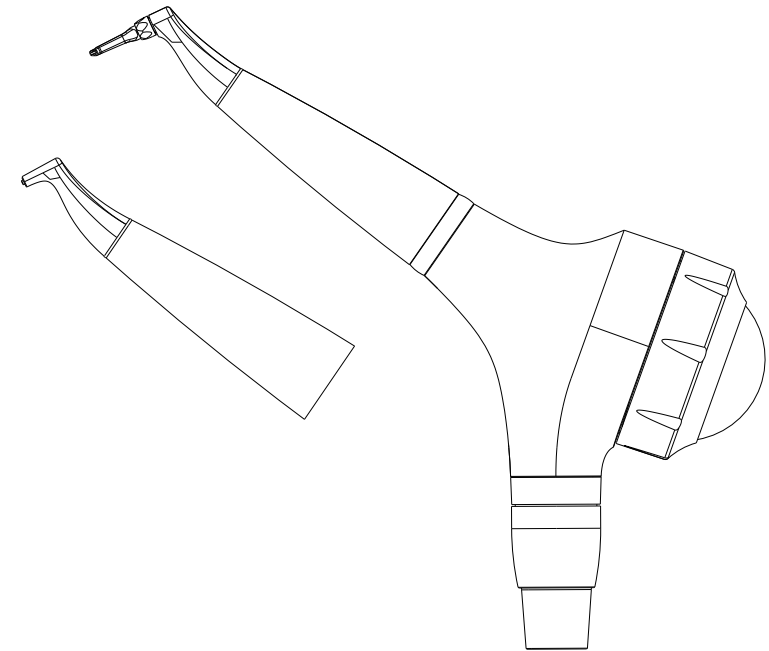




iJet 2S

Powder Jet Scaler

Operation Instructions

Guilin Refine Medical Instrument Co., Ltd.

RF-I2S-M001 Version: 1.2 2024-10-18

15. Storage

Storage of sterilized products in a dry, clean and dust free environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C; refer to label and instructions for use.

After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

16. Service life

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in aging of the devices. If the number of permissible re-sterilization cycles is restricted, this will be pointed out in the product specific instructions.

 **The use of ultrasound baths and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.**

 **The devices may not be exposed to temperatures above 138 °C.**

It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

10. Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to AO value (see EN 15883).
A disinfection cycle of 5 min disinfection at 93°C has been validated for the product to achieve an AO value of 3000.

11. Drying

Automated Drying:
Drying of outside of products at 40°C, 5 min through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

12. Functional testing, maintenance

Visual inspection for cleanliness of the products and reassembling if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until products is visibly clean.
Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

13. Packaging

Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

14. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C)

Maximum sterilization temperature: 138°C

Drying time:

For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.

After sterilization:

- Remove the product from the autoclave.
 - Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
- Check that the sterilization wraps or pouches are not damaged.

⚠ Flash sterilization is not allowed on lumen products.

⚠ The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).

In such cases, please observe the respective valid standards (EN ISO 14937/ANSI AAMI ISO 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

•Maximum sterilization temperature 138°C

FORWARD

Thank you for buying a new Refine iJet 2S product.

INTRODUCTION

INTRODUCTION

It is a handheld dental device which is powered by a dental unit and jets the sandblasting powder on the surface of teeth.

Its characteristics are:

- This product can perform supragingival and periodontal sandblasting, all-round plaque removal and periodontal treatment.
- Anti-suction design, prevent powder and moisture from being sucked back, prevent cross infection and connector of dental unit cable pollution.
- Air flow adjustment function to meet the requirements of clinical use.
- The product is compact and lightweight, ergonomically designed, more comfortable to hold which relieves fatigue.

