

PEOPLE HAVE PRIORITY



Instructions for use



CE
0297

proxeo

Scaler with light
ZA-55 L / ZA-55 LM / ZA-55 LS

Scaler without light
ZA-55 / ZA-55 M

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Symbols in the instruction for use



WARNING!
(risk of injury)



ATTENTION!
(to prevent damage
occurring)



General explanations,
without risk to persons or
objects



Suitable for use in an
ultrasonic bath



Do not dispose of with
domestic waste

Symbols on the instrument / 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

The W&H quality policy gives customer satisfaction top priority. This W&H product has been designed, manufactured and tested in accordance with the requirements of current laws and standards.

For your safety and the safety of your patients

Please read the Instructions for use before using the device for the first time. They explain how to use the product and guarantee smooth, economical and safe operation.

Intended use

This medical device is an air-powered ultrasonic unit for use in dental treatments. It may be used in combination with the tips approved by the manufacturer for the removal of supragingival and subgingival calculus, tooth cleaning, root planing, root canal preparation and processing hard tooth and bone substance.

Misuse may damage the scaler and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user

We have based our development and design of the scaler on the requirements of the »dentists, dental hygienists, dental employees (prophylaxis) and dental assistants« target group.



Production according to EU Directive

The scaler is a medical device as defined by EU Directive 93/42/EEC.



Responsibility of the manufacturer

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

- > The scaler must be used in accordance with these Instructions for use.
- > The scaler has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 45).

Qualified use

The scaler is only intended for qualified use in dental medicine according to the applicable health and safety regulations, accident prevention measures and in observance of these Instructions for use. The scaler must only be prepared and maintained by persons who have been instructed in infection prevention, self-protection and patient safety. Improper use (e.g., due to lack of hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which have not been approved by W&H will invalidate all claims made under warranty or otherwise.

Service

In case of malfunction, contact an authorized W&H service partner immediately (see page 45).
Repair and maintenance work must be performed exclusively by authorized W&H service partners.

2. Safety notes



- > Operation of the scaler with light is only permitted on supply units that conform to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

The power supply unit for the supply unit must meet the following requirements, which must be guaranteed by the system assembler:

- > Double insulation for the maximum anticipated supply voltage between the primary and secondary circuit.
- > Double insulation for the maximum anticipated secondary voltage between the secondary voltage and the protective earth (PE).
- > The secondary circuits must be electrically isolated from one another.
- > The secondary circuits must be protected against short-circuit and overload.
- > The leakage currents of the applied part must be in compliance.
- > The secondary voltage must be limited to max. 3.3 V AC/DC.



- > Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- > Always provide sufficient coolant and ensure the appropriate suction. Turn off the scaler immediately in the event of failure in the coolant supply.
- > As drive air for the scaler, use only filtered, oil-free and cooled air supplied by dental compressors.
- > Check the scaler for damage and loose parts (e.g., scaler tip) before every use.
- > Do not operate the scaler if it is damaged.
- > Perform a test run prior to each treatment.
- > Do not use the scaler where soft tissue injuries exist in the oral cavity (the air pressure may cause septic substances to infiltrate the tissue or trigger embolisms).
- > Run the rinsing function of the dental unit once a day
- > Do not use the scaler as a light sensor.
- > Avoid eye contact with the optic outlet.

Tips



- > Only use W&H tips and the W&H tip changer or tips/tip changers from another manufacturer which are approved for the W&H scaler.
- > Ensure that the original shape of the tip is not changed (e.g., by dropping).
- > Tips must not be bent back to shape or reground.
- > Check the set power setting every time the device is restarted.
- > Only insert the tip when the scaler is idle.
- > Never touch the vibrating tip.
- > Place the tip changer on the inserted tip of the idle scaler immediately after every treatment (protects against injuries and infections, protects the tip).
- > Use the tip card supplied to check the wear to the tips (1AU, 2AU, 3AU, 1AP, 2APr, 2API).
The wear of the tips must not amount to more than 2 mm.



Danger zones M and G

The scaler is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide according to IEC 60601-1/ANSI/AAMI ES 60601-1.



The scaler is not suitable for use in oxygen-enriched atmospheres.



