



STERILE R



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PRIMA DENTAL

Diamond Dental (Sterile – Single-use ONLY) Instructions for Use (IFU)

Prima Diamond Rotary Dental Burs (Sterile) are available with numerous head diameters, head shapes, shank sizes and working lengths. The Predator Zirconia are further plated with a protective coating contributing to wear resistance. The range includes patterns designed to meet the needs of a wide range of applications. These devices are supplied sterile for single use and in combination with a rotary handpiece.

These devices are for clinical use by professional users only, where professional is defined as personnel who are qualified to perform dental, orthodontic or oral surgery procedures through specialized education and training.

The device types are further broken down with reference to application and grit size in Tables 1 and 2 below:

Table 1: Diamond Rotary Dental Burs subdivision and application.

Bur Type	Application
Operative	Effective evacuation and removal and/or shaping of carious dentine Ideal for rapid reduction of all dental materials including amalgam, precious/non-precious metals and tooth structure For finishing and shaping all dental materials including composite, ceramics, amalgam and enamel
Predator Zirconia	Specifically for sintered Zirconia in both endodontic treatment and crown removal
Predator Diamond	For crown preparation
Predator Endo	For access into the pulp chamber and preparation of the chamber walls, in one operation. It is used to remove the pulp chamber roof without damaging the chamber floor.

Table 2: ISO grit specifications for Diamond Rotary Dental Burs, the colour bands which are marked with an asterisk (*) are for the Predator Zirconia only.

Colour	Grit Size Range (µm)	Abbreviation	Median Grain Size (µm)	Grit Designation
Yellow	Extra Fine (10 to 36)	EF	25	M10 to M36
Red	Fine (27 to 76)	F	46	M27 to D76
Blue	Medium (64 to 126)	M	107	D64 to D126
Green	Coarse (107 to 181)	C	151	D107 to D181
Black	Very Course (151 to 213)	VC	181	D151 to D213
Pink*	Fine (27 to 76)	F	46	M27 to D76
Turquoise*	Medium (64 to 126)	M	107	D64 to D126

1. INTRODUCTION

Prima Diamond Rotary Dental Bur (Sterile) are a type of rotary cutting instrument manufactured from a single piece of high quality stainless steel (420F) plated at the operational end with a natural diamond grit. These devices are intended to be coupled with a rotary dental handpiece which results in the rotation of the bur. These devices cannot be disassembled.

The burs are packed in a pouch (PET sterile packaging (Polyester/Polyethylene laminate 12 µm /38 µm PET / PE) in a dedicated cleanroom facility and terminally sterilised using Gamma Irradiation. These burs are identified as single-use devices **ONLY** and are not intended to be re-processed or re-used.

The bur pattern selected will be chosen to cut a specific material in a specific application. Table 3 gives **guidance** on recommended operational speeds but it is the responsibility of the user to identify the correct parameters for use in their given procedure:

Table 3: Recommended operational speeds with respect to head diameter.

Head diameter 1/10mm	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

2. INTENDED PURPOSE

The Diamond rotary dental burs are indicated for a wide range of restorative procedures, including the removal of caries and/or old restorations, the preparation of cavities for restoration, the finishing of restorations and the removal of crowns. The diamond rotary dental burs can be used to cut and shape a wide variety of materials, including enamel, dentine, amalgam, composite, glass ionomer cements, polymer/ceramic veneers and precious/non-precious metals. The selected bur pattern is used to cut a specific material in a specific application.

These devices are supplied sterile for single use and in combination with a rotary handpiece.

3. CLINICAL INDICATIONS

Diamond Dental burs have no diagnostic capability and are solely used for the treatment of conditions seen within the oral cavity. Common applications of diamond dental burs includes the treatment/ removal of caries (also known as cavities) or tooth decay. Additional purposes for dental bur usage is in the treatment of malocclusion corrections; malocclusion is a term that covers crowded teeth, crossbite, overbite, underbite and open bite conditions.



4. CONTRAINDICATIONS

Diamond dental burs manufactured by Prima Dental are comprised of (420F) Stainless Steel. This grade of Stainless Steel does not contain Nickel, however plating containing Nickel is subsequently applied

A risk exists for those with a known nickel sensitivity suffering from an allergic response and therefore the use of these diamond burs is not recommended for use in those with a known allergy or sensitivity to nickel.

Nickel is known to the State of California to be a carcinogen – causing cancer, birth defects or other reproductive harm.

5. SIDE EFFECTS

In those with unknown sensitivity to nickel the use of these devices may result in a local or systemic allergic response. Allergic response to nickel may result in cheilitis, gingivitis, stomatitis, perioral dermatitis, burning mouth syndrome or lichenoid.

