

INSTRUCTIONS FOR USE – Interproximal Diamond Bur

This IFU is applicable to all current and previous generations of the products listed below.

Part Number	Grip	Grit	Diameter	Head Length	Overall Length
FG392-016F	Friction	Fine Grit	1.6 mm	5 mm	19mm

Diamond Rotary Dental Bur (Non-sterile) Instructions for Use (IFU)

Prima Diamond Rotary Dental Burs (Non-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. All diamond burs are supplied mechanically clean but **NOT** sterile. These devices are supplied non-sterile for sterilisation before use and for use in combination with a rotary dental 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:

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 (Non-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 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 non-sterile for sterilisation before use and for use in combination with a rotary dental 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

- 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(are) 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.
- Clean and sterilize the burs before initial use and thereafter in accordance with the instructions provided herein.
- 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
- These devices have only been validated for steam sterilisation by autoclave. Use of any other method could result in premature failure of the device.
- Any re-processing method deviation from that defined within this IFU is not validated.
- Delays between the use of and the reprocessing of a used bur, must be kept to under 1 hour so as to reduce the likelihood of contaminants drying and making cleaning more difficult.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used with these burs.
- Do not use a bur for any application other than its intended use.
- When removing burs from a blister pack, always use the tab mechanism. Never use the burs to pierce the packaging; doing so subjects the bur to adverse side loading and introduces undue stress on the device.

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. When previously unused 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. 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 for use is non-sterile; however, on reprocessing in accordance with the instructions for use, sterilisation 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 reprocessed prior to use.

9. PRE-TREATMENT

Before Usage

Burs must be checked prior to use within a dental or orthodontic procedure for signs of contamination, damage or deterioration/wear. Any bur found in a sub-standard condition should be disposed of as per the guidelines defined herein.

Before Cleaning

Prima Dental do not have any special requirements regarding any pre-treatment of burs before reprocessing, nor is there a standard requirement. Local requirements for the handling of such devices should be checked prior to use and are the responsibility of the end user. Manufacturer's instructions for any reagents or equipment used must be adhered to.

10. REPROCESSING

The methods detailed in the below sections have been validated by an approved third party on behalf of Prima Dental Manufacturing Ltd. and were found to be effective and suitable for preparing these diamond burs for re-use. Ref BS EN ISO 17664:2017).

a. CLEANING AND DISINFECTION

Due to the reduced effectiveness and reproducibility of manual cleaning, automated cleaning and steam sterilisation are the preferred processes for cleaning unused and soiled burs.

b. AUTOMATED CLEANING AND DISINFECTION

Note: The use of a washer-disinfector complying with EN ISO 15883 shall be used for the below process:

Step 1: Prepare a 0.1% neutral/mild pH enzymatic detergent according to manufacturer's instructions (in the lowest recommended concentration). Rinse burs under running tap water for at least 1 minute. Soak burs in detergent solution for 2 minutes, scrub the burs under running water with a soft bristle brush to remove any remaining debris/soiling for at least 1 minute. Place the burs onto a clean cloth to avoid any contact between them during the next cleaning procedure.

Step 2: Load the burs and dedicated bur block/stand (if applicable) into the washer-disinfector

Step 3: Run the automatic was cycle with the following parameters:

- 2 minutes prewash at 30°C +/-5°C with tap water,
- 10 minutes main wash with a neutral pH detergent and tap water at 25°C +/-5°C,
- 1 minute rinse with tap water at 30°C,
- 10 minute rinse with distilled water rinse at 30°C,
- 20 minutes air drying phase at high temperature (100°C).

Step 4: Remove the burs at the end of the washer programme

Step 5: Check the load is dry, if necessary, dry the burs using paper towelling.

Step 6: Visually inspect all the burs for cleanliness with the aid of magnification if necessary. If traces of contamination are identified repeat the cleaning process.

Step 7: Check all burs for signs of damage or deterioration.. Any found with evidence of such should be disposed of immediately according to the disposal instructions herein.

When using an automated washer-disinfector, the user should ensure that the process has been validated with the selected cleaning and disinfectant agents. Any cleaning and disinfectant agents must be compatible with the materials used in the bur and the manufacturer's instructions for such agents must be adhered to.

c. MANUAL CLEANING AND DISINFECTION

In the event that manual cleaning is the only option, the burs must be cleaned in a bath/sink reserved specifically for this purpose.

Step 1: Pre-clean under running tap water directly after use

Step 2: Place the burs and dedicated bur block/stand in a fresh bath with a neutral pH cleaning solution, ensuring all burs are sufficiently immersed, follow the cleaning agent/manufacturer's instructions. Soak for at least 10 minutes

Step 3: After soaking and with the burs still immersed, using a soft bristle brush, clean the burs brushing away from the body in a slow controlled manner so as to avoid spreading contaminants by spraying and/or splashing.

Step 4: Remove the burs from the bath and rinse under warm running water for at least 60 seconds and until visibly clean

Step 5: Immerse the burs in disinfectant adhering to the manufacturer's instructions, ensure all burs are sufficiently immersed.