Zone M, also referred to as the »medical environment«, includes the part of a room in which potentially explosive atmospheres may occur as a result of the use of analgesics or medical skin cleaning or disinfectant agents, but only in small quantities and only for a short time.

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



Zone G, also referred to as an »enclosed medical gas system«, comprises not necessarily fully enclosed cavities in which permanent or temporary potentially explosive mixtures may be generated, supplied or used in small quantities.

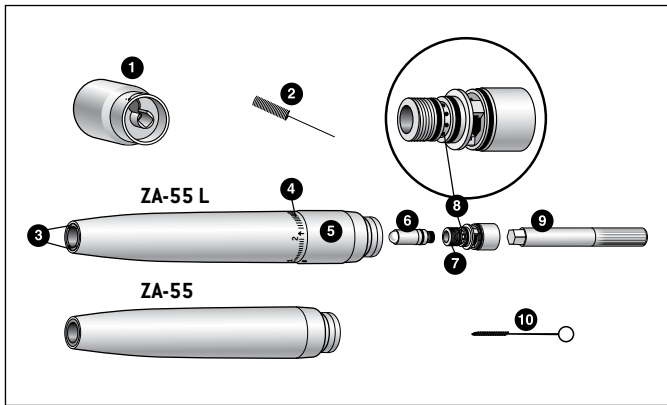
Hygiene and maintenance before using for the first time



The scaler is supplied in a clean condition sealed in PE foil.

- > Lubricate the scaler before using it for the first time.
 - > Sterilize the scaler, tips, tip changer and the nozzle cleaner.
-
- > Oil service page 33 – 34
 - > Sterilization page 35 – 36

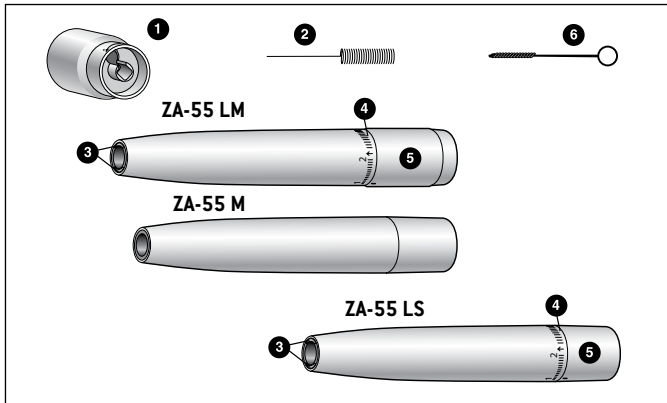
2. Product description – Scaler



Scaler with/without light and Roto Quick connection

- ❶ Tip changer
- ❷ Nozzle cleaner
- ❸ Optic outlet*
- ❹ Power level marking*
- ❺ Adjuster ring for the power setting*
- ❻ Bulb*
- ❼ Bulb holder*
- ❽ Spray filter*
- ❾ Allen key*
- ❿ Small cleaning brush

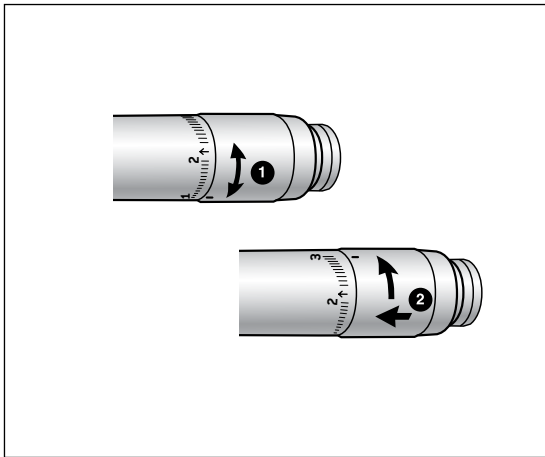
* Only on ZA-55 L



**Scaler with/without light
and *Multiflex*[®] / *Sirona*[®] connection**

- ❶ Tip changer
- ❷ Nozzle cleaner
- ❸ Optic outlet*
- ❹ Power level marking*
- ❺ Adjuster ring for the power setting*
- ❻ Small cleaning brush

* Only on ZA-55 LM / ZA-55 LS



Adjuster ring for the power setting on the scaler with light (ZA-55 L / ZA-55 LM / ZA-55 LS)

- > Power level marking 1: Gentle
- > Power level marking 2: Standard
- > Power level marking 3: Short-term for increased ablation




Power level marking 3: Avoid any type of overinstrumentation.

