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## **Spring Diamonds - FG Diamond Dental Burs**

### **Instructions for Use**

The Spring Diamond dental bur is a rotary cutting device made of stainless steel which is coated with diamond particles on the working end, intended to cut hard structures in the mouth such as teeth, metals, porcelains and similar materials. Spring Diamonds are designed for use in Friction Grip dental handpieces and are available in a variety of head shapes, lengths and diameters. They may be cleaned and sterilized for reuse according to the instructions below.

#### **Undesirable Side Effects**

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Attention should be paid to the speed of work (RPM)
  - Always refer to the product packaging for the Maximum RPM. Use of the bur beyond the RPM range may cause the bur to break and result in patient or user harm.
  - Operating a bur with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Proper irrigation is required while using the device. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Do not apply excessive pressure on the bur as this could cause undesirable heat or may cause the bur to fail and cause patient or user injury.
- Diamond burs must be thoroughly cleaned and steam sterilized prior to the first use and each subsequent reuse to prevent the risk of infection or cross-contamination.
- Do not use chemical or dry heat to sterilize Spring diamond burs, as these processes have not been validated for use. Use of these processes may be corrosive to the device and could result in premature device failure.
- Proper cleaning is required after use of the device to prevent cross-contamination. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Use a rubber dental dam while using diamond burs to avoid possible aspiration or swallowing of the device.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause patient or user injury.
- Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the diamond bur

**Precautions**

- Always inspect the burs before use. Use of worn-out or dull burs could cause undesirable heat or may cause the device to fail.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage and cause patient or user injury.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
- Never force a bur or disc into a handpiece as this could cause damage to the handpiece collet.
- Eye protection must be worn to protect against eject particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.

*The below mentioned recommendations with the respect to cooling, contact pressure, disinfection, cleaning and sterilization are to be strictly observed. The diamond bur should only be used for intended application. Non-observance of these safety recommendations may lead to damage of the handpiece and or injury*

- All burs should be sterilized before use according to the instructions provided. – There is an increased risk of infection in reusable instruments which have not been properly reprocessed.
- Clean and sterilize burs in accordance with the directions before first use and before each reuse to prevent cross-contamination. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Insert the bur all the way into the chuck; do not extend the bur from chuck. Securely tighten the bur in the handpiece chuck. A loose or extended bur could eject from the chuck or break and cause injury. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
- Ensure the air pressure to the handpiece does not exceed the manufacturer’s recommended settings.
- Never force a bur or disc into a handpiece as this could cause damage to the handpiece collet.
- Make sure to provide sufficient cooling by means of air/water spray in order to avoid undesirable heat generation during preparation. Insufficient cooling may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns
- Do not apply excessive pressure on the bur.

**Use of pressure**

- Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time, it generates excessive heat.
- The use of excessive pressure when using grinding tools can cause the abrasive particles to break off or the instrument to become clogged and lead to heat generation.

- During polishing, excess pressure can lead to heat generation.
- Due to overheating, excess pressure can damage the dental pulp or, due to broken off cutting edges, it can result in undesired rough surfaces. In such cases, even instrument breakage cannot be excluded
- Maintain the handpiece in good working order and ensure it is correctly lubricated, as specified by the manufacturer.
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage.
- Always wear eye protection and other appropriate personal protective equipment when using dental burs and provide eye protection for patients and assistants and to protect against eject particles
- Always wear gloves when handling contained instruments to avoid possible infection/cross-contamination.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Use a rubber dental dam while using DIAMOND Burs to avoid possible aspiration or swallowing of the device.
- Burs which are damaged, worn, bent or not concentric should be properly discarded. Do not use worn-out burs. A bur in poor condition will affect the procedure and can damage the handpiece.
- Used burs should be considered contaminated instruments and appropriate handling precautions are necessary. Use personal protective equipment, including gloves, masks and safety glasses when handling.

#### Discarding worn instruments and parts

- ✓ Spring Health's burs can principally be reused several times – unless specifically indicated and labelled otherwise. Rotating instruments are subject to wear. The option of and accountability for multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the products. If in doubt, the products should always be sorted out early and replaced.
- ✓ Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.
- ✓ Bare patches on diamond instruments indicate a lack of abrasive particles and can be a sign of blunt instruments. This leads to excessive temperatures during instrument use.
- ✓ Instruments that are bent and/or do not run true should be discarded forthwith.
- ✓ With the reuse of disposable products the risk of infection cannot be excluded and a risk-free functional safety cannot be guaranteed.
- Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the diamond bur

#### Contraindications

- Diamond burs contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity

#### Speed Recommendations for Rotary Instruments

Following the instrument-specific speed recommendations produces the best results.

