Ultrasonic Scaler Tips User Manual

1. Product Name

Ultrasonic Scaler Tips

2. Specification

G1,G2,G4,G5,G1-S,G2-S,G4-S,G5-S,P1,P3,P4,P50L,P50R,P52,P53L,P53R,P56,P59,P3D,P4D,P1-S,P3-S,P4-S,P50L-S,P50R-S,P52-S,P53L-S,P53R-S,P56-S,P59-S,P3-SD,P4-SD,E1,E3,E4,E5,E6,E7,E8,E9,E10,E30,E31,E3D,E4D,E5D,E6D,E7D,E8D,E9D,E1-S,E3-S,E4-S,E5-S,E6-S,E7-S,E8-S,E9-S,E10-S,E30-S,E31-S,E3-SD,E4-SD,E5-SD,E6-SD,E7-SD,E8-SD,E9-SD,E30-SD,E31-SD,TC1,TC1D,TC1-S,TC1-SD.

3. Components and functions

This product consists of a working part and a tail part. The tail part is connected to the ultrasonic scaler, and this product can be fixed or replaceable. It is driven by the ultrasonic scaler, and is used for cleaning and shaping of tooth surface, root canal and other parts.

4. Scope of application

This product is used with the ultrasonic scaler for cleaning and shaping of tooth surface, root canal and other parts.

5. Date of Manufacture

Please refer to label on packing.

6. Contraindications

6.1 Patients with hemophilia are forbidden to use.

6.2 Patients or doctors with cardiac pacemakers are forbidden to use.

6.3 Patients with heart disease, pregnant women and young children should be cautious to use.

7. Classification of tips

7.1 Scaling:G1,G2,G4,G5,G1-S,G2-S,G4-S,G5-S

7.2 Periodontic:P1,P3,P4,P50L,P50R,P52,P53L,P53R,P56,P59,P3D,P4D,P1-S,P3-S,P4-S,P50L-S,P50R-S,P52-S,P53L-S,P53R-S,P56-S,P59-S,P3-SD,P4-SD

7.3 Endodontic:E1,E3,E4,E5,E6,E7,E8,E9,E10,E30,E31,E3D,E4D,E5D,E6D,E7D,E8D,E9D,E1-S,E3-S,E4-S,E5-S,E6-S,E7-S,E8-S,E9-S,E10-S,E30-S,E31-S,E3-SD,E4-SD,E5-SD,E6-SD,E7-SD,E8-SD,E9-SD,E30-SD,E31-SD

7.4 Cavity Preparation:TC1,TC1D,TC1-S,TC1-SD

8. Instructions

8.1 Scaling

8.1.1 G1/G1-S:Used for removal of all-round supragingival calculus.
Applicable power: 1-10/G

8.1.2 G2/G2-S:Used for removal of supragingival large calculus.
Applicable power: 1-10/G

8.1.3 G4/G4-S: Used for supragingival and interdental space scaling.
Applicable power: 1-10/G

8.1.4 G5/G5-S:Used for removal of marginal supragingival calculus and plaque.
Applicable power: 1-10/G

8.2 Periodontic

8.2.1 P1/P1-S: Used for removal of subgingibal calculus and periodontal irrigation.
Applicable power: 1-10/P

8.2.2 P3/P3-S: Used for removal of calculus in the deep part of periodontal pocket and its irrigation.
Applicable power: 1-6/P

8.2.3 P4/P4-S:Used for removal of calculus in shallow pockets.
Applicable power: 1-6/P

8.2.4 P50L/P50L-S: Used for subgingibal calculus probing, subgingibal proximal surface scaling and root planning.
Applicable power: 1-10/P

8.2.5 P50R/P50R-S: Used for subgingibal calculus probing, subgingibal proximal surface scaling and root planning.
Applicable power: 1-10/P

8.2.6 P52/P52-S: Used for supragingival scaling.
Applicable power: 1-10/P

8.2.7 P53L/P53L-S: Used for subgingibal calculus probing, subgingibal proximal surface scaling and root planning.
Applicable power: 1-10/P

8.2.8 P53R/P53R-S: Used for subgingibal calculus probing, subgingibal proximal surface scaling and root planning.
Applicable power: 1-10/P

