REFINE

CE 0123

Ultrasonic Scaler Tip Users Manual

<Product Name>

Ultrasonic Scaler Tip

<Model>

(See Label on the package)

<Product Description>

The working tip is replaceable and connected with ultrasonic scaler handpiece. Driven by the ultrasonic scaler, the working tip usually consists of the working part and the rod.

<Intended use>

The Ultrasonic Scaler Tip connected with the ultrasonic scaler is intended used to clean and shape the teeth surface, root canal.

<Intended patient population with indications>

Adults and Pediatrics with the following indications:

Periodontal cleaning regularly.

Periodontal disease treatment.

<Intended user>

The Ultrasonic Scaler is intended to be operated by professionally trained and qualified dentist.

<Contraindications>

1.The hemophilia patient is forbidden to use this equipment.

2.The patients or doctors with heart pacemaker are forbidden to use this equipment.

3.The heart disease patient, pregnant woman and children should be cautious to use the equipment.

<Compatibility Descriptions>

1. Gx, GxT (x: 1-999)Female screw series for Scaling .

2. Px, PxL, PxR, PxLT, PxRT, PxLDT, PxRDT, PxLD, PxRD, PxD, PxT, PxDT (x: 1-999) Female screw series for Perio.

3. Ex, ExD, ExT, ExDT (x: 1-999) Female screw series for Endo .

4. GDx, GDxT (x: 1-999) Female screw series for Scaling.

5. PDx, PDxD, PDxT, PDxL, PDxR, PDxLT, PDxRT, PDxLDT, PDxRDT, PDxLD, PDxRD, PDxDT (x: 1-999) Female screw series for Perio.

6. EDx, EDxD, EDxT, EDxDT (x: 1-999) Female screw series for Endo.

7. GSx (x: 1-999) Male screw series for Scaling.

8. PSx, PSxD (x: 1-999) Male screw series for Perio.

9. ESx, ESxT, ESxD, ESxDT (x: 1-999)Male screw series for Endo.

10. GCx, GKx (x: 1-999)Male screw series for Scaling.

11. EKx (x: 1-999) Male screw series for Endo.

12. Ax, AxT (x: 1-999)Amdent series of scaler tip.

13. SBx, SBxT, SBxR, SBxL, SBxRT, SBxLT(x: 1-999) Female screw series for Cavity Preparation.

14. SBDx, SBDxT, SBDxR, SBDxL, SBDxRT, SBDxLT(x: 1-999)Female screw series for Cavity Preparation.

15.SBSx(x: 1-999),SBSL, SBSR: Male screw series for Cavity Preparation.

15. USx, USxL, USxR , ULx , UCx , UPx , UEx , Ulx (x: 1-999) Oral Surgery series tips.

16. 201, 202, 203:Female screw series for Scaling.

17. ETx (x: 1-999)Female screw series for Endo .

18.ExD-S(x: 1-999)Female screw series for Endo.

19.Sx (x: 1-999)Female screw series for Scaling.

20.PCx(x: 1-999)Female screw series for Scaling, .

<Instructions of Use>

1. Scaling,Cavity Preparation tips should work with Scaling function on the Ultrasonic Scaler. Perio tips should work with Perio function on the scaler. Endo tips should work with Endo function on the scaler.

2. Select suitable tip according to operation needs, install on the handpiece tightly by torque wrench.

3. Turn on the Ultrasonic scaler for operation. During operation, do not let the scaler tip contact the teeth surface with vertical direction, do not press too hard in case of damaging the teeth or damaging the tip.

4. After operation, rinse the tip and handpiece by letting the scaler work 30 seconds with water, uninstall the tip and handpiece for sterilization.

<Precautions>

1. Make sure the tip installed on the handpiece tightly and spray well during operation.

2. Scaler tip must be cleaned, disinfected and sterilized before each use, please conform to the recommendations of the manual in attachment 1"Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing".

The following sterilizing methods are forbidden:

•Boil in water.

•Dip in iodine, alcohol and glutaraldehyde.

•Bake in oven or microwave oven.

4. The maximum cleaning, disinfection and sterilization cycles of Ultrasonic Scaler Tip are identified as 300 cycles.

5. Do not bend nor polish the tip.

6. After the golden color coated tips have contacted with Oxidizing solution such as H2O2 or NaClO, please use clean water to rinse the tip.

<Storage>

The tip should be stored in a clean, dry, ventilated, relative humidity of 10% to 93%, atmospheric pressure of 70kPa ~ 106kPa, temperature of -20℃ ~ +40℃ non-corrosive gas indoor environment.

<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.

Tips, endochuck, torque wrench, endo wrench and handpiece, those which 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.

Tips and endochucks are sharp instruments and easy to scratch people. Should you dispose it in the medical waste containers for sharp instruments.

< Symbol instruction >

	Caution
	Refer to instruction manual/booklet
	Manufacturer
	Date of manufacture
	Handle with care
	Keep dry
	For indoor use only
134°C	Can be autoclaved
	Recovery
106kPa 70kPa -20°C +40°C	Atmospheric pressure for storage 70kPa-106kPa
-20°C +40°C	Temperature limitation -20° C-+40° C
	Humidity limitation 10%-93%
LOT	lot number
MD	Medical device
CE 0123	CE marking with identification number of the Notified Body
EC REP	Authorized representative in the European Community
OK	Green: No Wear-Tip is OK Tip replacement is not necessary
NO	Yellow: Wear of 1mm-Tip is showing some wear Tip replacement is not necessary
NO	Red: Wear of 2 mm-Tip is badly worn Tip replacement is necessary
	Effective length

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. Dont 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 ℃ , 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.

Note: We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

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 Fax: +86-773-7796686
E-mail: refine@refine-med.com
Website: http://www.refine-med.com

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

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