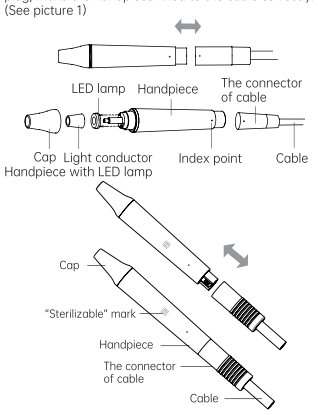
Ultrasonic Scaler Handpiece Instruction Manual

1 Description of device

1.1Description
Ultrasonic scaler handpiece is the accessory of scalers. It is the handheld energy transformation part of ultrasonic piezo scaler, by using piezoceramics to transfer electric energy to mechanical energy to eliminate the dental calculus.
1.2 Model and Specifications
1.2.1 Model: (See package label for details)
1.2.2 Specification: Detachable handpiece with LED light
1.3 Structure and composition: The handpiece is composed of cover and ulrasonic transducer.
1.4 Scope of application: The handpiece is used for the dental calculus elimination and root canal cleaning.
1.5 Contraindication
1.5.1 The hemophilia disease patient is not allowed to use this equipment.
1.5.2 The patients with heart pacemaker are forbidden to use this equipment.
1.5.3 The heart disease patient, pregnant woman and children should be cautious to use the equipment.
1.6 The classification of the device
1.6.1 Operating mode: Continuous operation
1.6.2 Protection against electric shock: Class II equipment
1.6.3 Protection degree against water(used on the pedal): IPX1
1.6.4 Degree of safety of application in the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide :
Equipment not suitable for being used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
1.7 The main technical specification
1.7.1 Power input: 190VAC ~ 230VAC
1.7.2 Output primary tip Vibration excursion: 1μm ~ 200μm
1.7.3 Output tip Vibration frequency:
28kHz ~ 42kHz
1.7.4 Output half-excursion force: 0.1N ~ 2N
1.7.5 Tip's output power: 3W ~ 20W
1.7.6 Water pressure: 0.01 MPa ～ 0.5 MPa
1.8 Working Condition
1.8.1 Environmental temperature:
+5° C ~ +40° C
1.8.2 Relative humidity: 30% ~ 75%
1.8.3 Atmospheric pressure: 70kPa ~ 106kPa
1.8.4 Inflow water temperature: ⩽ +25° C

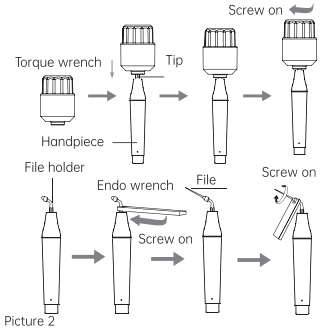
2 Installation of product

2.1 Installation of handpiece
2.1.1 Open the packing box, make sure that all the parts and accessories are complete according to the packing list. Contact with dealer if necessary.
2.1.2 Keep dry the handpiece connector and cable plug socket before installing the handpiece.
2.1.3 Make sure that the bottom jack point is at the plug, make the handpiece fixed to the cable correctly. (See picture 1)



Picture 1
2.2 Installation of tips
2.2.1 Fix the tip to handpiece by torque Wrench until hearing the "Ka Ka"sound.
2.2.2 Diagram of the scaler tips, file holder installation and connection.
(See picture 2)

Notes: The detachable handpiece is a high-tech device which should be used carefully. In case stepping on the foot switch by accident, unscrew the scaling tips after each operation.



Picture 2

3 Product function and operation

3.1 Scaling function
3.1.1 Connect the handpiece and the connector correctly, and adjust the water and vibration intensity to a suitable level.
3.1.2 The handpiece can be handled in the same gesture as a pen in hand.
3.1.3 Select a suitable scaling tip as you need, screw it on the handpiece tightly by the torque wrench.
3.1.4 The machine works at a very fast frequency during normal operation. With the normal vibration of the working tips and the normal atomisation of the water, you only need to touch the teeth gently and move them back and forth at a certain speed to remove the calculus, and there is no obvious feeling of heat in the working tips.
3.1.5 Don't make the tip overexert on the surface of the teeth in case of hurting the teeth and damaging the tip.
3.1.6 After finishing operation, keep the machine working for 30 seconds on the water supply condition in order to clean the handpiece and the scaling tip.
3.2 Instructions for the use of the main components
3.2.1 Cap: It can be screwed out so that the user can remove the cap regulaly for cleaning.
3.2.2 Handpiece: main part, High temperature sterilizable.
3.2.3 "O" ring: The "O"ring is watertight and should be replaced in the event of breakage or excessive wear.
3.2.4 LED lamp: Illuminate the oral area, detachable and sterilizable.

