

Instructions for use



PEOPLE HAVE PRIORITY



Surgical

Handpieces with
mini LED+ and generator
S-9 L G, S-11 L G

Handpieces without light
S-9, S-10, S-11, S-12, S-15

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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!

Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the State in which he or she practices to use or order the use of the device.

Symbols on the handpiece / packaging



CE 0297
from the manufacturer



Catalogue number



Data Matrix Code for
product identification, e.g.,
in hygiene/maintenance
process



Thermo washer disinfectable



Serial number



Sterilizable up to the
stated temperature



Date of manufacture



UL Component Recognition
Mark indicates compliance
with Canadian and U.S.
requirements

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This W&H product has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms 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 W&H product and guarantee a smooth and efficient operation.

Intended use

Surgical treatment of dental hard tissue.

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

Qualifications of the user

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



Production according to EU Directive

The handpiece is a medical product according to the EU Directive 93/42/EEC.



Responsibility of the manufacturer

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

- > The handpiece must be used in accordance with these Instructions for use.
- > The handpiece 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 51).

Skilled application

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

The handpiece 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 51). Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

2. Safety notes – General



- > The operation of the handpiece 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 handpiece must be stopped immediately.
- > Check the handpiece for damage and loose parts each time before using.
- > Do not operate the handpiece if it is damaged.
- > Only attach the handpiece onto the motor, when the motor is at a complete standstill.
- > Never touch the chuck lever of the handpiece during operation or while it is still running down.
- > Never touch the rotary instrument which 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 handpiece head (risk of burning)!

Hygiene and maintenance prior to initial use



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

- > Lubricate the handpiece.
- > Sterilize the handpiece, the nozzle cleaner and the coolant tube.

- > Oil service page 33, 39
- > Sterilization page 41

2. Safety notes – Handpiece with mini LED+ and generator



- > Avoid contact between LED and soft tissue (risk of burning due to the LED heating up).
- > Do not use the handpiece as 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 handpiece is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



The handpiece 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.

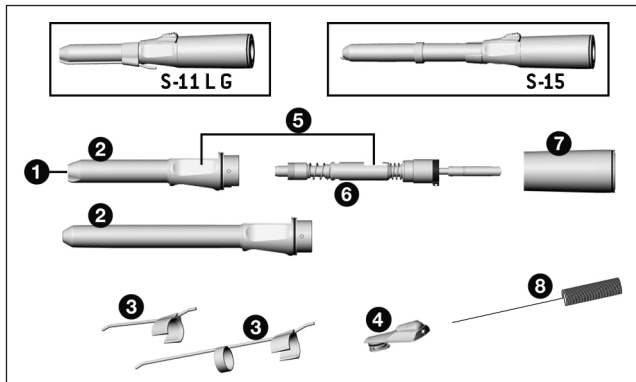


Risks due to electromagnetic fields

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 product and consider the application.
- > Weigh the risks and benefits.
- > Keep the product 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.

3. Product description – Straight handpiece S-11 L G, S-11, S-15

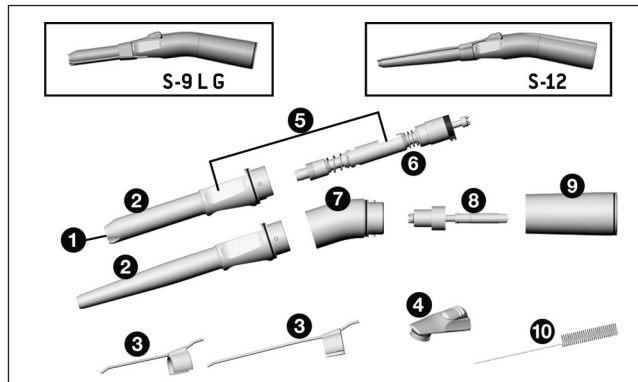


- ❶ LED (only S-11 L G)
- ❷ Handpiece head*
- ❸ Coolant tube (movable)
- ❹ Chuck lever
- ❺ Area of chuck lever
- ❻ Shaft
- ❼ Sheath*
- ❽ Long nozzle cleaner