6. WARNINGS & PRECAUTIONS

- Sterisafe diamond dental burs are sold in a sterile condition for single-use only and should NOT be re-processed and/or re-used.
- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal.
- Suitable PPE including gloves, surgical mask and eye protection should be worn when re-processing these devices.
- During use eye protection shall be worn to protect against ejected particles.
- During use surgical masks shall be worn to avoid inhalation of dust and/or dust generated.
- Never exceed the maximum speeds as indicated by the manufacturer as it may result in generation of excessive heat.
- Do not apply excessive pressure on the bur during use as this can cause excessive heat generation and/or may cause the bur to fail.

- Beware of moving parts and the risk of laceration and entrapment type injuries
- Ensure the bur is fully seated and gripped into the collet of the handpiece prior to use.
- Prior to use inspect the bur for signs of damage and discard any defective burs.
- Proper irrigation is required while using the device. Inadequate irrigation may generate excessive heat and cause patient discomfort, necrosis or patient burns.
- Ensure handpiece(s) is in good working condition prior to conducting the procedure. Failure to use a properly maintained handpiece can lead to procedural delays, injury to the user and injury to the patient through aspiration, swallowing or damage to the preparation site due to the vibration.
- During use ensure that the bur is moved continuously to avoid excessive heat generation caused by friction.
- Never force a bur into a handpiece as this could damage the hand piece collet resulting in the compromised engagement of the bur shank
- Do not use a bur for any application other than its intended use.
- Damage to the packaging may indicate the sterile barrier has been compromised
- Prolonged duration between opening of the packaging and use of the device may impact the sterility of the device
- Device should not be used after the date of expiry identified on the device labelling.

7. INSPECTION OF BURS

To ensure that the device meets the intended performance and safety defined by Prima Dental they should always be inspected prior to use. On removal from the original packaging the device should be inspected to identify any damage. The device should be free from cracks, machining burs, chips, machine oils, bends, device fracture and loose or missing diamond grit. Particular attention should be paid to the coating on the head of the bur, any device identified with any of the aforementioned deficiencies should be disposed of as per the instructions herein.



8. INSPECTION OF PACKAGING

The packaging of the device, should be examined for damage. Damage to the packaging on receipt from the supplier should be reported to Prima Dental and the device should not be used in case sterility has been compromised. The labelling enables identification and traceability of the device, where identification is not possible the device(s) should be disposed of as per the instructions herein.

The device supplied with these instructions is for single use; however, pouches should be examined to ensure that the seals are intact and that there are no punctures to the packaging. Any breaches in the pouch identified may indicate that the device is no longer sterile and should therefore be disposed of.

9. STORAGE

The burs should be stored in their original packaging until required for use. Storage should be in dry, clean conditions at ambient temperature. The storage environment chosen should ensure the integrity of the device is maintained and prevents damage.

10. DISPOSAL

Burs as a cutting instrument regardless of their contamination status should be disposed of as sharps waste. All sharps waste is incinerated and therefore the contamination status is not applicable. In all instances, local guidelines regarding the disposal of medical devices should be adhered to.

11. DECONTAMINATION

In the event that the device is required to be returned to Prima Dental, please ensure any contaminated and/or potentially contaminated burs have been appropriately and effectively cleaned and are suitably packaged for return a statement of decontamination is required for acceptance of such returns due to the nature of the device and its use. All returns shall be addressed 'F.A.O. Quality Department' at the below address.












12. PRODUCT SHELF LIFE

With appropriate storage and handling to all unopened pouches, product sterility will be maintained for five (5) years as indicated on the labelling.

13. FEEDBACK

As part of our documented quality management system (QMS) and continuing commitment to monitor and act on post market feedback, Prima Dental welcome any feedback regarding the appearance and performance of our products and packaging. If you have any comments you wish to make, please contact us by writing to or e-mailing us at the address given below. Please communicate the Lot No in all correspondence.

EXPLANATION OF SYMBOLS


Symbol	Explanation	Symbol	Explanation
	Batch code		Catalogue number
	Manufacturer		Caution
	Do not Re-use		Consult instructions for use
	Date of Manufacture	Rx ONLY	Device for professional use only (US FDA)
	Do not use if packaging is damaged	MD	Medical Device
	Temperature Range	STERILE R	Sterilised using Irradiation
	Use-by Date		Do Not Resterilise

CONTACT US

For further support, please contact us quoting the 7-digit LOT number printed on the device label.

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