



User's Manual for Tips of Piezo Bone Surgery

Product Name: Tips of Piezo Bone Surgery

model: US1、US2、US3、US4、US5、US1L、US1R、US6、UL1、UL2、UL3、UL4、UL5、UC1、UI1、UI2、UI7、UI8、UI9、UP1、UP2、UP3、UP4、UP5、UP6、UP7、UE1、UE2、UE3、UE4

Intended Use: used for cutting bone, the formation of bone and the collection of bone pieces.

Contraindications:

1. The hemophilia disease patient is not allowed to use.
2. The patients or doctors with heart pacemaker are forbidden to use.
3. The heart disease patient, pregnant women and children should be cautious to use.

Cautions:

1. The tip screwed on to the handpiece must be tightened.
2. The tip must be tightened while worked with spray.
3. The tip must be cleaned and disinfected before use.
4. When the tip or coating damaged or worn, please replace a new one.
5. Do not bend or grind the tip.
6. The Golden Tips must be cleaned by water immediately after they soaked in the H₂O₂, NaClO, or it may damages the tips.

Installation and used:

Use the torque wrench to screw the insert, till the voice off click-clack.



Usage:

- US1: Used for osteotomy, five teeth bone saw, sharp.
- US2: Used for osteotomy, more precise and efficient. With depth marking 7-8.5-10mm on the surface.
- US3: Used for highly sophisticated cutting of narrow delicate bones at thin regions of anatomy.
- US4: Used for the formation of bone and the collection of bone. Circular, sharp at the perimeter.
- US5: Used for the plastic of bone abd the collection of bone. Scalpel with a reversed trapezoid tip, sharp at three sides.
- US6: Used for highly sophisticated cutting of narrow delicate bones, more precise and efficient.
- US1L: Used for cutting bones from different angles with best efficiency.
- US1R: Used for cutting bones from different angles; with best efficiency.
- UL1: Used for peeling off the nasal mucosa in upper jaw. Flat smooth at the perimeter.
- UL2: Used for peeling off the nasal mucosa in upper jaw, protecting organs to the greatest degree.
- UL3: Used for non-wound bone cutting near soft tissue or sensitive regions. Tip with diamond-coated.
- UL4: Used for cutting slight bone to avoid hurting soft tissue.
- UL5: Use to peel of mucosa of maxillary sinus.
- UC1: Used for cutting ligaments, minimally damnnification exelcymosis.
- UI1: Used for implant, with tip ball ø1.6mm.
- UI2: Used for implant, with tip ball ø2.0mm.
- UI7: Used for the final bone implant sites preparation.
- UI8: For implantation, in plus size. Maximum ø1.6mm.
- UI9: Implant tip, front size ø2.8mm.
- UP1: Root surface scaling, clean the root surface.
- UP2: Periodontal Surgery: remove the tip of the broken root. Endodontic surgery: remove inflammatory tissue.
- UP3: For scaling, to remove calculus and clean the root surface.
- UP4: Root surface debridement and root planning (diamond coated).
- UP5: Used for perio, go deep into periodontal pocket for treatment.
- UP6: Bone formation, root planning within the operation area.
- UP7: Used for bone trimming and root canal expansion.
- UE1: Used for the root canal retrogression, efficient root apical polishing (diamond coated).
- UE2: Used for root canal softly treatment.
- UE3: Used for the root canal retrogression, efficient root apical polishing (diamond coated).
- UE4: Used for root canal softly treatment.

Storage conditions:

The tips should be stored in clean, dry, ventilated, non-corrosive gases indoor place.

Connect the accessories:

Use the torque wrench to screw the tip.

Cleaning, Disinfection and Sterilization

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

This device shall not be exposed to high temperature above 138° C.

Processing limit:

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for tips is 300 times.

1 Initial processing

1.1 Processing principles

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.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Let the Ultrasonic Surgical works for 20-30 seconds under irrigation mode to flush the handpiece and tip;
2. Remove the handpiece from the Ultrasonic Surgical, and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water);
3. Dry the product with a clean, soft cloth and place it in a clean tray.

Notes:

- a) The water used here must be pure water, distilled water or deionized water.

2 Preparation before cleaning

Steps:

Tools: Endo wrench or torque wrench, tray, soft brush, clean and dry soft cloth

1. Remove the tip from product with endo wrench or torque wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd, and then put the tip and wrench into a clean tray.
2. Then use soft cloth to dry the product and accessories and put them into a clean tray.

3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

3.1 Automated cleaning

- The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.
- There should be a flushing connector connected to the inner cavity of the product.
- The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Notes:

- a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

- b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

- c) After cleaning, the chemical residue should be less than 10mg / L.

4 Disinfection

Disinfection must be performed no later than 2 hours after the operation. Automated disinfection is preferred if conditions permit.

4.1 Automated disinfection-Washer-disinfector

The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector.

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
3. Start the program.
4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Notes:

- a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
- b) With this equipment, cleaning, disinfection and drying will be carried out together.
- c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).
- d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000; Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600

- (d2) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000

- e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

- f) After cleaning, the chemical residue should be less than 10mg / L.

- g) The air used for drying must be filtered by HEPA.

- h) Regularly repair and inspect the disinfecter.

5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.
2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80° C ~ 120° C and the time should be 15 ~ 40 minutes.

Notes:

- a) The drying of product must be performed in a clean place.
- b) The drying temperature should not exceed 138 °C;
- c) The equipment used should be inspected and maintained regularly.

6 Inspection and maintenance

In this chapter, we only check the appearance of the product.

1. Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

2. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

3. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Notes:

- a) The package used conforms to ISO 11607;
- b) It can withstand high temperature of 138 ° C and has sufficient steam permeability;
- c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;
- d) Avoid contact with parts of different metals when packaging.

8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
2. The highest sterilization temperature is 138 ° C;
3. The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.
4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Notes:

- a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
- b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

- c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
- d) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

9 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. 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.

Notes:

- a) The storage environment should be clean and must be disinfected regularly;
- b) Product storage must be batched and marked and recorded.

10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation.
3. Avoid exposure to sun or rain or snow during transportation.

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