

Instructions for use



CE
0297

PEOPLE HAVE PRIORITY



Piezo Scaler

Handpiece

PB-3, PB-3 S, PB-3 LED S, PB-3 LED E S

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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



Suitable for the
ultrasonic bath



Do not dispose of with
domestic waste

Symbols on the handpiece / packaging



CE mark
with identification number
of the Notified Body



Data Matrix code
for product information
including UDI (Unique
Device Identification)



Data structure in
accordance with
Health Industry Bar Code



Article number



Thermo washer
disinfectable



Type B applied part
(not suitable for
intracardiac application)



Serial number



Sterilizable up to the stated
temperature



Date of manufacture



Satelec thread

1. Introduction



For your safety and the safety of your patients

These Instructions for Use explain how to use your W&H product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients are of paramount importance to us.



It is therefore essential to read the safety notes on Pages 8 to 13.

Intended use

Drive unit with piezoceramic oscillating system that moves the scaler tip in linear oscillation. The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontic application and preparation of tooth enamel.

Misuse can damage the drive unit and hence cause risks and hazards for patients, users and third parties.

Skilled application

The handpiece is intended only for informed use in the medical dental field, 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 maintained according to the manufacturer's recommendations and in line with infection control procedures for the safety and well-being of patients. Improper use, (e.g. through poor hygienic maintenance), noncompliance 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.

Qualifications of the user

In the development and design of the handpiece, we have assumed the target group of users to be dentists, dental hygienists, dental employees (prophylaxis) and dental assistants.



Production according to EU-Directive

The medical device complies with the regulations of Directive 93/42/EEC.



Responsibility of the manufacturer

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

- > The handpiece must be used in accordance with these Instructions for Use.
- > The handpiece system contains no parts which are repairable by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 37).

Returns

- > Refer all questions to your authorized W&H service partner (see page 37).
- > Always return equipment in the original packaging!

2. Safety notes



Please observe the following instructions under all circumstances

- > Sterilize the handpiece, tips and accessories prior to initial use.
- > Perform a test run prior to each use.
- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction (except for in endodontic applications).
- > In case of coolant supply failure, the handpiece must be stopped immediately (max. operating time without coolant is 30 sec.). The exception to this is in endodontic applications, where coolant is not used (max. operating time 2 minutes).
- > Check the handpiece and supply hose for damage and loose parts prior to each use (e.g. tip, LED, O-ring).
- > Always operate the handpiece with the handpiece cap fitted.
- > Replace faulty or leaky O-rings on the hose coupling immediately.



Handpiece PB-3 LED S, PB-3 LED E S

- > Do not look directly into the optic outlet.
- > If the LED fails, change the LED socket (see page 21 and 26).
- > Only change the LED socket when the handpiece is completely still.
- > Always operate the handpiece with the LED socket fitted.

Tips

- > Only use tips that have been approved by W&H and the associated tip changers or spanners.
- > An overview of the correct power settings is included with every tip.
- > With periodontal tips, the handpiece is suitable for the removal of concretions in the subgingival region, but not for applications which demand sterile conditions. Choose the lower performance range when carrying out periodontal treatments on hypersensitive patients in order to guarantee optimum pain-free treatment.
- > Ensure that the original shape of the tips is not affected (e.g. by being dropped).



- > The tips must not be bent back into shape or resharpened.
- > Locate and secure the tip only with the handpiece switched off.
- > Never touch the tips when vibrating.
- > Insert the tip changer onto the inserted tip of the stationary handpiece after every treatment (protection against injury and infection, tip protection). Tips that are changed using the spanner must be removed immediately after treatment with the handpiece.
- > Check for the effect of wear on the tips using the accompanying tip card.
- > Change tips if there are visible signs of wear.



Approved coolants and rinsing liquids

- > Sodium chloride (table salt) NaCl
- > Hydrogen peroxide (H₂O₂) (1 – 3 %)
- > Water
- > Liquids with the active substance chlorhexidine 0.2%



Inappropriate use

Improper use, in addition to incorrect assembly, installation, modification or repairs of the handpiece or non-compliance with our instructions invalidates all claims under warranty and any other claims!



