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Dental Air Polishing Handpiece

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Preface

Guilin Woodpecker Medical Instrument Co., Ltd. is a high-tech enterprise researching, developing, producing and selling dental products. Woodpecker owns a sound quality control system. It has two brands: Woodpecker and DTE. Our main products include Ultrasonic Scaler, Curing Light, Apex Locator, Ultrasurgery,etc.

1. Product introduction

1.1 Product introduction

Features of this device:

a) Both Supragingival and subgingival air polishing are available, enabling all-round biofilm removal and periodontal treatment;

b) Anti-suction design prevents powder and moisture from being sucked back, and prevents cross infection and dental unit interface contamination.

c) Three-section design enables ease of loading and unloading, cleaning and maintenance;

d) The tail cord connector can be removed for powder clearing;

e) The compact and handy product conforms to ergonomic design, allowing more comfortable holding and relieving use fatigue.

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1.2 Model and specifications

1.2.1 Model: AP-H/AP-H Plus

1.2.2 Specifications:

Length: 177mm, Width: 52mm, Height: 88mm

1.3 Configuration

Diagram of product external structure and accessories (Figure 1)

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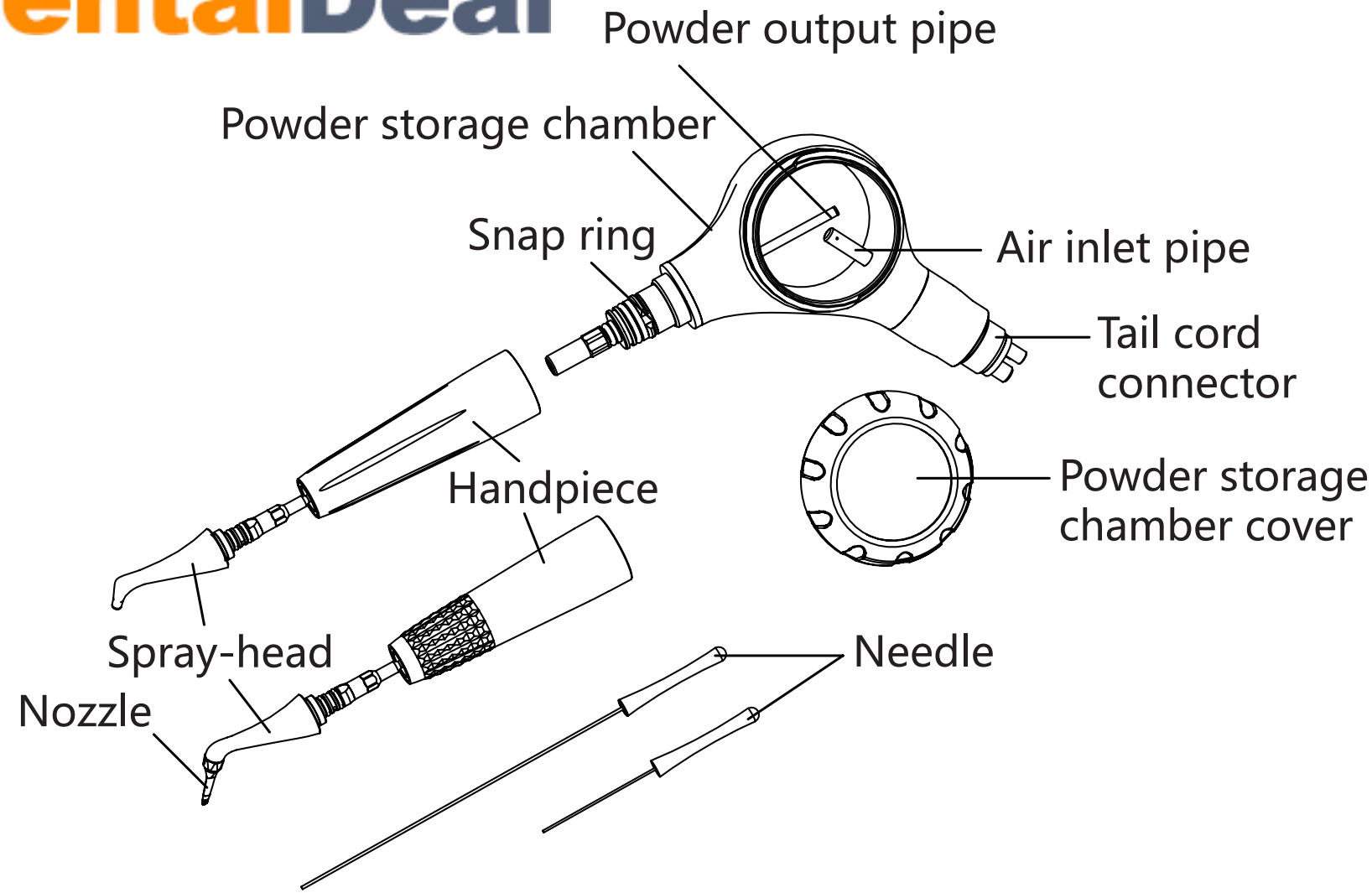


Figure 1 Schematic diagram of structure

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1.4 Product performance structure and composition

AP-H； This product is composed of handpiece, powder storage chamber, tail cord connector and needle.