- ❶ Set power level 1 to 2 by turning the adjuster ring.
 - > There is a safety lock at power level 2.
- ❷ To bypass it, press the adjuster ring forwards and turn it to power level 3.

Product description – Tips

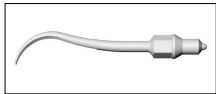
Application areas of approved W&H tips

 The following tips have been approved for power level marking 1 – 3 (ZA-55 L / ZA-55 LM / ZA-55 LS).



Prophylaxis tips

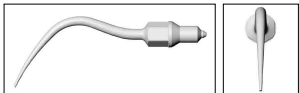
1AU: Universally applicable, also for cambered molar surfaces inclined towards lingual.



2AU: For anterior teeth of the lower jaw, lingual surfaces and in cases of stubborn adhesion of thick, hard collars of dental calculus.

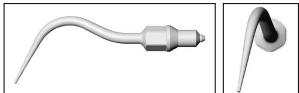


3AU: For removing plaque from the neck of the tooth and removing nicotine stains.



Periodontology tips

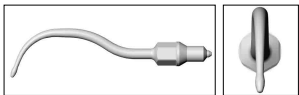
1AP: Removal of subgingival deposits, especially suitable for deep periodontal pockets.



2APr: Right-curved tip for removal of subgingival deposits.



2APl: Left-curved tip for removal of subgingival deposits.

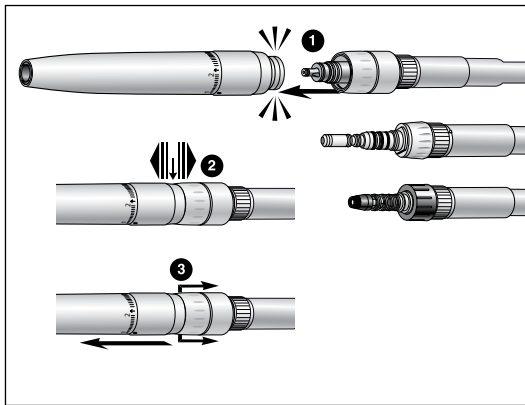


3AP: With a diamond coating on the instrument tip for periodontal debridement of furcations and concavities.



Use the diamond-coated 3AP periodontology tip, applying very light pressure (0.3 N) to avoid any type of overinstrumentation.

4. Starting operation



Attachment and detachment



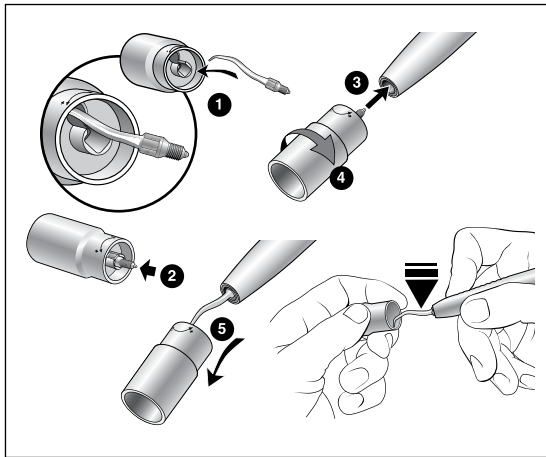
Do not attach or detach while in operation!



- 1** Place the scaler on the Roto Quick / *Multiflex*[®] / *Sirona*[®] coupling.
- 2** Check that the scaler is securely attached to the coupling.
- 3** Retract the Roto Quick coupling's retention sleeve and detach the scaler by pulling axially.

or

Remove the scaler from the *Multiflex*[®] / *Sirona*[®] coupling by pulling axially.



