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Glidewell™ Contra-angle Electric Handpiece Instruction Manual

Model: GL-15L and GL-45L

Prismatik Dentalcraft, Inc.

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1 Product introduction

1.1 Overview

The contra-angle handpiece is driven by a micro electric motor to rotate at a certain speed, thereby driving the dental bur to move to achieve dental surgeries such as grinding and cutting.

Features:

- a) Low noise.
- b) Precise and adjustable speed, stable cutting and large force.
- c) Long serve life.
- d) Adaptable to electric motors with standard E-type interface.

1.2 Technical parameters

Model	GL-45L	GL-15L
No-load speed	≤175800 r/min	≤212500 r/min
Chuck type	Mechanical chuck	
Speed ratio	1:4.2	1:5
Handpiece Coupling type	Standard E-type interface (ISO 3964) needle	
Surgical instruments	Type 3 1.6mm diameter bur in ISO 1797-1	
Bur length	20-25 mm	
Maximum diameter of bur front end	2 mm	

Model	GL-45L	GL-15L
Shank size	ISO 1797-1 diameter 1.6 mm	
Minimum suitable length of shank	12.5 mm	
Cooling pressure setting range	1.5-3 (Recommend 2) bar (GL-45L)	1.5-3 (Recommend 2) bar (GL-15L)
Cooling air consumption at 2 bar air pressure	> 1.5 NI/min (GL-45L)	> 1.5 NI/min (GL-15L)

Model	GL-45L	GL-15L
Lighting mode: Optical fiber (Illumination of output end > 7000lx)	GL-45L	GL-15L
Light source: LED SG15L (Illumination: 20000-65000lx)		
Water cooling method	At 200kPa (2.0 Bar), the water flow of contra-angle handpiece should not be less than 50mL/min.	

1.3 Scope of application

It is suitable for clamping dental bur and driving it to move to achieve dental surgeries such as grinding and cutting.

1.4 Product structure and composition

The product consists of handpiece, driving shaft and head.

1.5 Parts list

Please refer to the packing list for machine configuration.

1.6 Operation conditions

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

1.6.2 Relative humidity: 30% ~ 75%

1.6.3 Atmospheric pressure: 70kPa ~ 106kPa

1.6.4 Cooling water temperature: $\leq +25^{\circ}\text{C}$

1.7 Warnings

- 1.7.1 The product must be used within the scope mentioned in the manual, all contents in the manual should be carefully read and understood before operation. If the user does not operate in accordance with the instructions or use this product for other purposes, the manufacturer will bear no responsibilities.
- 1.7.2 The use of the product must comply with the requirements of the relevant operating standards and regulations of the medical department. The product is specially manufactured for oral treatment and cannot be used for other purposes. It is intended for use by medical technicians and dental professionals only.
- 1.7.3 The contra-angle handpiece should be kept clean before and after use.
- 1.7.4 Please check the handpiece through rotation outside the mouth before treatment. Check carefully whether there is vibration, noise or heating. If there is any abnormality, please stop using and contact the original dealer.
- 1.7.5 If there is an accident during correct use, please stop using it immediately.
- 1.7.6 Avoid strong impact and dropping.

1.7.7 Do not arbitrarily disassemble or modify the handpiece

1.7.8 Please prepare a backup handpiece in case that handpiece malfunctions during operation.

1.7.9 Do not use non-recommended burs. The bur used should meet the standard of ISO 3823-1.

When using a bur, you must know whether the specified speed and specification of the bur meet the use requirements of this contra-angle. Using a bur that is bent, cracked, deformed, damaged or does not meet the specifications may lead to sudden breakage and flying out during operation, resulting in injury and contra-angle damage.

1.7.10 Please keep the bur chuck clean. Otherwise, stains on the surface of the shank will prevent the bur from being properly secured, causing the bur to fly out during use.

1.7.11 Do not use the contra-angle handpiece without a bur.

1.7.12 Do not press the button on the head while operating. Otherwise, it may cause head overheating or the bur to fly out.