* Symbols on the parts ❷ and ❼

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

3. Product description – Angled handpiece S-9 L G, S-9, S-10, S-12

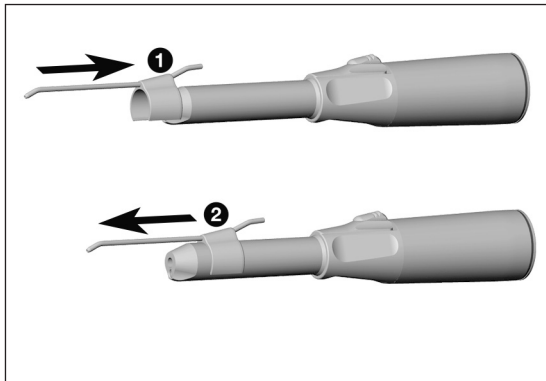


- ❶ LED (only S-9 L G)
- ❷ Handpiece head*
- ❸ Coolant tube (movable)
- ❹ Chuck lever
- ❺ Area of chuck lever
- ❻ Shaft
- ❼ Knee*
- ❽ Lower shaft
- ❾ Sheath*
- ❿ Long nozzle cleaner

* Symbols on the parts ❷, ❽ and ❾

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

4. Operation – Assembly/Removal

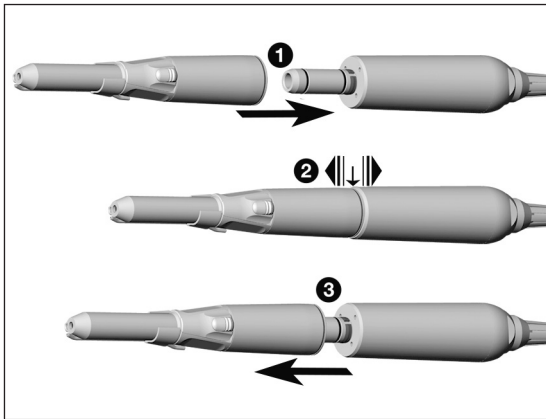


Coolant tube

① Fit the coolant tube.

or

② Pull off the coolant tube.



Handpiece



Do not assemble or remove the handpiece during the operation!

- 1 Push the handpiece onto the motor.



When using a locking pin between motor and handpiece: See Instructions for use of the drive unit.

- 2 Check the secure hold on the motor.

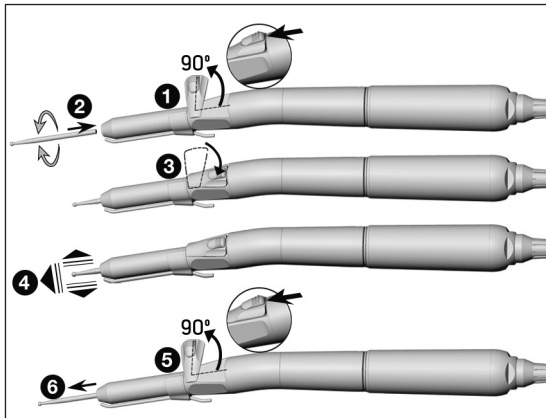
or

- 3 Remove the handpiece from the motor by pulling in an axial direction or by pressing the release button.

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 handpiece is stationary.
- > Never touch the rotary instrument which is still rotating.
- > Do not activate the chuck lever of the handpiece during operation. This leads to detachment of the rotary instrument and/or makes the handpiece hot.



To change rotary instrument

- 1 Unlock and swivel the chuck lever.
- 2 Insert the rotary instrument until back stop.



When using a locking pin:

Insert the rotary instrument until back stop and turn until the locking pin engages.

- 3 Return the chuck lever to the initial position.
- 4 Check secure location by applying slight axial tension.

or

- 5 Unlock and swivel the chuck lever.
- 6 Remove the rotary instrument.

Test run



Do not hold the handpiece at eye level.

- > Insert the rotary instrument.
- > Start the handpiece.



In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) or discoloration of the LED, **stop the handpiece immediately** and contact an authorized W&H service partner (see page 51).

