

PEOPLE HAVE PRIORITY



Instructions for Use



CE
0297

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!
(if persons could
be injured)



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, 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 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.



Observe the safety notes.

Intended use

Surgical treatment of organic hard tissue.




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.

Production according to EU Directive

 The medical device meets the requirements of Directive 93/42/EEC.
0297

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 57).

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.

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 coolant function.
- > Always ensure that sufficient and adequate coolant 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.
- > 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.
- > 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 probe.
- > Do not look directly into the LED.



The medical device is not approved for operation in potentially explosive atmospheres.

Risks due to electromagnetic fields



The functionality of implantable systems, such as cardiac pacemaker 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

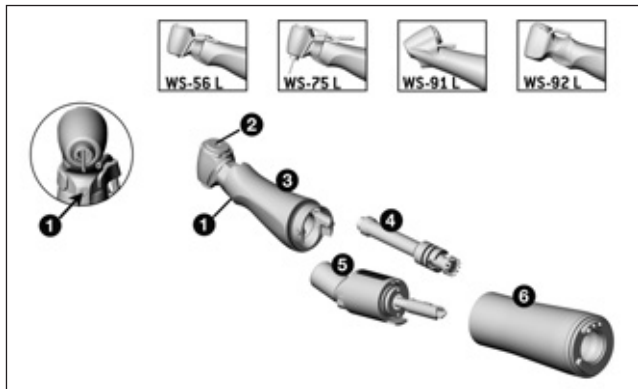


- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device, the nozzle cleaner, the Y-manifold, the spray clips and the coolant tube for internal bur cooling system.

3. Product description

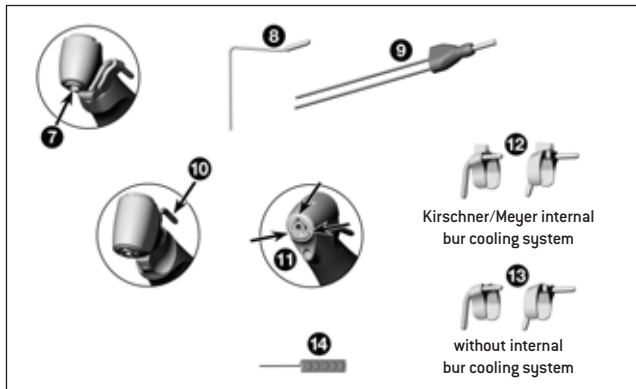


WS-56 L, WS-75 L, WS-91 L, WS-92 L

- 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



WS-75 L

- 7** Hexagon chucking system
- 8** Coolant tube for internal bur cooling system
- 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



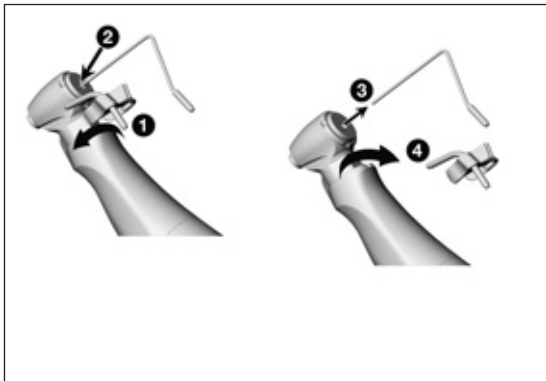
Do not assemble or remove the medical device during operation!



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.



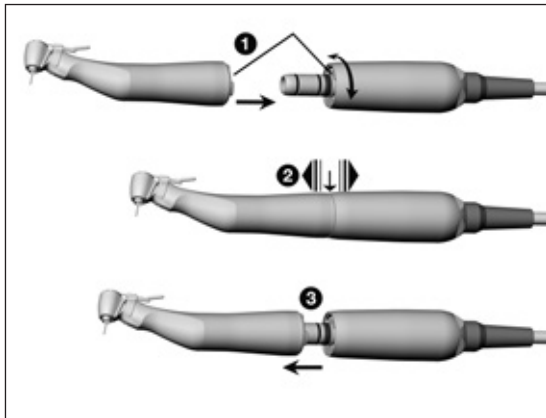
WS-56 L
Spray clip

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

- 1 Attach the spray clip.
- 2 Insert the coolant tube for internal bur cooling system.

or

- 3 Remove the coolant tube for internal bur cooling system.
- 4 Remove the spray clip.



