excalibur PRO® mini

Before using the products, please see the instruction manual as indicated below.

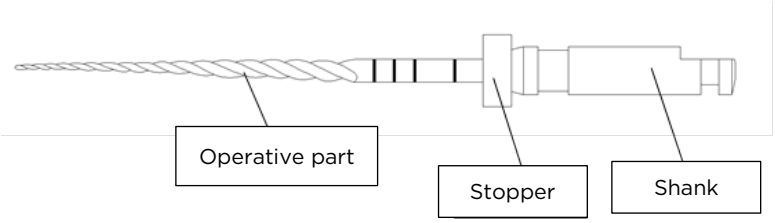
1. BRIEF OF THE PRODUCT

The Excalibur PRO Mini is a root canal instrument designed for establishing a glide path in the root canal before enlarging, it is used by installing on the contra angle of Endo Motor to do the movements of lifting and vertical reciprocation.
It was special heat treatment to make it Nanocoating alloy and with unique flexibility.
It is non-uniform taper instrument (more than 1% taper), which is type 4 classification base on ISO 3630-1:2019.
It is sterile instrument.

2.PRODUCT STRUCTURE AND MATERIALS

The Excalibur PRO Mini is composed of operative part, stoppers and shank.
The main Materials:

1) Operative part: Nickel Titanium
2) Shank: Brass C3604
3) Stoppers: Colorless translucent rubber (CAN19-259705.001)



3.BEFORE USING

Warnings

3.1. Only skilled dentists are allowed to use.
3.2. Do not use this product except for the dental service and treatment. Use it in accordance with the intended use.

Contraindications and prohibitions

Do not use this product for a patient who indicates sensitization and allergic reaction.

4. RE-PROCESSING

4.1. Our Dental Root Canal Instruments are single use and not approved for re-use.
4.2. Our product has been terminally sterilized by irradiation and is ready for immediate use.
4.3. If the package is found to be compromised before use, please refer to Chapter 7 for complete instructions on cleaning, disinfection, and re-sterilization.

5. SPECIFICATIONS AND METHOD OF USE

5.1. The Specification of Excalibur PRO Mini as the below table (based on ISO 3630-1 & ISO3630-5).

Excalibur PRO Mini				
Size	**Working Length (mm)**	**Tip Diameter (mm)**	**Taper (%)**	**Color of ring**
E20	21 mm 25 mm 31 mm	0.20	4	Yellow
E25		0.25	4	Red

5.2. Before using the Excalibur PRO Mini, please use manual K-Files begin from #08 to #015 (not larger than #15) to probe the root canal.
5.3. Choose the most appropriate size for each case and follow the general method.
5.4. Recommended reciprocating speed: 400-500 rpm/min, Torque: 4 N.cm. Reciprocating angles: 30º CW, 150 º CCW.
5.5. This Excalibur PRO Mini is under the provisions of ISO 3630 performance test, products' durability for twisting and bending must exceed specified value of our standard.

6. PRECAUTIONS FOR USE

6.1. Choose the most appropriate type for each case and follow the general method.
6.2. Before using it, check that the instruments, when outside the oral cavity, have no deformations, scratches and cracks.
6.3. If the head of the product is thin, long or large, there are possibilities for breaking or twisting. Because of this, be sure to avoid using unreasonable angle and excessive pressure.
6.4. Wear rubber dams, etc., to avoid accidental ingestion and falling.
6.5. Do not use this instrument for any purpose except for listed applications above.

6.6. Only for use by dentists.
6.7. This product should be treated as medical waste when disposed.
6.8. Dispose the product if damaged or contaminated.
6.9. After using it, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.
6.10. Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.
6.11. This product has a possibility to be corrosive if sunk into NaOCl, EDTA, etc. for a long time.

7. CLEANING, DISINFECTION AND STERILIZATION

When the package is broken, then it is non-sterilized, must be cleaned, disinfected and sterilized before using.

7.1. GENERAL RECOMMENDATION

7.1.1. Please use cleaning agents suitable for cleaning surgical instruments, rubber, medical plastics, instruments and other medical instruments, such as multi-enzyme cleaning agents. When using, please strictly abide by the manufacturer's regulations regarding the concentration, temperature, action time and shelf life of the solution used. Do not use hydrogen peroxide (H_2O_2) solution.
7.1.2. For your own safety, please wear personal protective equipment (gloves, glasses, masks).
7.1.3. The user should be responsible for the sterilization or disinfection of the product in the first cycle and each subsequent use, as well as the use of damaged or dirty equipment after sterilization.
7.1.4. In the final rinsing step, deionized water must be used regardless of whether an automatic washer sterilizer or manual cleaning method is used. Tap water can also be used for other rinsing steps.
7.1.5. Only immerse the operative part of the instrument in contact with the patient into the NaOCl solution concentrate with a concentration not exceeding 5%.
7.1.6. Before or during disinfection or cleaning, avoid equipment drying out. Dry biological materials may be difficult to remove.
7.1.7. Only use the appropriate support of the device for post-processing.
7.1.8. Do not use labeling systems or identification marks directly on the device.
7.1.9. Only use washer-disinfectors approved in accordance with EN ISO 15883 and regularly maintained and verified.