The W&H electronic is only designed to be used with the handpieces. Use of other handpieces could result in deviation of the electronic or could lead to electrical damage.



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.



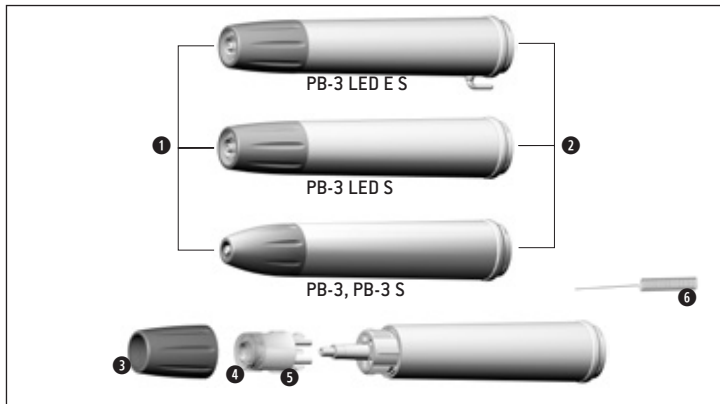
Zonen G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.



This medical device complies with the reference values defined in EN 50527-2-1/2011 for unipolar and bipolar pacemakers and is therefore suitable for patients with pacemakers.

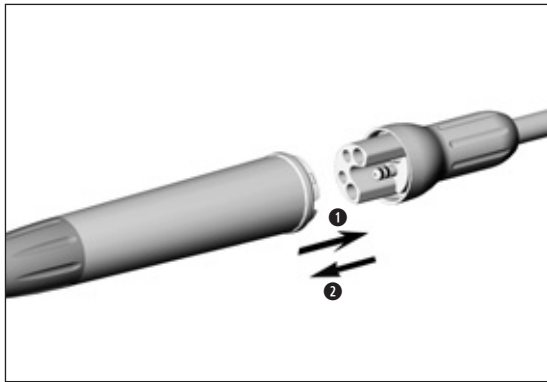
> Keep a safe distance of at least 30 cm between the control unit and your patients during operation.

3. Description handpiece




- ① Thread of the handpiece
- ② Connection for supply hose
- ③ Handpiece cap
- ④ Optic outlet
- ⑤ LED socket
- ⑥ Nozzle cleaner

4. Handpiece assembly/removal

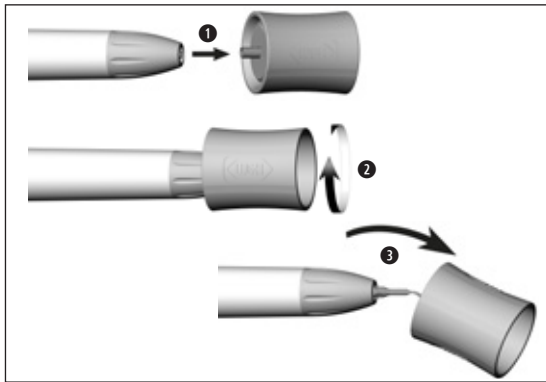


❶ Push the handpiece onto the supply hose.

 Note the positioning of the connections!

❷ Remove the handpiece by pulling in an axial direction.

5. Insert/remove tip with tip changer



Inserting the tip

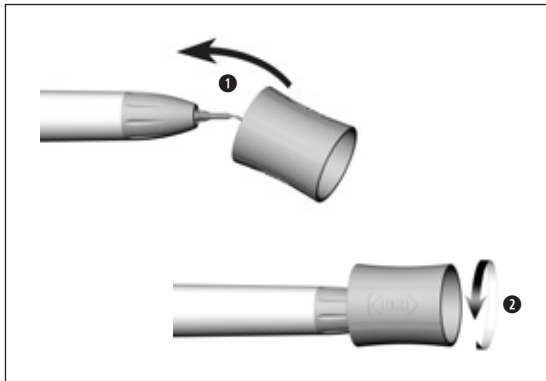
- 1** Position the tip on the thread of the handpiece.
- 2** Turn the tip changer until it audibly engages.
- 3** Carefully withdraw the tip changer.