4 Notes

4.1 Don't pull out the handpiece when in operation.
4.2 Pull out the handpiece and remove the tip after operation.
4.3 Please use the original factory fitted tips
The internal screw thread of the scaling tips produced by some manufactures is coarse, rusty and collapsed. This will damage the external screw thread of the handpiece irretrievably. Please use Manufatruer1 brand scaling tips.
4.4 We are a company specialising in the manufacture of medical devices and are only responsible for the safety of these products if maintenance, repairs and alterations are carried out by us or our authorised distributors and if the replacement parts are original to us and are operated in accordance with the instructions for use.

5 Trouble shooting

Fault	Possible causes	Solutions
Handpiece doesn't work	The tip is loosened	Tighten it
	Handpiece fault	Take out the handpiece and send it back for repair
	Cable fault	Contact our dealers or us
	The connect plug between the cable and circuit board is loosened	Contact our dealers or us
There is no spray when getting through the electricity	The water control switch is not on	Turn on the water control switch
	No pressure or low pressure	Check the pressure
There is no water when getting through the electricity	The water control switch is not on	Turn on the water control switch
	There is impurity in the solenoid valve	Contact our dealers or us
	Water way clogs	Clean the water line by three-way syringe
Low vibration	The tip hasn't been screwed on the handpiece tightly	Screw the tips tightly by torque wrench
	The tip is shaken loose by vibration	Screw on the tip tightly
	The coupling between the handpiece and the cable isn't dry	Dry it, especially the water between handpiece and connector
	The tip is worn out or deformed	Change another tip
The handpiece generates heat	The water control switch is in a low setting	Tum the water control switch to a higher grade
There is water seeping from the coupling between the handpiece and the cable	The waterproof "O" ring is damaged	Change a new "O "ring
LED light doesn't work	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one
	LED lamp installed backwards	Please install the "+"of the LED lamp to the "+" of the handpiece

If the problem still can't be solved, please contact with local dealer or manufacturer.

6 Cleaning, disinfection and sterilization

⚠ 1.Remove the cap, light conductor, and LED lamp before cleaning, disinfection and sterilization. (Picture 1)
2.The maximum cleaning, disinfection and sterilization cycles of Ultrasonic Scaler Handpiece are identified as 300 cycles.

6.1 Beginning work
6.1.1 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.
6.1.2 To prevent injury to people and damage to property, please heed the corresponding directives.
6.1.3 The instructions in this manual are only applicable to the product which it was delivered with.
6.2 Introduction
6.2.1 These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.
6.2.2 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.
6.2.3 It is recommended to use steam sterilization.
6.2.4 Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.
6.2.5 If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.
6.2.6 We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.
6.3 Reprocessing - instructions for reusable products
6.3.1 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.
6.3.2 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.
6.4 Preparation - basic principles
6.4.1 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.
6.4.2 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.
6.5 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.
6.6 Transportation
Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
6.7 Preparation for decontamination
The products must be reprocessed in a disassembled state, as far as possible.
6.8 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.
6.9 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.
6.10 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.
6.11 Drying
Automated Drying:
Drying of outside of products at 40℃ , 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.
6.12 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.
6.13 Packaging
Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
6.14 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
6.15 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.
6.16 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.

7 Transportation, Storage And Maintenance

7.1 Transportation
7.1.1 Excessive impact and shake should be prevented during transportation. Lay it carefully and lightly and don't invert it.
7.1.2 Don't put it together with dangerous goods during transportation.
7.1.3 Avoid solarization and getting wet in rain or snow during transportation.
7.2 Storage
7.2.1 Don't store the machine together with the articles which are combustible, poisonous, caustic, or explosive.
7.2.2 This equipment should be stored in a room where the relative humidity is 10% -93%, atmospheric pressure is 70kPa -106kPa, and the temperature is -20° C ~ +55° C.
7.3 Maintenance
The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry and ventilated place.

8 Environmental Protection

There is not any harm factor in our products. You can deal with it based on the local law.

9 After Service

If the equipment does not work properly due to quality problems within one year from the date of sale, we will be responsible for repairing it free of charge with the warranty card, for details refer to the warranty description in the warranty card.

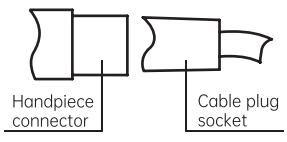
10 Symbol instruction

	Caution
	Refer to instruction manual/ booklet
	Date of manufacture
	Manufacturer
	Class II equipment
IPX1	Can resist water that drips vertically onto the product.
	For indoor use only
	Waste electrical and electronic equipment
	Atmospheric pressure limitation: 70kPa-106kPa
	Temperature limit: -20℃ ~ +55℃
	Humidity limitation: 10% ~ 93%

11 Statement

⚠

Before installing the handpiece, make sure that the handpiece connector and the cable plug socket are completely dry.



Guilin Refine Medical Instrument Co., Ltd.
No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-773-7796686 Email:refine@refine-med.com
Website: http://www.refine-med.com

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

RF-USH-M002 Edition: V1.2 Modify: 20240719