Instructions for Use

CE
0297

Surgical

Handpiece
SZ-75

Contents

Symbols

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 intends to use or order the use of this medical device.

Manufacturer

Symbols

CE XXXX — CE marking with identification number of the Notified Body

 — DataMatrix Code for product information including UDI (Unique Device Identification)

HIBC — Data structure in accordance with Health Industry Bar Code

REF — Catalogue number

 — Thermo washer disinfectable

Sterilizable up to the stated temperature

SN — Serial number

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

MD — Medical device

 — Date of manufacture

 — Consult Instructions for Use

1. Introduction

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

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


Observe the safety notes.

Intended use
Surgical treatment of organic hard tissue.

Intended part of the body
> Mouth
> Mouth Space

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

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

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

> The medical device must be used in accordance with these Instructions for Use.
> The medical device has no components that can be repaired by the user.
> Modifications or repairs must only be undertaken by an authorised W&H service partner (see page 43).

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

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

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

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

2. Safety notes

- > Before using the medical device for the first time, store it at room temperature for 24 hours.
- > The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- > Always ensure that you have a second medical device ready for use during the operation.
- > Check the medical device for damage and loose parts each time before using.
- > Do not operate the medical device if it is damaged.
- > Only attach the medical device onto the motor when the motor is at a complete standstill.
- > Perform a test run each time before using.
- > Avoid overheating at the treatment site.

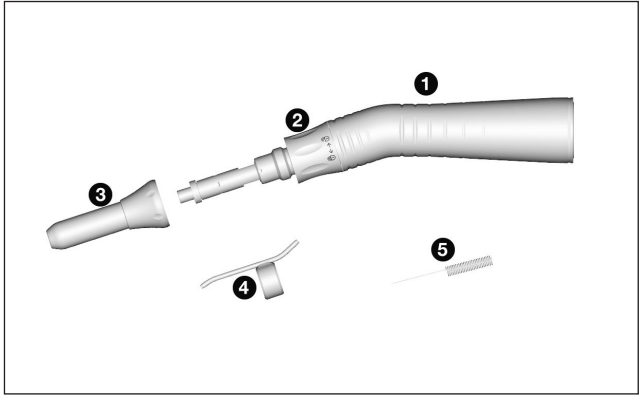
The medical device has a considerably higher level of efficiency than normal contra-angle handpieces and has been designed to fit W&H drive units. When using the medical device on other surgical units, the user assumes sole responsibility. The manufacturer accepts no liability. Any concessions can be granted directly by the manufacturer of the drive units.

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, and the coolant tube.

3. Product description



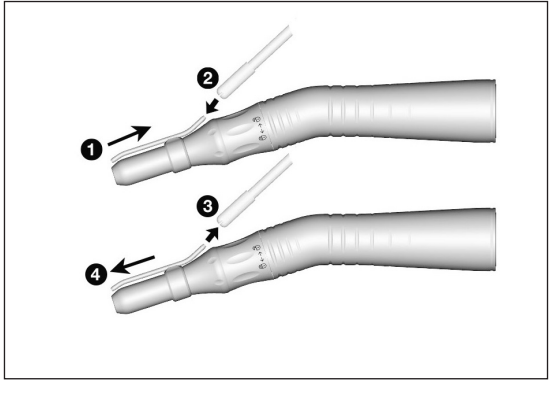
1. Sheath
2. Chuck ring*
3. Handpiece head
4. Coolant tube
5. Nozzle cleaner

* Symbol on the part 2

= Chucking system open

←→ = Direction of rotation

= Chucking system locked

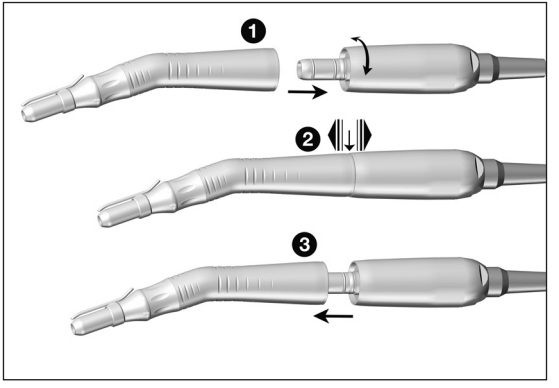


Coolant tube

❶ Fit the coolant tube.
❷ Insert the coolant tube into the irrigation tubing.

or

❸ Remove the irrigation tubing.
❹ Pull off the coolant tube.



Do not assemble or remove the medical device during operation!

❶ Push the medical device onto the motor.

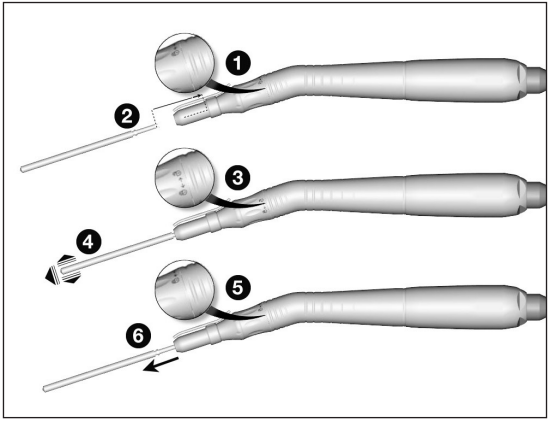
❷ Verify full engagement.

❸ Remove the medical device.

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.

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

> With hexagon

> Instrument shaft diameter 2.35 mm

To open the chucking system: Turn the chuck ring to the left

To close the chucking system: Turn the chuck ring to the right

❶ Open the chucking system.

