
- ❸ Remove the Y-manifold.

Rotary instruments



- > Use only rotary instruments which are in perfect condition and pay attention to the direction of rotation of the rotary instrument. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when the medical device is stationary.
- > Never touch the rotary instrument while it is still rotating.
- > Do not activate the push-button of the medical device during operation. This leads to detachment of the rotary instrument and/or makes the medical device hot.



To change the rotary instrument

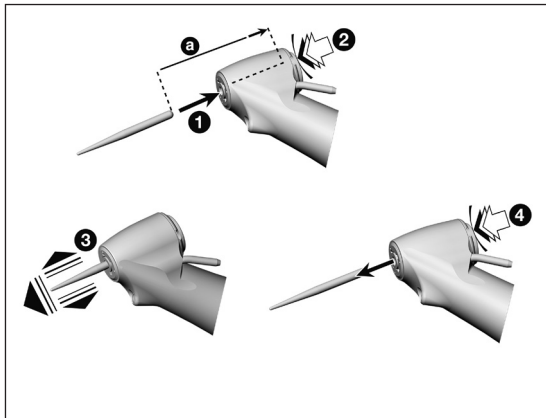
WS-56 L

> Instrument shaft diameter 2.35 mm

- ➊ Insert the rotary instrument until the limit stop.
- ➋ Turn the rotary instrument until it engages.
- ➌ Check secure location by applying slight axial tension.

or

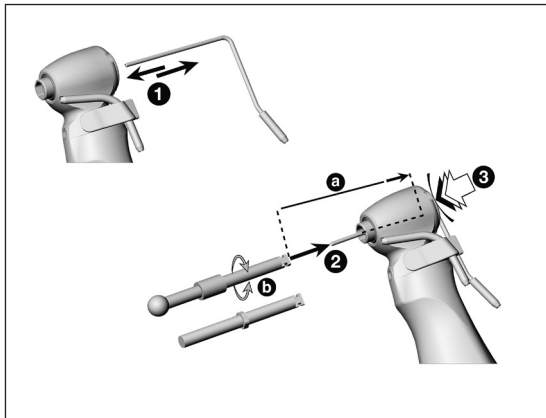
- ➍ Activate the push-button and remove the rotary instrument.



WS-91 L, WS-92 L

> Instrument shaft diameter 1.6 mm

- ① Insert the rotary instrument.
 - ② Activate the push-button, at the same time insert the rotary instrument until the limit stop [a].
 - ③ Check secure location by applying slight axial tension.
- or
- ④ Activate the push-button and remove the rotary instrument.



WS-75 L

- > *Using internal bur cooling*
- > Without using internal bur cooling
- > With hexagon
- > Instrument shaft diameter 2.35 mm

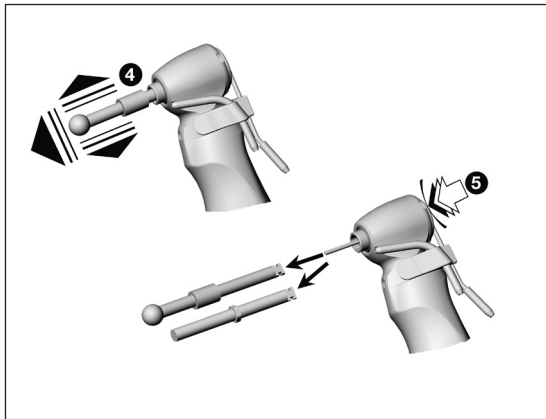
❶ *Insert the coolant tube for internal bur cooling.*

or

❶ Remove the coolant tube for internal bur cooling.

❷ Insert the rotary instrument *over the coolant tube* until the limit stop [a].

❸ Activate the push-button and turn the rotary instrument until it engages [b].



④ Check secure location by applying slight axial tension.

or

⑤ Activate the push-button and remove the rotary instrument.



Ask your implant supplier for an applicable rotary instrument with hexagon.

Test run




Do not hold the medical device at eye level.


- > Insert the rotary instrument.
- > Place the medical device with the contra-angle head positioned downwards.
- > Start the medical device.




In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) or discoloration of the LED, **stop the medical device immediately** and contact an authorized W&H service partner (see page 55).

5. Hygiene and maintenance

- 
 - > Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.
 - > You can process the medical device manually or mechanically.

- 
 - > Wear protective clothing.
 - > Remove medical device from the motor.
 - > Remove the rotary instrument.

