

# DENTEX DENTAL INDUSTRIAL CORP.

# **INSTRUCTION FOR USE**

# **Product Description**

Dental diamond instrument (hereinafter referred to as Diamond Bur) are products provided to qualified dental operators (professionals) to cut, trim and grind other related dental materials.

### • Table 1. Shank types

Shank types	Diameter	Illustration	ISO NO.	ISO Shank Type
FG / Z-Diamond -FG Standard	Ø 1.60 mm	19 mm	314	Type 3 (Standard)
FG Short	Ø 1.60 mm	——————————————————————————————————————	313	Type 3 (Short)
RA Standard	Ø 2.35 mm	22 mm —	204	Type 1 (Standard)
HP / Z-Diamond -HP Standard	Ø 2.35 mm	44.5 mm	104	Type 2 (Standard)

#### • Table 2. Diamond grit sizes

Designation	Color code (Standard)	Color code (Zirconia)	Grit size range (μm)	ISO NO.
Super Coarse (SC)	• black ring	-	151~181	544
Coarse (C)	• green ring	• • green & green ring	107~151	534
Medium (M)	without mark	• • blue & blue ring	91~126	524
Fine (F)	• red ring	• red & red ring	40~60	514
Extra Fine (XF)	<ul><li>yellow ring</li></ul>	Cha	20~30	504

#### • Table 3. Recommended Speed Ranges

(The actual maximum speed depends on the dimension and shape of diamond bur. Do not exceed the maximum speed to avoid increasing the risk of injury.)

Shank (FG)			Shank (RA / HP)			
Head diameter in (Ø 1/10 mm)	Recommended Maximum (RPM)	_	ad diameter in Ø 1/10 mm)	Recommended Maximum (RPM)		
008 - 010	160,000		008 - 070	40,000		
012 - 021	300,000	Z-Diamond (Zirconia)				
023 – 027	160,000	Shank	Head diameter in (Ø 1/10 mm)	Recommended Maximum (RPM)		
029 - 040	100,000	FG	012 - 018	200,000		
041 - 050	80,000	HP	012 - 024	40,000		

#### • APPLICATION

	Cavity preparation	W	Root canal preparation		ŤΫ́	Root planing		<i>V</i> O	Crow	n and	bridge technique
<b>√</b>	Crown preparation		Oral surgery	[ {	(F)	Removal of old	fillings	X	Crow	n rem	oval
	Working on fillings	3	Model casting technique		Ac	crylic technique	Tr Im	nplantol	ogy	M	Spray-cooling

# The user must comply with the following warning and using instructions and safety recommendations before using diamond bur.

## Warning

- Before using diamond bur, diamond bur must be sterilized by high temperature and high pressure (or other disinfection methods approved by the regulations) to avoid cross-infection; if diamond bur is not sterilized, so that it is contaminated with infectious pathogens, it will cause the patient to be infected, and even will cause serious personal injury or death.
- During the operation, dental professionals should use gloves which comply with the relevant regulations to perform the operation, and should wear goggles to protect the eyes during the operation.

#### **Instructions for use**

#### • Precautions applicable to the first use of diamond bur:

When taking it out of the package and before using, please check whether the following situations occur: After inspection, if the following conditions or other abnormal conditions are found, please do not use the product and return the abnormal product to the original dealer.

- Check for any damage that may be caused during transportation.
- There should be no defects in the cutting edge.
- Check whether diamond bur with the sharp and slender characteristics has become skewed.

#### • Precautions for re-use of diamond bur:

It is proved by experiments that diamond bur can still retain a certain effective cutting performance after 3 consecutive cycles of use.

One cycle is cleaning and sterilizing diamond bur after 5 minutes of continuous use.

Please check whether the following situations occur in re-used diamond bur:

After inspection, if the following conditions or other abnormal conditions are found, please do not use the product; Please also note that when the diamond bur is excessive re-used, effective cutting will not be performed and excessive heat is easily generated and conducted to the cutting object.

- Visual inspection and ensure that all contaminants have been removed.
- Check diamond bur for damage and the condition of diamonds.
- There should be no defects in the cutting edge.
- Abandon the damaged or corroded diamond bur.
- Check whether diamond bur with the sharp and slender characteristics has become skewed.
- After the sterilization, there may be the sign of fading (this should be a normal phenomenon which will not affect the operating).

#### Cleaning method

- Disposable paper or cloth can be used to remove excess dirt.
- Ultrasonic cleaning can be used to remove excess deposits (during the cleaning process, diamond bur should avoid to touch each other or touching any hard surfaces).
- The cleaning fluid should use a neutral pH cleaner or liquid disinfectant (such as: DGHM / VAH or FDA / EPA approved or CE certification).