CONFIGURATION

Structure and Accessories:

- 1 Locking cap
- 2 Periodontal nozzle
- 3 Periodontal sandblasting handpiece
- 4 Subgingival sandblasting handpiece
- 5 Seal ring 1
- 6 Seal ring 2
- 7 Main body
- 8 Powder chamber seal ring
- 9 Powder chamber cap dome
- 10 Powder chamber cap ring
- 11 Air gear switch
- 12 Torque wrench
- 13 Cleaning spray nozzle
- 14 Short cleaning needle
- 15 Long cleaning needle

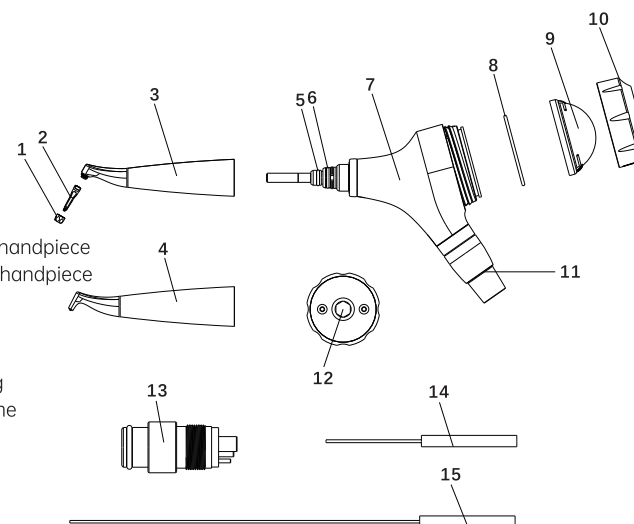


Figure 1 Product Component Diagram

PERFORMANCE, STRUCTURE AND COMPOSITION

The product consists of a main body, a sandblasting handpiece, a tail connector, and a powder chamber.

SCOPE OF APPLICATION

The product can be used with prophylaxis powder to remove supragingival and periodontal plaque, soft tartar and stains on the teeth surface.

Recommended prophylaxis powder for supragingival scaling: sodium bicarbonate, glycine, erythritol, mesh number between 80~250. Recommended dental Power Jet Handpiece for periodontal scaling: glycine, erythritol, with a mesh number of more than 500.

CONTRA-INDICATION

Patients suffering from chronic bronchitis or asthma must not, under any circumstances, be treated by this product. The jet of air and powder could cause respiratory difficulties.

TECHNICAL DATA

Water input pressure	0.7bar~2.2bar(70~220kPa)
Air input pressure	3.5bar~4.5bar(350~450kPa)
Water flow	50~80ml/min
Operating conditions	Environment temperature: +5°C~+40°C Relative humidity: 30%-75% Atmosphere pressure: 70kPa-106kPa
Storage and transport Conditions	Relative Humidity: 10%-93% Atmospheric Pressure: 70kpa-106kpa Temperature: -20°C - +55C
Manufacturing Date	See the packing
Life time	5 years

APPLICATIONS

- Remove subgingival plaque for placing sealants.
- Removes periodontal plaque and prevents periodontitis.
- Surface Preparation prior for bonding/cementation of inlays onlays, crowns and veneers.
- Surface preparation prior to placing composite restorations.
- Cleaning prior to bonding orthodontic brackets.
- Effectively remove plaque and stain for orthodontic patients.
- Cleaning implant fixture.
- Remove stain for shade determination.
- Remove plaque prior to fluoride treatment.
- Polishing on the surface of teeth after scaling treatment by piezo scaler.

PRECAUTIONS ⚠

Please read the following warnings to avoid potential injury to people or damage to the device.

- During the operation, the operator should wear protective glasses and protective masks throughout the process, Patients should wear protective glasses
- It is recommended to use a suction device to suck off excess powder during operation.
- If the powder gets into the glasses accidentally, please rinse immediately with plenty of water and consult an ophthalmologist.
- Do not aim the nozzle directly at fillings, crowns or dentures, as this may cause damage to these restorations
- This device can only be used by dentists or professional operators.
- For cleaning and disinfection, use disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts). Use of other disinfectants may

4. Preparation - basic principles

4.1 It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

4.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

5. Preparation at the point of use

Disconnect product. Remove gross soiling of the products with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the products in a humid surrounding.

6. Transportation

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

7. Preparation for decontamination

The products must be reprocessed in a disassembled state, as far as possible.

8. Pre-cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

9. Cleaning

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

Automated Cleaning:

Use a washer-disinfector (WD) meeting the requirements of the ISO 15883 series.