AP-H Plus:This product is composed of handpiece, nozzle, powder storage chamber, tail cord connector and needle.

1.5 Scope of application

The product can be used for removal of supragingival and subgingival biofilm and pigment and for implant maintenance.

1.6 Contraindications

1.6.1 The hemophilia patient is forbidden to use this equipment.

1.6.2 The patients with heart pacemaker are forbidden to use this equipment.

1.6.3 The doctors with heart pacemaker are forbidden to use this equipment.

1.6.4 Heart disease patients, pregnant women and children should be cautious to use the equipment.

1.6.5 Patients with respiratory diseases such as asthma and chronic bronchitis are forbidden to use this equipment.

1.7 Main technical parameters

1.7.1 Input water pressure: 0.7bar to 2.2bar (70-220kPa)

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1.7.2 Input air pressure: 3.5bar to 4.5bar (350-450kPa)
1.7.3 Working mode: continuous operation, Intermittent operation
1.7.4 Weight: About 0.150kg
1.7.5 Connector: Meets the requirements of YY / T 0514
1.7.6 Operation environment:
a) Environment temperature: + 10℃ ~ +40℃
b) Relative humidity: 30% ~ 75%
c) Atmospheric pressure: 50kPa ~ 106kPa

2. Installation and operation

2.1 Schematic diagram

2.1.1 Schematic diagram of Dental Air Polisher

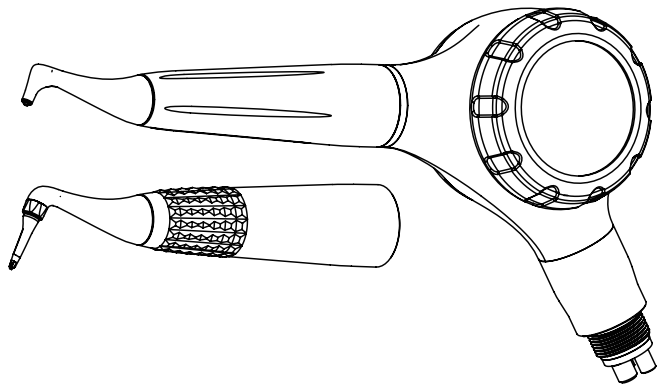


Figure 2 Product schematic diagram

2.1.2 Schematic diagram of handpiece connection

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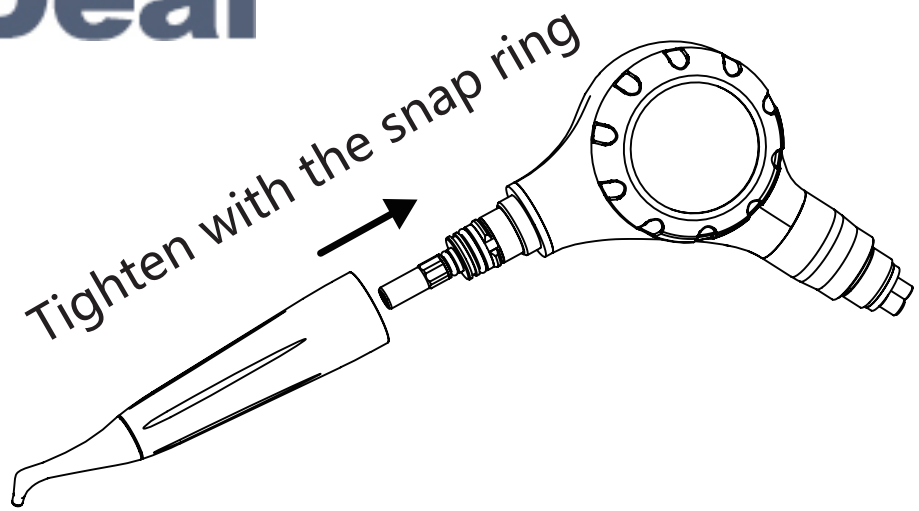


Figure 3 Schematic diagram of handpiece connection

2.2 Product installation

2.2.1 Set up external dental devices

Water supply system:

Pressure: 0.7bar-2.2bar(70-220kPa)

Temperature: Up to40℃

Air supply pressure:

Adjust the air supply pressure of the external dental equipment to obtain the air supply pressure of 3.5 bar to 4.5 bar (350-450kPa).

[Note]: Excessive air pressure will cause cracks or ruptures on the powder storage chamber and powder storage chamber cover of the Dental Air Polisher, and even cause harm to the human body.

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2.2.2 Installation and connection

2.2.2.1 Connection between Dental Air Polisher and handpiece pipeline

After drying the Dental Air Polisher interface and the handpiece pipeline interface with an air gun, directly insert the Dental Air Polisher interface into the handpiece pipeline, and then tighten the nut of the pipeline.

[Note]: Fully dry the Dental Air Polisher interface and the handpiece pipeline interface before connection, so as to avoid the spray-head blockage from damp powder during use.