Check secure location of the tip by applying slight axial tension.



Press the tip with about 1 N (= 100 g) pressure onto a firm sterile object to test the loading capacity of the tip.



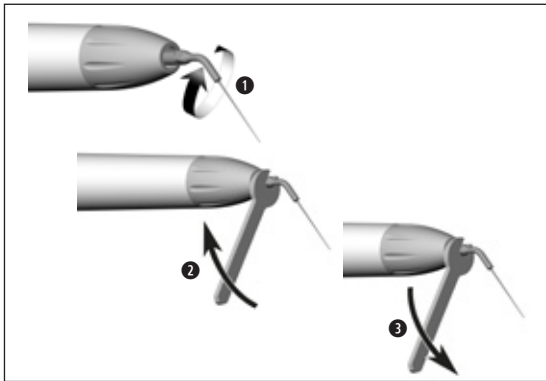
Removing the tip

- 1 Place the tip changer onto the tip.
- 2 Unscrew the tip with the tip changer.



Leave the tip in the tip changer until the hygienic maintenance process!

Insert/remove tip with spanner



Inserting the tip

- 1 Position the tip on the thread of the handpiece.
- 2 Screw the tip down using the spanner.



Check that the tip connection is secure by applying axial tension.

Removing the tip

- 3 Unscrew the tip using the spanner.

6. Test run



Do not hold the handpiece at eye level.

- > Attach the handpiece to the supply hose.
- > Insert the tip.
- > Start the handpiece.
- > If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) or discolouration of the LED, stop the handpiece immediately and contact an authorized W&H service partner [see page 37].

7. Hygiene and maintenance



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



- > Wear protective clothing.
- > Remove the tip from the handpiece.
- > Remove the handpiece from the supply hose.

- > Clean and disinfect the handpiece immediately after every treatment, to flush out any liquid (e. g. blood, saliva etc.) which may have seeped in and to prevent settling on the internal parts.

- > Sterilize the handpiece, the tips and accessories following manual or mechanical cleaning and disinfection.

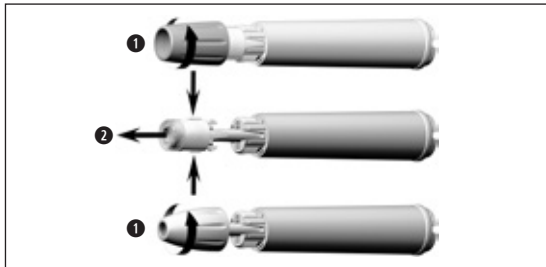
Handpiece, tips and accessories

Pre-disinfection

> If heavily soiled: Clean first with disinfectant cloths.



Only use disinfectants that have no proteinfixing effects.

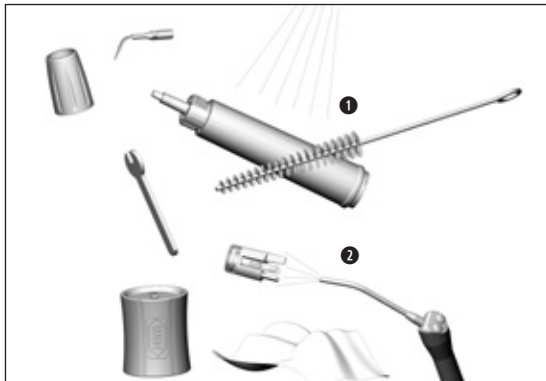


Disassemble handpiece PB-3 LED S, PB-3 LED E S with LED

- 1 Unscrew the handpiece cap.
- 2 Simultaneously push the marking (push) located opposite and unplug the LED socket.

without LED

- 1 Unscrew the handpiece cap.