- Exceeding the maximum admissible speed (rpm) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.
- When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible rpm must never be exceeded
- Non-compliance with the maximum admissible speed puts safety at risk.

The following table provides recommended RPM Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (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
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
080 - 100	45,000	10,000 - 20,000

### **Cleaning and Sterilization Instructions**

Spring Diamonds are provided non-sterile and should be cleaned and sterilized before use and subsequent reuse.

#### **Warnings**

1. Read all instructions before operating this product. The manufacturer accepted no liability for any damage resulting from improper use of this product.
2. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended.
3. Do not use Cold Sterilizing Methods for the sterilization of Diamond Burs. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.
4. This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

#### **Reuse Limitations**

The end of life is determined by wear and damage in use and Diamond Burs should be inspected during the cleaning process for defects such as bent or broken tips, missing diamond particles, etc.

Delay in cleaning after use must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.

Reusability The instruments can be reused – in case of adequate care and if they are undamaged and clean as indicated in chapter “Specific aspects”. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

#### **Manual Cleaning Procedure**

If hand cleaning is the only available option, Diamond Burs should be cleaned in a sink reserved for cleaning instruments.

Rinse the Diamond Bur (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute.

Prepare a fresh neutral-pH cleaning solution. Follow the manufacturer's instructions. Immerse the Diamond Bur (and instrument block) and soak for at least ten (10) minutes.

After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.

Special care should be taken to clean crevices and other hard-to-reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed. Thoroughly rinse the Diamond Bur (and instrument block) under running warm water for at least one (1) minute and until visibly clean.

Dry the device using a non-shedding wipe or clean compressed air.

### **Ultrasonic Cleaning Procedure**

Prepare a fresh neutral-pH cleaning solution; place the Diamond Bur in the dedicated instrument block (if applicable) and then place in an ultrasonic unit. Follow the agent manufacturers' instructions for correct concentration, exposure time, temperature, and water quality. Completely submerge the device in the cleaning solution and sonicate for at least fifteen (15) minutes.

Perform a final thorough rinse of the device and instrument block (if applicable) under running warm tap water for at least (1) minute.

Visually inspect to confirm the removal of debris. Repeat the cycle if needed.

Dry the device using a non-shedding wipe or clean compressed air.

### **Inspection**

1. Carefully inspect each device to ensure that all debris has been removed.
2. Visually inspect the device for damage or wear that would prevent proper operation.
3. Do not use if the tip is broken or bent.
4. Do not use if there are missing or worn diamond particles.
5. Do not use if there is evidence of corrosion.

### **Packaging**

Singly: Pack the Diamond Bur in pouches validated for sterilization.

In Sets: Place the Diamond Bur in the dedicated instrument block.

### **Sterilization**

Use the following cycles for steam sterilization

<b>Cycle Type</b>	<b>Minimum Sterilization Exposure Time (minutes)</b>	<b>Minimum Sterilization Exposure Temperature</b>	<b>Minimum Dry Time (minutes)</b>
Autoclave, Gravity	15	135°C (275°F)	30

Ensure that the sterilizer manufacturer's maximum load is not exceeded.

### Storage

The Diamond Bur should be stored in the sterilization pouch (or instrument block) until needed.

### Additional Information

These processes have been validated as being capable of preparing Spring Diamonds for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.



### Authorized Representative



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### Symbols Used on Labelling

<b>Symbol</b>	<b>Explanation</b>	<b>Symbol</b>	<b>Explanation</b>
	<b>Medical device manufacturer</b> Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.		<b>Non-sterile</b> Indicates a medical device that has not been subjected to a sterilization process.
	<b>Authorized representative in the European Community</b> Indicates the Authorized representative in the European Community.		<b>Quantity</b>
	<b>Batch code</b> Indicates the manufacturer's batch code so that the batch or lot can be identified.		<b>Do not use if package is damaged</b> Indicates a medical device that should not be used if the package has been damaged or opened.
	<b>Date of manufacture</b> Indicates the date when the medical device was manufactured.		<b>Title/Meaning/Referent:</b> Catalogue number <b>Function/description:</b> To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be

			placed adjacent to the symbol.
	<p>Title/Meaning/Referent: Operator's manual; operating instructions                  Function/description: To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.</p>		<p>CE mark                  The product meets the essential requirements of the Medical Device Directive 93/42/EEC                  1984 – NB number.</p>