❷ Insert the rotary instrument until limit stop.

❸ Close the chucking system.

❹ Verify full engagement.

❺ Open the chucking system.

❻ Remove the rotary instrument.

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 leakage) **stop the medical device immediately** and contact an authorized W&H service partner.

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

> Wear protective clothing, safety glasses, face mask and gloves.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by, for example: the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) or 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

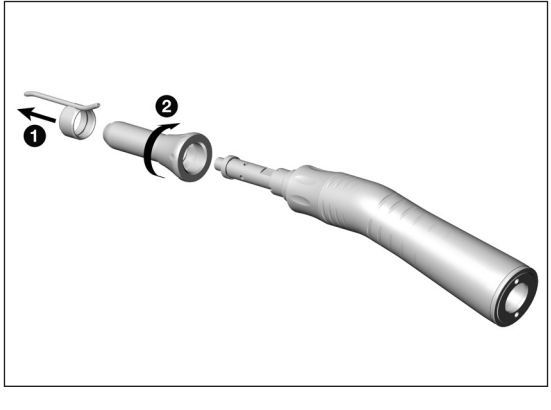
> We recommend a regular service for the W&H medical device after 250 processing cycles or one year.

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 outlets are rinsed out.

> Wipe the entire surface of the medical device 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.



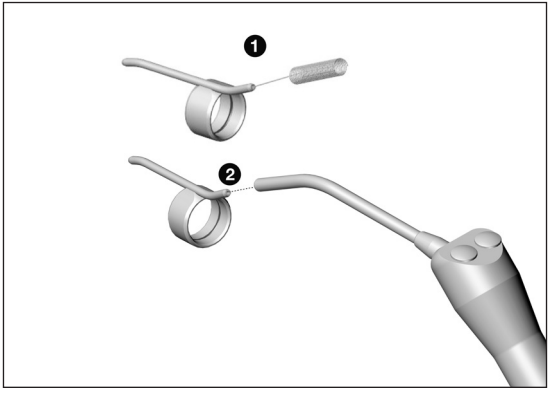
Disassemble the medical device

1. Pull off the coolant tube.
2. Remove the handpiece head off the sheath by turning it once.

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.

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



Cleaning of the coolant tube

The coolant tube and the nozzle cleaner can be cleaned in an ultrasonic bath and/or in the 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 tubes contact an authorized W&H service partner.

> W&H recommends wiping down with disinfectant.

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

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

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

External coolant tubes and spray clips

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

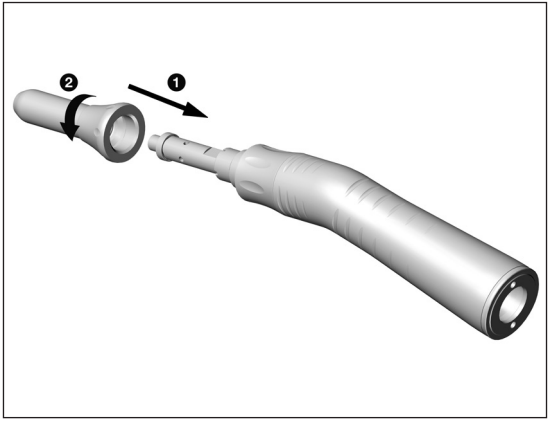
Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

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

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

Inspection

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



Reassembling the medical device

Reassemble the medical device following manual cleaning and disinfection.
> Without coolant tube

❶ Attach the handpiece head until the limit stop.
❷ Tighten the handpiece head.

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.

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.

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

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

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

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

> Pull off the coolant tube from the medical device before sterilizing.
> Sterilize the coolant tube and the medical device.

Recommended sterilization procedures

> “Dynamic-air-removal prevacuum cycle” (type B) / “Steam-flush pressure-pulse cycle” (type S)*/**
> 134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes
> “Gravity-displacement cycle” (type N)**
> 121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

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

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

Drying times:

"Dynamic-air-removal prevacuum cycle" (type B):	132°C (270°F) – 30 minutes**
"Steam-flush pressure-pulse cycle" (type S):	132°C (270°F) – 30 minutes**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55, ANSI/AAMI ST79

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

6. Servicing

Repairs and returns

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

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

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

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

Supplier: W&H partners

000301xx	Assistina 301 plus
30310000	Assistina TWIN (MB-302)
10940021	Service Oil F1, MD-400 (6 pcs)
02038200	Spray adaptor
08030410	Coolant tube
00636901	Long nozzle cleaner

8. Technical data

		SZ-75
Transmission ratio		20:1
Colour coding		green
Motor connection according to standard		ISO 3964
Rotary instruments Maximum permitted bur length* Minimum chucking length	ISO 1797 (Ø mm) (mm)	2.35 100 engaging
Maximum drive speed*	(rpm)	50,000
Coolant volume	ISO 14457 (ml/min)	> 50
Maximum torque at rotary instrument Using rotary instrument with hexagon	(Ncm) (Ncm)	70* 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.
For safe use, follow the respective manufacturer's instructions regarding maximum speed of the rotating instrument.

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

9. Disposal

Ensure that the parts are not contaminated on disposal.

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

> Medical device

> Packaging

Explanation of warranty terms

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

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

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

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

12 months warranty

Authorized W&H service partners

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

Or simply scan the QR code.

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, **Austria**

t + 43 6274 6236-0,
office@wh.com

f + 43 6274 6236-55
wh.com

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