Revision History

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1	A0	New Issue	2023-05-23

Instructions For Use

Dental Burs(Carbide)

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

1. Brief of the product

Dental Burs are intended for access cavity preparation and coronal restoration or for retrograde procedure.

The Dental Burs(Carbide) are used in combination with active device for cutting, chipping and drilling on hard structures such as teeth, bones, and restorations in the oral cavity.

2. Product Structure and materials

2.1 Components of the product

1) The DENCO's Carbide Burs FG and HP are One-piece made of Tungsten carbide
2) The DENCO's Carbide RA are composed of shank and working head, the shank is made of Stainless Steel and the working head is made of Tungsten carbide.

2.2 Different types of shanks are available for Dental Burs (Carbide):

- Type 1 (ISO 1797) shank: Right Angle (RA) used in combination with an electric motor.
- Type 2 (ISO 1797) shank: Handpiece (HP) used in combination with an electric motor.
- Type 3 (ISO1797) shank: Friction Grip (FG), used in combination with a turbine.

2.3 Carbide Burs shall be used with a water-cooled handpiece.

3. Safety Notes

<Warnings>

- Strictly follow this Instruction for Use and the General Processing Instructions For Endodontic Products (see section 8) to minimize following risks to the device, the patient and/or the user:
  - ○ Breakage of instrument.
  - ○ Cross-contamination.
  - ○ Heat generation due to insufficient lubrication and irrigation.
  - ○ Swallowing of working part of the instrument.
  - ○ Toxic or allergic reactions caused by processing residues.

<Contraindications and prohibitions>

None Known

<Adverse Reactions>

In the present technical state, no adverse reaction has been reported so far

4. Re-Processing

4.1 The DENCO Endo Compactors are reusable instruments, the maximum number of processing cycles of the DENCO Endo Compactors is 8 (number of processing cycles validated without affecting the functionality and safety of the products).

Pls follow the processing instructions for the disinfection, cleaning and sterilization steps before each reuse

as Item 7 of this IFU.

4.2 Do not re-use silicone stoppers. Remove and discard silicone stoppers after each use.

4.3 LIMITATION ON RE-USE

• The products shall not be processed more than the number of maximum cycles indicated in the table in section 4) STEP-BY-STEP INSTRUCTIONS. It is the responsibility of the user to monitor the number of processing cycles. Meanwhile re-use is permitted only when the product is defect free and following a visual inspection (see item below). Since certain applications may cause the instruments to prematurely reach the end of their useful life the "Max number of processing cycles" will not always be reached (e.g. when shaping an extremely curved root canal with a file).

• In any case inspect the products before re-use, and discard them in case of defects. These include but not limited to the following:

- Plastic deformation (bent, unwound, distorsion, sign of twisting, elongation, uneven flutes);
- Breakage;
- Loss of colour coding or marking;
- Bent instrument;
- Untwisted threads;
- Damaged cutting surfaces and edges;
- Dull cutting blades;
- Missing size marking;
- Corrosion (e.g. dull spots);
- Wear.

• For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:

- Use a new file and discard it after the canal was treated (single canal use).
- Use manual instead of Endo Compactors.
- Use small size, flexible files (this will help avoid canal transportation).
- Visually inspect the active part for all the defects listed in the former paragraph during use (i.e after each wave).
- Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

5. Specifications

The Specification of DENCO Dental Burs(Carbide) as the below table:

