

产品描述

Product Description

1. Device Composition 设备组成

Woodpecker Contra-angle handpiece (model: CA161、CA161-RR) is a kind of geared angle handpiece according to ISO 7785-2 and is use to hold and drive rotary instruments for the purposes of rotary processing, intended for the endodontic treatment.

啄木鸟弯手机 (型号: CA161、CA161-RR) 是一种符合 ISO 7785-2 标准的齿轮角手机, 用于固定和驱动旋转器械以进行旋转加工, 用于牙髓治疗。

Remark: The figure below is schematic diagram.Differences between different models in the table 1-1,The components in the table 1-2 and attachments in the table 1-3 are sold together with the device. 备注: 下图为示意图。表1-1中不同型号的区别, 表1-2中的组件和表1-3中的附件与设备一起销售。



Figure 1 Structure of CA161



Figure 3 Structure of CA161-RR

Table 1-1 Differences between different models		
Model	CA161	CA161-RR
Output Speed Range 输出速度范围	100~1200 rpm	100~2500 rpm
Output Torque Range 输出扭矩范围	0.4~5.0 Ncm	0.6~4.2 Ncm
Chuck type	Push-button	
Gear ratio	6:1	
Rotation mode	Continuous forward, continuous reverse and reciprocating rotation 连续正向、连续反向和往复旋转	Continuous forward, continuous reverse and reciprocating rotation (Axial reciprocating motion is performed simultaneously with all rotational motions) 连续正向、连续反向和往复旋转（轴向往复运动与所有旋转运动同时进行）
File shank attachment	Φ2.35mm ISO1797-1 Type1	
Minimum fitting length of shank	11mm	

Maximum overall length of the rotary instrument	46mm
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Table 1-2 Description of main part of Contra-angle handpiece




Number	Model	Fig	Configuration 配置
1	CA161		1.Gear ratio 6:1 2.Output Speed Range: 100~1200 rpm 3.Output Torque Range: 0.4~5.0 N cm 4. Chuck type: Push-button 5.File shank attachment: $\Phi 2.35\text{mm}$ ISO1797-1 Type1
3	CA161-RR		1.Gear ratio 6:1 2.Output Speed Range: 100~2500 rpm 3.Output Torque Range: 0.6~4.2 N cm 4.Chuck type: Push-button 5.File shank attachment: $\Phi 2.35\text{mm}$ ISO1797-1 Type1

Table 1-3 Description of accessories of Contra-angle handpiece

Number	Attachments	Fig	Configuration	Description	Function	Remark
1	Lubricating fitting 注油嘴		—	For maintenance of the contra-angle handpiece during daily use	Conveniently bend the inside of the contra-angle handpiece to inject lubricant.	Real accessory

2 Intended Use, User and Patient

2.1 Intended use: The Contra- angle Handpieces are 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. 牙科弯手机用于夹持车针、牙钻、牙锉等旋转器械，并带动其运动，实现切割、磨削、钻孔等牙科操作。

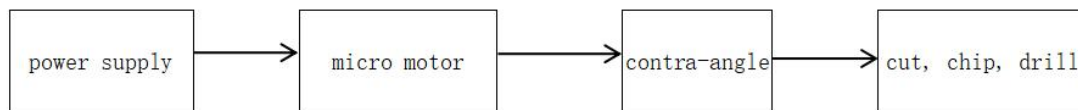
2.2 Intended user: Professional dentists 目标用户：专业牙医

2.3 Intended patient: Patients who need root canal treatment 目标患者：需要进行根管治疗的患者

3 Operation Principle

The Contra-angle handpiece is a kind of geared angle handpiece and is use to hold and drive rotary instruments for the purposes of rotary processing, intended for the endodontic treatment.

弯手机是一种带齿轮的角度手机，用于保持和驱动旋转器械，以进行旋转加工，用于牙髓治疗。



4 Software

There is no software in the contra-angle handpieces.

5 Contraindication

- 1) The hemophilia patient is forbidden to use this equipment.
- 2) The patients or doctors with heart pacemaker are forbidden to use this equipment.
- 3) Patients with allergic constitution and a history of drug allergy are forbidden to

use this equipment;

- 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.
- 5) Patients with heart disease and children should be cautious to use the equipment.
- 6) People with mental disorders should be cautious to use this equipment;
- 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.
- 8) Pregnant women, lactating women, or women of childbearing age who have a plan of pregnancy should be cautious to use this equipment.