- 
 - > Clean and disinfect 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.



After manual cleaning, disinfection and lubrication you must carry out a final sterilization (wrapped) in the class B or S steam sterilizer according to EN 13060.

For Canada: Hospital grade sterilization with pre and post vacuum cycle.

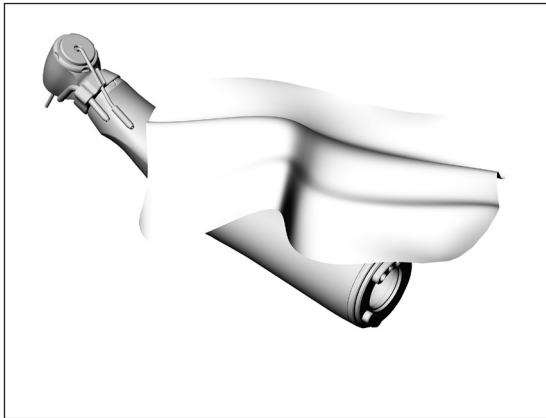


Reassemble the medical device following manual cleaning and disinfection.

- > Without spray clip
- > Types and serial numbers must be identical



- > Sterilize the reassembled medical device following manual or mechanical cleaning, disinfection and lubrication.
- > Sterilize the spray clip.

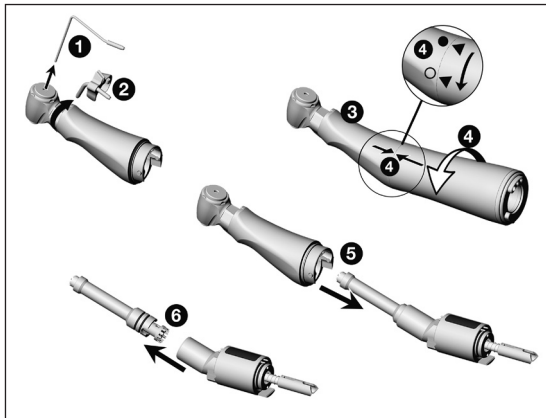


Pre-disinfection

- > If heavily soiled: Clean first with disinfectant cloths.

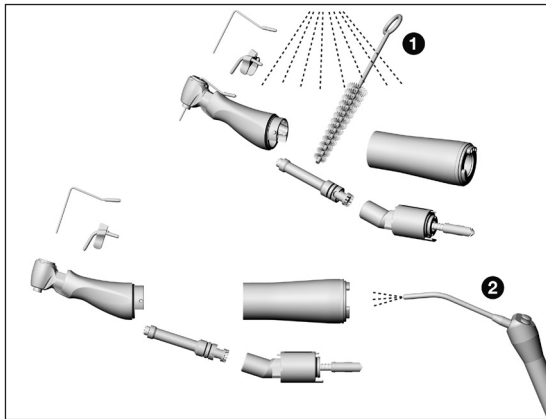


Only use disinfectants that have no protein-fixing effects.



Disassembling the medical device

- ❶ Remove the coolant tube for internal bur cooling.
- ❷ Remove the spray clip.
- ❸ Hold the contra-angle head firmly with one hand.
- ❹ Press sheath gently against knee. At the same time twist the sheath off the knee.
- ❺ Remove the knee from the contra-angle head.
- ❻ Remove the middle gear from the knee.

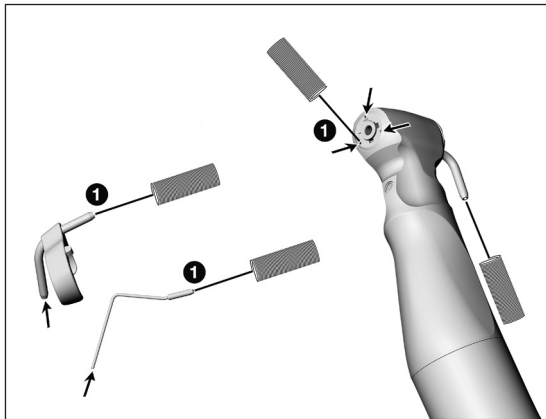


Manual cleaning internal and external

- 1 Rinse and brush off under demineralized water ($< 38^{\circ}\text{C}$ / $< 100^{\circ}\text{F}$).
- 2 Remove any liquid residues (absorbent cloth, blow dry with compressed air).



