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ES MANUAL DE INSTRUCCIONES DE LA TURBINA DENTAL (Pag.2)

EN DENTAL TURBINE HANDPIECE INSTRUCTION MANUAL (Pag.38)

Lea atentamente el manual antes de utilizarlo
Please read the manual carefully before use

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1 Product introduction

1.1 Product introduction

The dental turbine handpiece utilizes compressed air to drive the cartridge at high speeds, thereby driving specifically-functioned burs to perform drilling, grinding, and other procedures on teeth. The main features of Woodpecker turbine handpiece are as follows:

- a. Multiple bur sizes designed to meet the requirements of different treatment areas.
- b. Newest designed handpiece head angle provides a better field of view and angle for improved operational efficiency.
- c. High precision of cartridge, low radial runout during high-speed rotation, low noise, high efficiency of cutting.
- d. Newest handpiece design, easy cleaning.
- e. Handpiece and bur chuck can be autoclaved with high temperature.

1.2 Type

HP33-M4 (HS33-M4), HP-33 Q-M4 (HS33-K), HP-33 F-M4 (HS33-N).

1.3 Components

The components of the equipment are listed in the packing list.

1.4 Structure and compents (As shown in Picture 1)

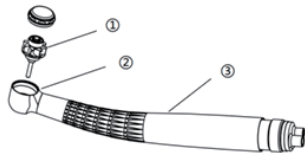
1.4.1 This equipment is mainly composed by cartridge, head and handpiece.

Note: ①cartridge ②head ③handpiece

1.5 Scope of application

Designed for clamping of dental cutting tools to conduct drilling and grinding procedures.

1.6 Contraindications



Picture 1

- 1.6.1 The homophile patients are forbidden to use this equipment.
- 1.6.2 The patients with heart pacemaker are forbidden to use this equipment.
- 1.6.3 The doctors with heart pacemaker are forbidden to use this equipment.
- 1.6.4 The heart disease patient, pregnant woman and children should be cautious to use this equipment.

1.7 Cautions

- 1.7.1 Before using this equipment, please read every article of this instruction carefully.
- 1.7.2 This equipment is specifically designed for dental prevention and treatment, and could not be used for other purposes.
- 1.7.3 This equipment is high speed rotating handpiece, please be careful when operating.
- 1.7.4 This equipment could only be used by professional dentists.
- 1.7.5 It is prohibited to bump and fall when operating.
- 1.7.6 Do please lock the bur and back cap before operation.

1.8 Main technical specifications

Type	Air pressure(kgf/cm ²)	speed(r/min)	Chuck type
HP33-M4 (HS33-M4)	2.0-2.2	300000~400000	Push-button
HP-33 Q-M4 (HS33-K)	2.0-2.2	300000~400000	Push-button
HP-33 F-M4 (HS33-N)	2.5-2.7	300000~400000	Push-button

Note:

- 1.“B2” means two-hole coupling, “M4” means four-hole coupling.
- 2.The air consumption of each model in recommended operating pressure is $\leq 35\text{L}/\text{min}$.

3. Flow rate is greater than 50mL/min at a water supply pressure of 0.20MPa (2.0kgf/cm²).

1.9 Operating environment

1.9.1 Environment temperature: +5°C ~ +40°C

1.9.2 Relative humidity: 30% ~ 75%

1.9.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Operation instructions

2.1 Regarding the bur

2.1.1 Do not use disqualified burs.

2.1.2 The diameter of the bur shank should be $\Phi 1.59$ - $\Phi 1.60$ mm, complying with ISO international standards, with a length 17mm~25mm. The maximum diameter at the front end of the bur should be $\Phi 2$ mm.

2.1.3 Do not use bent, damaged, or defective burs.

2.1.4 Please keep the bur clean. The dirt will accumulate in the chuck hole, resulting in loosening and abnormal wear of the chuck.

2.1.5 Do not use short bur (mini bur) on standard handpiece, otherwise the bur will drop off because of carelessness.

2.1.6 Do not use long bur on mini handpiece, otherwise the bearing will damage because of overload of head.

2.1.7 Before operation, ensure that the specified speed and specifications of the bur are compatible with this handpiece.