6 Precaution

The Dangers:

- 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; 治疗前请检查口腔外的操作。充分注意检查是否有振动、噪音或发热。如有意外问题，请停止操作;
- 2) Avoid strong impact and dropping;避免强烈撞击和跌落;
- 3) Do not arbitrarily disassemble or modify the Contraangle Handpieces;请勿随意拆卸或改装弯手机;
- 4) Please prepare a backup Contra-angle Handpieces to cope with the case that Contra-angle Handpieces malfunction during operation;请准备备用弯手机，以应对弯手机在使用过程中出现故障的情况;
- 5) Do not use nonrecommended shanks/files. Otherwise, the running shanks/files may bend or fly out;不要使用非推荐的刀柄/锉刀。否则，运行中的刀柄/锉刀可能会弯曲或飞出;



- 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; 请保持柄/锉柄清洁。否则，手柄表面的污渍会影响柄/锉的正确固定，导致柄/锉在使用过程中飞出；
- 7) Do not use the Contra-angle Handpieces without shanks/files; 不要使用没有柄/锉刀的弯手机；
- 8) Do not press the button while operating. Otherwise, it may cause head overheating or flying shanks/files; 操作时请勿按下按钮。否则，可能会导致头部过热或飞刀柄/锉刀；
- 9) For safety, please wear protective goggles or dust mask while cutting; 为安全起见，切割时请佩戴防护眼镜或防尘口罩；
- 10) Do not exert too much force to treatment site; 治疗部位不要用力过大；
- 11) Please carry out regular maintenance and inspection; 请进行定期维护和检查；
- 12) If the Contra-angle Handpieces has not been used for a period of time, before operation, please maintain it as per maintenance regulations Maintenance. 如果弯手机有一段时间没有使用，在使用前，请按照保养规定维护保养。
- 13) Damage or serious wear will lead to increased transmission resistance, abnormal sound and so on. As a result, the vibration of Contra-angle Handpieces handpiece will be strong; the drill will shake greatly; and there will be abnormal sound, etc. The operator should timely replace the Contra-angle Handpieces according to clinical conditions. If the Contra-angle Handpieces wears to a certain extent, please replace that with a new one; 损坏或严重磨损会导致传动阻力增加、异响等。因此，反角手机的振动会很大；钻头会剧烈晃动；并且会有异响等。操作者应根据临床情况及时更换弯手机。如果反角手机磨损到一定程度，请更换新的；
- 14) Improper use will damage this product, and then hurt the patients, users and



the third parties.使用不当会损坏本产品,进而伤害患者、使用者和第三方。

7.Specification

7.1 Specification of main unit

Table 1-1 Differences between different models		
Model	CA161	CA161-RR
Output Speed Range 输出速度范围	100~1200 rpm	100~2500 rpm
Output Torque Range 输出扭矩范围	0.4~5.0 Ncm	0.6~4.2 Ncm
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File shank attachment	Φ2.35mm ISO1797-1 Type1	
Minimum fitting length of shank	11mm	
Maximum overall length of the rotary instrument	46mm	

7.2 Use environment

Ambient temperature: +5°C ~ +40°C

Relative humidity: 30% ~ 75%



Atmospheric pressure: 70kPa ~ 106kPa

7.3 Device safety classification

Degree of protection against harmful ingress of water: Ordinary equipment (IPX0).

Not waterproof.

Classified by operation mode: Intermittent operating device


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.

8. Performance

Item 项目	Technical requirement 技术要求
Appearance and Structure 外观与结构	<p>1. The outer surface should be flat, smooth and tidy, without obvious concave convex, crack and sharp edge. The contour of transition should be clear without obvious scratch</p> <p>2. The surface characters and marks shall be clear, accurate and firm.</p> <p>1、外表面应平整、光滑、整齐，无明显凹凸、裂纹和锐边。过渡轮廓应清晰无明显划痕</p> <p>2、表面文字和标记应清晰、准确、牢固。</p>
Speed	<p>Contra-angle handpiece output speed depends on the motor output speed, according to the speed ratio is not the same, different types of handpiece output speed is not the same.弯手机输出转速取决于电机输出转速，根据速比不同，不同型号的手机输出转速也不一样。</p>
Rotation direction 旋转方向	<p>The handpieces output spin is the same as the motor input spin.手机输出旋转与电机输入旋转相同。</p>

Noise 噪音	The A-weighted sound pressure level generated by the handpiece shall not exceed 80 dB.手机产生的 A 计权声压级不得超过 80 dB。
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9. Cleaning/ disinfection and sterilization