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

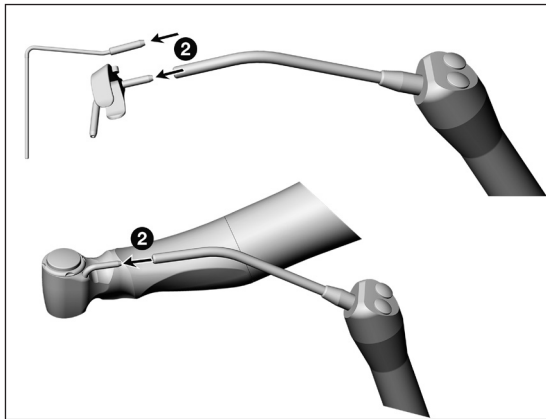


Cleaning the external coolant tubes WS-91 L, WS-92 L: Cleaning the spray nozzles



The coolant tube for internal bur cooling, the spray clips and the nozzle cleaner can be cleaned in an ultrasonic bath.

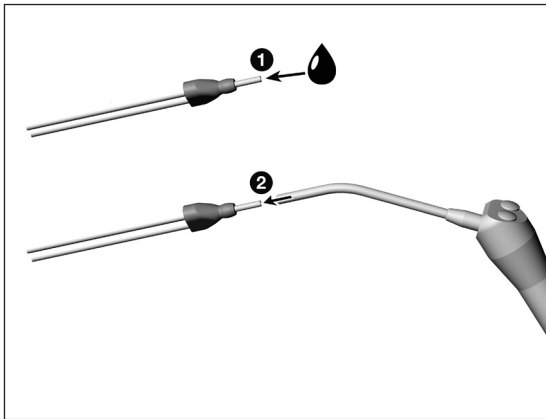
- 1 Clean coolant outlets carefully with the nozzle cleaner to remove dirt and deposits.



- 2** Blow through the coolant tube and coolant outlets with compressed air.



In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner (see page 55).



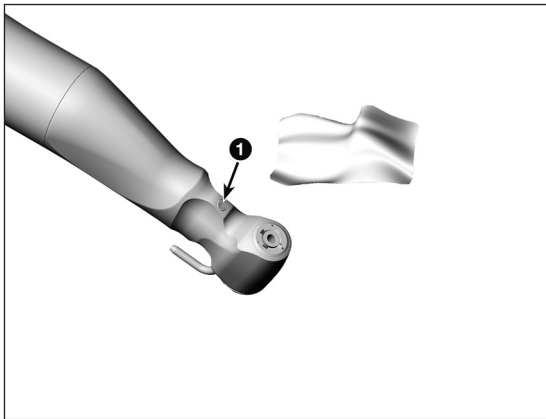
WS-75 L

Cleaning the Y-manifold



The Y-manifold can be cleaned in an ultrasonic bath and/or in a thermo washer disinfectant.

- ❶ Rinse with demineralized water [$< 38^{\circ}\text{C}$ / $< 100^{\circ}\text{F}$].
- ❷ Remove any liquid residues using compressed air.

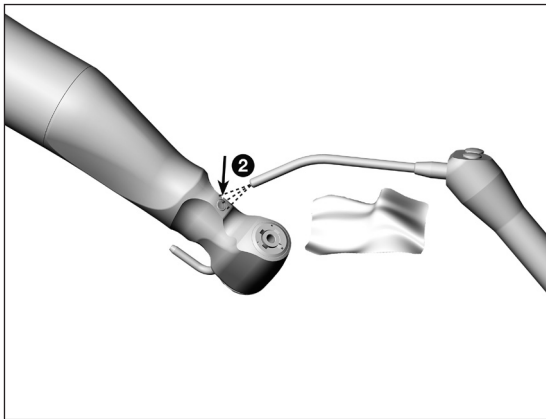


Cleaning the LED



Avoid scratching the LED!

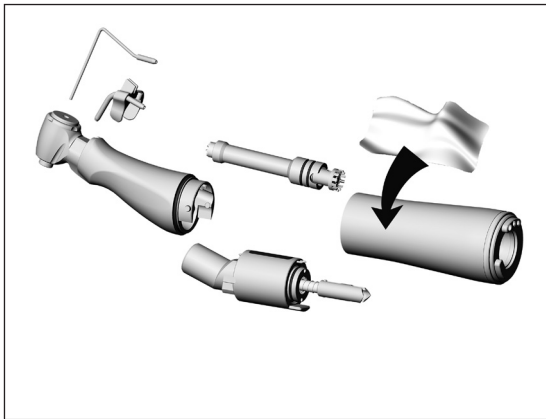
- 1 Wash the LED with cleaning fluid and a soft cloth.