Manual cleaning internal and external

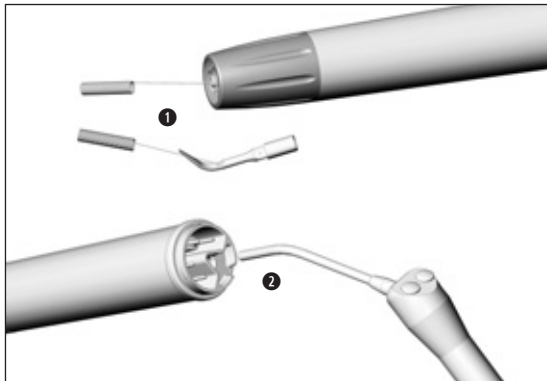
- ① Rinse under demineralized water ($< 38\text{ }^{\circ}\text{C}$) with the aid of a brush.
- ② Then remove any liquid residues (absorbent cloth, blow dry with compressed air).



Do not place the handpiece and the tip changer in disinfectant solution or in an ultrasonic bath.



You can clean and disinfect the tips in a bur bath or ultrasonic bath.



Clean spray nozzles

- 1 Clean spray nozzles carefully with the nozzle cleaner to remove dirt and deposits.



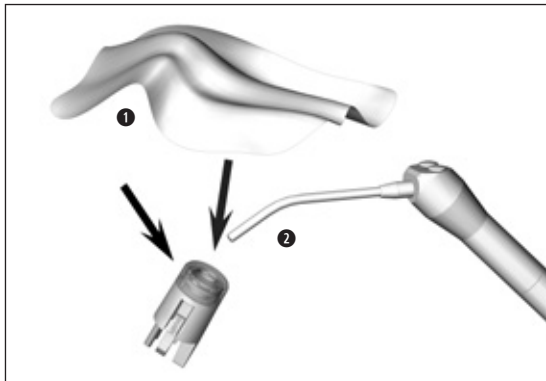
Clean and disinfect the nozzle cleaner in an ultrasonic bath/disinfection bath.

Clean the coolant tube

- 2 Blow through the coolant tube with the air syringe.



In the case of clogged up coolant outlets or coolant tubes contact an authorized W&H service partner (see page 37).



Cleaning of the optic outlet (handpiece PB-3 LED S, PB-3 LED E S)



Avoid scratching the optic outlet!


- ① Wash the optic outlet with cleaning fluid and a soft cloth.
- ② Blow the optic outlet with air syringe or dry it carefully with a soft cloth.



Carry out a visual inspection after each cleaning process. If the optic outlet is damaged, do not use the handpiece and consult an authorized W&H service partner [see page 37].



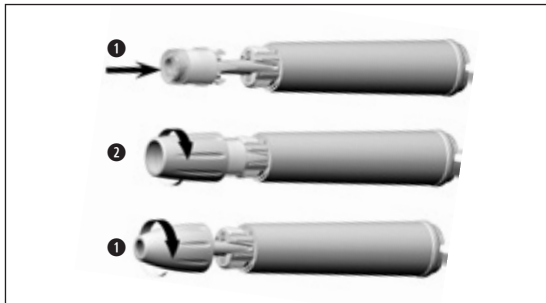
Manual disinfection

 W&H recommends wiping 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 disinfectants.



After manual cleaning and disinfection you must carry out a final sterilization (wrapped) in the class B or S steam sterilizer (according to EN 13060).



Reassemble handpiece PB-3 LED S, PB-3 LED E S with LED

① Fit LED socket onto handpiece.



Note the positioning of the connections!

② Screw on the handpiece cap.

without LED

① Screw on the handpiece cap.