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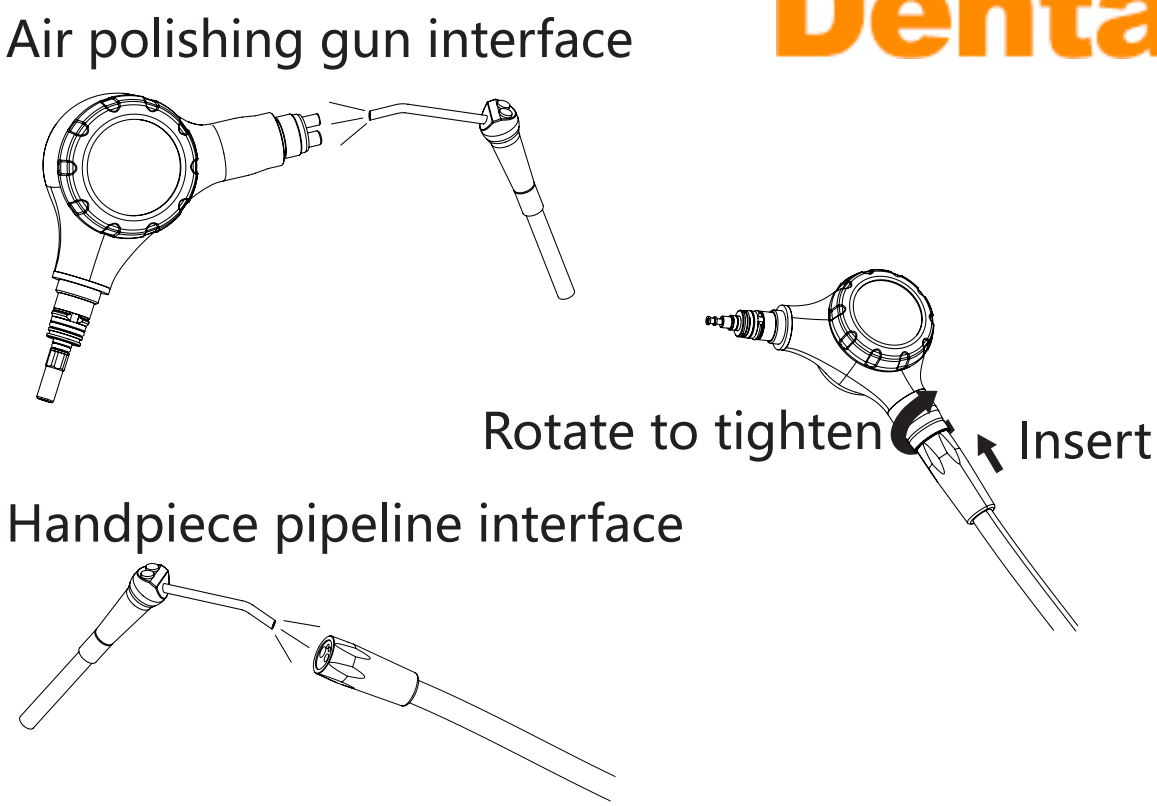


Figure 4 Tail cord connection

2.2.2.2 Handpiece connection

After drying the inside of the handpiece and the Dental Air Polisher interface, directly insert the handpiece into the handpiece interface of the gun for connection.

[Note]: Fully dry the Dental Air Polisher interface and the handpiece

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pipeline interface before connection, so as to avoid the spray-head blockage from damp powder during use.