- 2** Blow the LED dry with compressed air or dry it carefully with a soft cloth.



Carry out a visual inspection after each cleaning process.
Do not use the medical device if the LED is damaged and contact an authorized W&H service partner (see page 55).



Manual disinfection



W&H recommends wiping down with disinfectant.

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

Mechanical cleaning internal and external and lubrication



W&H recommends mechanical cleaning and lubrication with W&H Assistina 3x3.

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

Mechanical cleaning and disinfection internal and external

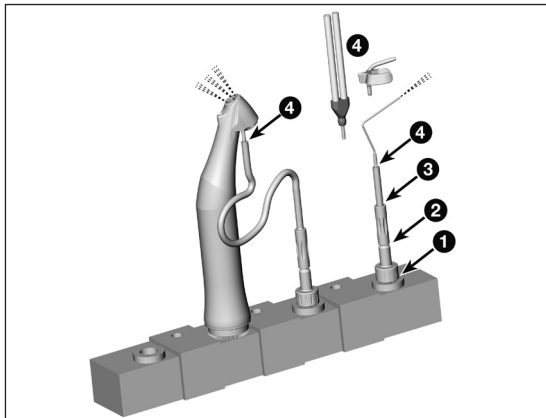


The medical device can be cleaned and disinfected in a thermo washer disinfectant.

- > Use the W&H adaptor kit for the thermo washer disinfectant to prepare the external coolant tubes and spray clips.
- > Note the manufacturer's specifications on equipment, cleaning agents and detergents.



- > Make sure the medical device is completely dry internally and externally after thermo washer disinfection. Remove any liquid residues with compressed air.
- > Lubricate the dry medical device immediately after thermo washer disinfection.

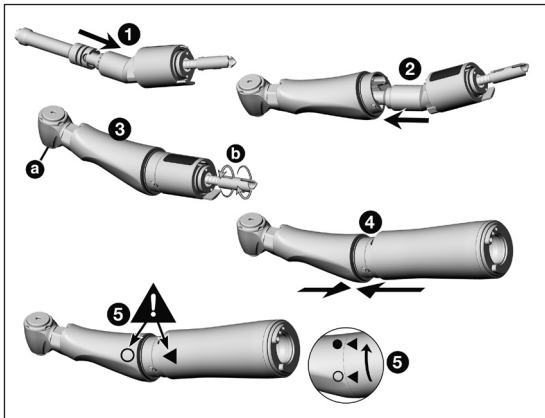


Mechanical cleaning and disinfection of the external coolant tubes



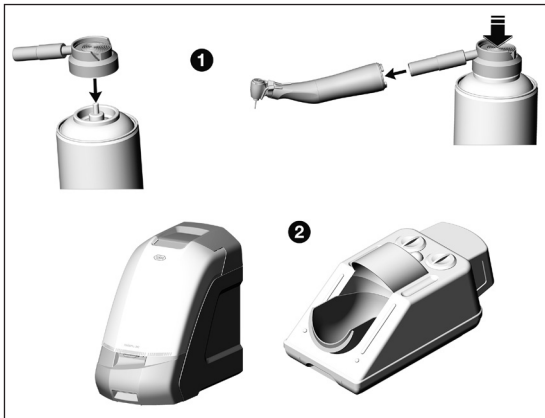
Use the W&H adaptor kit REF 07233500 for the thermo washer disinfecter.

- 1 Screw the W&H adaptor into the adaptor on the injector rail.
- 2 Screw the W&H intermediate adaptor onto the W&H adaptor.
- 3 Put the W&H silicone hose over the W&H intermediate adaptor.
- 4 Insert the external coolant tube, the coolant tube for internal bur cooling, the Y-manifold or the spray clip into the W&H silicon hose.



Reassembling the medical device

- ➊ Insert the middle gear into the knee.
- ➋ Insert the knee into the contra-angle head.
- ➌ Check free running of the chucking system (a) and shaft (b).
- ➍ Insert the sheath onto the contra-angle head.
- ➎ Note the symbols and turn until locked.



