

Instructions for use

Mechanical
Cleaning and oil service

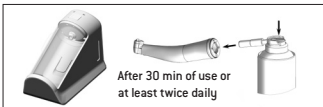
Manual
Cleaning and oil service



syneq FUSION



CE
0297



Notes for
Hygiene and maintenance
(page 18 – 40)

**Intensiv-Reciprocating
contra-angle handpiece with light WG-69 LT**

**Intensiv-Reciprocating
contra-angle handpiece without light WG-69 A, WG-68 A**

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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



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



Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

Symbols

	CE marking with identification number of the Notified Body		Consult Instructions for Use		Data structure in accordance with Health Industry Bar Code
	Catalogue number		Sterilizable up to the stated temperature		Handpiece, Air turbine
	Serial number		Thermo washer disinfectable		Handpiece, Air turbine, with illumination
	Date of manufacture		Medical Device		Package unit
	Manufacturer		UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements		Non-sterile

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

The reciprocating/oscillating contra-angle handpieces are for the following applications:

Preparation, removing protrusions or excess of filling materials and cements, finishing and polishing in the interdental, supragingival and subgingival regions, plaque removal and IPR (interproximal reduction) in orthodontics.



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, dental hygienists, dental employees (prophylaxis) and dental assistants 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.
- > Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 49).



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



- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- > In case of coolant supply failure, the medical device must be stopped immediately.
- > Use only filtered, oil-free and cooled air supplied by dental compressors to operate the medical device.
- > Check the medical device for damage and loose parts each time before using.
- > Do not operate the medical device if it is damaged.
- > Perform a test run each time before using.
- > Avoid overheating at the treatment site.



- > Do not touch the soft tissue with the head of the medical device. Risk of burning if the medical device overheats!
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the treatment water decontamination system, as well as its handling.



- > 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).

Hygiene and maintenance prior to initial use



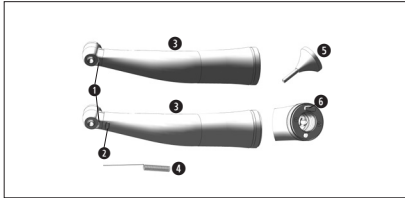
- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



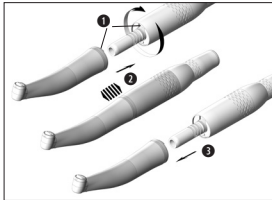
- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device, the nozzle cleaner and the tip ejector.

3. Product description

Medical device



- ❶ Spray nozzles
- ❷ Compact glass rod
(WG-69 LT)
- ❸ Grip profile
- ❹ Nozzle cleaner
- ❺ Tip ejector
- ❻ Nose



Do not assemble or remove the medical device during operation!

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



- 2 Verify full engagement.

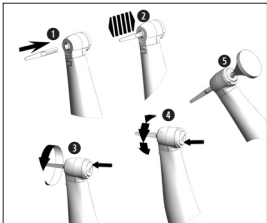
- 3 Remove the medical device.



Files/Tips

The insert used carries out a reciprocating movement.

- > Use only files/tips which are in perfect condition. Follow the operating instructions of the manufacturer.
- > Insert file/tip only when the medical device is stationary.
- > Do not interfere with the running or slowing down of files/tips.



Changing files/tips

- 1 Insert the file in the head of of the contra-angle handpiece until limit stop.



- 2 Verify full engagement.

- 3 Press / lock button for freely 360 ° rotation of the file.
- 4 Press / lock button for fixing the file in selected positions.
- 5 Remove the file with the tip ejector.

Test run



Do not hold the medical device at eye level!

- > Insert the file/tip.
- > 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.

5. Hygiene and maintenance

General notes



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



The information on the validated reprocessing procedures serves as an example of an ISO 17664 compliant processing of the medical device.



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



Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar (43.5 psi) 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 1,000 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 file/tip.
- > Remove the medical device.

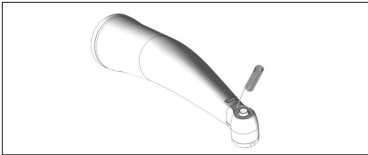


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.



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.

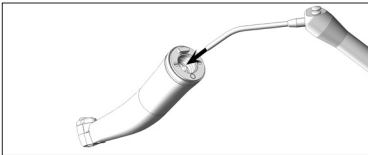


Clean spray nozzles

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



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

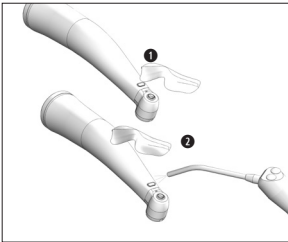


Cleaning the coolant tube

Blow through the coolant tube using compressed air.



In the case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner.



Cleaning of the light source



Avoid scratching the light source!

- ❶ Wash the light source with cleaning fluid and a soft cloth.
- ❷ Blow the light source 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 light source is damaged and contact an authorized W&H service partner.



W&H recommends wiping down with disinfectant.



Evidence of the basic suitability of the medical device 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 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) 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 medical device following cleaning, disinfection and lubrication.

Lubrication



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

Recommended lubrication cycles

- > Essential after every internal cleaning
- > Before each sterilization or
- > After 30 minutes of use or at least twice daily

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.

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.
Suppliers: W&H partners

01603400	Tip ejector
02015101	Nozzle cleaner

Scan the QR code to find accessories, consumables and spare parts for this medical device.



Files are available from trade sources or directly from the INTENSIV company:

Intensiv SA, Via al Molino 107, CH-6926 Montagnola, P.O. Box 741, CH-6916 Grancia, Switzerland
t +41 91 986 50 50, **f** +41 91 986 50 59, **E-Mail:** info@intensiv.ch, <http://www.intensiv.ch>

8. Technical data

	WG-69 LT / WG-69 A	WG-68 A
Transmission ratio	2 : 1	1 : 1
Colour coding	green	blue
Motor coupling acc. to	ISO 3964	
Recommended files/tips	Intensiv Ortho-Strips System / Intensiv Proxoshape / Intensiv Bevelshape *	
Min. chucking length	until back stop	
Chucking	sliding chuck *	
File stroke (mm)	0.9	
Max. motor speed (rpm)	40,000	20,000
Spray flow rate ISO 14457 (ml/min)	> 50	
Water setting range (rec. water pressure) ** (bar)	0.5 – 2	
Chip air setting range (rec. chip air pressure) ** (bar)	1.5 – 3	
Chip air consumption at 2 bar (l/min)	> 1.5	

rpm (Revolutions per minute)



- * A shorter chuck length is not possible. When using other files/tips, the user must ensure by correct selection of the operating conditions that there is no danger to the user, patient or third parties.

- ** The chip air / water pressure must be set at the same time.
The chip air must be higher than the water pressure



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 (file/tip):

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 24 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 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 "wh.com/yco-branded"

Or simply scan the QR code.





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