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尺寸 Size	190×285mm	出血尺寸 Hemorrhage line	6mm
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装订 & 注释 Binding & Annotation	折疊	印刷颜色 Printing Colour	彩印
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 桂林市啄木鸟医疗器械有限公司 Guilin Woodpecker Medical Instrument Co., Ltd.			

Dental Handpiece Instruction For Use

1 Product introduction

1.1 Overview

The GenENDO Dental Handpiece (CA 361-H) and kinds of geared angle handpieces according to ISO 14457:2017 and are used to hold and drive rotary instruments for the purposes of rotary processing, intended for the endodontic treatment.

Features:

- a) Smooth transmission, low vibration, low noise and high cutting efficiency.
- b) Long service life.

1.2 Technical specifications

Model	GenENDO Dental Handpiece (CA 361- H)
Chuck type	Push-button
Gear ratio	6:1
Rotation mode	Continuous forward, continuous reverse and reciprocating rotation
File shank attachment	Φ2.35mm ISO1797-1 Type1
Minimum fitting length of shank	11mm
Maximum overall length of the rotary instrument	46mm

1.3 Structure and compositions

The product consists of handle, driving medium and head.

1.4 Configuration

Please refer to packing list for more details of configuration.

1.5 Indications for use

The GenENDO Dental Handpiece (CA 361-H) are medical devices and designed for holding and driving dental root canal instruments in continuous and reciprocating movement.

These devices must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

1.6 Operation conditions

1.6.1 Environment temperature:10°C~40°C

1.6.2 Relative humidity:30%~75%

1.6.3 Atmospheric pressure:70kPa~106kPa

1.7 Warnings

1.7.1 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.

1.7.2 Avoid strong impact and dropping;

1.7.3 Do not arbitrarily disassemble or modify the Contra- angle Handpieces;

1.7.4 Please prepare a backup Dental Handpiece to cope with the case that Dental Handpiece malfunction during operation;

1.7.5 Do not use non- recommended shanks/files. Otherwise, the running shanks/files may bend or fly out;

1.7.6 Please keep the shanks/files handle clean. Otherwise, the stains on the surface of handle will affect the correct fixation of shanks/files, causing the shanks/files to fly out during operation;

1.7.7 Do not use the Dental Handpiece without shanks/files.

1.7.8 Do not press the button while operating. Otherwise, it may cause head overheating or flying shanks/files;

1.7.9 For safety, please wear protective goggles or dust mask while cutting;

1.7.10 Do not exert too much force to treatment site;

1.7.11 Please carry out regular maintenance and inspection;

1.7.12 If the Dental Handpiece has not been used for a period of time, before operation, please maintain it as per Clause 4 Maintenance.

1.7.13 Damage or serious wear will lead to increased transmission resistance, abnormal sound and so on. As a result, the vibration of Dental Handpiece handpiece will be strong; the drill will shake greatly; and there will be abnormal sound, etc. The operator should timely replace the Dental Handpiece according to clinical conditions. If the Dental Handpiece wears to a certain extent, please replace that with a new one.

1.7.14 Improper use will damage this product, and then hurt the patients, users and the third parties.

1.8 Contraindications and warnings

1.8.1 This device must not be used on patients with hemophilia.

1.8.2 This device must not be used on patients with a cardiac pacemaker & doctors with a cardiac pacemaker are prohibited from using this device.

1.8.3 This device must not be used on patients with allergic constitution and a history of drug allergy.

1.8.4 This device must not be used on 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.

1.8.5 Use with caution in patients with heart disease and in young children.

1.8.6 Use with caution in patients with mental disorders.

1.8.7 Use with caution in patients with severe systemic infection or systemic diseases such as diseases in heart, liver, kidney, hematopoietic system, digestive system and endocrine system.