Daily oil service

Recommended lubrication cycles

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

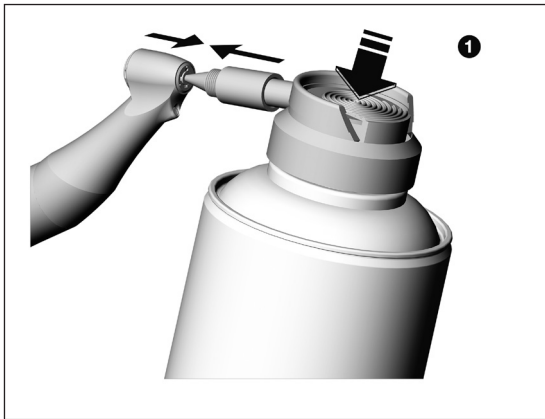
❶ With W&H Service Oil F1, MD-400

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

or

❷ With W&H Assistina

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



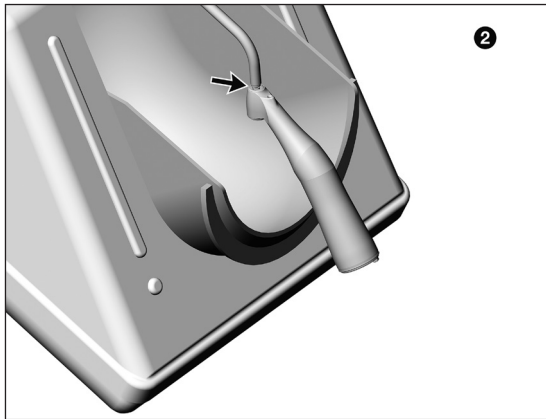
WS-91 L, WS-92 L

Weekly oil service of the chucking system

① With W&H Service Oil F1, MD-400

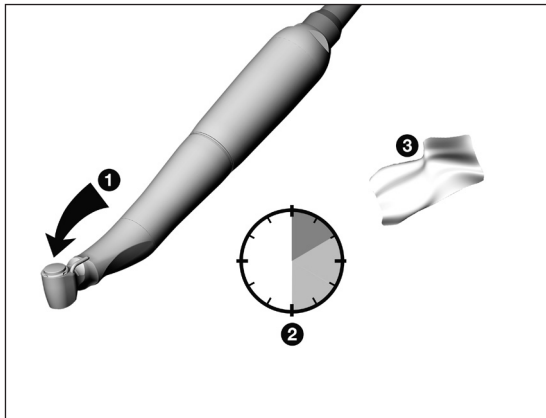
- > Fit the spray cap REF 02036100 onto the oil spray can.
- > Hold the medical device firmly.
- > Press the tip of the spray nozzle firmly into the chucking system.
- > Spray for approximately 1 second.

or



2 Only with W&H Assistina 301

- > Fit the adaptor REF 02693000 onto the maintenance attachment. Direct exit nozzle downwards.
- > Press the medical device with the chucking system onto the adaptor from below.
- > Start the Assistina.
- > Press the chucking system onto the adaptor for approximately 10 seconds.
- > Remove the medical device from the adaptor.
- > Close the cover of the Assistina and allow it to run for the remainder of the maintenance cycle [approximately 25 seconds].



Test run following oil service

- 1 Place the medical device with the contra-angle head positioned downwards.
- 2 Start the medical device 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.

- 3 Wipe the medical device with gauze or soft cloth.

Sterilization and storage



- > Pull off the spray clip from the medical device before sterilizing.
- > Sterilize the spray clip and the medical device.



W&H recommends sterilization according to EN 13060, class B.

For Canada: Hospital grade sterilization with pre and post vacuum cycle.

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect and lubricate the medical device before sterilizing.
- > Wrap the medical device and the accessory in sterile goods packing according to EN 868-5.
For Canada: Place the medical device and the accessory in a standard handpiece sterilization pouch.
- > Make sure that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.



Y-manifold

W&H recommends that the Y-manifold is replaced after 50 sterilization cycles.



Medical device

The standard ISO 14457 stipulates a durability of at least 250 sterilization cycles.

In the case of the medical device from W&H, we recommend you to have a regular service carried out after 500 sterilization cycles or one year.

Approved sterilization procedures

- > Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060. Sterilization holding time a minimum of 3 minutes at 134 °C (273 °F). Required pressure -0.85 bar (-12.3 psi) up to 2.16 bar (31.3 psi).
- or
- > Steam sterilization class S with sterilizers in accordance with EN 13060. The sterilizer manufacturer must give its express approval for the sterilization of the medical device. Sterilization holding time a minimum of 3 minutes at 134 °C (273 °F).

