



# **Dental Low Speed Handpiece Instruction Manual**

WJ-45L/WJ-45TL/WJ-SG45L/WJ-SG45TL/WJ-SG45CL/WJ-45/WJ-45T/WJ-SG45/WJ-SG45T/WJ-SG45C/WJ-SG15L/WJ-SG15

**GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.**

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# 1 Product introduction

## 1.1 Overview

It is used to clamp rotating instruments such as burs, dental drills, and dental files, and drive their movements to realize dental operations such as cutting, grinding and drilling. Features:

- a) Low noise.
- b) Adjustable accurate speed; stable and strong cutting force.
- c) Long service life.
- d) Adaptable to electric motor that has standard E shape connector.

## 1.2 Technical specifications

|  |   |                               |  |
|--|---|-------------------------------|--|
| Model  | WJ-SG45;<br>WJ-SG45CL                       | WJ-45、WJ-SG45 WJ-45L、WJ-SG45L | WJ-45TL、WJ-SG45TL<br>WJ-SG15L、WJ-45T<br>WJ-SG45T、WJ-SG15 |
| Chuck  | Mechanical type chuck                       |                               |  |
| Gear ratio   | 1:3   | 1:4.2                         | 1:5  |
| Connector  | Standard E shape connector(ISO 3964-2016)   |                               |  |
| Shanks for rotary instruments                      | ISO 1797-1-2011, type3, $\phi$ 1.6mm needle |                               |  |
| length of rotary instrument                        | 20-25mm                                     |                               |  |
| Maximum working diameter of the rotary instruments | 2mm   |                               |  |
| Minimum length of rod                              | 12.5mm                                      |                               |  |

|   |   |                                  |  |
|---|---|----------------------------------|--|
| Model   | WJ-SG45C<br>WJ-SG45CL                                     | WJ-45、WJ-SG45<br>WJ-45L、WJ-SG45L | WJ-45TL、WJ-SG45TL<br>WJ-SG15L、WJ-45T<br>WJ-SG45T、WJ-SG15 |
| Cooling water                                   | 0.5-2 bar(1.5 bar is recommended)                         |                                  |  |
| Cooling air pressure                            | 1.5-3 bar(2 bar is recommended)(Internal water injection) |                                  |  |
| Cooling air consumption under pressure of 2 bar | > 1.5 NI/min  |                                  |  |

|       |   |  |
|-------|---|--|
| Model | WJ-45、WJ-SG45、WJ-SG45C<br>WJ-45T、WJ-SG45T、WJ-SG15 | WJ-45L、WJ-SG45L、WJ-SG45CL、<br>WJ-45TL、WJ-SG45TL、WJ-SG15L |
|-------|---|--|

|               |   |  |
|---------------|---|--|
| Light source  | - | With light fibre channel(light Intensity:20000-650000lx) |
| Optical fiber | - | With light fibre channel (light Intensity>7000lx)        |

Note:WJ-SG45、WJ-SG45L、WJ-SG45T、WJ-SG45TL、WJ-SG15、WJ-SG15L、WJ-SG45C、WJ-SG45CL are external water injection ,do not provide cooling air.

### 1.3 Intended use

It is used to clamp rotating instruments such as burs, dental drills, and dental files, and drive their movements to realize dental operations such as cutting, grinding and drilling.

1.3.1 Intended user: Professional dentists, Professional credentials have received professional education and can use the device correctly.

1.3.2 Intended patient: Patients who need dental treatment procedure for the removal of decayed matter, cavity and crown preparations, and removal of fillings and surface finishing of tooth and restoration surfaces

1.3.3 indication : dental caries.

#### 1.4 Contraindication

Unknow.

#### 1.5 Structure and compositions

Dental Low Speed Handpieces mainly consists of contra-angle, driving system, handle, etc. these components can not site disassembly.

#### 1.6 Configuration

Please refer to packing list for more details of configuration.



## 1.7 Operation conditions

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

1.7.2 Relative humidity: 30%~75%

1.7.3 Atmospheric pressure: 70kPa~106kPa

1.7.4 Cooling water temperature: ≤+25° C

## 1.8 Device safety classification

1.8.1 Type of protection against electric shock: class II equipment (when conneted to the Dental Electric Motor).

1.8.2 Degree of protection against electric shock: B type applied part (when conneted to the Dental Electric Motor).

1.8.3 Classified by operation mode: Intermittent operating device (when conneted to the Dental Electric Motor).

1.8.4 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide:  
Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8.5 The equipment cannot be used in the nuclear magnetic resonance environment.