Put the products into the machine on a tray. Connect the products with the WD by using suitable adapter and start the program:

4 min pre-washing with cold water (<40°C)

Emptying

5 min washing with a mild alkaline cleaner at 55°C

Emptying

3 min neutralising with warm water (>40°C);

Emptying

5 min intermediate rinsing with warm water (>40°C)

Emptying

The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

⚠ Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

Attachment 1

(Reprocessing instructions of cleaning, disinfecting and sterilizing)

1. Beginning work

- 1.1 Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.
- 1.2 To prevent injury to people and damage to property, please heed the corresponding directives.
- 1.3 The instructions in this manual are only applicable to the product which it was delivered with.

2. Introduction

- 2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.
- 2.2 The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental instruments are based on the potential risk of infection associated with their use.
- 2.3 It is recommended to use steam sterilization.
- 2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.
- 2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.
- 2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

3. Reprocessing - instructions for reusable products

3.1 The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

⚠ Important: Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used.

3.2 Reusable products must be cleaned, disinfected and sterilized prior to first use. Reprocessing procedures have only limited implications to this device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

⚠ In case of damage the product should be reprocessed before sending back to the manufacturer for repair.

cause discoloration or cracking.
* For details, contact the manufacturer of the disinfectant.
* In this operation manual, disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts) is called by "disinfectant alcohol".

INSTALLATION AND USE

DIAGRAM

Diagram of Power Jet Scaler

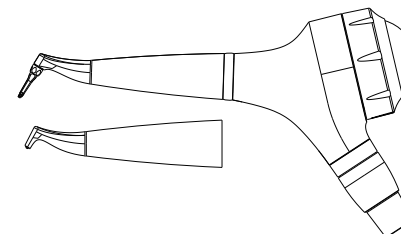


Figure 2 Product Diagram

INSTALLATION

1. Setting up external dental equipment:

Water supply system:

- Pressure: 0.7bar~2.2bar(70~220kPa)
- Temperature: up to 40°C

Air supply pressure:

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

⚠ Excessive air pressure will cause cracks or ruptures in the powder chamber and powder chamber cover, and even cause human injury.

2. Installation and connection

Connection between Power Jet Scaler and quick connector:

Use the 3-way prayer to dry the Power Jet Scaler tail connector and the quick connector, directly insert the quick connector into the Power Jet Scaler tail connector, and then tighten the quick connector. (See Figure 3)

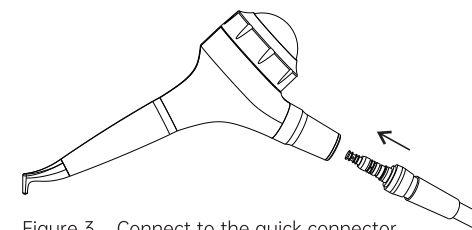


Figure 3 Connect to the quick connector

⚠ Before installing the device, please ensure that the quick connector, Power Jet Scaler, powder chamber, powder chamber cap, tail connector, air inlet pipe and air outlet pipe in the powder chamber are completely dry. Drying can be done with a 3-way prayer.

Connection between Power Jet Handpiece and the main body:
After drying the inside of the handpiece and the connector of the main body, directly insert the handpiece into the interface of the main body. (See Figure 4)

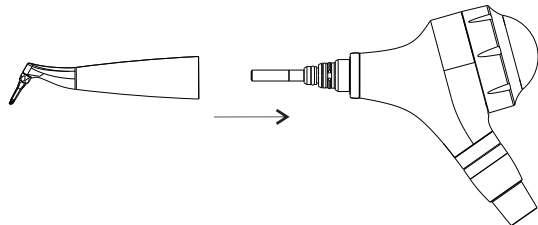


Figure 4 Connect the handpiece to the main body

Adjust the water flow:
Before loading the prophylaxis powder, adjust the water flow so that the Power Jet Scaler gets an even amount of water.