2.2 Install and uninstall the bur (wrench type handpiece)

2.2.1 Pull the shank of the bur chuck back and fit it onto the handpiece head. (picture 2)

2.2.2 Push the shank of the bur chuck forward, making its head into the hole and lock. Rotate it

counterclockwise by 1/4 turn (do not over-rotate). This will unlock the bur, allowing its removal.

2.2.3 While installing the bur, rotate it clockwise and tighten it. (Picture 3)

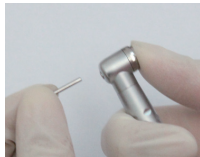
2.3 Install and uninstall the bur. (push-button type handpiece): press the back cap, you can get out the bur (Picture 4)



Picture 2



Picture 3



Picture 4

2.4 Enter the bur into the end, otherwise the bur will drop off, and lead to unbalanced load of the

cartridge and accelerated the damage of bearing.

2.5 Connecting the handpiece to its hose

2.5.1 Connecting the handpiece to its hose (without coupling): Connect the air inlet tube, water inlet, air return tube and atomization tube of handpiece connector to the handpiece hose. Then tighten by rotating in the threaded direction.

2.5.2 Connecting the handpiece to its hose (with coupling): Connect the air inlet tube, water inlet tube, air return tube, atomization tube and electrical plug of coupling connector to the handpiece hose.

2.5.3 Installation and use for couplings HP33-M4 (HS33-M4), HP-33 F-M4 (HS33-N)

HP33-M4 (HS33-M4):

A) Remove the coupling: Hold the handpiece with one hand, hold the coupling with the other hand and pull it back to remove the coupling.

B) Install the coupling: Insert the coupling into the handpiece tightly and check the handpiece before

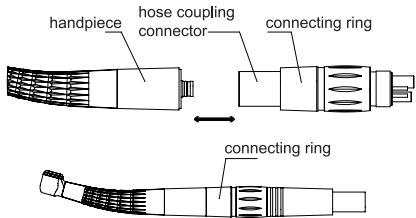
operating in the patient's mouth.

C) Control of atomization: Align the two points to the same line for maximum water flow. Rotate the adjustment sleeve to the right to gradually reduce the water flow, and adjust it to the far right to stop the water flow.

HP-33 F-M4 (HS33-N):

A) Remove the coupling: While pulling up the connecting ring, pull the handpiece out of the hose coupling connector.

B) Install the coupling: Insert the handpiece straight into the hose coupling connector, and try to push and pull the handpiece after installation to confirm that it is firmly connected.



Water flow reaches the maximum when the two points in the same line

2.6 Cautions

2.6.1 Users of dental handpieces must undergo professional training and be familiar with the relative usage information.

2.6.2 Gripping part of the bur could not be too short, otherwise it will lead to unbalanced load of the cartridge and accelerated damage of the bearing.

2.6.3 Do not operate the handpiece without clamping the bur or testing rod, as it may cause the chuck to fly out due to the reactive force and damage the bearing.

2.6.4 Please don't press the cover until the handpiece is totally stopped.

2.6.5 Please do the pre-operation inspection outside the patient's mouth before operating. If any looseness, vibration, abnormal noise, or heat is detected, stop using it immediately and contact the manufacturer or authorized repair center.

2.6.6 Damaged handpiece cartridge might probably cause high noisiness, and damage the hearing if long-time use, please replace it timely.

2.6.7 Please use standard burs with a shank size of 1.59-1.60mm, which should comply with Class III specifications in ISO 1797 standard. The maximum length should be 25mm, in accordance with ISO

6360-1 standard. Using bent, cracked, deformed, damaged, or non-compliant burs may cause accidents such as sudden breakage or flying out during operation, causing injury and damaging the handpiece.

2.6.8 When the handpiece is not in use, please install a bur or a testing rod.

2.6.9 Please don't install or un-install the bur or handpiece until the machine is totally stopped.

2.6.10 The pressure and flow rate of the air and water sources must meet the requirements of this machine.

2.6.11 Use dry and clean compressed air to ensure the service life of the handpiece. Regularly maintain the air compressor and the air/water filtration system to ensure the quality of compressed air and water. Using unfiltered water will cause blockage of the pipe joints and premature damage to the atomizer.