## 1.9 Warnings

- 1.9.1 Please check the operation outside oral cavity before treatment. Pay full attention to check whether there is vibration, noise, or heating. If there is any unexpected problem, please stop operation.
- 1.9.2 Avoid strong impact and dropping;
- 1.9.3 Do not arbitrarily disassemble or modify the handpiece;
- 1.9.4 Please prepare a backup Dental Low Speed Handpiece to cope with the case that handpiece malfunction during operation;
- 1.9.5 Do not use non-recommended needles. Otherwise, the running needle may bend or fly out;
- 1.9.6 Please keep the needle handle clean. Otherwise, the stains on the surface of handle will affect the correct fixation of needle, causing the needle to fly out during operation;

- 1.9.7 Cooling water should be supplied during operation. Otherwise it may cause overheating;
- 1.9.8 For safety, please wear protective goggles or dust mask while cutting;
- 1.9.9 Please carry out regular maintenance and inspection;
- 1.9.10 If the contra-angle has not been used for a period of time, before operation, please maintain it as per Clause 4 Maintenance.
- 1.9.11 Damage or serious wear will lead to increased transmission resistance, abnormal sound and so on. As a result, the vibration of Dental Low Speed Handpiece will be strong; the drill will shake greatly; and there will be abnormal sound, etc. The operator should timely replace the contra-angle according to clinical conditions. If the contra-angle wears to a certain extent, please replace that with a new one.
- 1.9.12 Improper use will damage this product, and then hurt the patients, users and the third parties.
- 1.9.13 Any serious incident that has occurred in relation to the device should be reported to manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 1.10 Risk information

### 1.9.1 clinical benefits

Unknow.

### 1.9.2 Contraindications

Unknow.

### 1.8.3 residual risks and undesirable side-effects

Unknow.

## 1.10 safety precautions

1.10.1 For repairs and purchase of spare parts, please contact our authorized supplier.

1.10.2 The accuracy of the speed monitoring depends on the high-precision performance of the handpiece installed on the micro motor. If the handpiece of other manufacturers is used, the actual speed value may not be displayed correctly. To ensure the actual matching display speed, please use the matching dental electric motor.

1.10.3 Read this operating manual Handpiece before use and fully understand the functions of each part and connect method.

1.10.4 Check the Dental Low Speed before use to confirm that there is no abnormality. If the device is permanently malfunctioning (excessive vibration, noise and heat generation, etc.), please immediately close it and return it to the authorized dealer.

## 2 Operation instructions

## 2.1 Installation/disassembly of handpiece

### 2.1.1 Installation

Insert the electric motor plug into the Dental Low Speed Handpiece, and align the positioning block on the Dental Low Speed Handpiece with the positioning notch on the electric motor. If the Dental Low Speed Handpiece is installed in place, you can hear a click, and there should be no relative rotation between the Dental Low Speed Handpiece and the electric motor.

If there is no click sound, you can rotate the Dental Low Speed Handpiece until you hear the sound, and there should be no relative rotation between the Dental Low Speed Handpiece and the electric motor.

### 2.1.2 Disassembly

Hold the motor and contra-angle, and then pull the contra-angle out. Figure 1

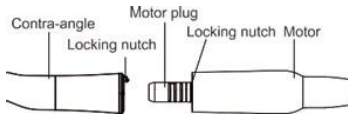


Figure 1

 Notice

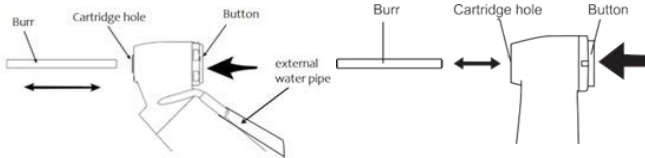
- Install and disassemble the Dental Low Speed Handpiece only after the motor is completely out of operation.
- Connect only to the adapter motor with a maximum speed of less than 40,000 rpm.
- The connector of this product is in accordance with ISO 3964-2016 standard.


## 2.2 Installation/Disassembly of needle and pipe

- 1) Insert the needle into the head as shown in Figure 2;
- 2) Press the button on head, and push to insert the needle to the end of head.
- 3) When removing the needle, first press the button, and then directly unplug the needle.