5. Hygiene and maintenance



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



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



- > Clean and disinfect the handpiece **immediately after every treatment**, to flush out any liquid (such as 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.

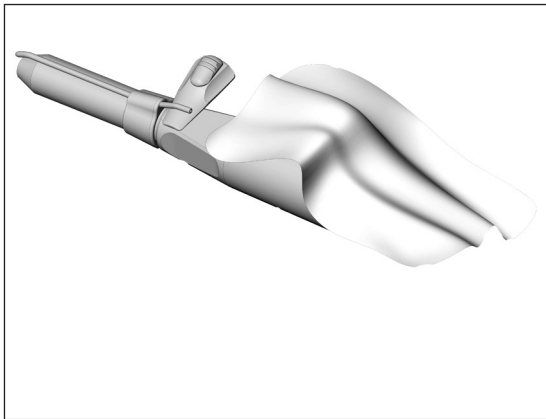


Reassemble the handpiece following manual cleaning and disinfection.

- > Without coolant tube
- > Types and serial numbers must be identical



- > Sterilize the reassembled handpiece following manual or mechanical cleaning, disinfection and lubrication.
- > Sterilize the coolant tube.

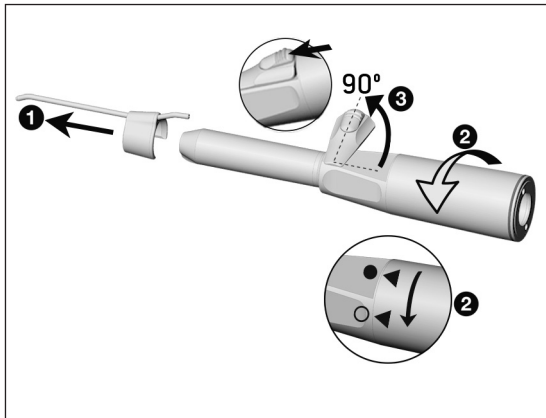


Pre-disinfection

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



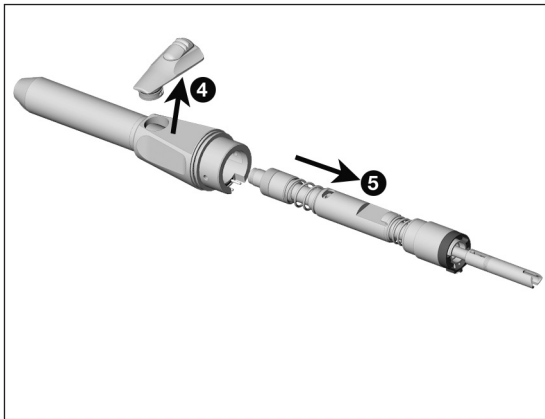
Only use disinfectants that have no protein-fixing effects.



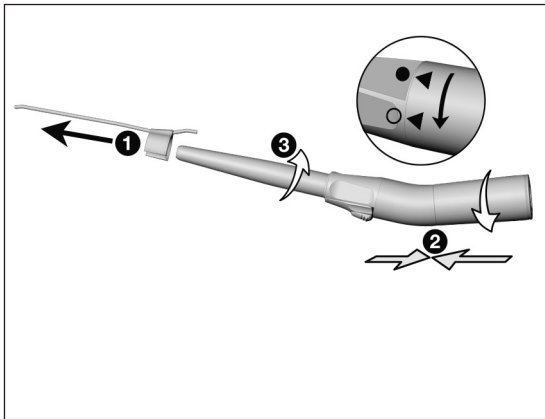
Disassemble straight handpiece

S-11 L G, S-11, S-15

- 1 Pull off the coolant tube.
- 2 Turn off the sheath from the handpiece head by turning once.
- 3 Unlock and swivel the chuck lever.