8.2.9 P59/P59-S: Used for subgingibal calculus probing and scaling.
Applicable power: 1-6/P

8.2.10 P56/P56-S: Used for removal of supragingival large calculus and plaque.
Applicable power: 1-10/P

8.2.11 P3D/P3-SD: Used to level off the surface of endo after the periodontal flap surgery.
Applicable power: 1-6/P

8.2.12 P4D/P4-SD: Used to locate root canal and remove calcification on the one-third of crown.
Applicable power: 1-6/P

8.3 Endodontic

8.3.1 E1/E1-S: 120 °angle holder for 0.7mm-0.8mm endo file for root canal cleaning.
Applicable power: 1-3/E

8.3.2 E3/E3-S: Used for lateral condensation of gutta percha by heating effect.
Applicable power: 1-3/E

8.3.3 E4/E4-S: Used for removal of foreign filling material during re-treatment.
Applicable power: 1-6/E

8.3.4 E5/E5-S: Used for removal of foreign filling material during re-treatment.
Applicable power: 1-6/E

8.3.5 E6/E6-S: Used for removal of calcification and filling material in cavity to access canal orifice.
Applicable power: 1-6/E

8.3.6 E7/E7-S: Used for removal of broken instrument.
Applicable power: 1-3/E

8.3.7 E8/E8-S: Used to brush the canal walls during re-treatment.
Applicable power: 1-6/E

8.3.8 E9/E9-S: Used for root canal cleaning, performing oscillating cleaning of the root canal after root canal preparation is completed.
Applicable power: 1-6/E

8.3.9 E10/E10-S: Used for root planning in the retrograde preparation of root canal.
Applicable power: 1-6/E

8.3.10 E30/E30-S/E30-SD: Used for removal of deep foreign particles in canal.
Applicable power: 1-3/E

8.3.11 E31/E31-S/E31-SD: Used for removal of foreign particles in one-third of the canal.
Applicable power: 1-3/E

8.3.12 E3D/E3-SD: Used for enlargement of the canal walls to remove the broken instrument.
Applicable power: 1-3/E

8.3.13 E4D/E4-SD: Used for removal of hard material in canal during re-treatment.
Applicable power: 1-3/E

8.3.14 E5D/E5-SD: Used for removal of hard material in canal during re-treatment.
Applicable power: 1-3/E

8.3.15 E6D/E6-SD: Used for removal of foreign material in cavity to access canal orifice.
Applicable power: 1-10/E

8.3.16 E7D/E7-SD: Used for removal of calcification and filling material in cavity to access canal orifice during re-treatment.
Applicable power: 1-3/E

8.3.17 E8D/E8-SD: Used for root canal restrogression, efficient root apical polishing.
Applicable power: 1-6/E

8.3.18 E9D/E9-SD: Used for removal of calcification and filling material in cavity to access canal orifice during re-treatment.
Applicable power: 1-3/E

8.4 Cavity Preparation

8.4.1 TC1/TC1D/TC1-S/TC1-SD: Used for removal of cervical caries and caries on the occlusal surface.
Applicable power: 1-10/P

9. Precautions

9.1 The tip must be cleaned, disinfected and sterilized before and after each use.

9.2 Change a new one when the tip is damaged or there are visible signs of wear.

9.3 The tip must be tightened and there must be fine spray coming out from the tip when operating.

9.4 Water is needed for cooling and lubricating when working and the water does not need to be completely atomized. Dentists can adjust the water flow as needed.

9.5 Diamond-coated tips need to be cleaned by water after contacting with the oxidizing solution to extend the service life.

9.6 Do not screw the tip when the scaler is running.

9.7 Do not contact with strong corrosive solution.

9.8 The tip is suitable for the scaler of Eighteen, EMS & Satelec.

9.9 Do not twist or rub the tip.

9.10 The tip is only used by trained and qualified professionals (such as dentists) in hospitals or clinics.

9.11 Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

9.12 A washer-disinfector that meets the ISO 15883 standard can be used for cleaning and disinfection.

10. Storage conditions and transport

10.1 The tip should be stored in a clean, dry, non-corrosive, and well-ventilated room with a relative humidity of 20% to 80%, an atmospheric pressure of 70kPa to 106 kPa, and an ambient temperature of -20℃ to +55℃.