Load prophylaxis powder:
After connecting the Power Jet Handpiece, unscrew the powder chamber cover of the Power Jet Scaler, put the prophylaxis powder into the chamber, clean the powder at the thread position of the chamber cover, and then tighten the chamber cover. (See Figure 5)

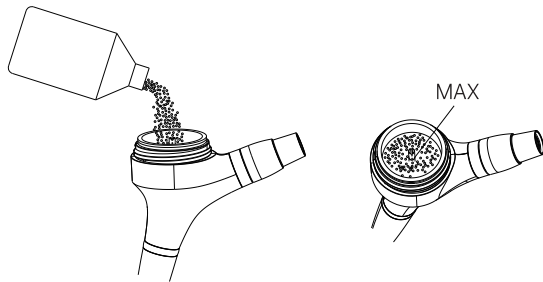


Figure 5 Prophylaxis powder filling

⚠ Please use only powder provided or recommended by Refine.
Make sure the powder chamber is absolutely dry.
Do not go over the 'MAX' limited.
The opening of air inlet and outlet pipe should not be covered by powder.
Clean the threads of the powder chamber before screwing on the cap.
Do not shake the device as this could cause the powder to clog the tubes.

STORAGE, TRANSPORTATION AND MAINTENANCE

STORAGE

1. Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
2. Do not put it with other dangerous goods together during transportation.
3. This device should be stored in an environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70kPa to 106kPa, and a temperature of -20°C to +55°C.
4. After sterilization, the product should be packaged in a medical sterilization bag or a clean airtight container and stored in a special storage cabinet. Retention must not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Preventive measures
-The storage environment should be clean and should be disinfected regularly.
-Product storage must be batched, marked and documented.

TRANSPORTATION

1. Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
2. It should not be mixed with dangerous goods during transportation.
3. Avoid sun, rain and snow during transportation.

MAINTENANCE

1. At the end of each day, use long and short needles to clean up each pipeline of the equipment.
2. Replace the powder chamber cap seal ring, seal ring 1 and seal ring 2 every 6 months.
3. Ultrasonic cleaning of the handpiece with hot water soak once a week.

ENVIRONMENTAL PROTECTION

The product doesn't contain battery or toxic substances. And there are no components which should be removed specially from the main unit for disposal and scrapping.
After the device is out of its service life, you must not discard it in domestic household waste. Please comply with the Waste Electrical and Electronic Equipment (WEEE) directives and the medical waste disposal regulations of your country.
Handpiece could easily contact to the biological sources and cause biological hazards, shall be detached from the main unit and reprocessed before the disposal and scrapping.
Handpiece are sharp instruments and easy to scratch people. Should you dispose it in the medical waste containers for sharp instruments.

AFTER-SALE SERVICE

After this product is sold, if it cannot work normally due to quality problems, please contact the local dealer or the company with the warranty card for replacement or repair. Damages due to non-adherence to the operation instructions or wear out of parts are excluded from warranty.

⚠ The warranty of your product will be cancelled if you try to open it.

SYMBOLS

	Trademark		Serial Number		Production Date		Refer to instruction manual/booklet
	Manufacturer		Valid Period		water-disinfectant for thermal disinfection		sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Caution!		Atmospheric pressure		Temperature Limitation		Humidity Limitation
	CE Mark		Medical device		Waste electrical and electronic equipment		Unique device identifier

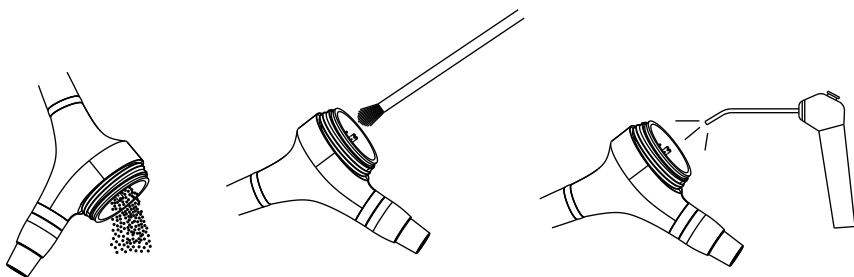


Figure 10 Powder cleaning

2. Handpiece and body cleaning

- Remove the handpiece, connect the handpiece to the cleaning spray nozzle, the connector the nozzle to the hose of dental unit. Keep the air running for at least 10 seconds to thoroughly clean the handpiece tubes. (See figure 11)

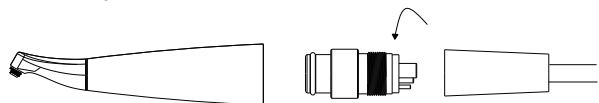


Figure 11 Handpiece cleaning

- Wash the powder chamber cap, cap ring, cap dome and handpiece with distilled or deionized water.
- Clean the threads of the powder chamber, body surface and handpiece surface with alcohol (ethanol, isopropanol).
- If the nozzle is clogged, use a thru-needle to unblock.