4) Installation external water pipe show in Figure 2(left).



 Notice

a) After the needle is locked, gently pull the needle/drill to ensure that the needle is securely locked.

- b) If the needle/drills are not installed securely, they may fly out or be hard to be removed.
- c) Drills should be used as medical devices and registered with a MDD or MDR CE certificate. Additionally, shanks for rotation should meet the requirements of ISO 1797-1:2017.

### 3 Cleaning, disinfection and sterilization

|              |  |
|--------------|--|
| <b>Steps</b> | <b>Reprocess of dental low speed handpiece</b> |
|--------------|--|

## Warnings

1. Before use, please carefully read the Instruction Manual of handpiece.
2. Before first use, please must clean and sterilize the Dental Low Speed handpiece.
3. 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.
4. The products may not be exposed to temperature above 138°C. This device shall not be exposed to high temperature above 138°C.
5. After the device is damaged or reaches the Processing limit, please cleaned and sterilized the Dental Low Speed Handpiece before scrapping to prevent cross infection, attention should be paid to sharp objects during handling to prevent injury.

|                           |  |
|---------------------------|--|
| <b>Processing limit</b>   | 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.   |
| <b>Initial processing</b> | <p>1. Processing principles</p> <p>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.</p> <p>Please also observe the applicable legal requirements in your country as well as the</p> |

hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

## 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 contra angle from the motor handpiece, and rinse away the dirt on the surface of contra angle with pure water (or distilled water/deionized water);
- 2) Dry the contra angle with a clean, soft cloth and place it in a clean tray.

### Cautions:

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

Use a clean soft brush to carefully brush the head and back cover of the contra-angle until

|                       |   |
|-----------------------|---|
|                       | the dirt on surface is not visible. Then use soft cloth to dry the contra-angle and accessories and put it into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.   |
| <b>Transportation</b> | Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.  |
| <b>Cleaning</b>       | <p>Preparation before cleaning Steps:</p> <p>Tools: tray, soft brush, clean and dry soft cloth.</p> <p>1.Remove the shanks/files and disconnect the contra-angle from the motor handpiece,put the contra-angle into the tray(Refer to article 2: Operation instructions)</p> <p>2.Use a clean soft brush to carefully brush the head and back cover of the contra-angle</p> |

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

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.

#### **Automated cleaning**

Use a washer-disinfector meeting the requirements of the ISO 15883 series.

Carefully place the contra-angle in the disinfection basket. Fastening of the contra-angle if only permissible if they are freely moveable in the fixture. The contra-angle are not permitted to make contact with one another. Use a suitable rinsing adaptor, and

connect the internal water lines to the rinsing connection of the washer-disinfector and start the program:

- 4min pre-washing with cold water( $<40^{\circ}\text{C}$ );
- Emptying
- 5min washing with a mild alkaline cleaner at  $55^{\circ}\text{C}$ ;
- Emptying
- 3min neutralizing with warm water( $>40^{\circ}\text{C}$ );
- Emptying
- 5min intermediate rinsing with warm water( $>40^{\circ}\text{C}$ );
- Emptying



|                     |  |
|---------------------|--|
|                     | <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte(Dr. Weigert).</p> <p>Note Acc. To EN ISO 17664 no manual reprocessing methods are require for these devices. If a manual reprocessing method has to be used, please validate it prior to use.</p> <p>The used cleaner is 0.5% neodisher MediClean forte.The intrinsic suitability of the contra-angle for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility. (The used cleaner is 0.5% neodisher MediClean forte).</p> |
| <b>Disinfection</b> | Not applicable.  |
| <b>Drying</b>       | If your cleaning and disinfection process does not have an automatic drying function,  |

dry it after cleaning and disinfection.

1. Spread a clean white paper (white cloth) on the flat table, point the contra angle against the white paper (white cloth), and then dry the contra angle with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the contra angle 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.  |
| <b>Inspection and maintenance</b> | <p>In this chapter, we only check the appearance of the handpiece.</p> <ol style="list-style-type: none"><li>1. Check the handpiece. If there is still visible stain on the handpiece after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.</li><li>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.</li><li>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.</li></ol> |

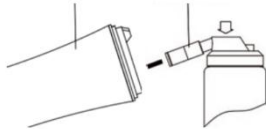
|   |
|---|
| 4.If the service time (number of times) of the handpiece reaches the specified service life (number of times), please replace it in time. |
|---|

**Injection**

Spray lubricating oil onto the dental low speed handpiece after cleaning and drying:  
The nozzle of cleaning lubricant is aligned with the air intake hole at the end of the contra angle to inject oil for 1-2 seconds.