Inserting the tip

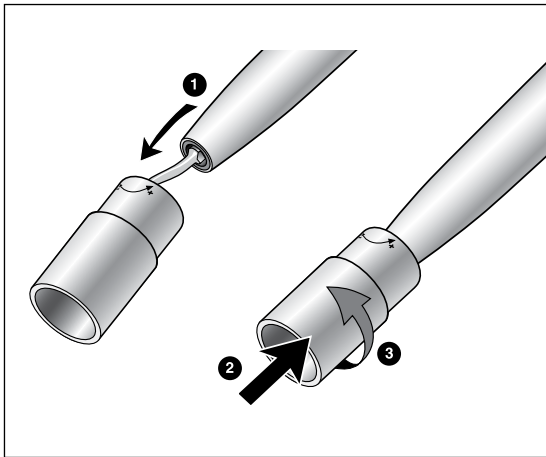
- 1 Place the tip in the notch.
- 2 Push the tip into the tip changer.
- 3 Insert the thread of the tip into the opening on the scaler.
- 4 Screw the tip in tightly.
- 5 Pull the tip changer off carefully.



Check the secure attachment of the tip by pulling axially.



Press the tip against a hard, sterile surface [e.g., tip changer] with approx. 10 N [=1 kg] to test the load-bearing capacity of the tip.



Removing the tip

- 1 Place the tip in the notch.
- 2 Press the tip changer onto the tip.
- 3 Unscrew the tip.



Leave the tip in the tip changer until the hygiene and maintenance process!

Test run



Do not hold the scaler at eye level.

- > Insert the tip.
- > Start the scaler.
- > In the event of malfunctions (e.g., vibrations, unusual noises, overheating, coolant failure or leakage), **stop the scaler immediately** and contact an authorized W&H service partner (see page 45).

5. Hygiene and maintenance



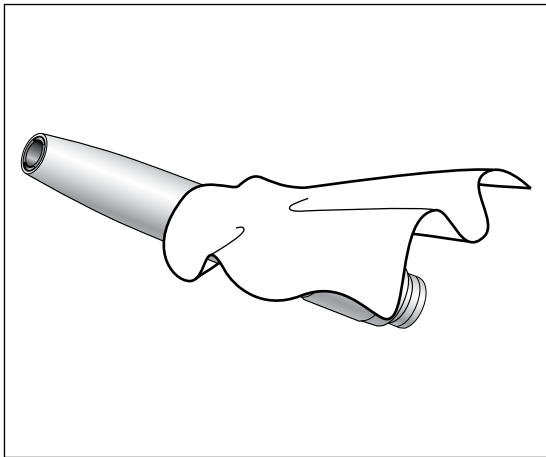
- > Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.
- > The scaler, the tips and the tip changer can be treated manually or mechanically.



- > Wear protective clothing.
- > Remove the scaler from the Roto Quick / *Multiflex*[®] / *Sirona*[®] coupling.
- > Remove the tip from the scaler.

- > Clean and disinfect the scaler, the tips and the tip changer **immediately after each treatment**, in order to rinse out any liquids (e.g., blood, saliva, etc.) that may have entered and to prevent inside parts from seizing up.

- > Sterilize the scaler, the tips and the tip changer after manual or mechanical cleaning, disinfection and lubrication.
- > Sterilize the nozzle cleaner after manual cleaning and disinfection.

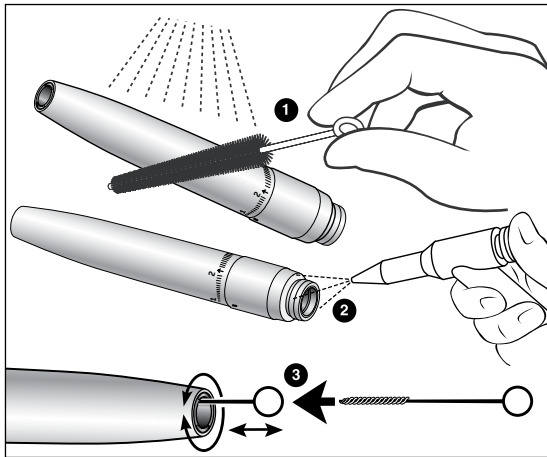


Pre-disinfection

- > If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants which have no protein-fixing effect.