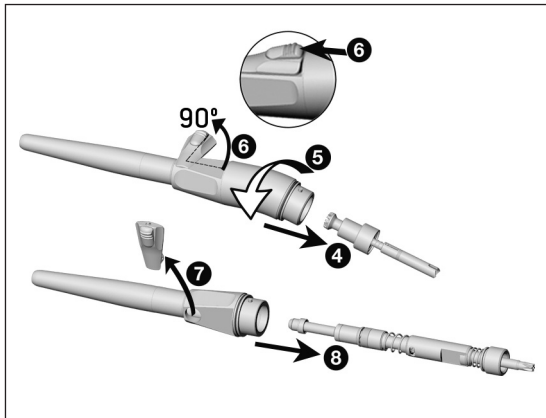
- ④ Remove the chuck lever.
- ⑤ Remove the shaft from the handpiece head.



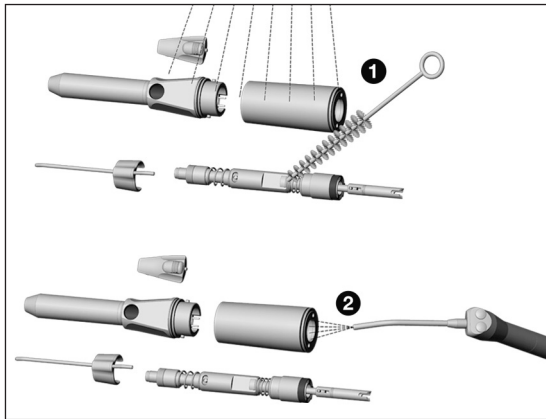
Disassemble angled handpiece

S-9 L G, S-9, S-10, S-12

- 1 Pull off the coolant tube.
- 2 Press sheath firmly against knee.
- 3 Turn off the sheath from the handpiece head by turning once.



- ④ Remove the lower shaft from the knee.
- ⑤ Turn off the knee from the handpiece head.
- ⑥ Unlock and swivel the chuck lever.
- ⑦ Pull off the shaft until back stop and remove the chuck lever.
- ⑧ Remove the shaft from the handpiece head.

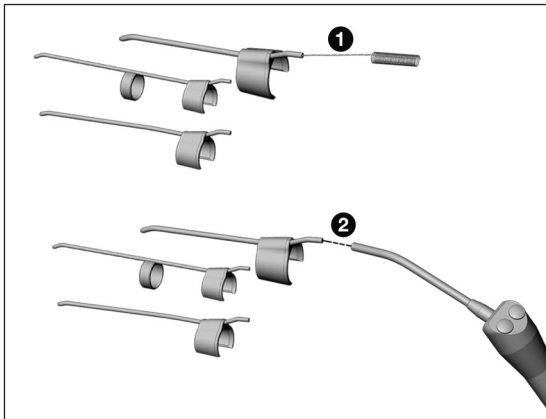


Manual cleaning internal and external

- 1 Rinse and brush off under demineralized water (< 38 °C / < 100 °F).
- 2 Remove any liquid residues (absorbent cloth, blow dry with compressed air).



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



Cleaning of the external coolant tubes

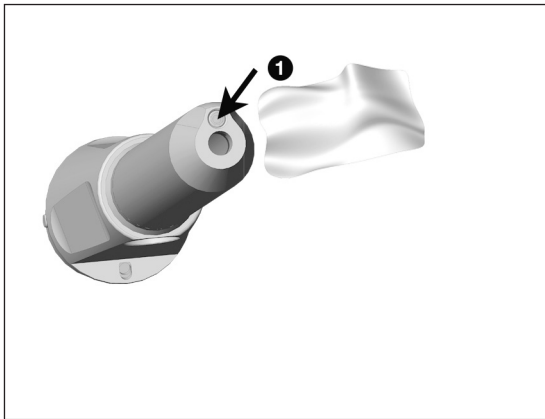


The removable coolant tube and the nozzle cleaner can be cleaned in an ultrasonic bath.

- 1 Clean coolant outlets carefully with the nozzle cleaner to remove dirt and deposits.
- 2 Blow through the coolant tube with the air syringe.



In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner (see page 51).



