PRIMA DENTAL

NON STERILE CE 0123

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

Prima Dental Steel Rotary Dental Bur (Non-sterile) are available with numerous head diameters, head shapes, shank sizes and working lengths. All metal cutting burs, orthodontic burs, gold finishing burs, oral surgery burs and operative burs manufactured by Prima Dental are included within the scope of this IFU.

| Bur Type | Application |
|---|---|
| Operative | Effective evacuation and removal and/or shaping of carious dentine |
| Orthodontic | For de-bonding of adhesive materials and interproximal spacing |
| Metal Cutting | Ideal for rapid reduction of all dental materials including amalgam, precious/non-precious metals and tooth structure |
| Gold Finishing | For finishing and shaping all dental materials including composite, ceramics, amalgam and enamel |
| Oral Surgery | A comprehensive collection of surgical burs covering a range of applications including endodontic surgery, implantology and traumatology |

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.

## 1. INTRODUCTION

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 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. The following table gives guidance:

| Application | Bur Type | Material | 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 Trimming | Standard | Metals | 018 to 027 | < 30,000 |
| Prosthetic Polymer Trimming | Standard | Polymer | 018 to 027 | < 20,000 |

## 2. INTENDED PURPOSE

Dental burs are rotary cutting devices and are intended to be used to cut and shape tooth and bone within the mouth. Similarly, they are also designed to cut and/or remove materials, including enamel, dentine, amalgam, composite, glass ionomer cements, adhesives, polymer/ceramic veneers and precious/non-precious metals commonly used within dental and orthodontic procedures.

These devices are supplied non-sterile, cleaning of the steel bur prior to its use is required. Steel burs are supplied mechanically clean, but NOT sterile. **Steel burs are intended for single-use only, and should therefore NOT be re-processed**. The devices are intended for use in combination with a rotary dental handpiece.

## 3. CLINICAL INDICATIONS

Indications for use are patients, both adult and children that are suffering from caries, tooth decay or those undergoing procedures for a malocclusion. Malocclusion covers the following conditions; crowded teeth, crossbite, overbite, underbite and open bite. Dental burs can also be used in the removal of crowns, fillings and other dental hardware and adhesives that may no longer be required or are causing pain and discomfort to the patient. Oral surgery burs may be utilised in those requiring endodontic procedures, implantology or traumatology.

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## 4. CONTRAINDICATIONS

No contraindications have been identified for the device

## 5. WARNINGS & PRECAUTIONS

- Clean the burs before initial use in accordance with the instructions provided herein.
- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during disposal.
- Suitable PPE including gloves and eye protection 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.

## 6. 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 receipt from the supplier the device should be inspected to identify any damage. When previously unused the device should be free from cracks, machining burs, chips, machine oils, chatter marks and device fracture. Particular attention should be paid to the flutes and teeth of the bur. Any device identified with any of the aforementioned deficiencies should be disposed of as per the instructions herein.

## 7. INSPECTION OF PACKAGING

The packaging of the device, both from the supplier and after sterilisation 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.

## 8. 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.

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### 9. 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. Repeat cleaning steps if required.

### 10. DRYING

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

### 11. 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 flutes and teeth for chips/cracks and shanks for chatter marks, distortion and general wear & tear.* Any found in a condition which causes concern, must be immediately discarded.

### 12. CONTAINMENT and TRANSPORTATION:

Steel burs can be transported wet or dry, although if transported wet, there is an increased risk of staining and/or corrosion. In order to prevent damage and/or deterioration during transportation suitable protection must be used. 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.

### 13. STORAGE

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

### 14. 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.

**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 |  | Do not reuse |

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**CONTACT US**

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

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