Manual cleaning inside and outside

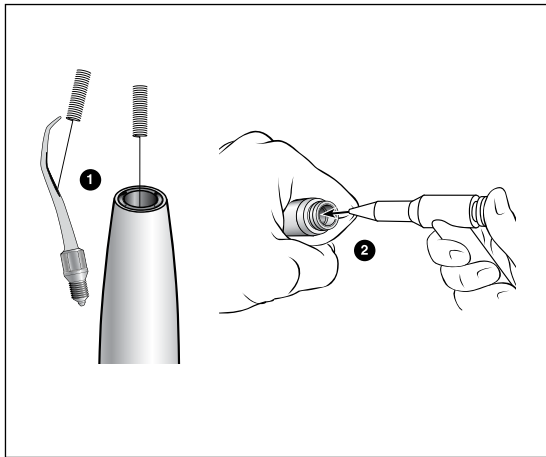
- 1 Rinse and brush off with demineralized water (< 38 °C / < 100 °F)
- 2 Remove any liquid residues (absorbent cloth, blow dry with compressed air).
- 3 Insert the small cleaning brush as far as it will go and clean the interior.



Do not place the scaler in disinfectant solution or in an ultrasonic bath!



You can clean and disinfect the tips and the tip changer in the drill bath or ultrasonic bath.



Cleaning the spray outlets

- 1 Use the nozzle cleaner to remove dirt and deposits from the outlets.



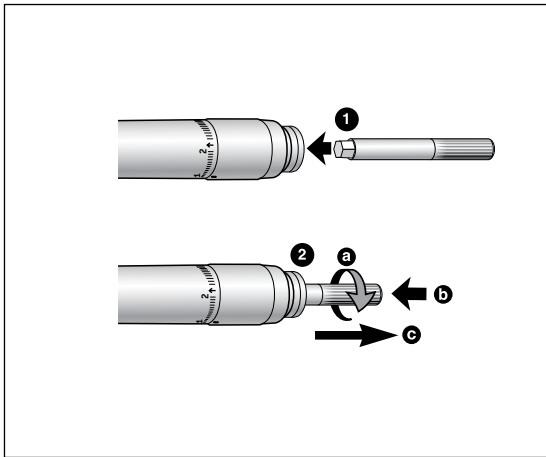
Clean and disinfect the nozzle cleaner in the ultrasonic bath/disinfection bath.

Cleaning the coolant channel

- 2 Blow through the coolant channel with the air gun.

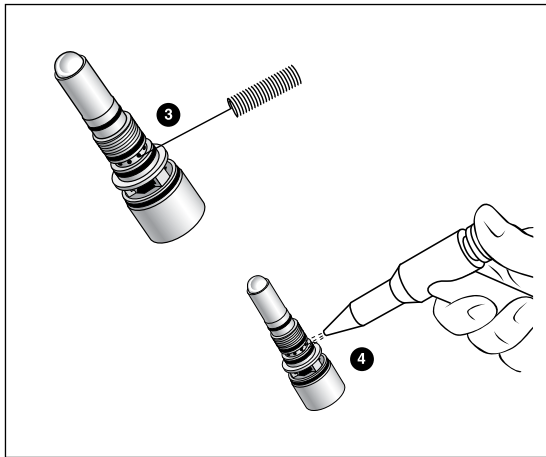


If the exit openings or coolant channels are blocked, contact an authorized W&H service partner [see page 45].

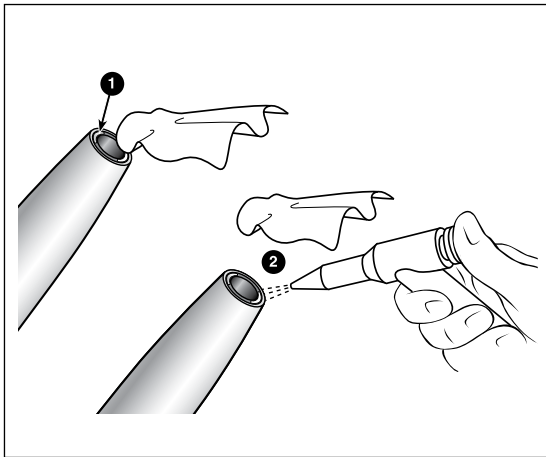


Cleaning the spray filter (ZA-55 L)

- ➊ Push the Allen key into the bulb holder on the scaler using axial pressure.
- ➋ Unscrew the bulb holder by turning the Allen key [a]. Press the Allen key [b] and pull the Allen key with the bulb holder out [c].