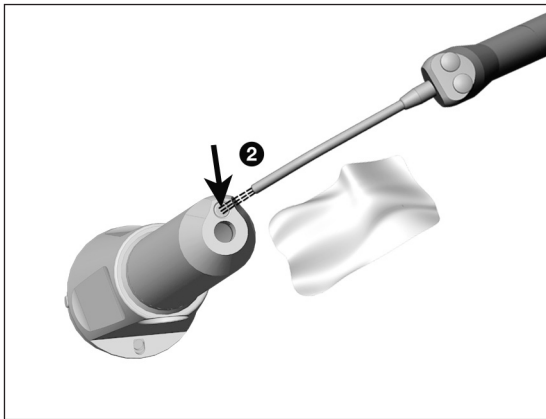
S-9 L G, S-11 L G

Cleaning of the LED



Avoid scratching of the LED!

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

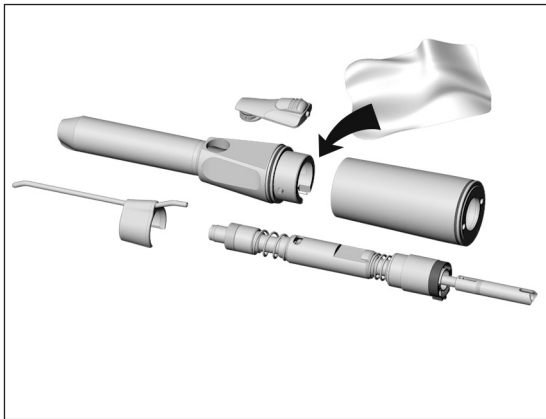


- ② Blow the LED dry with air syringe or dry it carefully with a soft cloth.



Carry out a visual inspection after each cleaning process.

Do not use the handpiece if the LED is damaged and contact an authorized W&H service partner (see page 51).



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 and lubrication



- W&H recommends mechanical cleaning and lubrication with W&H Assistina.
- > Follow the instructions in the Assistina Instructions for use.



S-10, S-12: only with W&H Assistina 301

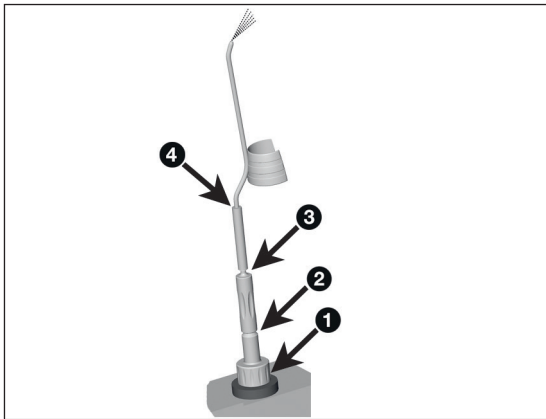
Mechanical cleaning and disinfection internal and external



- The handpiece 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.
 - > Note the manufacturer's specifications on equipment, cleaning agents and detergents.



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

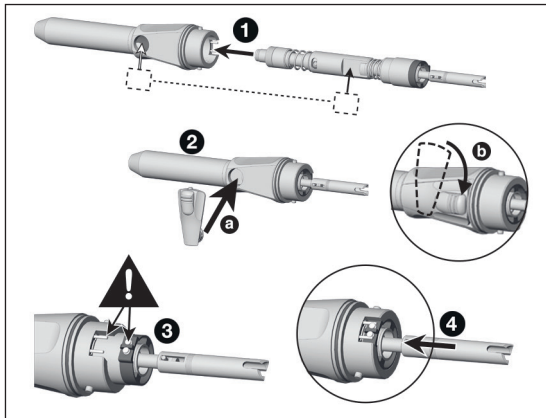


Mechanical cleaning and disinfection of the external coolant tubes



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

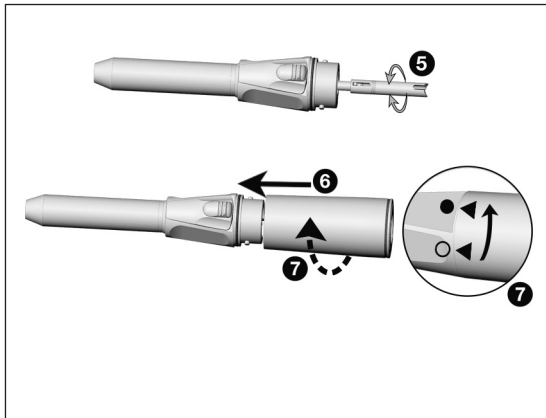
- 1 Screw the W&H adaptor into the adaptor on the injector rail.
- 2 Screw the W&H intermediate adaptor onto the W&H adaptor.
- 3 Put the W&H silicone hose over the W&H intermediate adaptor.
- 4 Insert the external coolant tube into the W&H silicone hose.