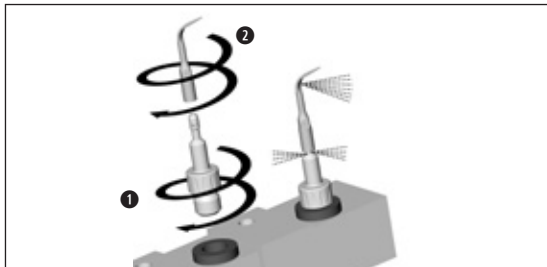
Handpiece, tips and accessories

Mechanical cleaning and disinfection inside and outside



The handpiece, the tips and the accessories can be cleaned and disinfected in the thermo washer disinfectant.

> Use the W&H adaptor kit REF 07233500 for the thermo washer disinfectant to prepare the tips.



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



W&H recommends processing in the thermo washer disinfector.

> Follow the manufacturer's recommendations for devices, cleaning and rinsing agents.



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

Sterilization and storage



W&H recommends sterilization EN 13060, class B

- > Note the instructions of the unit manufacturer.
- > Clean and disinfect before sterilizing.
- > Only sterilize the tip in the tip changer. This does not include tips which are replaced using the spanner.
- > Wrap the handpiece and the accessory in sterile goods packing according to EN 868-5.
- > Make sure that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.



The standard ISO 18397 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 500 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 their express approval for the sterilization of handpieces. Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F).



The handpiece PB-3 is not suitable for the hygienic processing and sterilization in universal hygienic units (DAC-Universal, KaVo-Lifetime and Siemens-HygieneCenter).

Before starting operation again

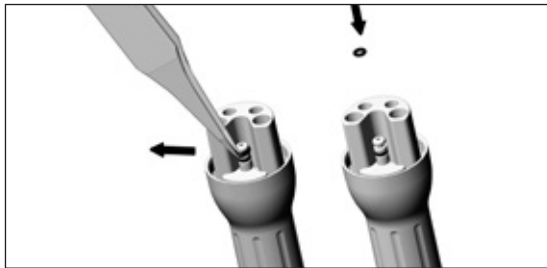


Wait until the handpiece is completely dry.

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

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

8. Changing the O-Rings



Hose coupling

- > Remove the two O-rings with a pair of tweezers and carefully replace them with new ones.

9. 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

06915000	Handpiece PB-3
07983950	Handpiece PB-3 S
07955620	Handpiece PB-3 LED S
07983980	Handpiece PB-3 LED E S
06578300	LED socket including handpiece cap
02060203	O-Ring for hose coupling (1 pc)
00636901	Nozzle cleaner
07233500	W&H Adaptor kit

10. Technical data

Handpiece

Max. power output to the handpiece
with load (ultrasonic):

Frequency (ultrasonic):

Max. oscillating amplitude (Tip 1U):

Coolant supply volume:

Water pressure:

Ambient conditions

Temperature in storage and transport:

Air humidity in storage and transport:

Temperature in operation:

Air humidity in operation:

Altitude:

PB-3, PB-3 S, PB-3 LED S, PB-3 LED E S

10W

27-32KHz

0,2 mm

min. 20ml/min; max. 50ml/min

1 – 6 bar

-40 °C (-40 °F) to +70 °C (+158 °F)

8 % to 80 % (relative), non-condensing

+10 °C (+50 °F) to +35 °C (+95 °F)

15 % to 80 % (relative), non-condensing

up to 3,000 m above sea level

Temperature information

Temperature of the handpiece at the operator side:	max. 71 °C (159.8 °F)
Temperature of the handpiece at the patient side (front area of the handpiece):	max. 50 °C (122 °F)
Temperature of the handpiece at the patient side (LED ring):	max. 48 °C (118.4 °F)
Temperature of the working part (tip):	max. 41 °C (105.8 °F)



The handpiece is defined as a type B applied part.

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / ANSI/AAMI ES 60601-1



Type B appliance (not suitable for intracardiac application)

11. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and country-specific laws, directives, standards and guidelines for disposal.

- > Waste electrical equipment
- > Accessories and spare parts
- > 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 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 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, nozzle cleaner, O-rings, 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 supplier 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 partner

Find you nearest W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

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