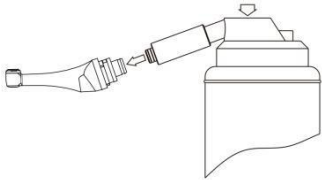
Steps	Contra-angle handpiece
 Warnings	<p>1. The contra-angle handpieces are not suitable for ultrasonic cleaning.</p> <p>2. The contra-angle handpiece should not be immersed in strong detergents or disinfectants (alkaline pH>9 or acid pH <5).</p> <p>1.弯手机不适合超声波清洗。</p> <p>2.弯手机不应浸泡在强清洁剂或消毒剂（碱性 pH>9 或酸性 pH<5）中。</p>
Resistance to sterilizing procedure 对灭菌程序的抵抗力	<p>The contra-angle handpiece could be capable of being subjected to 250 cycles of sterilizing procedure.手机可以进行 250 次消毒程序循环。</p>
Preparation at the Point of Use 使用点的准备	<p>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 contra-angle 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.术后过程必须立即进行，不迟于手术完成后 30 分钟。步骤如下： 拆下刀柄/锉刀并断开弯手机与马达手机的连接。使用后立即用冷水 (<40°C) 去除仪器上的脏污。不要使用热水 (>40°C)，因为这会导致残留物固定，从而影响再处理过程的结果。</p>
Transportati on 运输	<p>The contra-angle handpiece should be safety stored and transported to the point of reprocessing to avoid any damage and environment pollution.反角手机应安全储存，运输至再处理点，以免造成损坏和环境污染。</p>



Preparation for reprocessing	The products must be reprocessed in a disassembled state.产品必须在拆卸状态下进行再加工。
Pre-cleaning 预清洁	<p>Tools: tray, soft brush, clean and dry soft cloth</p> <p>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.</p> <p>Note: The water temperature should not exceed 40°C during the washing stage, otherwise the protein will solidify and be difficult to remove.</p> <p>工具：托盘、软刷、清洁干燥的软布</p> <p>执行手动预清洁，直到机头目测清洁。用流水冲洗车针夹头至少 10 秒钟。用软毛刷清洁表面。</p> <p>注意：洗涤阶段水温不宜超过 40°C，否则蛋白质会凝固，难以去除。</p>
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.关于清洗/消毒、漂洗和干燥，是区分手动和自动再处理方法。优先考虑自动再处理方法，特别是由于</p> <p>更好地标准化潜在和工业安全。</p> <p>Automatic cleaning 自动清洗</p> <p>The washer-disinfector should meet the requirements of the ISO 15883. Place the contra-angle handpiece in the washer-disinfector carefully.</p> <p>Ensure that contra-angle handpieces can not move freely in the washer-disinfector.</p> <p>The contra-angle 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;



	<ul style="list-style-type: none">•Emptying•3 min neutralizing with warm water(>40°C);•Emptying•5 min intermediate rinsing with warm water(>40°C);•Emptying <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte(Dr. Weigert)</p>
Disinfection 消毒	<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.根据国家对 A0 值的要求（参见 EN 15883），在洗衣机/消毒器中进行自动热消毒。 已验证 93°C 消毒 5 分钟的消毒周期使设备的 A0 值达到 3000</p>
Drying 烘干	<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: 1)Spread a clean white paper (white cloth) on the flat table, place the contra-angle handpiece on the white paper (white cloth), and then dry the contra-angle with filtered dry compressed air (maximum pressure 3 bar). When no liquid is sprayed on the white paper (white cloth), it indicates that the contra-angle 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. Note: 1).Dry the contra-angle handpiece repeatedly if necessary (refer to section "Drying").</p>

	<p>2).The air used for drying must be filtered by HEPA.</p> <p>3) The device should be dried in a clean area.</p> <p>5)The drying temperature should not exceed 137 °C.</p>
<p>Maintenance 维护</p>	<p>1. Functional Test and Visual inspection 功能测试和目视检查</p> <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.</p> <p>Before packaging and sterilization, make sure that the contra-angle handpiece has been maintained acc. to manufacturer's instruction.</p> <p>If the device is obviously damaged, smashed, detached, corroded or bent, it must be discarded and not allowed to continue to be used.</p> <p>If the accessories are found to be damaged, please replace it before use.</p> <p>And the new accessories for replacement must be cleaned, disinfected and dried.</p> <p>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 contra-angle handpiece to inject oil for 1-2 seconds.</p> 
<p>Packaging</p>	<p>The contra-angle 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 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	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!
Storage	Sterilized devices should be stored in a dry, clean and dust-free environment, refer to label and instructions for use.

