Carbide Rotary Dental Bur (sterile)
Instructions for Use (IFU)

EC REP

Emergo Europe B.V.
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The Netherlands

CE 0123 MD STERILE R

1. SCOPE

Prima Dental Manufacturing's carbide rotary dental burs are manufactured from either a single piece of tungsten carbide or, from a tungsten carbide tip, brazed to a surgical grade stainless steel stem.

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.

The range includes patterns designed to meet the needs of surgery and laboratory applications and in accordance with ISO standards. The bur pattern selected will be chosen to cut a specific material in a specific application. Table 1 gives guidance to the user.

Table 1: Recommended applications and operational speeds.

Application	Bur Type	Material	Head Size (mm)	Speed (RPM)
Cavity Preparation	Standard	Enamel/Dentine	010 to 023	< 450,000
Removal of Fillings	Standard	Amalgam/Composite	010 to 018	60,000 to 120,000
Excavation	Standard	Enamel/Dentine/Bone	010 to 023	< 2,000
Finishing Margins	Finishing	Enamel	010 to 016	10,000 to 20,000
Finishing Restorations	Finishing	Amalgam	012 to 023	18,000 to 30,000
Finishing Restorations	Finishing	Composite	012 to 023	10,000 to 20,000
Finishing Restorations	Finishing	Glass Ionomer	012 to 023	10,000 to 20,000
Cutting Bone	Standard	Bone	018 to 027	500 to 3,000
Crown & Bridge Finishing	Finishing	C&B Polymer	010 to 016	40,000 to 80,000
Crown & Bridge Metal Finishing	Standard	Metals	018 to 027	< 30,000
Prosthetic Polymer Trimming	Standard	Polymer	018 to 027	< 20,000

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 APPLICATIONS

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 licenced technician.

5. INTENDED POPULATION

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

6. CONTRAINDICATIONS

Dental burs are comprised of tungsten carbide or of tungsten carbide brazed to stainless steel. The Carbide Rotary Dental Bur (sterile) used in the manufacture of Prima Dental Burs has 10% cobalt as a constituent. Cobalt is a known allergen that can result in local or systemic allergic response and is therefore not recommended for use in those with an allergy or sensitivity to cobalt.

Nickel is used to braze the head of the bur to the shank and a nickel plating is applied to single piece gold finishing burs. A risk exists for those with a known nickel sensitivity suffering from an allergic response and therefore the nickel plated burs are not recommended for use in those with a known allergy or sensitivity to nickel.

Nickel and cobalt are known to the State of California to be carcinogens – causing cancer, birth defects or other reproductive harm.

7. 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.

In those with unknown sensitivity to cobalt the use of these devices may result in a local or systemic allergic response. Allergic response to cobalt may result in contact dermatitis.

Incorrect use or excessive pressure may result in pulpitis, pulpal necrosis or damage to the enamel.

8. WARNINGS AND PRECAUTIONS

- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken.
- Suitable PPE including gloves, eye protection and a mask 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 broken and or damaged flute 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 both the bur and handpiece collet.
- 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.

9. 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.

10. 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 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.

11. STORAGE

Storage should be in dry, clean conditions at ambient temperature.

12. DISPOSAL

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

13. 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.

14. TRACEABILITY

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

15. EXPLANATION OF SYMBOLS

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

16. 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

DOC: IFU-42 Revision A10 Issue Date: 17 September 2024