- 1.7.13 Cooling water and air should be supplied during operation, and the pressure and flow of the air source and water source must meet the requirements of the machine. Otherwise, it may cause overheating.
- 1.7.14 For safety, please wear protective goggles or dust mask while cutting.
- 1.7.15 Do not exert too much force to treatment site.
- 1.7.16 Please carry out regular maintenance and inspection.
- 1.7.17 If the contra-angle handpiece has not been used for a long time, it should be maintained according to “4 Maintenance” before use.
- 1.7.18 When the dental handpiece is damaged or worn seriously, it will cause increased transmission resistance, abnormal sound, etc., manifested in high vibration of the contra-angle, severe shaking of the bur, abnormal sound, etc. The operator should replace the contra-angle in time according to clinical conditions. If the contra-angle handpiece wears to a certain extent, please replace it with a new one.

1.7.19 Improper use may damage the product and cause risks to patients, users and third parties.

1.7.20 All warnings and instructions on the instrument shall be followed during operation.

1.7.21 A damaged contra-angle cartridge may produce high noise, and long-time use may affect hearing.
Please replace it as soon as possible.

1.7.22 Spray hole can be dredged with cleaning needle.

1.7.23 The clamping part of the bur should not be too short (should meet the requirement of 1.2), otherwise the bearing load will be uneven and the bearing wear will be accelerated.

1.8 Contraindications and warnings

1.8.1 Patients with hemophilia are forbidden to use this equipment.

1.8.2 Patients or doctors with a heart pacemaker are forbidden to use this equipment.

1.8.3 Patients with allergic constitution and a history of drug allergy are forbidden to use this equipment.

- 1.8.4 Patients with oral and maxillofacial infections, various types of oral mucosal diseases that have not been cured, periapical disease, gingivitis, periodontal disease and oral cancer are forbidden to use this equipment.
- 1.8.5 Heart disease patients and children should be cautious to use the equipment.
- 1.8.6 People with mental disorders should be cautious to use this equipment.
- 1.8.7 Patients with severe systemic infection or systemic diseases such as diseases in heart, liver, kidney, hematopoietic system, digestive system and endocrine system should be cautious to use this equipment.
- 1.8.8 Pregnant women, lactating women, or women of childbearing age who have a plan of pregnancy should be cautious to use this equipment.

2 Operation instructions

2.1 Water injection mode

Model GL-15L and GL-45L contra-angle handpieces support external water injection. The water injection hose and external water tube shall be firmly connected. (Fig. 1). Other models of contra-angle handpieces can be injected internally. After installing and connecting the electric motor in 2.2.1, water can be injected normally.

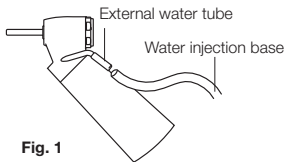


Fig. 1

2.2 Installation and disassembly of handpiece

2.2.1 Installation

Insert the electric motor plug into the contra-angle handpiece. When connecting the contra-angle with optical fiber, align the positioning block on the contra-angle with the positioning notch on the electric motor. If the contra-angle is installed in place, you can hear a "click" sound, and there should be no relative rotation between the contra-angle and the electric motor. If there is no "click" sound, rotate the contra-angle until you hear the sound. At this time, the contra-angle and the motor cannot rotate relative to each other. If there is no "click" sound, rotate the contra-angle until you hear the sound. At this time, the contra-angle and the motor cannot rotate to each other.

2.2.2 Disassembly

Hold the motor and contra-angle, and then pull the contra-angle out. (Fig.2)

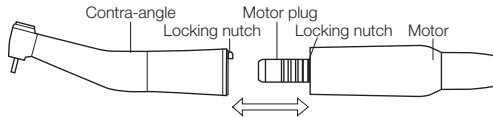


Fig. 2

⚠ Notice

- a) Install and disassemble the contra-angle handpiece only after the motor is completely out of operation.
- b) The connector of this product conforms to ISO 3964 standard.