Medical device

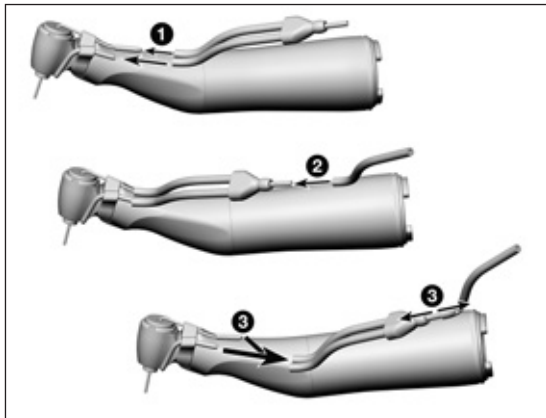
1 Push the medical device onto the motor and turn until it engages audibly.



2 Verify secure hold.

or

3 Remove the medical device.



WS-75 L

Y-manifold



Only when using the coolant tube for internal bur cooling system.

- 1 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 system.
 - 2 Insert the Y-manifold into the irrigation tubing.
- or
- 3 Remove the Y-manifold.

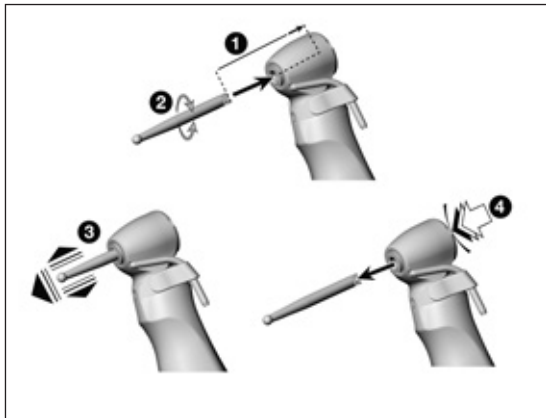
Rotary instruments



- > 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.



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).



To change the rotary instrument

WS-56 L

> Instrument shaft diameter 2.35 mm

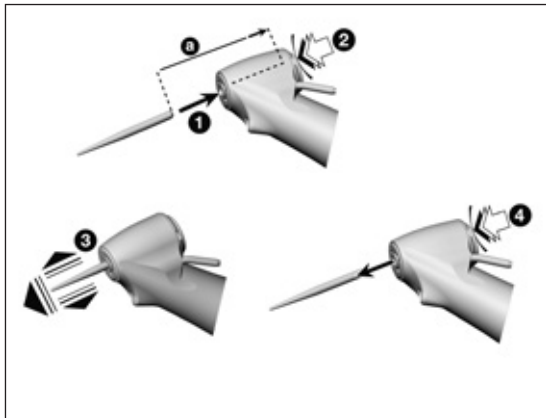
- 1 Insert the rotary instrument until the limit stop.
- 2 Turn the rotary instrument until it engages.



- 3 Verify secure hold.

or

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



WS-91 L, WS-92 L

> Instrument shaft diameter 1.6 mm

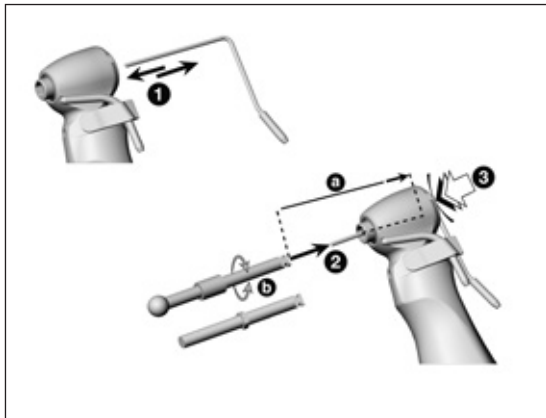
- 1 Insert the rotary instrument.
- 2 Activate the push-button, at the same time insert the rotary instrument until the limit stop [a].