Step 6: After disinfecting, rinse the burs thoroughly with running water to remove all traces of chemical residue. dry as instructed to in section 14.0

Step 7: Visually inspect the burs with the aid of magnification if necessary, to confirm removal of all debris/soiling, repeat cleaning process if required.

Step 8: Visually inspect the burs with the aid of magnification if necessary, for any signs of damage and/or deterioration such as corrosion,

Step 9: Pay particular attention to the flutes and teeth (ref chips/cracks) and shanks (ref chatter marks, distortion and general wear and tear). Any found in a condition which causes concern, should be immediately discarded.

d. DRYING

Burs that are cleaned/disinfected manually can be dried using either a paper-towel or a non-shredding wipe, Burs cleaned/disinfected as part of an automated cleaning and disinfectant process will dry in-situ or using a paper towel if necessary

e. INSPECTION AND MAINTENANCE

To ensure the proper function and continued safe performance of the burs, after cleaning inspect burs thoroughly for any signs of damage and/or deterioration such as corrosion, *pay particular attention to the diamond coating for wear or loose diamond grit.* Any found in a condition which causes concern, must be immediately discarded.

f. CONTAINMENT AND TRANSPORTATION

Diamond burs can be transported wet or dry within the dental setting, although if transported wet, there is an increased risk of staining and/or corrosion. In order to prevent damage and/or deterioration during transportation, burs must be contained in a clean, dry and well maintained bur block/stand or dedicated instrument tray. To minimise the risk of cross contamination, avoid storing clean and soiled burs in the same bur block/stand or instrument tray.

g. STERILISATION

Note: Sterilisation equipment complying with applicable international standards EN ISO 17995-1, EN ISO 13060 shall be used for the below process:

If using an autoclave with a pre-vacuum cycle, pack the burs in appropriate instrument trays or pouches validated for steam sterilisation. If using an autoclave without a pre-vacuum cycle, the burs should not be packed or wrapped, but should be contained in appropriate bur blocks/stands with perforated lids.

Note: Local legislation may require burs to be wrapped in pouches for processing in either type of autoclave system.

Prima Dental Manufacturing Ltd validated the steam sterilisation process in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time* of 3 minutes minimum and 6 minutes maximum, at a temperature of 134°C and a drying time of 30 minutes.

*the holding time is the minimum time for which the minimum temperature is sustained.

- Follow the autoclave manufacturer's instructions, in particular, care must be taken not to exceed the maximum recommended load for the autoclave.
- Place the packaged burs into the sterilisation chamber.
- Start the programme as per below.

Cycle Duration (minimum)	Cycle Duration (maximum)	Cycle Temperature (°C)	Cycle Drying time (min)
3 minutes	6 minutes	134	30

- Remove the burs at the end of the cycle and allow time to cool down.
- Check the packaging for possible damage and screening effects.
- In the event of faulty packaging, product sterility will be compromised. In such cases the burs must be repacked and re-sterilised.

h. STORAGE

The burs should be stored in their original packaging until required for use. This area should be a dry and clean environment. Once opened and no longer in the original packaging the device should be ideally stored in a sterilisation container (instrument tray, bur stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents from water. 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.

i. VALIDATION

The above processes have been validated and found appropriate and effective for preparing Prima Dental diamond dental rotary bur (non-sterile) for reuse. It remains the responsibility of the re-processor to ensure that the equipment, materials and personnel used for such purposes, achieves the required results. This may require validation and monitoring of the process. Any deviation from these instructions shall be properly evaluated for effectiveness and any potentially adverse results.

11. LIMITATIONS

Determined by wear and damage which may have occurred during use, burs shall be routinely inspected for defects and/or other deterioration following preliminary cleaning and again after use/reprocessing. The recommended cycles of use should not exceed those stated in Table 4:

Table 4: Number of recommended cycles with respect to bur grit size.

Diamond Bur Grit Size	No. of Cycles Recommended for Safe Use
Extra Fine	Less than or equal to 30
Fine	Less than or equal to 30
Medium	Less than or equal to 35
Coarse	Less than or equal to 40
Extra Coarse	Less than or equal to 40
Extra Coarse with Gold Coating	Less than or equal to 60

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with a neutral pH are recommended.

Delays between the use and the reprocessing of a used bur must be kept to a minimum so as to avoid contaminants drying, thereby making cleaning more difficult. Therefore keep used burs immersed in the cleaning/disinfecting agent in accordance with manufacturer's instructions, but in any event, do not exceed 12 hours. Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

12. 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.

13. 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.

14. FEEDBACK

As part of our documented 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
	Non-Sterile Device		Consult instructions for use
	Date of Manufacture	Rx ONLY	Device for professional use only (US FDA)
	Do not use if packaging is damaged		Medical Device
	Temperature Range		

CONTACT US

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

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Revision A11

Issue Date: 26 July 2023