1.8.8 Use with caution in pregnant women, lactating women, or women of childbearing age who have a plan of pregnancy

2 Operation instructions

2.1 Connecting and Disconnecting the Dental Handpiece

2.1.1 Connecting

The Dental Handpiece can be connected at 3 or 6 adjustable head positions. Adjust to a suitable angle during use. Align the positioning pins of the Dental Handpiece with the positioning slots of the motor handpiece and insert the head until it clicks (see Figure 1).When performing the APEX measurement, mount the insulating sleeve and pull it fully over the Dental Handpiece. We recommend performing the treatment with a cofferdam and wear appropriate insulated gloves, while using an insulating sleeve. This will prevent inaccurate measurements caused by undesired leakage currents. During the measurement, the instrument must not come into contact with the patient's mucosa, metallic tooth restorations, or the mucosal electrode.

When removing the Dental Handpiece, pull it straight out (see Figure 1).

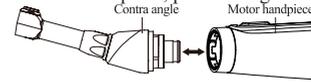


Figure 1

2.1.2 Disconnecting

⚠ CAUTIONS

- a) The Dental Handpiece can be connected or disconnected only after the motor handpiece has completely stopped running.
- b) Check the Dental Handpiece is securely assembled to the motor handpiece.

2.2 Inserting and Removing the shanks/files

2.2.1 Insertion See Figure 2.

- 1) Lightly hold down the push-button and insert the shank/file.
- 2) Turn the shank/file back and forth until it engages with the latch mechanism.
- 3) Push the shank/file inwards to click and release the push-button to lock the shanks/files.

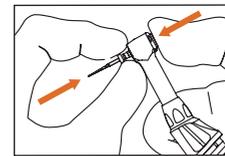


Figure 2

2.2.2 Removal

See Figure 3.

Press the push-button and pull out the shank/file.

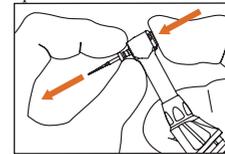


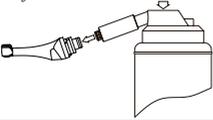
Figure 3

⚠ CAUTIONS

- a) When connecting and disconnecting the shank/file, turn the power off beforehand.
- b) If it is necessary to use the insulating sleeve, first mount the insulating sleeve, then insert the shank/file. Remove the shank/file before removing insulating sleeve.
- c) After the shanks/files is locked, lightly pull out the shank/file to ensure that the shanks/files is locked.
- d) Always clean the shank of the file to be installed. Allowing dirt to enter the chuck could cause deterioration of chucking force.
- e) If the shank/file are not installed securely, it may fly out or be hard to be removed.

3 Cleaning, disinfection and sterilization

Steps	Dental Handpiece handpiece
⚠ Warnings	1.The Dental Handpiece are not suitable for ultrasonic cleaning. 2.The Dental Handpiece handpiece should not be immersed in strong detergents or disinfectants (alkaline pH>9 or acid pH <5).
Resistance to sterilizing procedure	The Dental Handpiece handpiece could be capable of being subjected to 600 cycles of sterilizing procedure.
Preparation at the Point of Use	The post-operative process must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows: Remove the shanks/files and disconnect the Dental Handpiece handpiece from Motor handpiece. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Transportation	The Dental Handpiece handpiece should be safety stored and transported to the point of reprocessing to avoid any damage and environment pollution.
Preparation for reprocessing	The products must be reprocessed in a disassembled state.
Pre-cleaning	Tools: tray, soft brush, clean and dry soft cloth Perform manual pre-cleaning until the handpiece is visually clean. Rinse the chuck of bur with running water for at least 10 seconds. Clean the surface with a soft bristle brush. Note: The water temperature should not exceed 40°C during the washing stage, otherwise the protein will solidify and be difficult to remove.