- 3** Clean the outlets on the bulb holder carefully using the nozzle cleaner (or a soft brush) making sure they are free of dirt and deposits.
- 4** Blow out the outlets with the air gun from the outside.
 - > Screw the bulb holder back in again.



Cleaning the optic outlet ZA-55 L / ZA-55 LM / ZA-55 LS

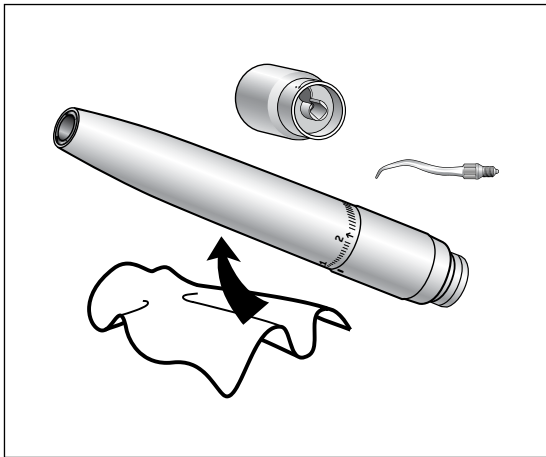


Avoid scratching the optic outlet!

- 1** Wash the optic outlet with cleaning fluid and a soft cloth.
- 2** Dry the optic outlet with the air gun or carefully with a soft cloth.



Carry out a visual inspection after cleaning each time. Do not put the scaler into operation if the optic outlet is damaged and contact an authorized W&H service partner [see see page 45].



Manual disinfection



W&H recommends wiping down with disinfection.

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



After manual cleaning, disinfection and an lubrication, you must carry out a thermal disinfection (unwrapped) or sterilization (wrapped) in a class B or S steam sterilizer (as per EN 13060).

Mechanical cleaning and disinfection (internal and external)



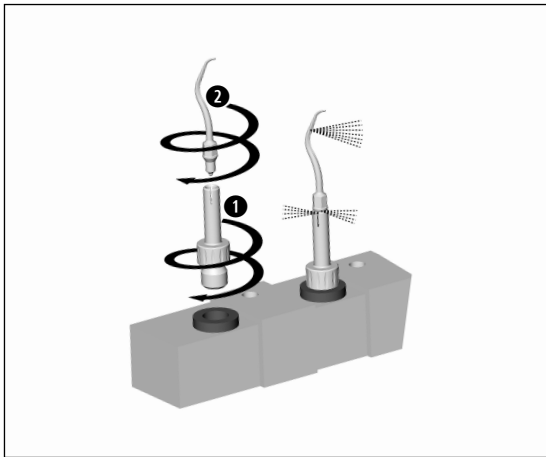
- W&H recommends mechanical cleaning and lubrication with W&H Assistina 3x3.
- > Follow the instructions in the Assistina Instructions for use.



- The scaler, the tips and the tip changer can be cleaned and disinfected in the thermo washer disinfectant.
- > Follow the manufacturer's recommendations for devices and cleaning & rinsing agents.
 - > Use the W&H adaptor set for the thermo washer disinfectant for preparing the tips.



- > Ensure that the scaler is completely dry, both inside and out, following thermo washer disinfection. Remove any liquid residues with compressed air.

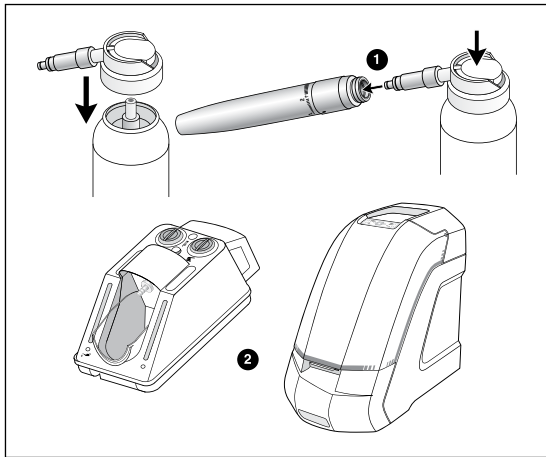


Mechanical cleaning and disinfection of the tips



Use the W&H adaptor set REF 07233500 for the thermo washer disinfectant.