2.6.12 This handpiece should not be used in explosive environments (such as anesthetic gases).

3 Cleaning, disinfection and sterilization

This Manual is only applicable to the reprocess of high speed turbine handpiece manufactured by Guilin Woodpecker Medical Instrument Co., Ltd.

Note:

1. Before use, please carefully read the Instruction Manual of handpiece.
2. Before first use, please clean and sterilize the handpiece.

Warnings

The use of ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the life span of products. The manufacturer takes no responsibility in such cases.

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

3.1 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 allowed maximum times of sterilization for handpiece is 600 times. The allowed maximum times of sterilization for the bur chuck is 1000 times.

3.2 Initial processing

3.2.1 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.

3.2.2 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. Remove the handpiece from the comprehensive dental treatment instrument, and rinse away the dirt on the surface of handpiece with pure water (or distilled water/deionized water);
2. Dry the handpiece with a clean, soft cloth and place it in a clean tray.

Cautions

1. The water used here must be pure water, distilled water or deionized water.

3.2.3 Preparation before cleaning steps:

Tools: Bur chuck(only for the wrench type), tray, soft brush, clean and dry soft cloth.

1. Use the chuck provided by Guilin Woodpecker Medical Instrument Co., Ltd to remove the bur from handpiece and put it into the tray.
2. Use a clean soft brush to carefully brush the screw thread, head and back cap of the handpiece until

the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps:



Install the bur chuck into the head and then rotate the handpiece to get the bur out.



For the push button type: Press the back cap with one hand, and pull the bur out with the other hand.

3.3 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.

3.3.1 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 handpiece, the flushing period is sufficient, and ultrasonic cleaning is prohibited.

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".

Precautions:

1. 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 handpiece.
2. In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.
3. After cleaning, the chemical residue should be less than 10 mg/L.

3.4 Disinfection

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

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. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
2. Start the program.
3. After the program is finished, remove the handpieces from the washer-disinfector, conduct inspection (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the handpiece repeatedly if necessary (refer to section "Drying").

Precautions:

1. Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
2. With this equipment, cleaning, disinfection and drying will be carried out together.

3. Cleaning: (a) The cleaning procedure should be suitable for the handpiece to be treated. The flushing period should be sufficient (5-10 minutes). (b) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (d) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

4. Disinfection: (a) Direct use after disinfection: temperature (> 90 degrees C), time (> 5 minutes) or A0 (> 3000), continue sterilization after disinfection and reuse: temperature (> 90 degrees C), time (> 1 minutes) or A0 (> 600) (b) The disinfection temperature used here is 93 degrees C, time is 2.5 minutes, A0 > 3000.

5. 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).

6. After cleaning and disinfection, the chemical residue should be less than 10 mg/L.

7. The air used for drying must be filtered by HEPA.

8. Regularly repair and inspect the disinfectant.

3.5 Drying

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

1. Spread a clean white paper (white cloth) on the flat table, point the handpiece against the white paper (white cloth), and then dry the handpiece with filtered dry compressed air (maximum pressure 3 bar).

Until no liquid is sprayed onto the white paper (white cloth), the handpiece 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.

Precautions:

1. The drying of product must be performed in a clean place.
2. The drying temperature should not exceed 138 °C;
3. The equipment used should be inspected and maintained regularly.

3.6 Inspection and maintenance

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

1. Check the handpiece. If there is still visible stain on the handpiece after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the handpiece. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.
3. Check the handpiece. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

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

3.7 Lubrication

Oil lubrication of sterilized and dried products.

The nozzle of cleaning lubricant is aligned with the air intake hole at the end of the handpiece to inject oil for 1-2 seconds.



3.8 Packaging

The disinfected and dried handpieces and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).

Precautions:

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

3.9 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.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Precautions:

1. Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

2. Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

3. Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

4. 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.

4 Maintenance

4.1 The handpiece should be lubricated with oil after each use or before high-temperature sterilization or after every 30 minutes of continued use.