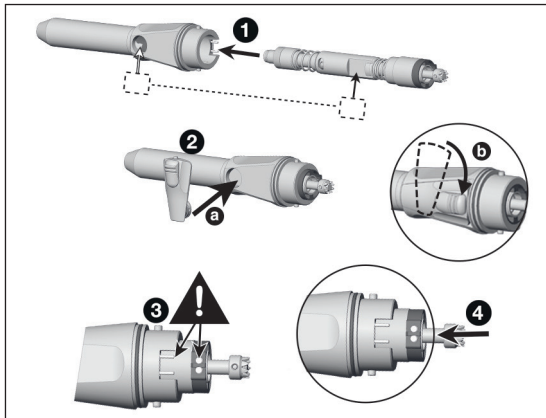
Reassemble straight handpiece

S-11 L G, S-11, S-15

- 1 Note the positioning of the area of chuck lever. Insert the shaft into the handpiece head.
- 2 Insert chuck lever [a] and turn it to initial position [b].
- 3 Only S-11 L G: Position the golden contacts on the shaft and handpiece head so that they are facing each other.
- 4 Push the shaft into the handpiece head.



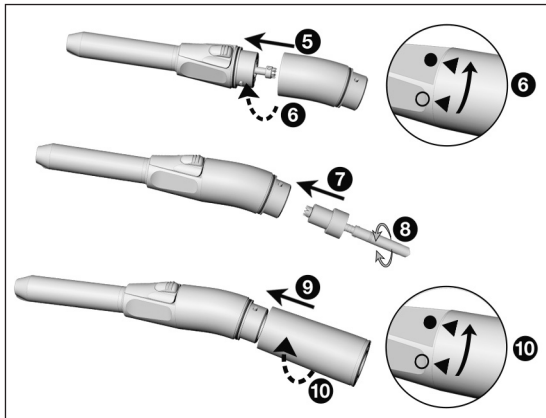
- ⑤ Check free running of the shaft.
- ⑥ Insert the sheath onto the handpiece head.
- ⑦ Note the symbols and turn until locked.



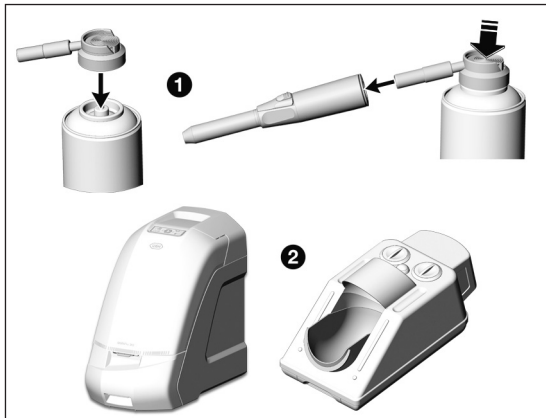
Reassemble angled handpiece

S-9 L G, S-9, S-10, S-12

- 1** Note the positioning of the area of chuck lever. Insert the shaft into the handpiece head.
- 2** Insert chuck lever (a) and turn it to initial position (b).
- 3** **Only S-9 L G:** Position the golden contacts on the shaft and handpiece head so that they are facing each other.
- 4** Push the shaft into the handpiece head.



- 5 Insert the knee onto the handpiece head.
- 6 Note the symbols and turn until locked.
- 7 Insert lower shaft into the knee.
- 8 Check free running of the lower shaft.
- 9 Insert sheath onto the knee.
- 10 Note the symbols and turn until locked.



