Ultrasonic Scaler Tips

User Manual

1. Product name

Ultrasonic Scaler Tips

CE 0123

2. Product model

Material	Model	Thread specification	Function
30Cr13	G3、G4、G5、G6、G8、G9	M3–6H	For supragingival scaling
	P3、P33、P1		For periodontal treatment
	E1、E2、E3、E4、E5、E8、E9、E14、E15		For root canal washing
	S–G1、S–G2、S–G3、S–G4、S–G5、S–G6	M3*0.6–6H	For supragingival scaling
	S–P1		For periodontal treatment
1Cr17Ni2	G1、G2、G12、G13	M3–6H	For supragingival scaling
	P2L、P2R、P4、P5、P7、P13L、P13R、P15		For periodontal treatment
	IM2、IM3、IM4L、IM4R		For implant maintenance
TC4	P10、P11、P12、P12L、P12R、P16、P17、P18	M3–6H	For periodontal treatment
	IM1		For implant maintenance

3. Material, Structure and Composition

The Ultrasonic Scaler Tips are made of stainless steel or TC4 titanium alloy. Connected with the handpiece by using M3–6H thread or M3*0.6–6H thread.

The Ultrasonic Scaler Tips consists of working part and rod. Driven by ultrasonic scaler.

4. Intended use

The Ultrasonic Scaler Tips connected with the ultrasonic scaler for use in dental applications. It is mainly used for the treatment of periodontal defects. In addition, the device is used in the area of prophylaxis, peri–implantitis treatment as well as dental hygiene.

4.1 Intended patient population

Adults patients with periodontal disease.

4.2 Intended users

Dentist.

5. Performance

5.1 Hardness

Material	Hardness
TC4 titanium alloy	HRC33 ~ 39
Stainless steel	HRC38 ~ 51(except IM2, IM3, IM4L, IM4R)
	HRC18 ~ 25(IM2, IM3, IM4L, IM4R)

5.2 Supply of liquid

The amount of liquid delivered to the operating area of the products shall be at minimum of 10 mL/min and all shall not exceed 100 mL/min at the pressure in the range of 0.01 MPa ~ 0.5 MPa if product works in a water environment. If product works in an anhydrous environment, there is no supply of liquid.

6. Contraindications

1) Patients with cardiac pacemakers.
2) Patients with gingival malignant tumor
3) Patients with active angina pectoris, myocardial infarction within six months, and uncontrolled hypertension and heart failure
4) Patients with local oral inflammation in the acute phase (except acute necrotizing gingivitis)
5) Patients with bleeding diseases
6) Patients with acute infectious diseases
7) Pregnant

7. Safety precautions

7.1 Installation

The thread specification is M3*0.6 of the product that model prefix has an S– (such as S–G1, S–G2, etc., the visual performance is that the rod of product has only two milling surfaces).It is suitable for ultrasonic scaler of SATELEC, DTE, NSK.

The thread specification is M3 of the product that model prefix without an S– (such as G1, G2, etc., the visual performance is that the rod of product has four milling surfaces).It is suitable for ultrasonic scaler of VRN, Woodpecker, Mectron and EMS.

Product will not be screwed on the handpiece with different thread specifications. Forcibly screw will damage the thread of handpiece and product.

7.2 It must be tightened when the product is installed on the hand of handpiece. Only use the torque wrench to turn product clockwise until hear the click. When using product that works in a water environment, there must be supply of liquid to the needle tip, otherwise, please replace a new one and the original product shall be discarded. The supply of liquid shall be turned off when the product is used in an anhydrous environment. Before use, test whether the product vibration is normal at a low gear and the water outlet is biased, and then select a suitable

gear for work.

7.3 Product must be reprocessed before first use and after each treatment to prevent cross infection. See Article 9 for the specific reprocessing methods.

7.4 If the product is damaged (such as rust, crack or needle tip deformation) or worn 2mm (within the warning line), please replace a new one in time. If the products of IM1, IM2, IM3, IM4L, IM4R are worn to the extent that the metal parts are exposed, please replace a new one in time and the original products shall be scrapped.

7.5 Do not bend or polish the products.

7.6 It is recommended to use a rubber shield to protect when cleaning teeth.

7.7 Operators must undergo relevant professional training.

7.8 There is no supply of liquid for E3、E4、E5、E8、E9.

7.9 Product shall not be in contact with strong acid, alkali and corrosive chemicals. It can be used normally according to the instructions and can be reprocessed for 250 cycles without corrosion.

8. Working, storage and transport environment

8.1 Working environment：

Relative humidity:≤80%, atmospheric pressure:70kPa ~ 106kPa, temperature: 5℃ ~ 40 ℃.

8.2 Storage and transport environment:

Relative humidity:10% ~ 93%, atmospheric pressure: 70kPa ~ 106kPa, temperature:–20 ℃ ~ 55 ℃.

Product shall be stored in clean, dry and ventilated conditions.

9. Reprocessing

9.1Preparation

Basic principles

It is only possible to carry out effective sterilization after the completion of effective cleaning. 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 and sterilization, and that the validated parameters are adhered to during every cycle.Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.