After the above pre-cleaning, please conform to the attachment 1 "Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing" to conduct cleaning, disinfecting, sterilizing for handpiece.

The maximum cleaning, disinfection and sterilization cycles of handpiece is identified as 300 cycles.

CAUTIONS

1. Only the handpiece can be autoclavable under high temperature and pressure.
2. Make sure that there is no chemical liquid attached on the handpiece surface and the handpiece is completely dry before sterilization.
3. Do not clean or scour this device by high acidity cleanser or disinfectant.
4. Submerge only the handpiece in a disinfectant bath. Do not submerge the unit in a disinfectant bath.
5. It must be sterilized before the first use and after each patient uses it.
6. Clean up within 30 minutes after treatment, high temperature and high pressure sterilization treatment should be taken place within 2 hours after cleaning.

FUNCTION AND USE

AIR VOLUME SWITCH OPERATION

The air volume of the Power Jet Scaler has two gears. Rotate the air volume adjustment switch to switch between gears. (See Figure 6)

G – Supragingival sandblasting

P – Periodontal sandblasting

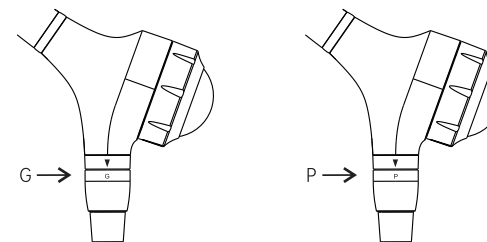


Figure 6 Gear switching

SUPRAGINGIVAL SCALING FEATURES AND REQUIREMENTS

1. Setting water and air

You can modulate the result according to the adjustments:

- Increasing the air pressure increases the cleaning effect and reduces the polishing effect.
- Increasing the water flow rate increases the polishing effect and reduces the cleaning effect.

2. Wear a face mask and eye protection

- Patients should wear goggles at all times to prevent powder from entering the eyes.
- Operators should wear goggles and protective masks throughout the process to prevent bacteria, viruses or sandblasting powder from being inhaled

3. Treatment

- Place absorbent cotton rolls under the lips to prevent the powder from being brought into the patient's saliva and effectively protect the gums.
- Use the high-speed evacuator of your dental unit to evacuate the air and powder mixture deviated by the treated tooth.
- The evacuator must be handled by the same operator.
- Do not direct the nozzle directly towards to the surface of teeth. Respect a distance of 3 to 5mm. Vary the angle between nozzle and tooth from 30 to 60 degrees. (See Figure 7)
- After the treatment, polish the teeth surfaces by setting the water flow rate to the maximum.

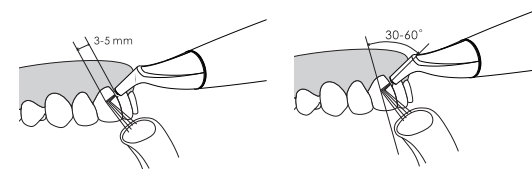


Figure 6 Subgingival Sandblasting

-  The air powder jet is powerful. It can cause injury to the gums or an emphysema caused by the introductions of air into the soft tissue spaces. Do not direct the nozzle directly at the gum tissue or into the gingival sulcus.

⚠ After the treatment, the keratin and protein layer on the tooth surface are completely removed, the teeth do not have any natural protection with respect to coloring. Tell you patient that during 2 to 3 hours following treatment, he should neither smoke, nor consume food or drinks which could strongly color the teeth (tea, coffee...).

PERIODONTAL SCALING FEATURES AND REQUIREMENTS

1. Install the periodontal nozzle before use, take the nozzle and assemble it to the top of the handpiece according to the positioning direction, then use the wrench to lock the locking cap to the nozzle. (See Figure 8)
- During installing the periodontal nozzle, pay attention to the installation direction. The nozzle has a protruding edge for positioning to prevent the nozzle from being installed in reverse, the base will not match;
- After inserting the nozzle in the correct direction, screw on the locking cap, use a wrench to lock the nozzle locking cap, and remove the wrench after locking.