Daily oil service

Recommended lubrication cycles

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

1 With W&H Service Oil F1, MD-400

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

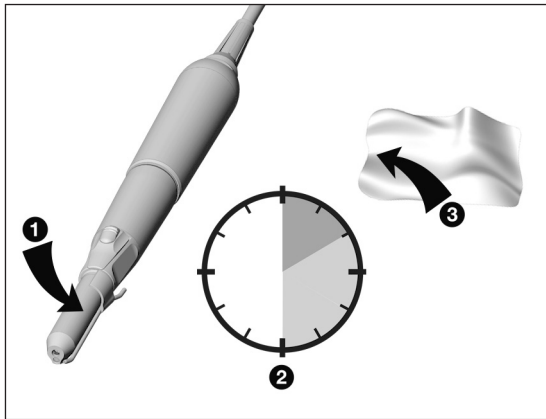
or

2 With W&H Assistina

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



S-10, S-12: only with W&H Assistina 301



Test run following oil service

- 1 Place the handpiece with the handpiece head downwards.
- 2 Start the handpiece for 30 seconds to remove excessive 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 handpiece with gauze or soft cloth.

Sterilization and storage



- > Pull off the coolant tube from the handpiece before sterilizing.
- > Sterilize the coolant tube and the handpiece.



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 handpiece before sterilizing.
- > Wrap the handpiece and the accessory in sterile goods packing according to EN 868-5.
For Canada: Place the handpiece 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.



The standard ISO 14457 stipulates a durability of at least 250 sterilization cycles.
In the case of the handpiece from W&H, we recommend you to have a regular service carried out after 1,000 sterilization cycles or one year.

Approved sterilization procedures



Follow your local and national directives, standards and guidelines.

- > 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 handpieces. 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

	Assistina 301
19922000	Assistina 3x2 (MB-200)
19923000	Assistina 3x3 (MB-300)
10940021	Service Oil F1, MD-400 (6 pcs)
02038200	Spray cap with nozzle
00636901	Long nozzle cleaner
06879500	Coolant tube for S-9, S-9 L G, S-11, S-11 L G
06903200	Coolant tube for S-10, S-12
07226900	Coolant tube for S-15
07233500	Adaptor kit for the thermo washer disinfecter

7. Technical data

Straight handpiece		S-11 L G	S-11	S-15
Transmission ratio		1:1	1:1	1:1
Colour coding		blue	blue	blue
Motor connection according to standard		ISO 3964	ISO 3964	ISO 3964
Rotary instruments	ISO 1797-1 (Ø mm)	2.35*	2.35*	2.35*
Permitted bur length	(mm)	45**	45**	45**
Minimum chucking length		until back stop	until back stop	until back stop
Maximum drive speed		40,000	50,000	30,000
Coolant volume		> 50	> 50	> 50

min⁻¹ (Revolutions per minute)

* System Stryker usable

** When using longer or shorter 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

Angled handpiece	S-9 L G / S-9	S-10	S-12
Transmission ratio	1:1	1:1	1:2
Colour coding	blue	blue	orange
Motor connection according to standard	ISO 3964	ISO 3964	ISO 3964
Rotary instruments ISO 1797-1 (Ø mm)	2.35*	2.35	2.35
Permitted bur length (mm)	45**	70**	70**
Minimum chucking length	until back stop	until back stop	until back stop
Maximum drive speed (min ⁻¹)	40,000 / 50,000	50,000	40,000
Coolant volume ISO 14457 (ml/min)	> 50	> 50	> 50

min⁻¹ (Revolutions per minute)

* System Stryker usable

** When using longer or shorter 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 handpiece at the operator side:	maximum 55 °C (131 °F)
Temperature of the handpiece at the patient side:	maximum 50 °C (122 °F)
Temperature of the working part (rotary instrument):	maximum 41 °C (105.8 °F)

Physical characteristics

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. Recycling and disposal

Recycling

W&H considers that it has a special duty towards the environment. The handpiece along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the handpiece



- > Follow your local and national laws, directives, standards and guidelines for the disposal of used electrical devices.
- > Ensure that the parts are not contaminated on disposal.

Disposal of the packaging material



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

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.

Explanation of warranty terms

This W&H product 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 12 months from the date of purchase.

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 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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Subject to alterations