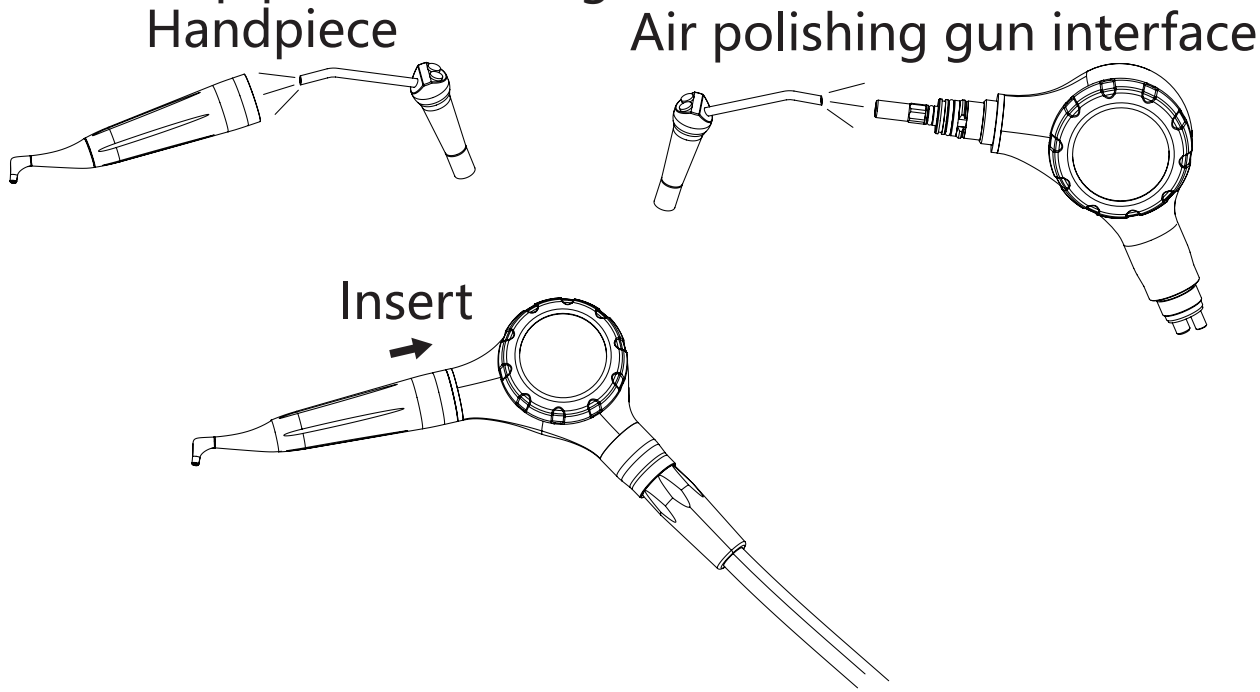


Figure 5 Handpiece connection

3. Product function and operation

3.1 Powder loading

After connecting the Dental Air Polisher, unscrew the powder storage chamber cover of the gun, put the powder into the chamber, clear the powder at the thread position of the powder storage chamber cover, and

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then tighten the cover.

[Note]: Only woodpecker brand powder can be used, and the amount of the powder added should not exceed the maximum scale mark.

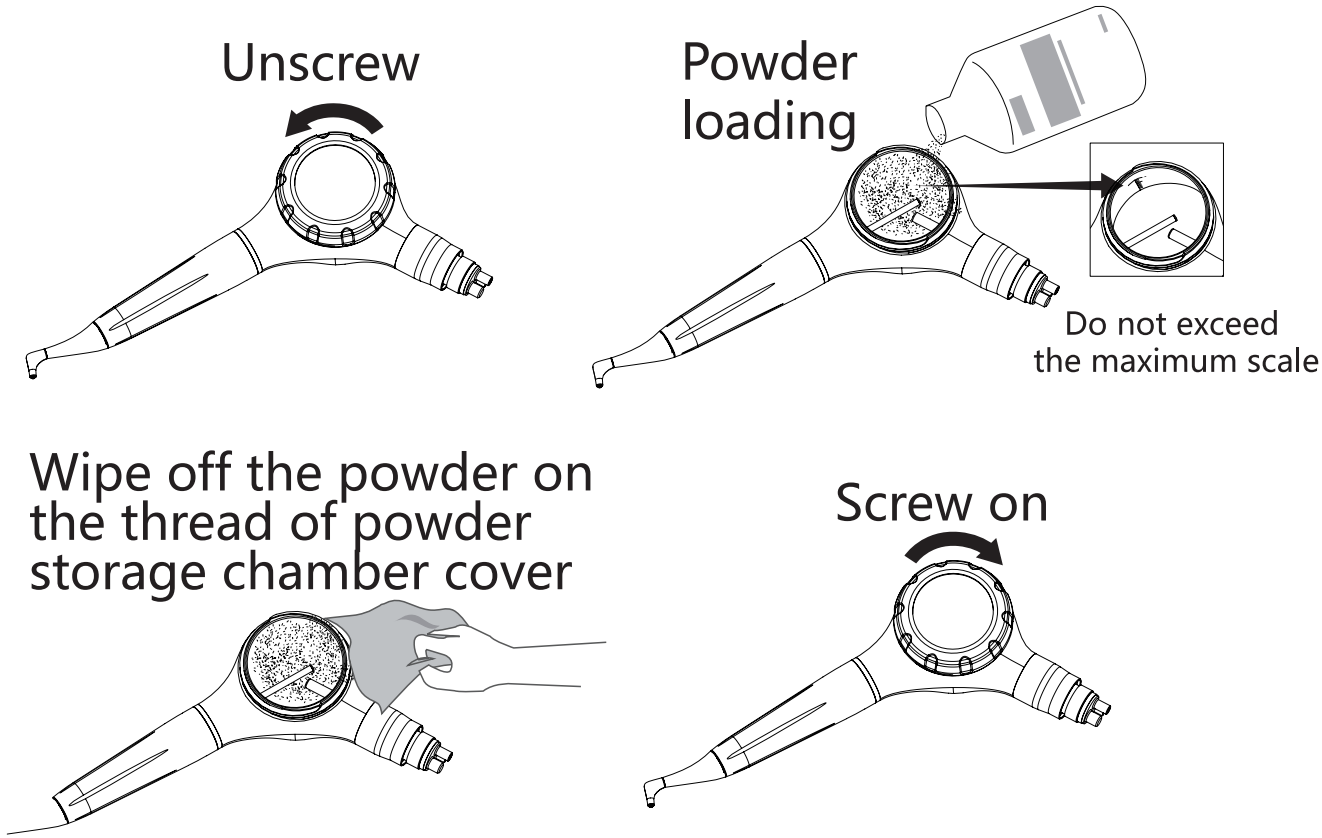


Figure 6 Powder loading

3.2 Product operation

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3.2.1 Supragingival air polishing

3.2.1.1 After loading the powder, please spray in the container outside the oral cavity for 1~3 seconds in advance to ensure that the air and water can be sprayed evenly before treating the patient.

