

# Steel Rotary Dental Bur (Non-sterile)

## Instructions for Use (IFU)



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### 1. SCOPE

Prima Dental Steel Rotary Dental Bur (non-sterile) are a type of rotary cutting instrument manufactured from a single piece of heat treated carbon steel. These devices are intended for singled use and to be coupled with a rotary dental handpiece which results in the rotation of the bur.

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)
Excavation	Standard	Enamel/Dentine/Bone	010 to 023	< 2,000
Finishing Restorations	Finishing	Amalgam	012 to 023	18,000 to 30,000
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).

These devices are supplied non-sterile, for single-use only. They should NOT be re-processed and/or re-used. The devices are intended for use in combination with a rotary dental handpiece.

### 3. CONTRAINDICATIONS

No contraindications have been identified for the device.

### 4. INTENDED APPLICATIONS

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

### 5. 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.

## **6. INTENDED POPULATION**

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

## **7. WARNINGS AND PRECAUTIONS**

- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during disposal.
- Clean the burs before initial use in accordance with the instructions provided.
- Suitable PPE including gloves, eye protection and a mask should be worn when using 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.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to steel and must not be used with these burs.
- Do not use a bur for any application other than its intended use.
- Cleaning by auto-claving is NOT recommended due to a propensity for corrosion.

## **8. 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.

## **9. 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 should enable identification and traceability of the device, where identification is not possible the device(s) should be disposed of as per the instructions herein.

## **10. PREPARATION BEFORE CLEANING**

There are no special requirements unless infection control requires the use of a disinfectant, in which case a disinfectant agent validated for cleaning dental burs shall be used and the manufacturer's instructions followed.

## **11. CLEANING**

Auto cleaning is the preferred process for cleaning. Use only validated washer disinfectors and appropriate agents validated for use on dental burs. When cleaning the burs follow the manufacturer's instructions.

If manual cleaning is the only available option, the burs shall be cleaned in a sink reserved specifically for this purpose. Rinse the burs under running cold water and keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfectant agent validated for use on dental burs. When brushing care shall be taken to avoid spreading contaminants by spraying or splashing. Use wire brushes with caution so as to safeguard against galvanic corrosion and discolouration.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided. After cleaning carefully inspect the burs to ensure all traces of contamination have been removed.

## **12. DRYING**

Burs can be dried using either a paper towel, a non-shredding wipe or dry heat not exceeding 140°C.

### 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. However, it should be noted that local infection controls may require additional steps such as disassembly prior to reprocessing. Local requirements for the handling of such devices should be checked prior to use and are the responsibility of the end user.

## **13. STORAGE**

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












## **14. DISPOSAL**

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

## 15. TRACEABILITY

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

## 16. 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	
	Non-Sterile Device		Consult Instructions for Use
	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
	Do Not Re-use		

## 17. 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)

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