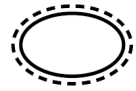


# Diamond Rotary Dental Bur (sterile)

## Instructions for Use (IFU)

**EC REP**  
Emergo Europe B.V.  
Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands



### 1. SCOPE

These Instructions for Use (IFU) provide general instructions for the Diamond Rotary Dental Burs (sterile). These burs are supplied sterile for single use and in combination with a rotary dental handpiece.

Prima Diamond Rotary Dental Burs (sterile) are available with numerous head diameters, head shapes, shank sizes and working lengths. Prima Diamond Rotary Dental Burs are manufactured from stainless steel with a nickel/diamond coating on the head of the bur.

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.

The burs are packed in a pouch (PET sterile packaging) 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.

### 2. INTENDED PURPOSE

The device is intended for use in combination with a dental rotary handpiece for a wide range of restorative procedures. The device can be used to cut/grind hard tissue such as tooth and bone or materials used in dental prostheses such as metal, plastic, porcelain and other hard materials. In line with the classification, the device is intended for transient use (i.e. Device is intended for continuous use for less than 60 minutes).

### 3. INTENDED APPLICATION

The rotary bur is intended for laboratory and dental applications in clinics and hospitals.

### 4. INTENDED USERS

Professional use – rotary burs are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these burs based on their training and experience. Therefore, user training is not needed to ensure specified performance and safe use of the medical device.

For laboratory applications, the use of these burs must be by a licensed technician.

### 5. INTENDED POPULATION

All patients (human) in need of dental care as determined by a qualified professional.

## 6. CONTRAINDICATIONS AND WARNINGS

The use of Prima Dentals Diamond Rotary Dental Burs is contraindicated on any patient with known allergy to Nickel; nickel is listed within Proposition 65 - OEHHA (ca.gov) as having potential detrimental human impacts.

## 7. DEVICES IN COMBINATION WITH PRIMA DENTAL'S DIAMOND ROTARY DENTAL BURS

Prima Dental's Diamond Rotary Dental Burs are compatible with any approved handpiece that can be operated with FG or RA shanks. The bur must always be positioned correctly within the handpiece before use. The security of the bur within the handpiece should be checked before use.

Maintain handpieces in good working conditions to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or 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.

## 8. STORAGE (PRE-USE)

Store in a dry and clean environment at ambient temperature, within the original packaging.

## 9. BUR SELECTION

The bur pattern selected will be chosen to cut a specific material in a specific application. Table 1 below provides the recommended speeds for the diamond rotary dental burs. The dental bur pattern and shape shall be selected at the physician's discretion and will be chosen according to the required application.

Table 1 gives guidance and provides recommended RPM for the user.

**Table 1: 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

## 10. CLINICAL PRECAUTIONS AND WARNINGS

- 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.

## **11. INSPECTION OF BURS**

Inspect the bur for any signs of damage or deterioration such as corrosion. Pay particular attention to the head of the bur for any loose material, coating abnormalities, wear, chips, flute damage, cracks or bending. Any burs found with any damage or deterioration which may cause concern should be discarded.

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.

## **12. INSPECTION OF PACKAGING**

The packaging of the device should be examined for damage. Damage or punctures to the packaging or seals should be reported to Prima Dental and the device should not be used in case the 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.

## **13. STORAGE**

Burs should be stored in dry, clean conditions at ambient temperature within the original packaging. The storage environment chosen should ensure the integrity of the device is maintained and prevents damage.

## 14. DISPOSAL

Used burs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.







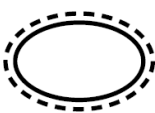






## 15. PRODUCT SHELF LIFE

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

## 16. TRACEABILITY

Each package includes lot number **LOT** on its label. This number must be quoted in any correspondence regarding to the bur.

## 17. EXPLANATION OF SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Batch Code		Catalogue Number
	Manufacturer	Prima Dental Manufacturing Ltd. Gemba House, Stephenson Drive, Gloucester, GL2 2HA, United Kingdom	
	Sterilised Using Irradiation		Consult Instructions for Use
	Do Not Re-use		Single Sterile Barrier System with Protective Packaging Outside
	Date of Manufacture	<b>Rx ONLY</b>	Device for Professional Use Only (US FDA)
	Caution		Do Not Use if Packaging is Damaged
	Medical Device		EU Authorised Representative
	Use-by Date		

## 18. CONTACT US

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

Phone: +44 1452 729751

Email: [sales@primadental.com](mailto:sales@primadental.com)