3.2.1.2 Generally, the handpiece is held in a pen-holding position.

3.2.1.3 When using an Dental Air Polisher for normal air polishing, it is recommended that the spray-head air outlet and the tooth surface be kept at a distance of 3-5mm, and the air polishing direction is recommended to be at an angle of 30-60° with the tooth surface, as shown in Figure 7.

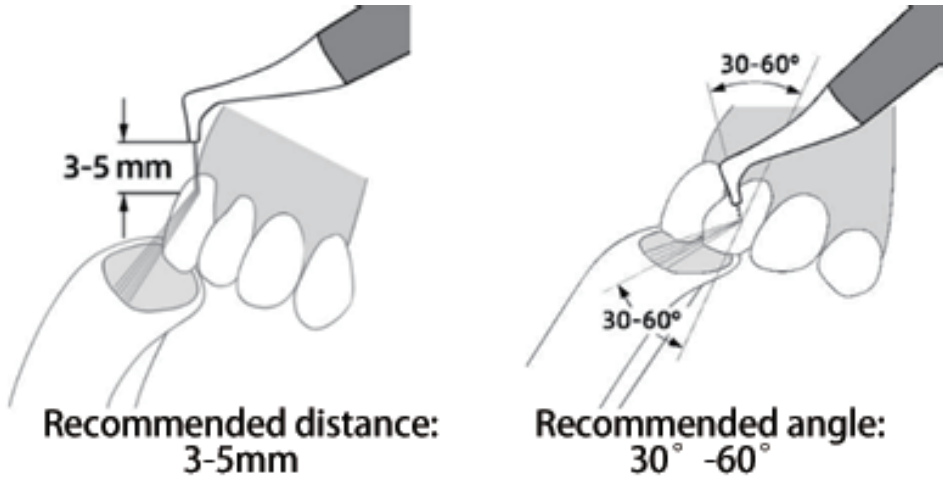


Figure 7 Schematic diagram of subgingival air polishing

3.2.2 Subgingival air polishing

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3.2.2.1 Install an accessory nozzle before use. Screw in the nozzle to the top of the subgingival handpiece, and then tighten the nozzle with a wrench (as shown in Figure 8).

3.2.2.2 After loading the powder, please spray in the container outside the oral cavity for 1~3 seconds in advance to ensure that the air and water can be sprayed evenly before treating the patient;

3.2.2.3 Generally, the handpiece is held in a pen-holding position.

3.2.2.4 When using the subgingival handpiece for normal subgingival air polishing, it is recommended to use a nozzle to remove the bioflm in the periodontal pocket at subgingival 4-9mm, and perform up and down motion for scaling.

3.2.2.5 The air polishing time of each periodontal pocket is recommended for no more than 5 seconds.

3.2.2.6 Please ensure that the handpiece has a normal waterway before use. Adjust the water flow and air pressure of the main unit to an appropriate level according to the conditions of biofilm or pigment when scaling. Do not spend too much time in local air polishing when scaling.

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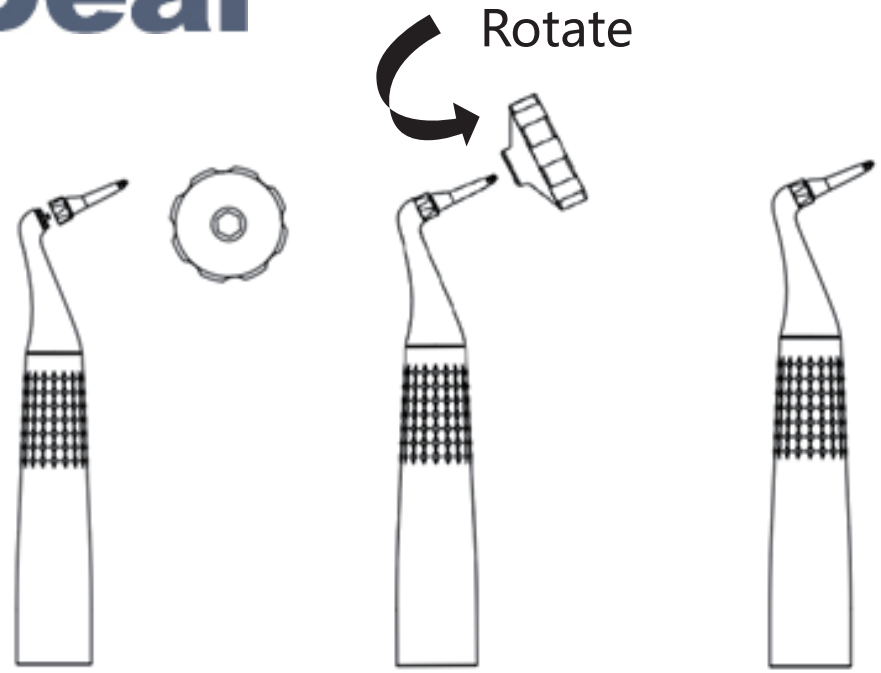


Figure 8 Tighten the subgingival nozzle

[Note]:

1. It is forbidden to pull out the tail plug when the handpiece is working.
2. Only subgingival powder can be used for subgingival air polishing.