Cleaning	<p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.</p> <p>Automatic cleaning</p> <p>The washer-disinfector should meet the requirements of the ISO 15883. Place the Dental Handpiece handpiece in the washer-disinfector carefully. Ensure that Dental Handpiece can not move freely in the washer-disinfector. The Dental Handpiece handpiece are not permitted to contact with each other. Start the program:</p> <ul style="list-style-type: none"> • 4min 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 • 5 min intermediate rinsing with warm water(>40°C); • Emptying • Drying the device at 80°C for 15min <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte(Dr. Weigert)</p>
Disinfection	<p>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.</p>
Drying	<p>Drying of outside of instrument through drying cycle of washer-disinfector. If necessary, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air. If your washer-disinfector does not have an automatic drying function, please dry the device after cleaning and disinfection. The drying method as below:</p> <ol style="list-style-type: none"> 1) Spread a clean white paper (white cloth) on the flat table, place the Dental Handpiece handpiece on the white paper (white cloth), and then dry the Dental Handpiece with filtered dry compressed air (maximum pressure 3 bar). When no liquid is sprayed on the white paper (white cloth), it indicates that the Dental Handpiece handpiece is completely dry. 2) The device can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80 °C and the time should be 15minutes. <p>Note:</p> <ol style="list-style-type: none"> 1) Dry the Dental Handpiece handpiece repeatedly if necessary (refer to section "Drying"). 2) The air used for drying must be filtered by HEPA. 3) The device should be dried in a clean area. 5) The drying temperature should not exceed 137 °C.
Maintenance	<ol style="list-style-type: none"> 1. Functional Test and Visual inspection <p>Visually inspect the cleanliness of the Handpiece. Perform Functional test according to instructions of use. If there is still visible stain on the device after cleaning, the entire cleaning process must be repeated. Before packaging and sterilization, make sure that the Dental Handpiece handpiece has been maintained acc. to manufacturer's instruction. If the device is obviously damaged, smashed, detached, corroded or bent, it must be discarded and not allowed to continue to be used. 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.</p> <ol style="list-style-type: none"> 2. Use lubricant to lubricate the handpiece and dried it prior to sterilization. Aim the nozzle of lubricant bottle to the air hole at the end of the Dental Handpiece handpiece to inject oil for 1-2 seconds. 
Packaging	<p>The Dental Handpiece handpiece should be quickly packaged in a medical sterilization bag (or special holder, sterile box).</p> <p>Precautions</p> <ol style="list-style-type: none"> 1) Only use a legally marketed or a FDA cleared sterilization pouch; 2) The package should 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 different metals when packaging.
Sterilization	<p>Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: at least 4 min at 132°C/134 °C (in EU: 5 min at 134 °C, in US: 4 min at 132 °C) Maximum sterilization temperature: 137°C Flash sterilization is not allowed on lumen instruments!</p>
Storage	<p>Sterilized devices should be stored in a dry, clean and dust-free environment, refer to label and instructions for use.</p>

4 Maintenance

4.1 After each use of the Contra- angle Handpieces or before high-temperature sterilization, and every 60 minutes of continuous use, oil lubrication must be applied.

4.2 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 shanks/files can rotate normally; work once every 2 minutes at no load; after empty work is completed, perform the operation in "3 Cleaning, disinfection and sterilization".

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.

6 Environment protection

This product contains no harmful ingredients and can be disposed and destroyed according to local regulations.

7 After-sales service

The GenENDO Dental Handpiece is covered by a limited warranty effective from the date of purchase, subject to specific terms and conditions. For full details on warranty coverage, including inclusions and exclusions, please visit our website at: <https://www.septodontcorp.com/eifu-genendo/> If you experience any issues with your GenENDO Dental Handpiece or require support, you will find contact details and instructions for after-sales service on our website.

8 Symbol description

	Follow instructions for use
	Date of manufacture
	Manufacturer
	Type B applied part
	Ordinary equipment
	Used indoor only
	Appliance compliance WEEE directive
	Temperature limitation for storage
	Atmospheric pressure for storage
	Humidity limitation for storage
	Keep dry
	Handle with care
	Recovery
	Can be autoclaved
	Serial number
	CE marked product
	Medical Device
	Authorised Representative in Switzerland
	UK responsible person
	Authorised Representative in the EUROPEAN COMMUNITY
	EU Importer

9 Statement

The Figures are only for reference. The final interpretation rights belong to Guilin Woodpecker Medical Instrument Co., Ltd. (Please refer to product packaging label for date of manufacture. Service life of product: ten years)

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