℞ Only

Glidewell

Glidewell™ Contra-angle Electric Handpiece Instruction Manual

Model: GL-11L

Prismatik Dentalcraft, Inc.

IFU-012667_1 090525

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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	GL-11L
Chuck type	Gland chuck
Gear ratio	1:1
Connector type	Standard E shape interface ((ISO 3964-2016))
Type of rotating equipment	ISO 1797:2017, type 1, ϕ2.35 mm needle
Maximum length of the rotary instrument	22.5 mm
Maximum working diameter of the rotary	4 mm
Rod type and size	ISO 1797:2017, type1 ϕ2.35 mm

Model	GL-11L
Minimum suitable length of the rod	12.5 mm
Spray water pressure setting range	0.5-2 (recommended 2) bar
Spray air pressure setting range	1.5-3 (recommended 2) bar
Spray water consumption at 2 bar water pressure	> 50 ml/min
Spray gas consumption at 2 bar gas pressure	> 1.5 Nl/min
Lighting method	Fiber optic
Rod type and size	LED lamp (light level: 20000-65000 1x)

Note: GL-11L with optical fiber can guide light.

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.

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

1.4 Structure and compositions

Contra-angle handpieces mainly consist of a contra-angle, driving system, handle, etc. These components cannot site disassembly.

1.5 Configuration

Please refer to packing list for more details of 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: ≤+25°C

1.7 Device safety classification

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

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

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

1.7.4 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.

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

1.8 Warnings

1.8.1 Please check the operation of the handpiece outside the 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.

1.8.2 Avoid strong impact and dropping.

1.8.3 Do not arbitrarily disassemble or modify the handpiece.

1.8.4 Please prepare a backup contra-angle handpiece in case of malfunction during operation.

1.8.5 Do not use non-recommended needles. Otherwise, the running needle may bend or fly out.

1.8.6 Please keep the needle handle clean. Otherwise, the stains on the surface of handle will affect the correct fixation of the needle, causing the needle to fly out during operation.

1.8.7 Cooling water should be supplied during operation. Otherwise it may cause overheating.

1.8.8 For safety, please wear protective goggles or a dust mask while cutting.
1.8.9 Please carry out regular maintenance and inspection.
1.8.10 If the contra-angle handpiece has not been used for a period of time, before operation, please maintain it as per Clause 4 Maintenance.
1.8.11 Damage or serious wear will lead to increased transmission resistance, abnormal sound and so on. As a result, the vibration of the contra-angle handpiece will be strong; the drill will shake greatly; and there will be abnormal sound, etc. The operator should timely replace the contra-angle handpiece according to clinical conditions. If the handpiece wears to a certain extent, please replace it with a new one.
1.8.12 Improper use will damage this product, and then affect the patients, users and the third parties.
1.8.13 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.9 Risk information

1.9.1 Clinical benefits: unknown.

1.9.2 Contraindications: unknown.

1.9.3 Residual risks and undesirable side effects: unknown.

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 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, heat generation, etc.), please immediately turn it off and return it to the authorized dealer.

2 Operation instructions

2.1 Installing/Removing the handpiece

2.1.1 Installation: Insert the motor plug into the contra angle, when connecting with the fiber optic contra angle, align the locking nutch on the contra angle with the positioning notch on the motor. If the contra angle is installed in place, a “click” can be heard. At this time there should be no relative rotation between the contra-angle handpiece and the motor. If no “click” is heard, rotate the contra angle until the sound is heard, at which point the contra angle is not rotated relative to the motor.

2.1.2 Removal: Disassemble the motor and contra angle by gripping them and pulling them out directly, as in Figure 1.

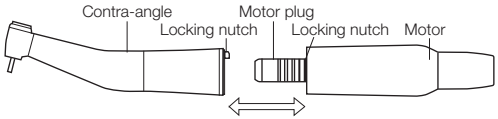


Figure 1.

Notice

a) Install or remove the contra angle only after the motor has completely stopped running.
b) Connect only to the adapter motor with a maximum speed of less than 41,000 rpm.
c) The connector of this product conforms to ISO 3964-2016 standard.