3.2.3 Instructions for main components

3.2.3.1 Handpiece: Working part, the spray-head of which can be pulled out by rotation. In case of blockage, the user can rotate the spray-head to loosen and pull out it, and then use the needle to negotiate. The spray-head can be sterilized at high temperature.

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3.2.3.2 Powder storage chamber: Working part, used for powder storage.

3.2.3.3 Nozzle: Disposable accessory.

3.3 Maintenance

3.3.1 Powder clearing

① Open the powder storage chamber cover and clear the remaining powder on it;

② Blow off the powder remaining in powder storage chamber with air;

③ Wipe off the powder residues on the surface of the Dental Air Polisher with alcohol cotton or dry towel.

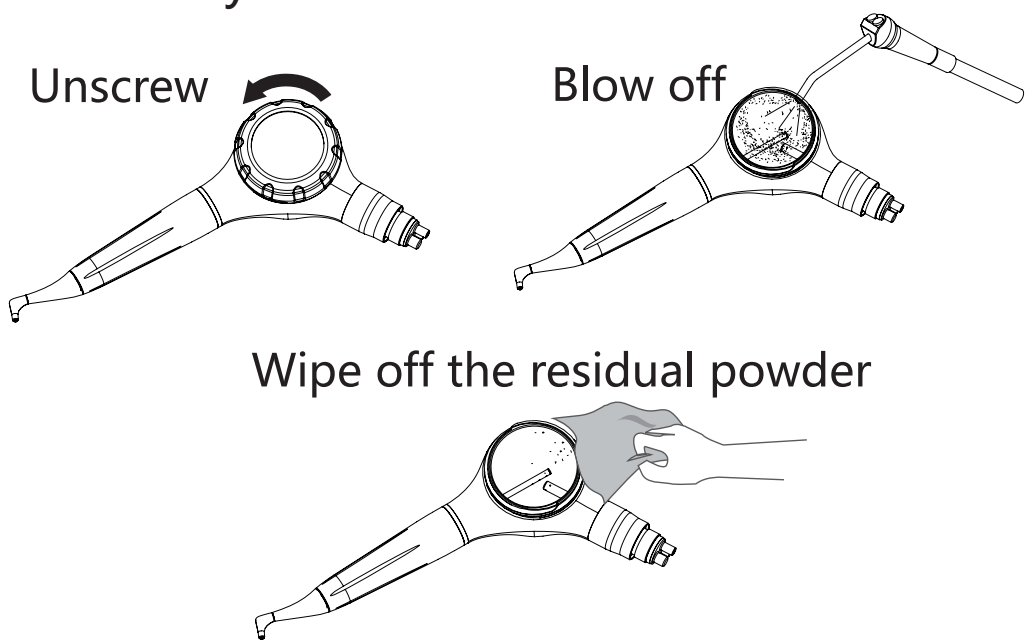


Figure 9 Schematic diagram of powder clearing

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3.3.2 Spray-head and handpiece cleaning

① Remove the handpiece of the air poishing gun, unscrew the spray-head and pull out it, as shown in Figure 10;

② Aim the air gun at the nozzle and blow out the powder inside the nozzle;

③ Use an air gun to blow the front and rear ends of the handpiece to clean the remaining moisture on the handpiece.

④ If the nozzle is blocked, please use the needle to clear it.

