iJet / iJet S

Powder Jet Scaler
Operation Instructions

Thank you for buying a new iJet product. It is a handheld dental device which is powered by a dental unit and jets the sandblasting powder on the surface of patient's teeth.

This product functions with the power which recommended by REFINE company.
This product removes dental plaque, soft deposits and surface stains from pits, grooves, interproximal spaces or smooth surfaces of the teeth.

MODEL

MODEL	CONNECTOR	HANDPIECE
iJet	M4 4holes	Supragingival nozzle, detachable, sterilizable
iJet S	KAVO Multiflex	Supragingival nozzle, detachable, sterilizable

COMPONENTES

1 Handpiece
2 Powder chamber cap
3 Body
4 Connector
5 Nozzle
6 Cap ring
7 Cap dome
8 Powder chamber seal ring
9 Powder chamber
10 Air inlet pipe
11 Air outlet pipe
12 Seal O-ring 1
13 Seal O-ring 2
14 Long cleaning needle
15 Short cleaning needle
16 Cleaning spray nozzle

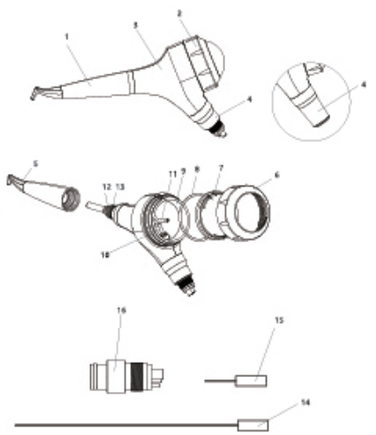


Figure 1 Product Component Diagram

APPLICATIONS

- Remove plague for placement of sealants.
- Surface Preparation prior for bonding/cementation of inlays inlays, 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 plague prior to fluoride treatment.
- Polishing on the surface of teeth after scaling treatment by piezo scaler.

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.

PRECAUTIONS ⚠

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

- **This product must be used only by trained and qualified person.**
- **Do not use this device to the following patients:**
  1. Patients with respiratory illness.
  2. Patients have injury in mucous membrane of more than 3mm pocket depth. (Due to long time jetting near the soft tissues or the salivary gland, powder can be introduced into the injury. In extremely rare cases, this would increase the risk of emphysema.)
  3. Patients with grave ulcers or mucosal inflammation in the mouth or in digestive organs.
  4. Patients with pulmonary ventilation disorder or liver dysfunction or heart dysfunction.
  5. Patients with allergies.
  6. Patients who wear contact lenses.
  7. Patients who need to limit sodium intake（Hypernatremia, Poisoned during pregnancy, Kidney deficiency, Chronic respiratory disease, Chronic diarrhea）.
- **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.**

PACKING LIST

1 × iJet / iJet S main unit
1 × Powder chamber seal ring
1 × Seal O-ring 1
1 × Seal O-ring 2
1 × Long cleaning needle
1 × Short cleaning needle
1 × Cleaning spray nozzle

INSTALLATION AND SET UP

⚠ **Before installation, make sure the quick connector or the hose of dental unit, handpiece, powder chamber, powder chamber cap, air inlet and outlet pipe completely dry. 3-ways sprayer can be used for drying.**

1. Connecting to quick connector or dental unit hose. (Figure 2)

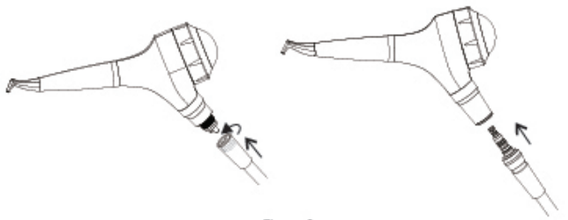
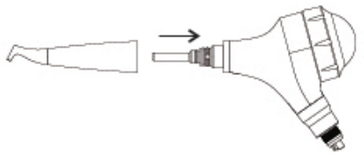


Figure 2

2. Connecting the handpiece to the body. (Figure 2)



(Figure 2)

3. Setting the water flow
   Set the water flow rate to obtain a uniform spray before using the unit for the first time while the powder chamber is empty.

4. Filling the powder chamber

⚠ **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.

OPERATING

⚠ **Use only dry, clean and oil-free air.**

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.
- After the treatment, polish the teeth surfaces by setting the water flow rate to the maximum.

⚠ **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 your 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...).**

CLEANING, DISINFECTING AND STERILIZING

1. Uncover the chamber cap, empty the powder chamber.
2. Keep operating the unit after shutting off the water supply. Use compressed air to blow out the remaining water and powder in the pipe.
3. Blow out the remaining powder in the chamber and connector with dry compressed air.
4. Remove the handpiece, connect the handpiece to the cleaning spray nozzle, the connect the nozzle to the hose of dental unit. Keep the air running for at least 10 seconds to thoroughly clean the handpiece tubes. (Figure 4)

(Figure 4)

5. Wash the powder chamber cap, cap ring, cap dome and handpiece with distilled or deionized water.
6. Clean the threads of the powder chamber, body surface and handpiece surface with alcohol (ethanol, isopropanol).
7. After the above pre-cleaning, please conform to the atttachment 1 "Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing" to conduct cleaning, disinfecting, sterilizing for handpiece.
8. The maximum cleaning, disinfection and sterilization cycles of handpiece is identified as 300 cycles.

⚠ **CAUTIONS**

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

MAINTENANCE

1. Clean the pipes of the device with long and short cleaning needles at the end of the working day.
2. The powder chamber seal ring, seal O-ring 1 and O-ring 2 need to replaced every 6 months.
3. Make sure the handpiece is cleaned by hot water ultrasonic cleaning once a week to avoid clog.

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.

WARRANTY

The warranty will be valid for 1 year from the date of purchasing. 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	Waste electrical and electronic equipment
Thermal Disinfection	Sterilizable at up to 134°C in the autoclave	Caution!
Atmospheric Pressure	Temperature Limitation	Humidity Limitation
Upward	Keep Dry	Unique device identifier
Medical device		

TECHNICAL DATA

Model	iJet / iJet S
Classification 93/42 EEC	Class II a
Service Pressure to the turbine connection: Water	0.07~0.22MPa, 50~80ml/min
Service Pressure to the turbine connection: Air	0.35~0.45MPa (3.5~4.5bar)
Net Weight	Approx. 0.16kg
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

TROUBLESHOOTING

Type of Problem	Solutions
No powder / air jet coming from the unit	The interior of the Scaler 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 Scaler and all the relevant tubes.

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.**

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.**

10. Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).
A disinfection cycle of 5 min disinfection at 93°C has been validated for the product to achieve an A0 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:
a. Remove the product from the autoclave.
b. 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

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 (alkaling 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.

Manufacturer Information

Guilin Refine Medical Instrument Co., Ltd.
Add: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-773-7796686 E-mail: refine@refine-med.com
Website: http://www.refine-med.com
Manufacturing Date: See the lables on the package
Validity Period: 5 years

EC REP MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, Germany

RF-IJT-M001 Version:1.5 20240508