- 1 Screw the W&H adaptor into the injector rail adaptor.
- 2 Screw the tip onto the W&H adaptor.



Oil service

❶ With W&H Service Oil F1, MD-400

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

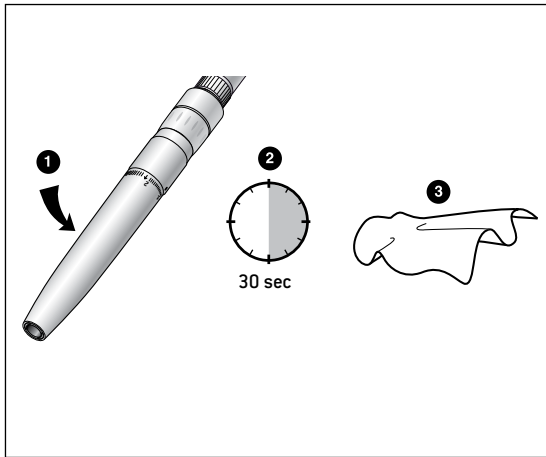
or

❷ With W&H Assistina

- > See Assistina Instructions for Use.

Recommended maintenance cycles

- > After every tenth internal cleaning process.
- > Before every tenth sterilization process.



Test run after oil service

- ➊ Point the scaler downwards.
 - > Start with the lowest drive speed when possible and increase it to the maximum speed within 5 – 10 seconds.
- ➋ Allow the scaler to run for 30 seconds in order to remove any excess oil.
 - > Repeat the entire hygiene and maintenance process if any dirt escapes.
- ➌ Wipe the scaler with a cellulose cloth or soft cloth.

Sterilization and storage



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

- > Note the manufacturer's specifications.
- > Clean, disinfect and lubricate prior to sterilization.
- > Only sterilize the tip in the tip changer.
- > Wrap the scaler and accessories in sterile goods packaging according to EN 868-5.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods dust-free and dry.



The standard ISO 15606 stipulates a durability of at least 250 sterilization cycles.

In the case of the W&H scaler, we recommend you have a regular service carried out after 1000 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 (273.2 °F)
- 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 scaler. Sterilization holding time a minimum of 3 minutes at 134°C (273.2 °F)



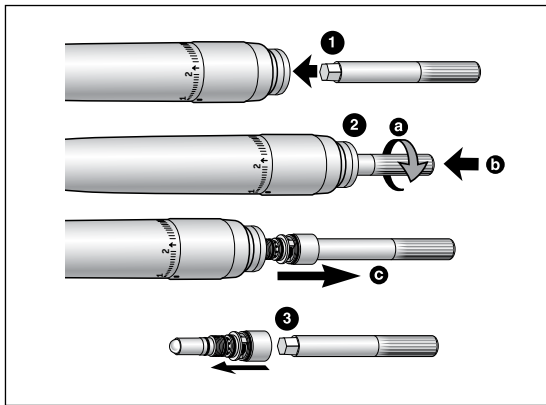
Before resuming operation

Wait until the scaler is completely dry.

Moisture in the scaler can lead to a malfunction! (Risk of short circuit)

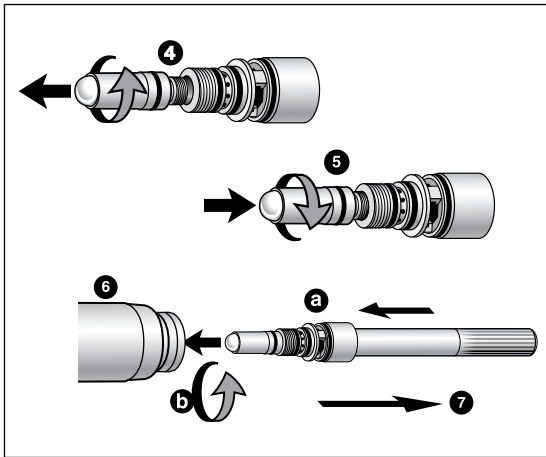
Wait until the scaler, the tip and the tip changer have cooled down completely. (Risk of burns)

6. Replacing the bulb (ZA-55 L)



The bulb poses a risk of burns!