- 3 Verify secure hold.

or

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



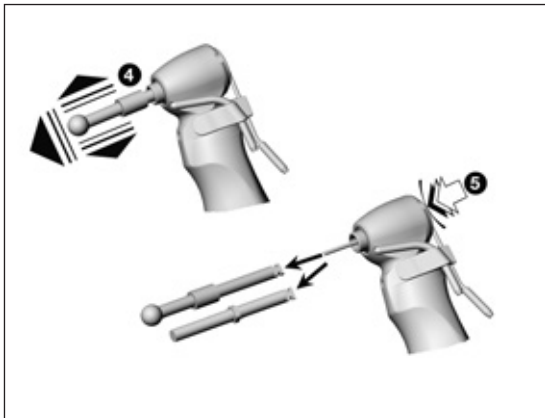
WS-75 L

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

❶ Insert the coolant tube for internal bur cooling system.

or

- ❶ Remove the coolant tube for internal bur cooling system.
- 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 Verify secure hold.

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.
- > Operate the medical device.



In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leaking) **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 the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichische 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.
- > W&H recommends that the Y-manifold is replaced after 50 processing cycles.
- > W&H recommends that the spray clips are replaced after 100 processing cycles.



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

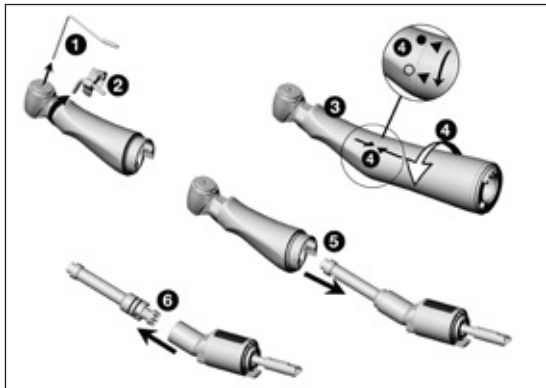
- > Operate the medical device for at least 10 seconds at idle speed.
- > Ensure that all coolant outlets are rinsed out.



- > Wipe the entire surface of the instrument with disinfectant.
- > Remove the rotary instrument.
- > 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.



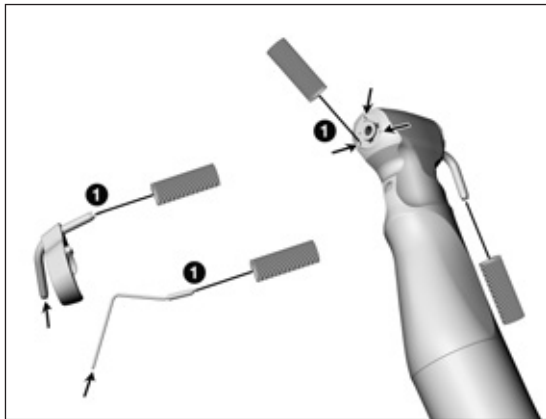
Disassembling the medical device

- 1** Remove the coolant tube for internal bur cooling system.
- 2** Remove the spray clip.
- 3** Hold the contra-angle head firmly with one hand.
- 4** Press sheath gently against knee. At the same time twist the sheath off the knee.
- 5** Remove the knee from the contra-angle head.
- 6** Remove the middle gear from the knee.



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.