For Canada

- > Steam vacuum sterilization (hospital grade sterilization), 4 minutes at 134 ± 2 °C (273 ± 4 °F) or
- > Gravity displacement sterilization, 6 minutes at 134 ± 2 °C (273 ± 4 °F)
- > All other sterilization methods are not approved and must not be used.

6. W&H Accessories and spare parts



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

Suppliers: W&H partners

000301xx Assistina 301 plus

19922000 Assistina 3x2 (MB-200)

19923000 Assistina 3x3 (MB-300)

02693000 Assistina adaptor for chucking system

10940021 Service Oil F1, MD-400 (6 pcs)

02038200 Spray cap with nozzle

02036100 Spray cap with nozzle for chucking system

07233500 Adaptor kit for the thermo washer disinfecter

02015101 Nozzle cleaner

06016400 Y-manifold (3 pcs)

02610500 Coolant tube for internal bur cooling

Spray clip for the left (3 pcs)

06946300 Kirschner/Meyer internal bur cooling system

06948400 Without internal bur cooling system

Sprayclip for the right (3 pcs)

06948300 Kirschner/Meyer internal bur cooling system

06949500 Without internal bur cooling system

7. Technical data

		WS-75 L
Transmission ratio		20:1
Colour coding		green
Permitted motor connection	(W&H)	EM-19 LC / EM-19
Rotary instruments	ISO 1797-1 (Ø mm)	2.35*
Maximum permitted bur length	(mm)	45**
Minimum chucking length		engaging
Maximum drive speed	(min ⁻¹)	50,000
Coolant volume	ISO 14457 (ml/min)	> 50
Maximum torque at rotary instrument	(Ncm)	70*
Using rotary instrument with hexagon	(Ncm)	105*

min⁻¹ (Revolutions per minute)

* When having a torque higher than 30 Ncm on the rotary instrument you have to use hardened shafts (>50 HRC, >520 HV) (risk of deformation).

** When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

7. Technical data

		WS-56 L	WS-91 L / WS-92 L
Transmission ratio		1:1	1:2.7
Colour coding		blue	orange
Permitted motor connection	(W&H)	EM-19 LC / EM-19	
Rotary instruments	ISO 1797-1 (Ø mm)	2.35	1.6
Maximum permitted bur length	(mm)	34**	25**
Minimum chucking length		engaging	until limit stop
Maximum drive speed	(min ⁻¹)	50,000	
Coolant volume	ISO 14457 (ml/min)	> 50	

min⁻¹ (Revolutions per minute)

** When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

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 (rotary instrument):

maximum 41 °C (105.8 °F)

Ambient conditions

Temperature for storage and transport:

-40 °C to +70 °C (-40 °F to +158 °F)

Air humidity for storage and transport:

8% to 80% (relative), non-condensing

Ambient temperature during operation:

+10 °C to +35 °C (+50 °F to +95 °F)

Air humidity during operation:

15% to 80% (relative), non-condensing

8. Disposal



Ensure that the parts are not contaminated on disposal.



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

- > Medical device
- > Waste electrical equipment
- > Accessories, consumables, spare parts
- > Packaging

Explanation of warranty terms

This medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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 manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase. Accessories and consumables (coolant tube, spray clips, nozzle cleaner, spray cap with nozzle, adaptor kit) 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.

24 months warranty

Authorized W&H service partners

Find your nearest W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

W&H (UK) Limited, Unit 6, Stroud Wood Business Centre, Park Street, St Albans, AL2 2NJ Hertfordshire
t +44 1727 874990, f +44 1727 872254, E-Mail: technical.uk@wh.com

W&H Impex Inc., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
t +1 519 944 6739, f +1 519 974 6121, E-Mail: service.ca@wh.com

W&H Austria GmbH, Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria
t +43 6274 6236-239, f +43 6274 6236-890, E-Mail: office.at@wh.com

A-DEC Australia, *Office and showroom*, Unit 8, 5-9 Ricketty Street, 2020 Mascot NSW
t +61 2 8332 4000, f +61 2 8332 4099, E-Mail: a-dec@a-dec.com.au

Manufacturer

W&H Dentalwerk Bürmoos GmbH

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