2.3 Installation/disassembly of bur

2.3.1 Insert the bur into the hole of the cartridge, as shown in Fig. 3 or Fig. 4.

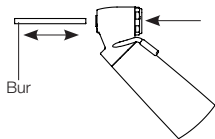


Fig. 3

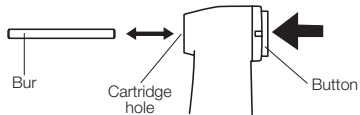


Fig. 4

2.3.2 Press the button on the head, and push to insert the bur to the end of the head.

2.3.3 When disassembling, press the button first and then pull out the bur directly.

2.3.4 Please install and uninstall the bur or contra-angle handpiece after the rotation stops completely.

Do not press the button during rotation.

a) After the bur is locked, gently pull the bur to ensure that the bur is securely locked.

b) If the bur is not installed securely or in place, it may fly out or be hard to remove.

3 Cleaning, disinfection and sterilization

3.1 Contra-angle handpiece cleaning

3.1.1 Disassembly

a) Remove the contra-angle from the motor.

b) Remove the bur from the contra-angle head.

3.1.2 Device body cleaning

- a) If the surface of the contra-angle handpiece is seriously contaminated, pre-clean it with disinfecting paper towels (this step can be decided according to the actual situation).
- b) Clean the surface with softening water and a brush.
- c) Clean up any liquid residues on the surface and inside of the contra-angle handpiece after cleaning, using an absorbent cloth or compressed air to blow dry.

Notice

Please use a soft brush, otherwise the surface of the contra-angle handpiece may be worn.

3.1.3 Nozzle cleaning

Use a cleaning needle to carefully clean the water spray hole to remove dirt and deposits, as shown in Fig. 5.

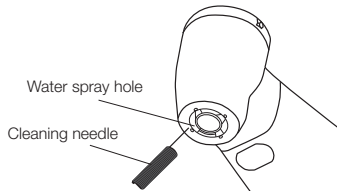


Fig. 5

3.2 Disinfection.

3.2.1 After cleaning the contra-angle handpiece, use a soft cloth dipped in methanol, ethanol or phenolic alcohol and other disinfectants to wipe the surface.

3.2.2 Do not use oxidizing potential water (strong acid, super acid) or disinfectant to clean, soak and wipe the contra-angle.

3.2.3 It is strictly forbidden to dip the contra-angle in the disinfectant.

Notice

Ultrasonic cleaning is forbidden.

3.3 Oiling lubrication

3.3.1 After removing the bur, use an E-type nozzle for oil injection for lubrication.

3.3.2 Shake the cleaning lubricant spray can to mix lubricant well with the propellant.

3.3.3 Insert the nozzle into the tail of the contra-angle. Put a tissue on the head and hold the handpiece to spray oil to it for 2-3 seconds. Check whether the tissue is clean. If it is clean, the contra-angle handpiece can be autoclaved. If not, spray again until the tissue is clean. (Fig. 6)

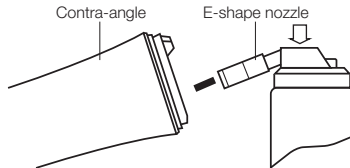


Fig. 6

 Notice

- a) Hold the contra-angle handpiece tightly to prevent it from slipping as a result of spray pressure during oiling.
- b) Oiling should be repeated until the contra-angle handpiece is clean and free from stains. If foreign objects remain inside the handpiece, it may cause bearing and gear damage.
- c) Keep the cleaning lubricant spray can upright.

3.4 Sterilization

3.4.1 This product can be disinfected by electrothermal sterilizer.

3.4.2 The product can be autoclaved at 132°C.

3.4.3 High temperature and high-pressure sterilization is recommended.

3.4.4 After use for each patient, high temperature and high-pressure sterilization should be performed according to the following steps.