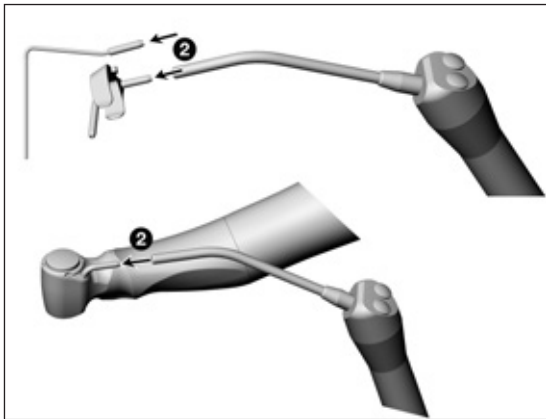


Cleaning the external coolant tubes WS-91 L, WS-92 L: Cleaning the spray nozzles



The coolant tube for internal bur cooling system, the spray clips and the nozzle cleaner can be cleaned in an ultrasonic bath and/or in the washer-disinfector.

- 1 Clean coolant outlets 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.



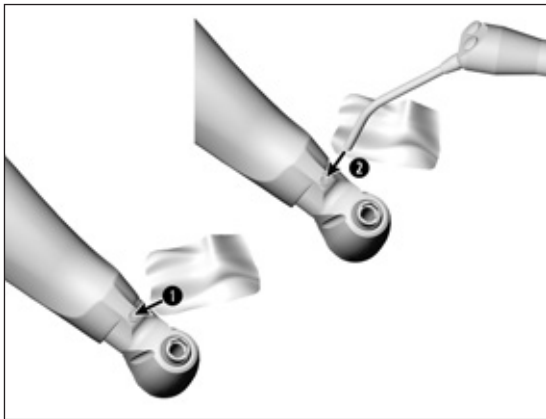
WS-75 L

Cleaning the Y-manifold



The Y-manifold can be cleaned in an ultrasonic bath and/or in the washer-disinfector.

- 1 Rinse with running tap water (< 35°C / < 95°F).
- 2 Remove 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 using 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.

WS-56 L, WS-75 L



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

> Follow the instructions in the Assistina Instructions for Use.



> 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 »mikrozid[®] AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).



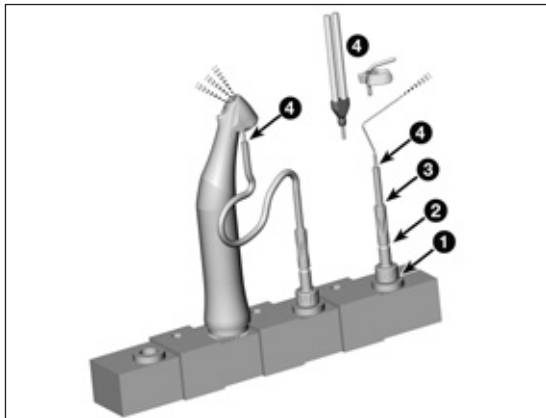
W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).

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



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).

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



Automated cleaning and disinfection of the external coolant tubes and spray clips



Use the W&H adaptor kit REF 07233500.

- 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 system, the Y-manifold or the spray clip into the W&H silicon hose.

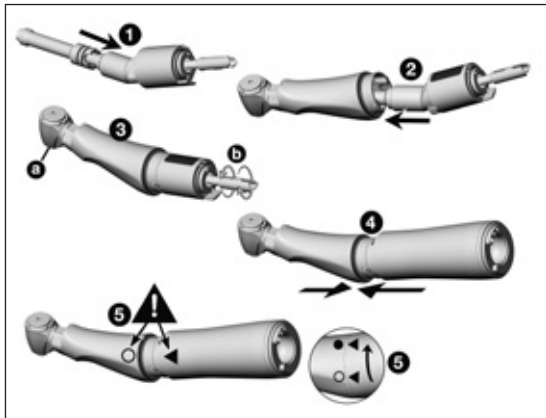


- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove liquid residues using compressed air.

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 cleaning and disinfection.