Dental low speed handpiece

nozzle



|                      |  |
|----------------------|--|
| <b>Packaging</b>     | <p>The disinfected and dried contra-angle and their accessories are assembled and quickly packaged in a medical sterilization bag (or special holder, sterile box).</p> <p><b>Precautions</b></p> <ol style="list-style-type: none"> <li>1) The package used conforms to ISO 11607;</li> <li>2) It can withstand high temperature of 137 °C and has sufficient steam permeability;</li> <li>3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;</li> <li>4) Avoid contact with parts of different metals when packaging.</li> </ol> |
| <b>Sterilization</b> | <p>Use only the following steam sterilization procedures (fractional pre-vacuum procedure*)</p>  |

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.Sterilization parameters: 5 min at 134°C, drying time: 20 min.

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.

**Precautions**

- 1) Only products that have been effectively cleaned is allowed to be sterilized;
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|  |  |
|--|--|
|  | *Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.  |
| <b>Storage</b>                                   | Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.   |
| <b>Reprocessing validation study information</b> | 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. |

## 4 Maintenance

When not in use for a long time, the following operations should be carried out once a week: oil lubrication, then manually

check whether the needle can rotate normally; work once every 2 minutes at no load;

## 5 Storage and transport conditions

### 5.1 Storage and transport conditions

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

5.1.2 Relative humidity: 10%~93%

5.1.3 Atmospheric pressure: 70kPa~106kPa

5.2 This product should be placed or stored in a dry and clean environment which is away from acid, alkali and other harmful chemicals and gases.

5.3 Sterilized instruments should be kept in sterilization bags and kept intact and sealed. If stored for more

than 7 days or if the sealed bags are damaged, the instruments should be reprocessed.

## 6 Environment protection

| Patr      | Toxic or harmful substances or elements |    |     |      |     |      |
|-----------|---|----|-----|------|-----|------|
|           | Pb                                      | Hg | Cr6 | Cr6+ | PBB | PBDE |
| Main unit | 0                                       | 0  | 0   | 0    | 0   | 0    |

1.The Dental Low Speed Handpiece meets EU RoHS environmental protection requirements.

2.When the handpiece is damaged or reaches the limit of use, the operator should clean and sterilize it in strict accordance with the requirements for reprocessing, and then hand it over to the local dealer or

manufacturer;

3. Local distributors or manufacturers should scrap and recycle handpiece as metal products when they receive damaged or reach the limit of use.





4. After the device is damaged or reaches the Processing limit, please cleaned and sterilized the Dental Low Speed Handpiece before scrapping to prevent cross infection, attention should be paid to sharp objects during handling to prevent injury.








## 7 After-sales service

After the sale of the product, if there is any quality problem and the device cannot work normally during warranty period, Woodpecker is responsible for the maintenance. Please refer to warranty card for the warranty period and other specific items.







This product is a precision equipment. If there is problem that needs to be repaired, returned to Woodpecker or handled by professionals is recommended.

## 8 Symbol

|   |                     |   |                     |
|---|---------------------|---|---------------------|
|  | Manufacturer        |  | Date of manufacture |
|  | Type B applied part |  | Class II device     |

|   |                   |   |  |
|---|-------------------|---|--|
|   | Used indoors only | <b>IPX0</b>   | General equipment                            |
|  | Serial number     |  | Products comply with WEEE directive          |
|  |                   |  | Autoclavable up to the specified temperature |
|  | Recyclable        |  | Avoid exposure to rain                       |



|   |  |   |  |
|---|--|---|--|
|   | CE marked product                              |   | Follow Instructions for Use                                  |
|  | Humidity limit for storage: 10% ~ 93%          |  | Atmospheric pressure for operation and storage: 70kPa—106kPa |
|  | Temperature limit for storage: -20° C ~ +55° C |  | Authorised Representative in the EUROPEAN COMMUNITY          |

## 9 Statement

9.1 Please refer to product packaging label for date of manufacture. Service life of product: 7 years.

9.2 If there are any issues not covered (such as: a notice to the user and/or patient that any series incident), the woodpecker will be announced on the website [www.glwoodpecker.com](http://www.glwoodpecker.com)



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