- 1** Push the Allen key into the bulb holder on the scaler using axial pressure.
- 2** Unscrew the bulb holder by turning the Allen key [a]. Press the Allen key [b] and pull the Allen key with the bulb holder out [c].
- 3** Remove the bulb holder from the Allen key.



- 4 Unscrew the defective bulb from the bulb holder.
- 5 Screw in the replacement bulb.
- 6 Insert the bulb holder on the Allen key [a]. Screw the bulb holder into the scaler [b] as far as it will go.
- 7 Then remove the Allen key again.

7. W&H Accessories and spare parts

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

Reference source: W&H Partner

301	Assistina
19922000	Assistina 3x2 (MB-200)
19923000	Assistina 3x3 (MB-300)
02690400	Assistina adaptor for all W&H products with Roto Quick system
04713200	Assistina adaptor for <i>Multiflex</i> [®] connection
02692000	Assistina adaptor for Sirona [®] connection
10940021	Service Oil F1, MD-400 (6 pcs)
02229200	Spray cap with nozzle for ZA-55 L / ZA-55
04396100	Spray cap with nozzle for ZA-55 LM / ZA-55 M
05908000	Spray cap with nozzle for ZA-55 LS

00636901	Nozzle cleaner
07308100	Tip changer
05452400	Small cleaning brush
04381200	Replacement bulb (for ZA-55 L)
04273200	Allen key (for ZA-55 L)
07233500	Adaptor set for the thermo washer disinfectant

07159700	Tip 1AU
07159800	Tip 2AU
07159900	Tip 3AU
07009100	Tip 1AP
05254400	Tip 2APr
05153300	Tip 2API
05280200	Tip 3AP

8. Technical data

Proxeo scaler		ZA-55 L / ZA-55	ZA-55 LM / ZA-55 M	ZA-55 LS
Coupling hose side acc. to standard		W&H Roto Quick	<i>Multiflex</i> ^{®*}	<i>Sirona</i> ^{®*}
Operating pressure	(bar)	3,4 ± 0,3**	3,4 ± 0,3**	3,4 ± 0,3**
Water pressure	(bar)	0,7 – 2	0,7 – 2	0,7 – 2
Coolant flow rate	ISO 15606 (ml/min)	30 – 60	30 – 60	30 – 60
Lowest permitted coolant flow rate	(ml/min)	30	30	30
Air consumption	(l/min)	30 – 40 / 34	30 – 40 / 34	30 – 40 / 34
Oscillating frequency	(kHz)	6	6	6
Oscillation amplitude	ISO 15606 (µm)	< 200	< 200	< 200
Bulb voltage	V DC (or V AC)	3,2 ± 0,1 (3,3 ± 0,1) / –	–	–
Power input	(A)	0,7 / –	–	–

* Multiflex[®] and Sirona[®] are trademarks of third parties not affiliated with W&H Dentalwerk Bürmoos GmbH.

** Adjust the operating pressure using a manometer at power level 3 (ZA-55 L , ZA-55 LM, ZA-55 LS).

Temperature information

Temperature of the scaler on the operator side:	max. 55°C (131 °F)
Temperature of the scaler on the patient side:	max. 50°C (122 °F)
Temperature of the working instrument (tip):	max. 41°C (105.8 °F)

Ambient conditions

Temperature during storage and transport:	-40°C (-40 °F) to +70°C (+158 °F)
Air humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature in operation:	+10°C (+50 °F) to +35°C (+95 °F)
Humidity in 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 the disposal.

- > Medical device
- > Waste electrical equipment
- > Sales packaging

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 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 24 months from the date of purchase. Accessories and consumables (tips, tip changers, replacement lamps, allen key, nozzle cleaners, cleaning brushes) 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
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