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

- 1 Insert the middle gear into the knee.
- 2 Insert the knee into the contra-angle head.
- 3 Check free running of the chucking system (a) and shaft (b).
- 4 Insert the sheath onto the contra-angle head.
- 5 Note the symbols and turn until locked.

Lubrication



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

Recommended lubrication cycles

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

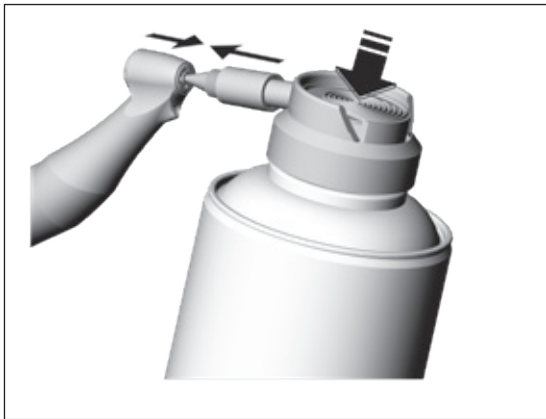
With W&H Service Oil F1, MD-400

- > 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.



WS-91 L, WS-92 L

Lubrication of the chucking system

With W&H Service Oil F1, MD-400

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

or

With W&H Assistina TWIN / Assistina 301 plus

- > 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.
- > Excess oil may result in the medical device overheating.



Wrap 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 procedure.
- > The sterilization package must be large enough for the sterilization goods.
- > The loading sterilization package must not be under tension.



W&H recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST79.



- > 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.



- > Pull off the spray clip from the medical device before sterilization.



- > Sterilize the spray clip and the medical device.

Recommended sterilization procedures

- > Fractionated pre-vacuum process (type B)
- > Gravity displacement process (type N)
- > Sterilization time at least 30 minutes at 121°C (250 °F) or at least 3 minutes at 134°C (273°F)
- > 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)) and the CertoClav MultiControl MC2-S09S273 gravitation sterilizer (CertoClav GmbH, Traun).

- > Fractionated pre-vacuum process (type B): temperature 134°C (273°F) – 3 minutes*
- > Gravity displacement process (type N): temperature 121°C (250°F) – 30 minutes**

* according to EN 13060, EN 285, ISO 17665 / ** according to 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. W&H Accessories and spare parts



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

Supplier: W&H partners

000301xx	Assistina 301 plus
19922000	Assistina 3x2 (MB-200)
19923000	Assistina 3x3 (MB-300)
30310000	Assistina TWIN (MB-302)
02693000	Assistina adaptor for chucking system
10940021	Service Oil F1, MD-400 (6 pcs)
02038200	Spray adaptor
02036100	Spray adaptor for chucking system

02015101	Nozzle cleaner
07233500	Adaptor kit for the washer-disinfector
06016400	Y-manifold (3 pcs)
02610500	Coolant tube for internal bur cooling system
	Spray clip for the left (3 pcs)
06946300	Kirschner/Meyer internal bur cooling system
06948400	Without internal bur cooling system
	Spray clip for the right (3 pcs)
06948300	Kirschner/Meyer internal bur cooling system
06949500	Without internal bur cooling system

8. 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 (Ø mm)	2.35
Maximum permitted bur length	(mm)	45*
Minimum chucking length		engaging
Maximum drive speed	(rpm)	50,000
Coolant volume	ISO 14457 (ml/min)	> 50
Maximum torque at rotary instrument	(Ncm)	70*
Using rotary instrument with hexagon	(Ncm)	105*

rpm (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.

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 (Ø mm)	2.35	1.6
Maximum permitted bur length	(mm)	34*	25*
Minimum chucking length		engaging	until limit stop
Maximum drive speed	(rpm)	50,000	
Coolant volume	ISO 14457 (ml/min)	> 50	

rpm (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 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
- > Waste electrical equipment
- > 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 adaptor, 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 authorized 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
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W&H Impex Inc., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
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Subject to alterations