10.Storage

10.1 Storage conditions 储存条件

- Environment temperature: -20°C~55°C
- Relative humidity:10%~93%
- Atmospheric pressure:70kPa~106kPa

10.2 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. 本产品应放置或储存在干燥、清洁、远离酸、碱等有害化学物质和气体的环境中。

11. Transportation

- Prevent excessive shock and vibration during transportation, and handpiece with care;
- It should not be mixed with dangerous goods during transportation;
- Avoid exposure to sun or rain or snow during transportation.



12.Lifetime

The lifetime of Contra-angle handpieces is 10 years.

13.Reference to previous and similar generations of the device

The Contra-angle handpiece CA161/CA161-RR is designed and manufactured by Guilin Woodpecker Medical Instrument Co., Ltd., the device is reference to similar device such as X-Smart of Dentsply company to design, and this is the first time to apply for CE mark under MDR, hence, there is no information reference to previous and similar generations of the device.

14.Statement

Guilin Woodpecker Medical Instrument Co., Ltd. is not use of and will not use of the following materials to manufacture the Contra-angle handpiece:

- derivatives of tissues or cells of human origin;
- derivatives of tissues of cells of animal origin;
- medicinal substances;
- substances or combination of substances that are absorbed or locally dispersed into the human body;
- presence of CMR and/or endocrine-disrupting substances, including phthalates;
- Nanomaterials;
- Latex.

15.Main Raw Materials List

Main component	Material	Material Specification	Contact (Direct /Indirect)?	Contact part
Contra-angle handpiece	aluminum铝	6061	Direct	Intact skin of operato,



				mucosa oral 口腔黏膜、完整 皮肤
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16.Disposal

When disposing of this equipment, or any of its components (such as fuses), follow all applicable national and local laws and guidelines. It shall be disposed according to the cleaning, disinfection and sterilization methods recommended in the manual before being discarded.在处理本设备或其任何部件（如保险丝）时，应遵循所有适用的国家和地方法律和准则。在丢弃前，应按照手册中推荐的清洗、消毒、灭菌方法进行处理。

17.GMDN Code

Code: 38347

Definition: A hand-held, mains electricity (AC-powered) dental device that includes a chuck or collet for attaching a dental endpiece (e.g., drill bit, bur, reamer, saw blade, polishing disk) intended to be used in dentistry to bore/excavate bones, teeth, and tough tissues. It is powered by a low-voltage electric micro-motor (e.g., 24 volt) that is an integral part of the device; the endpiece(s) are not included. It is typically connected through the dental delivery system or a freestanding independent control unit. This is a reusable device.

代码：38347

定义：手持电力（AC动力）牙科设备，其中包括用于连接牙科端件（例如，钻头，钻头，铰刀，铰刀，锯子，锯刀，抛光盘）的Chuck或collet，旨在用于牙科牙科 钻孔/挖掘骨骼，牙齿和坚硬的组织。它由低压电动运动器（例如24伏）提供动力，该电机是设备的组成部分。端件不包括。它通常通过牙科输送系统或独立独立控制单元连接。这是可重复使用的设备。



18.Classification 分类

The device is classified as IIa according to Rule 9 in Annex VIII of MDR (2017/745). All active therapeutic devices intended to administer or exchange energy are classified as class IIa.unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

The contra-angle handpieces is a non-invasive device intended for short-term use, and not direct in contact with human body especially the heart or central system.The way of administration of energy or exchanging energy may indirectly injure the tissues in the mouth when misused by operators or device under condition of malfunction. The device with low risk because of it's site of application.

The contra-angle handpieces not intended to control or monitor the performance of active therapeutic class IIb devices, or not intended directly to influence the performance of such devices.

The contra-angle handpieces not intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance.

The contra-angle handpieces is not intended for controlling, monitoring or directly influencing the performance of active implantable devices.

Based on the above analysis, the device is classed as IIa.

19.Device subcategory

MDA 0311 Active non-implantable dental devices.



桂林市啄木鸟医疗器械有限公司
GUILIN WOODPECKER Medical Instrument Co.,LTD.

File No.: ZMN-YF-BK10-01-001-001-1

Version: A

20.Conformity assessment procedure

Annex IX, (EU) 2017/745, MDR

21.EU Representative

Name: MedNet EC-Rep GmbH

Add: Borkstrasse 10 ,48163 Muenster ,Germany