

### **Instructions for Use for FG Carbide burs Rotary instruments**

In order for the TRI HAWK bur to perform as designed:

1. Use the bur ONCE and throw it away just as you would a needle or scalpel. All brands of burs are compromised after the first use.

Note: Multiple usages and sterilization drastically reduce cutting performance and greatly increase the likelihood of breakage/fracture for ALL burs

# 2. Product lengths

	Overall length +/- 0.5 (mm)		
Head length (mm)	Short	Regular	Extra Long
< 5.5 >5.5-8 >8-9 >9-10	16.5	19	25
>5.5-8	18.5	21	27
>8-9	19.5	22	28
>9-10	21.5	24	30

#### Warning: Do not extend bur from chuck.

- Sterilization: Instruments must be sterilized before first use and sterilized in an autoclave.
  - a. Prepare burs for sterilization: Package the burs in containers dedicated for the selected autoclave machine. The autoclave manufacturers' instructions
    must be followed. Do not exceed the maximum recommended load.
  - b. <u>Inspection after preparation:</u> Visually inspect the burs after cleaning to ensure contamination has been removed.
  - c. Sterilization before first use: Follow the autoclave manufacturer's instructions to sterilize the burs. Use distilled or deionized water. Do Not Use Tap water. Autoclave the instruments for a holding time not less than six minutes at a temperature of between 130°C and 135°C. Other validated time/temperature regimes may be used. The holding time is the minimum time for which the minimum temperature is sustained.
  - d. <u>Drying:</u> Run the instruments through a drying cycle, typically incorporated in the autoclave. Drying heat must not exceed 140°C. Refer to the autoclave manual for cycles available and proper operation.
- 4. <u>Disposal:</u> Used burs should be considered to be contaminated and appropriate precautions should be taken when handling and disposing of a used bur. Used burs must be discarded in a "sharps" container.
- 5. Proper and safe use: The device is to be used on the instruction of and by physician or licensed practitioner.
  - a. Clean and sterilize burs (if not supplied sterile) in accordance with the directions above before first use
  - b. Dispose of used instruments after first use as per disposal instructions above.
  - c. Always wear gloves when handling contaminated instruments.
  - d. Eye protection must be worn to protect against ejected particles.
  - e. Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
  - f. Burs are to be used in air powered turbine or electric contra-angle red ring 1:5 hand pieces at room temperature.
  - g. Maintain handpieces in good working order and correctly lubricated.

# Note: Ensure sure that your hand piece has been properly calibrated, balanced and maintained

- Ensure that the bur is securely gripped in the handpiece collet.
- i. Insert bur all the way to the end in hand piece chuck. Burs over 23mm (0.906 inches) in length should only be used per hand piece manufacturer's instructions. Burs must be securely tightened in hand piece chuck
- Do not use worn-out burs.
- k. Do not apply excessive pressure on the bur. Forces should not exceed 2 Newtons (approx. 0.45 pounds force). Higher forces do not result in a quicker material removal, but increase the thermal load on the tooth.
- I. Avoid removing the bur at too sharp an angle to avoid leverage and breakage.
- m. Spray cooling with a minimum flow of 50 ml/min must be provided. Additional cooling is required if burs longer than 21 mm or heads bigger than 2 mm are being used.
- n. The burs should be set to the working speed according to the graphical diagram below. It should be set before applying the bur to the object.

### Diamond rotary instrument - guidance for maximum RPM:

Instrument head diameter	Maximum permissible speed	Recommended operational speed (RPM)	
1/10 mm	(RPM)	. , ,	
007 - 010	450,000	100,000 - 220,000	
011 - 014	450,000	70,000 - 220,000	
015 - 018	450,000	55,000 - 160,000	
019 - 023	300,000	40,000 - 120,000	
024 - 027	160,000	35,000 - 110,000	
028 - 031	140,000	30,000 - 95,000	

6. <u>Storage:</u> The burs should be stored in the dry sterilization container (bur stand or pouch) until required. Storage should be in dry, clean conditions and at ambient temperature. Staining or corrosion may occur if the burs are kept in a wet environment, therefore, to be avoided.

Transport: Burs are to be transported in their original (factory) packaging, placed in a sealable plastic bag and then a bubble envelope. Burs must be transported between -38°C and 50°C. All shipments must contain a copy of these instructions.

Note: It remains the responsibility of the facility and the trained personnel to ensure that these processes are performed using the appropriate equipment, materials and personnel. This process may require continuous validation and monitoring to ensure required results are achieved.

Manufactured by:

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