9.2Initial processing at the point of use

The treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. Additional information, where necessary, is provided in the respective product–specific usage instructions.

Steps

9.2.1Rinse away any surface soiling on the product with distilled deionized water or cleaning agent.

9.2.2Rinse through all lumina (e.g. irrigation and aspiration connection) at least 3 times in the normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied

to the back nozzle.

9.3Cleaning

Preparation

When selecting the cleaning agent to be used, ensure that:

- These are fundamentally suitable for the cleaning of the products and compatible with one another,
- The chemicals used are compatible with the products.

It is absolutely essential that the concentrations and contact times specified by the manufacturer of the cleaning agent are adhered to. Only freshly prepared solutions may be used. The solution is not permitted to foam.Only sterilized or low microbe count distilled/deionized water (< 10 cfu/ml) can be used for all rinsing steps.

Steps for manual cleaning

9.3.1Completely disassemble the tips from handpiece, if applicable. Rinse the tips for 2 minutes with fresh distilled or deionized water.

9.3.2Then wipe it with 75% medical alcohol for five times.

The product adopts manual cleaning and it has been verified. Please do not modify the cleaning method without authorization, such as using disinfector for automated cleaned.

Notice: No automatic cleaning for the Ultrasonic Scaler Tips.

9.4Drying

After cleaning, put the tips into the oven for drying.The recommended drying condition is 138℃ for 20 minutes.

9.5Inspection and maintenance

If stains are still visible on the product after cleaning, the entire cleaning procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be disposed of (no further use is permissible).

9.6Packaging

Only cleaned products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:

- Resistant to 138℃, with adequate steam permeability,
- Maintained on a regular basis.

If single–use sterilization packaging is to be used, this must be suitable for steam sterilization (temperature resistant to 138℃ with adequate steam permeability).The material of sterilization packaging is made of medical paper and PET/CPP. The packaging material complies with the requirements of EN ISO 11607–1.

Step:

9.6.1Select a suitable sterilization packaging according to the size of the sterilized item and put the items in.

9.6.2Place the sharp and specially shaped devices in the correct position for safe removal when opened.

9.6.3Affix the strip of sterilization packaging(the strip of the packaging is sticky and it does not require additional processing for sealing such as heat sealing) and mark the sterilization time.

9.6.4Put the sealed sterilization packaging rightly into steam sterilizer.

9.6.5Pay attention to the color–changing: if sterilization is really implemented, it will turn black /grey from initial blue under steam sterilization.

9.6.6Open the strip along the direction printed on the packaging and then takes the items out.

9.7Sterilization

The product can withstand 250 reprocessing cycles.Do not exceed the maximum number of reprocessing cycles. Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:

- Steam sterilizer in accordance with EN 13060 or EN 285 validated in compliance with EN IS0 17665,
- Maximum sterilization temperature 138℃.

Steps for sterilization

9.7.1Sterilization at 134℃ for 4 minutes.

9.7.2Sterilization at 134℃ for a maximum of 20 minutes is permissible.

The hot–air sterilization and radio–sterilization procedure may not be used (as it causes the destruction of products). The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).

9.8Service life

The products have been designed for 250 reprocessing cycles and have 5 years service life from start with production, if the tips exceed 250 reprocessing cycles or 5 years, it should be not used any more. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products.The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling pH > 9 or acid pH < 5) can reduce the life span of products. The manufacturer accepts no liability in such cases. The products may not be exposed to temperatures above 138℃.

9.9Storage and transportation

After sterilization, keep sterilization packaging and stored it in the following environment to avoid infection and sterilization failure:

- Temperature:–20~55 ℃,
- Humidity: 10%–90%,
- Atmospheric pressure:70kPa~106 kPa.

The product can keep sterile for 6 months in sterilization packaging, when exceed the 6 months，it shall be

reprocessed again before use.

After reprocessing, it is necessary to confirm that the products can work normally before use. If products with visible damage, chip/flake loss, corrosion, rust or bent out of shape must be disposed of (no further use is permissible).

10. Warranty

Damages due to non-adherence to the operating instructions or wear out of parts are excluded from warranty.

11. Service

11.1 Should you product need servicing and repairs, please contact us or dealer.

11.2 We decline responsibility for the safety of the device and declare the warranty null and void if service or repair is carried out by an unauthorized third party or if non-genuine spare parts are used.

12. Symbols


Manufacturer's logo 
Batch code 
Refer to instruction manual/booklet 
Manufacturer


Date of manufacture 
Use-by date 
Caution! 
Keep dry 
Fragile,handle with care


This way up 
Humidity limitation 
Atmospheric pressure limitation 
Temperature limit


CE marking 
Medical device 
Unique device identifier 
Do not roll


Authorised Representative in the European Community


Sterilizable at up to 134℃ in the steam sterilizer (autoclave) attemperature specified.

13. Product disposal

13.1 Product must not be discarded in domestic household waste.

13.2 If you wish to definitively dispose of the product, please comply with regulations which apply in your country.

14. Manufacturer information


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