2.2 Mounting/dismantling of the needle (Figure 2)

1) Insert the needle until it is in the correct position.
2) Press the button on the head and insert the needle into the chuck until the needle snaps into the mechanical recess. Release the button.
3) When not pressing the button, gently push and pull the needle to confirm that the needle is secure.
4) When disassembling, press the button first, then pull out the needle.

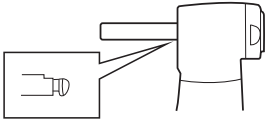


Figure 2.

Notice

a) After the needle is locked, gently pull on the needle to ensure that it is locked.
b) If the needle is not securely mounted or not in place, it may fly out or not be removed.

3 Cleaning, disinfection and sterilization

Steps	Reprocess of dental low speed handpiece
Warnings	1. Before use, please carefully read the Instruction Manual of handpiece. 2. Before first use, you must clean and sterilize the handpiece. 3. The use of an ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the lifespan of products. The manufacturer takes no responsibility in such cases. 4. The products may not be exposed to temperatures above 138°C. This device shall not be exposed to high temperatures above 138°C. 5. After the device is damaged or reaches the processing limit, please clean and sterilize the handpiece before scrapping.

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 this handpiece is 600 times.
Initial processing	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.

Initial processing	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: a) 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). b) 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 the surface is not visible. Then use a 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.

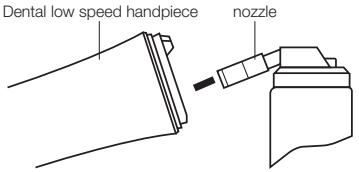
Transportation	Safe storage and transportation to the reprocessing area will avoid any damage and contamination to the environment.
Cleaning	Preparation before cleaning: Tools: tray, soft brush, clean and dry soft cloth. 1. Remove the shanks/files and disconnect the contra angle from the motor handpiece. Put the contra angle into the tray (Refer to article 2: Operation instructions). 2. Use a clean soft brush to carefully brush the head and back cover of the contra angle until the dirt on the surface is not visible. Then use a 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.

Cleaning	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 is only permissible if they are freely moveable in the fixture. The contra angle is 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: • 4 min pre-washing with cold water(<40°C); • Emptying • 5 min washing with a mild alkaline cleaner at 55°C; • Emptying • 3 min neutralizing with warm water (>40°C); • Emptying

Cleaning	• 5 min intermediate rinsing with warm water (>40°C); • Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note according to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use. 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).
Disinfection	Not applicable

Drying	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: 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.

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.

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

Packaging	The disinfected and dried contra angle 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 137 °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.
Sterilization	Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization. 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.

Sterilization	2. Sterilization parameters: 5 min at 132°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.

Sterilization	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	a) Only products that have been effectively cleaned 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.

Precautions	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.
Storage	Store sterilized instruments in a dry, clean and dust-free environment at modest temperatures, refer to label and instructions for use.

Reprocessing validation study information	It is the duty of the user to ensure that the reprocessing processes, including resources, materials and personnel are capable of reaching 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° C ~ +55° 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

Part Name	Toxic or harmful substances or elements					
	Pb	Hg	Cr6	Cr6+	PBB	PBDE
Main unit	O	O	O	O	O	O

1. The contra-angle 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 the handpiece as metal products when they receive damage or reach the limit of use.

7 After-sales service

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

This product is a precision equipment. If there is a problem that needs to be repaired, it is recommended that it 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
	5.7.7	Medical device – Indicates the item is medical device.
	5.7.10	Unique device identifier –Indicates a carrier that contains unique device identifier information.
	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

9.1 All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The industrial design, inner structure, etc, have claimed for several parents by manufacture, any copy or fake product must take legal responsibilities.

Manufactured For Prismatik Dentalcraft, Inc.
Address: 2144 Michelson Drive
Irvine, CA 92612, USA
E-mail: mail@glidewelldirect.com
Website: https://glidewelldirect.com/
U.S.: 888-303-3975

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