- a) Use a cleaning brush to remove stains on the handpiece surface. Do not use metal brush. Clean the contra-angle handpiece with water or isopropyl alcohol.
- b) Inject cleaning lubricant into the contra-angle handpiece for cleaning.
- c) Put the cleaned contra-angle handpiece into a sterilization bag and seal it (only when vacuum high temperature and high-pressure sterilization is used).
- d) It can be autoclaved at a temperature of 132°C and a pressure of 0.22MPa (2.2bar) for a duration of not less than 4 minutes.
- e) The sterilized contra-angle should be placed in a high-temperature and high-pressure sterilization bag and taken out when used to keep it clean.
- ⚠ Notice
- f) The product can undergo 500 times of sterilization. It is recommended that you conduct a regular overhaul once a year after 500 sterilizations.

- g) If the equipment has residual chemicals, do not sterilize it at high temperature and high pressure. Otherwise, the surface coating may fall off or the internal parts may be damaged.
- h) Please store the contra-angle handpiece in a place free from dust, sulfide or salt in the air.
- i) Do not touch the contra-angle handpiece immediately after high temperature and high pressure sterilization to prevent burns.

4 Maintenance

- 4.1 After each use, before high-temperature sterilization, or after every 60min of continuous use, oiling lubrication must be carried out (see 3.3 “Oiling lubrication” for details).
- 4.2 When the device is not in use for a long time, the following operations should be carried out once a week: Oiling lubrication, and then manually check whether the bur can rotate normally; No-load work once, 2 minutes each time; After no-load work is completed, operate according to the requirements of “3 Cleaning, disinfection and sterilization”.

5 Storage and transport conditions

5.1 Storage

5.1.1 Environment temperature: -20° C ~ +55° C

5.1.2 Relative humidity: 10% ~ 93%

5.1.3 Atmospheric pressure: 70kPa~106kPa

5.2 Transport

This product should be placed or stored in a dry, stable (no collision), clean environment away from acid, alkali and other harmful chemicals and gases.

6 Environment protection

The optical fiber guide is made of glass and should be disposed of according to the environmental protection requirements of glass products. The remaining metals can be recycled by classification.

7 After-sales service

After the date of sale but within the warranty period, if the device does not work normally or has a quality problem Glidewell is responsible for the repair. Please refer to the Warranty for details of warranty. As this product is a precision device, if there is a failure that requires repair, it is not recommended to disassemble it by yourself. It should be returned to Glidewell or handled by professionals.

8 Symbol Glossary

Symbol	Reference No. 21 CFR Part 801, Section	Title – Symbol Description
	Section 801.109(b)(1)	By Prescription Only – Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.
Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
	5.1.3	Date of Manufacturer – Indicates the date (YYYY-MM-DD) when the medical device was manufactured.
	5.4.3	Consult Instructions For Use – Indicates the need for the user to consult the instructions for use.

Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
MD	5.7.7	Medical device – Indicates the item is medical device.
UDI	5.7.10	Unique device identifier –Indicates a carrier that contains unique device identifier information.
SN	5.1.7	Serial number – Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
	5.3.4	Keep dry – Indicates a medical device that needs to be protected from moisture.
	5.3.1	Fragile, handle with care – Indicates a medical device that can be broken or damaged if not handled carefully.
	5.3.9	Atmospheric pressure limitation – Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
	5.3.8	Humidity limitation – Indicates the range of humidity to which the medical device can be safely exposed.
	5.3.7	Temperature limit – Indicates the temperature limit to which the medical device can be safely exposed.
	5.2.7	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.

Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
	5.4.4	Caution – Indicates the user needs to consult the instructions for use for important cautionary information such as warnings and precautions.
Symbol	Reference No. EN 50419:2022, Section	Title – Symbol Description
	Figure 1 Section 4.2	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.

9 Statement

Glidewell reserves the right to change the design of the equipment, the technique, fittings, instruction manual and the content of the original packing list at any time without further notice. The Figures are only for reference. The final interpretation rights belong to Glidewell.







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