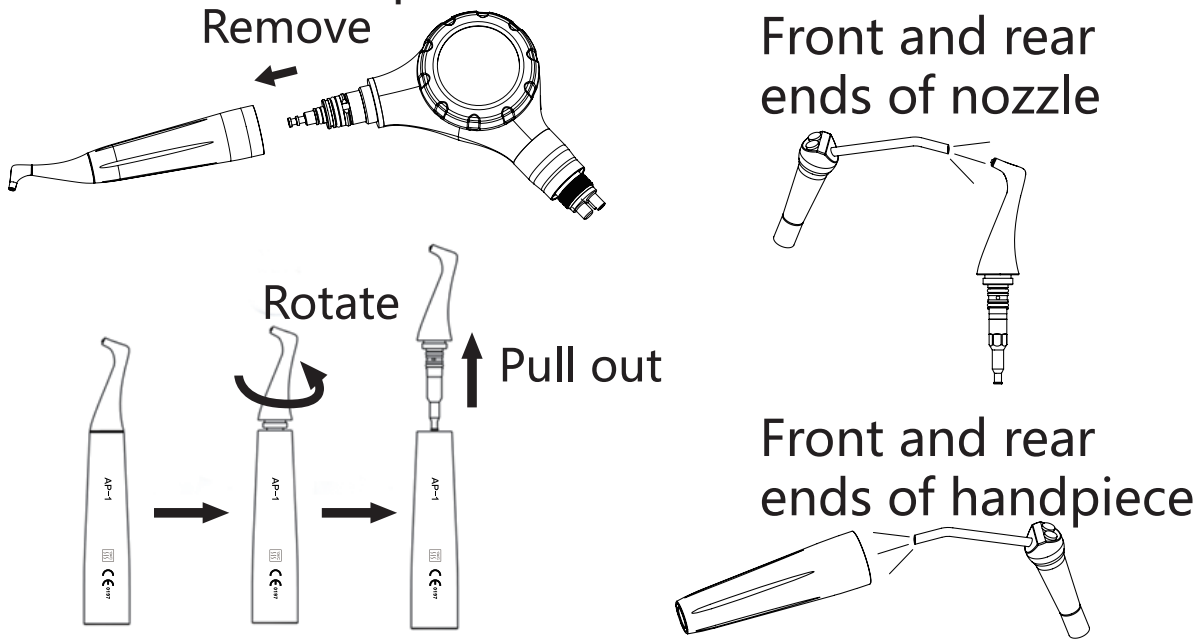


Figure 10 Schematic diagram of handpiece cleaning

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3.3.3 Daily maintenance

• Pay attention to daily check whether the handpiece of the Dental Air Polisher is cracked, deformed or falling off, to ensure that the handpiece can be used normally; pay attention to check and clean the sealing ring to ensure its integrity and cleanliness, otherwise it will affect the product sealing and normal operation;

• Keep the Dental Air Polisher dry. Rain, moisture and various liquids may damp the powder and affect its normal use;

• Do not throw, beat or vibrate the Dental Air Polisher. Rough treatment of the gun will damage the strength and sealing of equipment.

• Do not paint the instrument with pigment, which will leave debris in the detachable parts and affect the normal operation.

3.4 Troubleshooting

Fault	Possible cause	Solution

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No air coming out of the handpiece	The air source was not correctly installed.	Check whether the air source switch or airway of the dental unit is properly connected.
	Clogged spray-head	Negotiate the spray-head with a needle, then dry it with an air gun, or soak it in warm water and dry it.
	Clogged powder storage chamber	Check whether the holes on the air inlet pipe and powder outlet pipe in the powder storage chamber are blocked. If blocked, negotiate with a needle and blow off with an air gun.
No air coming out of the handpiece	The waterway was not correctly installed.	Check whether the air source switch or airway of the dental unit is properly connected.
	Clogged waterway of the handpiece	Blow the handpiece waterway with an air gun

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Water leakage at the connecting end between the spray-head and the handpiece	Damaged waterproof O-ring	Replace waterproof O-ring
Water leakage at the connecting end between the handpiece and powder storage chamber	Damaged waterproof O-ring	Replace waterproof O-ring

4. Cleaning, disinfection and sterilization

Warnings:

The use of ultrasonic cleaning equipment and strong cleaning disinfectant (alkaline pH> 9 or acidic pH <5) will shorten the service life of the product. In this case, the manufacturer is not liable. Do not expose the equipment to the high temperature above 138℃ .

Processing restrictions:

① Only the handpiece and spray-head of the Dental Air Polisher can

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be sterilized, the powder storage chamber, tail cord connector and the connecting end between the two cannot be sterilized;

② The product is designed for a large number of sterilization cycles, and the materials for manufacturing are selected accordingly. However, thermal and chemical stresses can lead to product aging each time they are re-prepared for use. The maximum allowable disinfection times of handpiece and spray-head are 1000.

4.1 Pre-treatment

4.1.1 Processing principles

Only after effective cleaning and disinfection can effective sterilization be carried out. Please ensure that as part of the sterility of the product in use, only fully validated equipment and product-specific procedures are used for cleaning / disinfection and sterilization, and that validated parameters are followed during each cycle.

Please also comply with the applicable legal requirements of your country/region and the health regulations of hospitals or clinics, especially other requirements regarding virus inactivation.

4.1.2 Preparation before cleaning

Tools: Air gun, tray, soft brush, soft cloth for cleaning and drying. Processing must be carried out immediately after the operation, no later

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than 30 minutes after the completion of the operation. The steps are as follows:

4.1.2.1 Remove the handpiece from the Dental Air Polisher, unscrew the spray-head from the handpiece counterclockwise and place it in the tray.

4.1.2.2 Use a clean soft brush to carefully scrub the handpiece and spray-head as well as the connection position between the handpiece and powder storage chamber until no dirt is visible on the surface; then rinse the dirt on the air polishing handpiece and spray-head surface with pure water (or distilled water / deionized water).

4.1.2.3 Dry the surface of the handpiece with a clean soft cloth and place it in a clean tray.

[Note]: The water used here must be pure water, distilled water or deionized water.