7.2. OPERATION STEPS OF CLEANING, DISINFECTION AND STERILIZATION

Step-by-Step instructions for processing prior to use/reuse as below table

Step	Processing instructions
Preparation at the Point of Use	Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Transportation	Safely store the device in humid surroundings and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination and Cleaning	The devices must be reprocessed in a disassembled state, as far as possible. Before cleaning, disassemble each instrument to the smallest removable unit according to the instructions. For lumen instrument, ensure that the lumen of device is not clogged. The patency of the lumen can be tested by injecting water into the lumen.
Pre-Cleaning	Do manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution. Clean the surfaces with a soft bristle brush.
Cleaning	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 reproducibility and standardization, and in personnel protection. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. The instruments are placed on the cleaning rack of the WD. A cleaning tray may be used to avoid the small device is washed away and lost during cleaning. The lumen of device is connected to the flushing port of the WD. The devices in the washer-disinfector are arranged in such a way that there is no rinsing shadow, and the water drains off quickly.

Step	Processing instructions
	Start the program: a) 4 min pre-washing with cold water (<40°C) b) emptying c) 5 min washing with a mild alkaline cleaner at 55°C d) emptying e) 3 min rinsing with warm water (>40°C); f) emptying g) 5 min intermediate rinsing with warm water (>40°C) h) Emptying The automated cleaning processes have been validated by using 0.5% Neodisher MediClean forte (Dr. Weigert) in the washer/disinfector of BeliMed WD425. Note: Demineralised water should be used for the automated cleaning process. Water quality refers to EN 285. Note Acc. to ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method must be used, please validate it prior to use.
Disinfection	Automated thermal disinfection in washer/disinfector under consideration of national requirements regarding to A0 value (see ISO 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at ≥ 93 °C due to the normally tolerable temperature fluctuations in WD.
Drying	Drying the instrument through drying cycle of washer/disinfector. If needed, (additional) manual drying can be performed through lint free towels. Insufflate cavities of products by using sterile compressed air.
Functional Testing, Maintenance	Visual inspection for cleanliness of the products and reassembling, if required. All instruments should be checked again for dryness. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use.

Step	Processing instructions
	Check that the product has no dents, cracks, deformations, scratches, etc. Check all markings on the product for clear visibility. Discard and replace any non-conform devices as necessary. Do not use the device with following defects: material deformation, cracks on the product, rust, brittle or other change in the material, etc. Before packaging and sterilization, make sure that these devices have been tested and maintained acc. to manufacturer's instruction.
Packaging	Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to ISO 11607. Make sure that the packaging material is suitable for steam sterilization.
Sterilization	Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respective country requirements. Following sterilization parameters are commonly used: 132°C, 4 min or 134°C, 5 min (standard program in EU). Drying time: For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After Sterilization: a) Remove the product from the autoclave. b) Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. c) Check that the sterilization wraps or pouches are not damaged.
Storage	Storage of sterilized instruments in a dry, clean and dust free environment at moderate temperature. Refer to the label and instructions for use.

8. TRANSPORTATION

8.1. To prevent damage to the medical device during transit, use specific racks, trays or rigid containers use.

8.2. When the package is broken, then it is non-sterilized, must be cleaned, disinfected and sterilized before using.

9. STORAGES AND DURATION OF USE

9.1. Keep products in a dry and clean environment, away from sources of moisture and direct sunlight.

9.2. Do not use after the expiration date indicated on the label.

10. SAFE DISPOSAL OF THE DEVICE

Products shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.

11. SERIOUS INCIDENT REPORTING

Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.

12. PACKAGING

Packaging unit: 6 pcs/ aluminium blister pack.

13. EXPLANATION OF RELATED SYMBOLS

Symbols	Explanation
	For Dental Use Only
	Do not reuse
	Material of the operative part: Nickel Titanium
	Material of the stoppers: Silicone
	Rotary Use shank
	Medical Device
	Unique device identifier
	Once the package is opened, it cannot be exchanged
	Do not use if package is damaged

Symbols	Explanation
LOT	Batch code
STERILE R	Sterilized using irradiation
REF	Catalogue number
	Use-by date
CE 0197	NB 0197 certified
EU REP	Authorized representative in the European Community
UK REP	Authorized representative in the United Kingdom
	Manufacturer
	Importer
eIFU Indicator	Consult electronic instructions for use

-The specifications, structures and materials are subject to be changed without previous notices for the demands of improvement.

-The content of this instruction manual is subject to be revised without previous notice.

CE 0197

Shenzhen Denco Medical Co., Ltd
Room 3108, Block 6, Tian'an Cloud Park, Bantian street, Longgang District, Shenzhen, 518129 Guangdong, P.R. China

EU REP
Share Info GmbH
Am Schulzentrum 12,
41564 Kaarst, Germany

UK REP
Wellkang Ltd
7 Beechcroft,
Busbridge Lane,
Godalming,
GU7 1QD, England, UK

Omologic, Homologación y Marcado CE, S.L.U.
Calle Santa Rosalía 21,
Escalera 2, 1ºB,
18007 Granada (Spain)

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