PRIMA DENTAL

NON STERILE CE 0123

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

Prima Dental Carbide 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 Carbide Rotary Dental Bur (Non-sterile) are a type of rotary cutting instrument manufactured from either a single piece of tungsten carbide or, from a tungsten carbide tip brazed to a stainless-steel shank. 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	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

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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 for sterilisation before use and 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.

⚠ 4. CONTRAINDICATIONS

Dental burs are comprised of tungsten carbide or of tungsten carbide brazed to stainless steel. The Carbide Rotary Dental Bur (Non-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.

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.

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.

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 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 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.
- 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 both the bur and handpiece collet.
- 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.

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 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.

8. 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.

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. 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.

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.

10. REPROCESSING

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.

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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: Pre-cleaning - for the removal of extensive contamination, prior to loading the burs into the washer-disinfector, rinse under cold tap water for ≥ 1 min.
Step 2: Load the burs and dedicated bur block/stand (if applicable) into the washer-disinfector
Step 3: Clean using 0.5% cleaner at 55°C± 2°C for ≥ 5 min with demineralized water.
Step 4: Rinse with demineralized water for ≥ 1 min.
Step 5: Thermo-disinfection with demineralized water at 93°C± 2°C for ≥ 5 min**.**
Step 6: Drying, dry as instructed in section 10.d
Inspection: After cleaning, carefully inspect the burs to ensure all traces of contamination have been removed. Repeat cleaning steps if required.

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 (ref section 1).

Note: for the purposes of Prima Dental' s reprocessing validation, proof of the general suitability for effective mechanical cleaning and disinfecting has been provided by an independent certified test laboratory using a Miele washer disinfector (Model No PG8581) and the cleaning agent Neodisher MediClean Forte (Dr Weigert GmbH & Co. KG Hamburg).
Test carried out in accordance to ISO/TS 15883-5:2005.
A0 value of the process was determined to be >3000 s

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: Clean the burs in a cleaning bath using a soft bristle brush until visibly clean for ≥10 seconds
Step 2: Place the burs (and bur block/stand) in a fresh bath using a neutral-pH cleaning solution, ensuring all burs are sufficiently immersed, follow the cleaning agent/manufacturer's instructions. Soak for at least ≥5 minutes,
Step 3: after soaking and keeping the burs immersed, using a soft bristle brush, brush away from the body in a slow controlled manner so as to avoid spreading contaminants by spraying and/or splashing,
Step 4: Rinse the instruments with clear tap water (drinking water quality) ≥10 seconds.
Step 5: check all burs for signs of damage and/or deterioration, refer to section 9.

Disinfection:
Step 1: Immerse the instruments in a disinfection bath with 80% ethanol for 5 minutes.
Step 2: Rinse the instruments with sterile water to remove all remaining chemicals.
Step 3: dry as instructed in section 10.d.
Inspection: After cleaning, carefully inspect the burs to ensure all traces of contamination have been removed. Repeat cleaning steps if required.

Note: for the purposes of Prima Dental's reprocessing validation, proof of the general suitability for effective manual cleaning and disinfecting has been provided by an independent certified test laboratory using the cleaning agent Neodisher MediClean Forte (Dr Weigert GmbH & Co. KG Hamburg) and 80% Ethanol as the disinfector.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

d. DRYING:

Only relevant to burs that are cleaned/disinfected manually, ref section 10.c. Burs 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.

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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 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.

f. CONTAINMENT and TRANSPORTATION:

Carbide 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.

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 a **vacuum** autoclave, pack the burs into a dedicated instrument tray or pouch in compliance with EN ISO 11607-1.
If using a **non-vacuum** autoclave, the burs shall be contained in a dedicated bur stand with perforated lid, or pouch in compliance with EN ISO 11607-1.

Note: Gravity sterilisation is no longer state of the art. For the purposes of Prima Dental's reprocessing validation, *proof of the general suitability for effective sterilisation has been provided by an independent certified test laboratory* using Systec vacuum steam steriliser (Recommended method) (Model No DX-45) and Systec gravity steriliser (Model No DB-23), ASSURE Plus sterilisation pouches were used.
Test carried out in accordance with EN 11737-2:2009

Use the following cycle times:

Cycle Time	Exposure Times (minutes)	Temperature	Drying Times (minutes)
Pre-vacuum (4 pulses)	≥ 3	134°C ±0	≥ 30
Gravity Displacement	≥ 10	135°C ±0	≥ 30

Note:
The instructions from the autoclave manufacturer must be followed and adhered to at all times.
Ensure that the maximum load as stipulated by the manufacturer of the steriliser is NOT exceeded,
Ensure that the minimum drying time (30 mins) is not compromised as failure to achieve this could result in a build- up of moisture and the burs corroding.
National legislation may require burs to be wrapped in pouches for processing in either type of autoclave system.

h. STORAGE

The burs should be stored in the 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.

i. VALIDATION

The above processes have been validated and found appropriate and effective for preparing Prima Dental carbide 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. 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		

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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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