4.2 Cleaning

Cleaning (automatic)

4.2.1 The detergent shall be CE certified to be effective according to EN ISO 15883.

4.2.2 The cleaning procedure is suitable for handpiece and spray-head. The rinsing time should be sufficient and ultrasonic cleaning is prohibited.

4.2.3 It is recommended to use a washer-disinfector in accordance with

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EN ISO 15883. For specific steps, see the automatic disinfection part in the next section, “Disinfection”.

[Note]:

a) The detergent used here must be compatible with the Dental Air Polisher and only freshly prepared solutions can be used.

b) At the washing stage, the water temperature should not exceed 45° C; otherwise the protein will solidify and be difficult to remove.

c) After cleaning, chemical residues should meet cytotoxicity test requirements. Note: Please write down the selected cleaning equipment, the steps and parameters of the processing program, and the detergent.

4.3 Disinfection

4.3.1 Place the handpiece and spray-head of the Dental Air Polisher carefully in the disinfection box. Contact between the handpieces is prohibited.

4.3.2 Use a suitable rinsing adapter and connect the internal water pipe to the washer-disinfector.

4.3.3 Start the program

4.3.4 After the procedure is completed, remove the handpiece and spray-head from the washer-disinfector for inspection (see the “Daily

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maintenance" section) and packaging (see the "Packaging" section). Dry the handpiece repeatedly if necessary (see the "Drying" section).

[Note]:

a) Disinfection must be carried out within 2 hours after the cleaning phase. Automatic disinfection is preferred if conditions permit.

b) The washer-disinfector shall be CE certified to be effective according to EN ISO 15883.

Conduct disinfection under high temperature. The temperature shall not exceed 134 ° C and disinfection at this temperature shall not exceed 20 minutes.

c)The disinfection cycle shall comply with EN ISO 15883.

4.4 Drying

If the automatic drying function is not included in your cleaning and disinfection process, please perform drying after cleaning and disinfection.

4.4.1 Lay a clean white cloth on the workbench, align the handpiece and spray-head with the cloth, and then blow the handpiece and spray-head with filtered dry compressed air (maximum pressure of 3 bar) for drying. If there is no liquid sprayed on the white cloth, the drying is completed.

4.4.2 Drying can also be done directly in a medical drying cabinet (or oven). The recommended drying temperature is 80 ℃ ~ 120 ℃ and the

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drying time should be 15 ∽ 40 minutes.

4.4.3 After drying, remove the handpiece and spray-head from the drying oven for testing (see "Daily maintenance").

[Note]:

a) Product drying must be done in a clean place.

b) Drying temperature shall not exceed 138℃ ;

c) The equipment in use should be inspected and maintained regularly.

4.5 Packaging

Assemble the disinfected and dried handpiece and its accessories, and quickly package them in a medical sterilization package (or an exclusive holder, a sterile box).

[Note]:

(1) The packaging used shall conform to ISO 11607;

(2) It can withstand the high temperature of 138℃ , and has sufficient steam permeability;

(3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the entry of pollutants;

(4) Avoid touching different metal parts when packing.

4.6 Sterilization

Only the following steam sterilization procedures (Fractionated pre-

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vacuum process) can be used for sterilization, and other sterilization procedures are prohibited:

4.6.1 The steam sterilizer complies with EN13060 or is certified by EN 285 and complies with EN ISO 17665;

4.6.2 The maximum sterilization temperature is 138℃ ;

4.6.3 At a temperature of 134° C, the sterilization time is at least 5 minutes;

4.6.4 The maximum sterilization time at 134° C is 20 minutes.

5. Storage and transportation

5.1 Storage

5.1.1 The product should be handled with care and away from the earthquake source. Ensure that it is installed or stored in a cool, dry and ventilated place indoors.

5.1.2 Do not mix the product with toxic, corrosive, flammable, or explosive materials during storage.

5.1.3 The product should be stored in the environment with relative humidity of 10% ~ 90%, atmospheric pressure of 50kPa ~ 106kPa and temperature of -10℃ ~ +40℃ .

5.1.4 After sterilization, the product should be packaged in a medical

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sterilization package or a clean sealed container and stored in a special storage cabinet. The storage time shall not exceed 7 days. If exceeded, it should be reprocessed before use.

Precautions:

(1) The storage environment should be clean and be disinfected regularly;

(2) Product storage must be batched, marked and recorded.

5.2 Transportation

5.2.1 Avoid excessive impact and vibration during transportation. Handle it with care and avoid inversion.

5.2.2 It should not be mixed with dangerous goods during transportation.

5.2.3 Avoid sunlight, rain or snow during transportation.

6. Symbols



Date of manufacture



Follow Instructions for Use



Recovery



Use indoor only

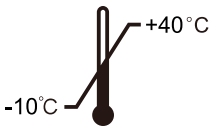
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Handle with care



Appliance complies with WEEE directive



Temperature limit for storage



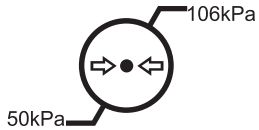
Maximum sand volume



Keep dry



Can be autoclaved



Atmospheric pressure for storage



Humidity limit for storage

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