#### Sterilization

- Put diamond bur into a suitable container and put it to a qualified high-pressure steam cooker. It must be sterilized at 134°C (274°F) for 4 minutes at least and the user must confirm the effective process and result of the sterilization.

- When putting diamond bur into the steamer for sterilization, be careful not to exceed the maximum load-bearing capacity of the steamer and should follow the precautions and use instruction of the autoclave correctly.

# Precautions for using Handpiece

- When using handpiece, if the user finds that diamond bur is moving ahead, the user must stop using it immediately and resume using after confirming the problem and eliminating the cause of fault.
- When the user removes diamond bur from the handpiece, the handpiece must be at a standstill. Please follow the use instruction of handpiece.
- Improper use leads to increased risk and inferior results. Please make sure the application and all instructions for use.
- When using a special speed or a special cutting force to approach the root canal of a tooth, be aware that the continuous force may be abnormal or dangerous.
- Make sure to use sufficient water spray to provide a cooling effect on to the materials in use.

# **Safety recommendations**

- 1. Be sure that the bur is inserted fully and tightly into the handpiece.
- 2. Select suitable speed according to recommended speed table. (Table 3)
- 3. Never exceed the maximum permissible speed. Exceeding the maximum speed will result in the increased risk of injury in personnel and device.
- 4. Excessive contact pressure has to be avoided because excessive contact pressure may lead to the increased risk of personnel's injury and the damage of device.
- 5. Applicable materials and precautions for diamond bur:
- 5.1. Z-Diamond (Zirconia): including all types of diamond grits.
- 5.2. General material: When using the following diamond grits, especially Coarse and Super Coarse grit, the user should pay attention to the following points before using:
  - Provide adequate cooling and minimum pressure. (If necessary, use spray cooling (minimum 50 ml/min)).
  - In order to achieve the best performance of Coarse grit or Super Coarse grit, it may be necessary to subsequently use Fine grit or Extra Fine grit.
- 6. Improper use leads to increased risk and inferior results. Please make sure the application and all instructions for use.
- 7. Discard any damaged bur or worn working parts immediately because the damaged or worn bur will lead to the user applying higher contact pressure which results in the increased operating temperature. This may lead to the increased risk and injury.
- 8. The device is to be sterilized prior to be used; without the sterilization could cause bio-contamination and/or cross-infection that could harm the patient seriously.

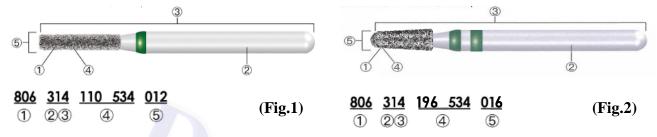
9. The sterilization parameters are

Cycle type	Exposure Temperature	At least exposure Time		
dynamic air removal	134°C	4 minutes		

10. The device is intended to be re-use up to times; over-time use could degrade the intended performance.

# **Ordering options**

- **Dx Order No.:** prefer to use Dentex number system, in order to prepare orders efficiently by computer.
  - Ex. 1.1. C206 (\*C: Diamond grit & designation \ \*206: Dx No.) (Fig.1)
    - 1.2. CZ246F (\*C: Diamond grit & designation \ \*Z246F: Dx No.- Z-Diamond (Zirconia)) (Fig.2)
- **Reference No.:** refer to the common use codes of European brands.
  - Ex. 2.1. C836 012 (\*C : Diamond grit & designation \ \*836 : Reference No \ \*012 : size Ø 1/10 mm) (Fig.1)
    - 2.2. CZ849 016 (\*C: Diamond grit & designation \ \*Z849: Reference No \ \*016: size \ 0 \ 1/10 mm) (Fig.2)
- **ISO No.**: accord to ISO 6360 Number Coding System and apply to the abbreviated form **3.**



- (1): Material of the working part
  - Diamond, Plated metallic binding
    - Ex.: 806
- ②、③: Shank and overall length
  - Shank: FG / Z-Diamond-FG
    - Ex.: 31
  - Overall length: Standard (19 mm)
    - Ex.: 4
  - Coupling dimensions according to ISO 1797 (Table 1)
- enter **4** : Shape and specific characteristics for groups of instruments
  - Shape: Cylindrical, side-and end-cutting (ISO 6360-2)
  - Specific characteristics for groups of instruments
    - Ex.: 534
  - Diamond grit design according to ISO 7711-3 (Table 2)
- (5): Nominal size ISO 2157
  - Largest diameter of the working part (Ø 1/10mm)

Ex. : 012=1.2 mm



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EC REP

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