Oil lubrication method: Take off the handpiece, align the nozzle with the air intake hole of the handpiece,

and inject after pressing it tightly. When injecting, the oil tank must be upright.

Attention:

Please use the corresponding oil nozzle to lubricate the handpiece with coupling.

4.2 The replacement of the cartridge (collet)

4.2.1 Take off the old cartridge

Insert a testing rod (included) to the hole of the cartridge chuck, then anticlockwise the cap by cap wrench, and you can take it off and disinfect it.

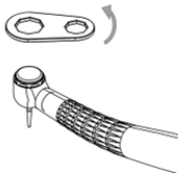
Push the testing rod in the direction of cartridge, then the cartridge can be taken off. (picture 5)

4.2.2 Install the new cartridge

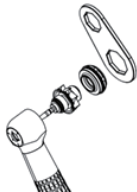
Put the pin side of the cartridge into the head cavity of the handpiece, and gently press it to the right position. Then align the cap and the thread of the handpiece's head, slowly screw the cap, and tighten it with cap wrench.(picture 6)

Notice

The thread of the cap and the head is extremely meticulous, please don't insert the wrench at the beginning, avoiding damaging the thread.



Picture 5



Picture 6

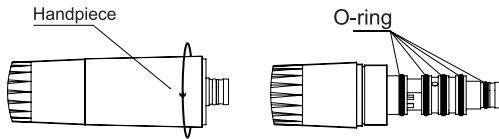
4.3 O-ring replacement (HP33F-M4)

If you encounter difficulty in assembling or disassembling the handpiece, or if there is water or air leakage at the interface, or if water is present during air exhaust, please promptly replace the O-ring.

- 1) Rotate, loosen and remove the handpiece sleeve in the direction shown in the figure.
- 2) Loosen and remove the O-ring to be replaced with your fingertips.
- 3) Place the new O-ring in the position of the original O-ring.
- 4) Tighten the handpiece sleeve onto the handpiece.

Attentions

- Do not pull hard when replacing the O-ring.
- When installing the O-ring, please don't put place it in the wrong position.



Picture 7

5 Troubleshooting

Faults	Possible causes	Solutions
Noisy, speed and cutting power is decreased significantly or the handpiece cannot rotate.	The bearing is damaged	Replace the bearing
The handpiece does not spray	The spraying hole is blocked	Clean the spraying hole.
The handpiece leaks	The O ring or the gasket is aging.	Replace the old parts
Voice is normal, speed is low	The air pressure is low.	Calibrate the working air pressure
Cannot hold the bur, or the bur cannot be installed.	The bur is non-standard or the chuck is damaged.	Replace the bur.

Faults	Possible causes	Solutions
Excessive bur swing and weak cutting force.	The O ring of head is aging or the bearing is damaged.	Replace the defective parts.
Poor atomization	The atomization water outlet and air outlet are blocked.	Use cleaning needle to clean.

If the problem persists, please contact the local distributor or Woodpecker for assistance.

6 Storage and transportation

6.1 Storage and transportation

6.1.1 Environment temperature: $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$

6.1.2 Relative temperature: 10% ~ 93%

6.1.3 Atmosphere pressure: 70kPa ~ 106kPa

6.2 This product should be stored or kept in a dry, clean environment, away from harmful chemicals, acids, alkalis, and gases.

7 Environment protection

Please dispose according to the local laws.

8 After service

If the equipment can't work as normal since of the quality, please contact the local distributor or Woodpecker.

9 Symbol instruction



Manufacturer



Date of manufacture



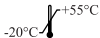
Follow Instructions for Use



Caution



Used indoor only



Temperature for storage -20°C ~ +55°C



Atmospheric pressure for storage
70kPa~106kPa



Do not run the handpiece when the bur
or the standard rod is not tightened.



Do not use disinfectant with acetone,
chloride etc. Do not immerse the
handpiece into disinfectant.



CE marked product



The product complies with the
WEEE directive



Sterilizable up to the temperature
specified



Humidity for storage 10% ~ 93%



Do not exceed 0.25MPa (2.5kgf/
cm²) during operation.



Lubricate the handpiece



Washer-disinfector for thermal
disinfection

11 Statement

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. All pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.



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