Instruction for Use

IFU no.: IFU-DB, Ver.3.1 Effective date: 2020-03-25

[Product name]: WAVE DENTAL Dental Burs.

[Product model]: Round head, Inverted cone head, Pear head, Straight fissure head, Straight fissure head with rounded end, Tapered fissure head, Tapered fissure head with rounded end. Wheel head.

[Intended use]: The Dental Burs is used to drill teeth by itself drilling force, normally used in the dental treatment room.

[Contraindication]: Dental burs contain a small nickel content and should therefore not be used on individuals, with a known sensitivity to this metal as in extreme cases it may cause hypersensitivity.

[User population]: Adult, not advised for low age children and infants.

[Structure]: The dental bur consists of the working part and the pole, the two parts are welded together.

[Main performance]:

- 1, The working part of the dental bur is made of cemented carbide, and the pole of the dental bur is made of steel.
- 2, The shape of the working part of the dental bur complies with the suitable shape which described in Figure 9 to Figure 22 of ISO 3823-1:1997 (EN ISO 3823-1:1998).
- 3, The shank dimension conform to the requirements of ISO 1797.
- 4, The run-out of the dental bur meets the requirements Clause 5.5 of ISO 3823-1:1997.
- 5, The corrosion resistance of the dental bur meets the requirements Clause 5.6 of ISO 3823-1:1997.
- 6, The neck strength of the dental bur meets the requirements Clause 5.7 of ISO 3823-1:1997.

[Use of product]:

- 1, Choose appropriate model and specification of dental bur based on acutal demand;
- 2, To clean the dental bur firstly according to methoded in [Cleaning and Sterilization method]:
- 3, To sterilze the dental bur according to method defined in [Cleaning and Sterilization method];
- 4, Match the dental bur with dental handpiece as follows:

Dental burs (ISO 1797-1 type)	Matched Dental handpiece	
Type 1: RA	Geared angle handpieces (ISO7785-2)	
Type 2: HP, diameter 2.35mm Straight handpieces (ISO7785-2)		
Type 3: FG	High-speed air turbine handpieces (ISO7785-1)	

- a) It MUST choose matched handpiece.
- b) Confirm that the dental bur handle has been inserted into the bottom of handpiece and firmly clamped according to the instructions of handpiece, and confirm that it is not half inserted.
- c) Before use, you should also turn on the handpiece to carry out the rotation test before the dental operation, and discard it immediately if there is any abnormality.

- 5, To insert the dental bur into the dental handpieces, and use to drill teeth by professional doctors.
- 6, After use, remove the dental bur.

[Use cautions]:

- 1, This product is a disposable product, cross-use is strictly prohibited. The product should be treated after use; cross-use will probably create infection for users.
- 2, This product can only be used by qualified dentists;
- 3, This product is a drilling tool, during use, it should touch the working surface lightly and not force and extrude.
- 4, Falling, knocking or extrusion of hard objects should be avoided, otherwise the product will be damaged;
- 5, To avoid contact with corrosive substances such as chlorine, acid and alkali.
- 6, The cleaning and sterilization method must be strictly completely followed, inadequate cleaning or sterilization (such as insufficient sterilization time of less than 30min, lower tempearture etc.), will cause fail of sterilization of dental bur, and probably create infection of users.

[Cleaning and Sterilization method]:

Before use, the dental bur must be cleaned and sterilized

1, Cleaning method:

To clean the dental bur by washing dental bur surface by brush with detergent for 10 min, and then rinse it with clean water and pure water for twice, each time for 5 min;

2, Sterilization method:

The device shall be sterilized strictly by high-pressure steam sterilization which conducts in the steam sterilizer, the pressure keeps on 0.1 MPa, temperatures 121° 126°C, keeps for 30 minutes.

[Storage]: The Dental Burs shall be stored in ventilated room with less than 80% humidity and without corrosive gas.

[Validity]: 8 years on the required storage environment.

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C E ₂₄₆₀	CE mark	LOT	Lot number	
(3)	Single use	\sim	Date of manufacture	
[]i	Consult Instructio for Use	**	Manufacturer	
NON	Non-sterile	EC REP	European union representative	
*	Keep dry		Use by	