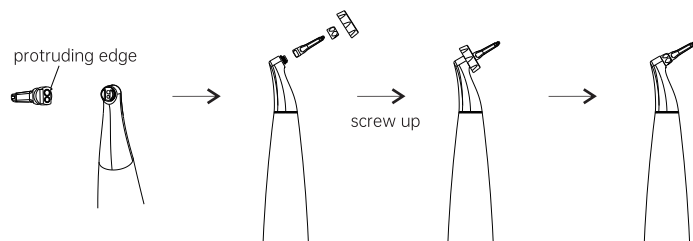


Figure 8 Installation of Periodontal Nozzle

2. After filling the powder, please spray it in the outer container for 1~3 seconds in advance to ensure that the air and water can be sprayed evenly before treating the patient.
3. Generally, the Power Jet Scaler is held in a pen-holding position.
4. When using the device to perform normal periodontal scaling, it is recommended to use the nozzle to remove the plaque from the periodontal pocket of 1~3mm below the gingival, and perform up and down lifting and scaling during use. (See Figure 9)
5. Scaling is recommended for less than 5 seconds for each periodontal pocket site.
6. Before use, please make sure that the water channel of the handpiece is unobstructed. When cleaning teeth, adjust the water volume and air pressure of the main unit to an appropriate gear according to the conditions of dental plaque or pigment; do not stay for too long in one part when cleaning teeth.

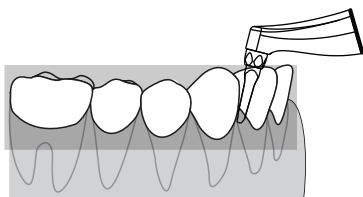


Figure 9 Periodontal sandblasting operation

⚠ It is forbidden to pull out the tail plug when the device is working; For periodontal scaling, use only periodontal prophylaxis powder. The periodontal nozzle is a disposable non-sterile product and must be disinfected with medical alcohol before use.

INSTRUCTIONS OF MAIN COMPONENTS

1. Handpiece: the nozzle on the handpiece can be rotated and pulled out. In the case of blockage, the user can rotate the nozzle to loosen it first, then pull out the nozzle, and then use a needle to unblock it, which can be sterilized by high temperature.
2. Powder chamber: used for containing prophylaxis powder.
3. Nozzle: single use only

TROUBLESHOOTING

Type of Problem	Solutions
No powder / air jet coming from the unit	The interior of the handpiece is clogged: Unscrew the chamber cap (the powder could be ejected), empty the chamber, clean the air inlet and outlet pipe with the long and short cleaning needles. Turn off the water supply, keep the device running, blow the remaining water and powder in the tubes with dry compressed air. The handpiece is clogged: Clean the tube in the handpiece with the long cleaning needle, clean the spray nozzle with the short cleaning needle. connect the handpiece to the cleaning spray nozzle, then connect the nozzle to the hose of dental unit. Keep the air running for at least 10 seconds to thoroughly clean the handpiece tubes. Clean the whole handpiece by hot water ultrasonic cleaning. Dry the handpiece after cleaning.
Water comes into the powder chamber	Check the connector of dental unit hose and quick connector. Replace the seal ring if necessary.
Water leakage from the connection between handpiece and body	Replace the seal O-ring 1 and O-ring 2.
Air or powder leakage from the chamber cap	Check the seal and the cleanliness of the thread on the powder chamber and on the cap. Replace the seal O-ring if necessary.
Weak air and powder jet, low cleaning efficiency	Refill or change the powder. Clean the handpiece and all the relevant tubes.

In case of any fault that could not be solved by the above methods, please contact your dealer or the nearest service center.

CLEANING, DISINFECTING AND STERILIZE

CLEANING

1. Powder cleaning (See figure 10)
 - Uncover the chamber cap, empty the powder chamber.
 - Keep operating the unit after shutting off the water supply. Use compressed air to blow out the remaining water and powder in the pipe.
 - Blow out the remaining powder in the chamber and connector with dry compressed air.