Product Name	Model Name	Specification

Dental Burs	Carbide Burs FG	FG1 FG2 FG3 FG4 FG5 FG6 FG7 FG8 FG34 FG35 FG36 FG37 FG38 FG39 FG41 FG56 FG57 FG58 FG59 FG60 FG168 FG169 FG170 FG171 FG172 FG169L FG170L FG171L FG172L FG245 FG246 FG329 FG330 FG331 FG332 FG331L FG557L FG558L FG559L FG698 FG699 FG700 FG701 FG702 FG699L FG700L FG701L FG702L FG 957 FG 958 FG 1155 FG1156 FG1157 FG1158 FG332L FG 468 FG556 FG557 FG558 FG559 FG560 FG556L FG1159 FG1160 FG1169 FG1170 FG1171 FG1172 FG1556 FG1557 FG1558 FG1559 FG 1701 FG 1702 FG 1931 FG 1932 FG 1957 FG 1958 FG 2057 FG 2058
	Carbide Burs RA	RA1 RA2 RA3 RA4 RA5 RA6 RA7 RA8 RA34 RA35 RA36 RA37 RA38 RA39 RA41 RA56 RA57 RA58 RA59 RA60 RA168 RA169 RA170 RA171 RA172 RA169L RA170L RA171L RA172L RA245 RA246 RA329 RA330 RA331 RA332 RA331L RA332L RA 468 RA556 RA557 RA558 RA559 RA560 RA556L RA557L RA558L RA559L RA698 RA699 RA700 RA701 RA702 RA699L RA700L RA701L RA702L RA 957 RA 958 RA 1155 RA1156 RA1157 RA1158 RA1159 RA1160 RA1169 RA1170 RA1171 RA1172 RA1556 RA1557 RA1558 RA1559 RA 1701 RA 1702 RA 1931 RA 1932 RA 1957 RA 1958 RA 2057 RA 2058 R15EZ R15ZB
	Carbide Burs HP	HP1 HP2 HP3 HP4 HP5 HP6 HP7 HP8 HP9 HP10 HP11 HP34 HP35 HP36 HP37 HP38 HP39 HP40 HP41 HP56 HP57 HP58 HP59 HP60 HP61 HP62 HP63 HP556 HP557 HP558 HP559 HP560 HP561 HP562 HP563 HP556L HP557L HP558L HP559L HP560L HP699 HP700 HP701 HP702 HP703 HP704 HP699L HP700L HP701L HP702L HP703L

6. Precautions for use:

6.1 Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.

6.2 Use of a rubber dam is recommended during the procedure to avoid swallowing or inhalation of the device.

6.3 For your own safety, wear personal protective equipment (gloves, glasses, mask, waterproof gown).

6.4 Processing step is mandatory before use according to section Hygiene, disinfection, cleaning and sterilization for all the products mentioned in this IFU.

6.5 Inspect the instrument before each use for signs of defects such as dull spots, deformations (bent), breakage, corrosion, damaged cutting edges, loss of color coding. With these indications the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.

6.6 Use an appropriate water-cooling system to avoid the risk of heat creation.

6.7 Before using any instrument, make sure it is well connected to the handpiece to avoid risks of swallowing/inhalation.

6.8 For safety reason, start the selected bur away without tissue contact.

6.9 Do not use labels or identification markers directly on the products.
6.10 Discard instruments generating unusual vibrations.
6.11 Discard instruments generating unusual noise.
6.12 Discard in case of loss of cutting efficacy during use.
6.13 Do not apply excessive pressure on the device.
6.14 Products shall be disposed according to local regulations for the safe disposal of sharp and contaminated devices.

7. Cleaning, Disinfection and Sterilization Method

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 on the concentration, temperature, action time and shelf life of the solution used. Do not use hydrogen peroxide (H2O2) 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 and Transportation	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 a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for	The devices must be reprocessed in a disassembled state, as far as

Decontamination and Cleaning	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 a 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 that 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. Note: Demineralised water should be used for the automated cleaning process. Water quality refer to EN 285.
Disinfection	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards 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 towel. 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. - 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 modest temperatures, refer to label and instructions for use.

8. Transportation

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

8.2 When the package was broken, then it is non-sterilize, 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 The shelf time of Dental Burs files are 5 years.

10. Disposal

For proper disposal, always observe national laws and recommendations of the authorities.

11. Packaging

11.1Minimum packaging unit: 5pcs/package in aluminum foil box.

12. Explanation of related symbols

Symbols	Explanation

MD	Medical device
For Dental Use Only	For Dental Use Only
LOT	Batch code
NON STERILE	Non-Sterile
REF	Catalogue Number
	Expired Date
	Consult instructions for use
EC REP	Authorized representative in the European Community
	Manufacturer
134°C	Can be sterilized at the specified temperature
	Assortment
6	6pcs/pack

13. WARRANTY AND LIMITED REMEDY / LIMITATION OF LIABILITY

Disclaimer: The instructions for use have been validated by DENCO. Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for endodontic treatment and/or processing when applicable. Denco accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the instructions for use set forth above. The user shall observe safe and lawful practices including, but not limited to, those set forth in this document.

<Legal manufacturer>

Shenzhen Denco Medical Co., Ltd

Address: Room 3108, Block 6, Tian'an Cloud Park, Bantian street, Longgang District, Shenzhen, 518129 Guangdong P.R. China

Factory Address: Room 101, 201, 301B, 401&801, Block 5, Renluo 6 Road No. 6, Shuikou Street, Huicheng District, Huizhou, 516000 Guangdong, P.R. China

www.dencoendo.com

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<EU representative>