10.2 Beware of heavy pressure and rain and snow during transportation.

11.Cleaning, Disinfection and Sterilization

11.1 Foreword

The parts for clinical application contamination are the outer surfaces of the tip. For hygiene and sanitary safety purpose, the tip must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Reprocessing procedures have only limited implications to the dental instrument. 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 device should be reprocessed before sending back to the manufacturer for repair.

11.2 General recommendations

The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.

For your own safety, please wear

personal protective equipment (gloves, safety glasses, etc.).
Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
Thoroughly clean and wash the component before autoclaving.
Do not use bleach or chloride disinfectant materials.

11.3 Reprocessing instructions

11.3.1 Preparation at the point of use:
Before cleaning, disconnect the tip from the main unit. Remove gross contaminations from the component with cold water (<40 ℃) immediately after use. Don't use a fixating detergent or hot water (>40 ℃) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Store the instrument in a humid surrounding.

WARNING

Do not submerge the tip or wipe it with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the component.
Observe suitable personal protective measures.

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

11.3.3 Preparation for Decontamination:
The device must be processed in a disassembled state.

WARNING

Observe suitable personal protective measures.

11.3.4 Pre-Cleaning:
Do a manual pre-cleaning, until the component is visually clean. Submerge the components 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.

11.3.5 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:
Carefully put the component into the washer-disinfector on a tray and set the parameters as follows, then start the program:
• 4 min pre-washing with cold water (<40 ℃);
• emptying
• 5 min washing with a mild alkaline cleaner at 55 ℃;
• emptying
• 3 min neutralizing with warm water (40 ℃);
• emptying
• 5 min intermediate rinsing with warm water (40 ℃);
• emptying
The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).
Note Acc. to 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.

WARNING

Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. Follow instructions and observe concentrations given by the manufacturer (see general recommendations).

11.3.6 Disinfection:
Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see ISO 15883).
A disinfection cycle of 5 min disinfection at 93 ℃ has been validated for the device to achieve an A0 value of 3000.
After cleaning, the instruments should be automated disinfected immediately. A manual disinfection is not recommended. Please use fully demineralized water.

11.3.7 Drying:
Automated Drying:
Drying the instruments according to drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

11.3.8 Functional Testing, Maintenance:
Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until the instrument is visibly clean.
Before packaging and autoclaving, make sure that the component has been maintained according to the manufacturer's instruction.

11.3.9 Packaging:
Pack the instruments in an appropriate packaging material for sterilization.

WARNING

Check the validity period of pouch given by the manufacturer to determine the shelf life.
Use pouches which resist to a temperature up to
141 ℃ and in accordance with EN ISO 11607.

11.3.10 Sterilization:
Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/ISO 17665) under consideration of the respective country requirements.
Minimum requirements: 5 min at 134 ℃.
Maximum sterilization temperature: 137 ℃.
Drying time: at least 8min.
Flash sterilization is not allowed on lumen instruments!

WARNING

Use only approved autoclave devices according to EN 13060 or EN 285.
Use a validated sterilization procedure according to EN ISO 17665.
Respect the maintenance procedure of the autoclave device given by the manufacturer.
Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters).
Waiting for cooling before touching.

11.3.11 Storage:
Storage of sterilized instrument in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

WARNING

Sterility cannot be guaranteed if packaging is open, damaged or wet.
Check the packaging before using it (packaging integrity, no humidity and validity period).

11.3.12 Reprocessing validation study information:
The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated.
Refer to cleaning/disinfection validation report No. RDS2020D0076 001, sterilization validation report No. RDS2020S0084 001.

WARNING

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

12. Symbol instruction

Symbol	Instruction
WARNING	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
SN	Serial number
	WEEE directive marking
	Keep dry
134℃	Can be autoclaved up to a maximum temperature of 134 ℃elsius
-20℃ 55℃	Temperature limitation
15% 85%	Humidity Limitation
70kPa 106kPa	Atmospheric pressure limitation
REF	Catalogue Number
	Manufacturer
	Date of manufacture
LOT	Lot of manufacture
Eighteeth	Manufacturer's LOGO
	Washer-disinfector for thermal disinfection

No. 26 Yandanghe Road,
Xinbei District, 213000
Changzhou, Jiangsu, China
Tel: +86-0519-85962691
Fax: +86-0519-85962691
Version:03
IFU-6635012
Issued:2025.06.04
Size:230×100mm

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