

Tungsten Carbide Dental Burs (non-sterile)

INSTRUCTIONS FOR USE

DESCRIPTION: Prima Dental Group tungsten carbide 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 range includes patterns designed to meet the needs of all surgery and laboratory applications.

SCOPE: These instructions are applicable to the cleaning of the tungsten carbide bur prior to initial use, and thereafter every subsequent re-use. Tungsten carbide burs are supplied mechanically clean, but NOT sterile.

INDICATIONS FOR USE: Prima Dental Group tungsten carbide burs can be used to cut or polish a wide variety of materials encountered in dentistry. These include tooth material such as enamel, dentine and bone, dental materials such as amalgam, composite, glass-ionomer cements, polymer and ceramic veneers and precious and non-precious alloys.

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) |
|--------------------------------|-----------|---------------------|------------|-------------------|
| 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 |

WARNINGS: Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, gloves and a mask should be worn when re-processing.

CONTRAINDICATIONS: Prima Dental's range of non-sterile carbide dental burs contain a small nickel content and should therefore not be used on individuals, with a known sensitivity to this metal as in extreme cases it may cause hypersensitivity.

In the event of burs being returned to Prima Dental Group, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned, and are appropriately packaged for return.

STORAGE (pre-use): Store in a dry and clean environment at ambient temperature. Store out of direct sunlight and away from other sources of heat.

PRECAUTIONS:

- 1/ eye protection shall be worn to protect against ejected particles,
- 2/ surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure,
- 3/ prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs,
- 4/ ensure the bur is fully seated and gripped in the hand-piece collet,
- 5/ ensure hand-pieces are maintained in good working order and remain adequately lubricated at all times to ensure maximum effectiveness of the device. Failure to properly maintain can lead to procedural delays, injury to the user or patient, aspiration or swallowing of the bur or damage to the preparation site due to vibration from a worn chuck or turbine,
- 6/ move the bur continuously when in use so as to avoid localised heating caused by friction,
- 7/ never exceed the maximum speeds as shown in the above table as this may generate undesirable heat,
- 8/ do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail,
- 9/ clean and sterilise the burs before initial use and thereafter, prior to re-use in accordance with the below instructions,
- 10/ when removing burs from a blister pack, always utilise the Solo-Peel tab mechanism. Never use the burs to pierce the rear foil strip as this subjects the bur to adverse side loading and introduces undue stress.

PREPARATION FOR 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.

LIMITATIONS: Re-processing will have little effect on Prima Dental Group tungsten carbide burs. The end of life is more determined by wear and damage induced during use.

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 hand cleaning is the only available option, the burs shall be cleaned in a sink reserved specifically for this purpose.

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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. Delays in re-processing must be kept to a minimum to avoid the risk of contaminant drying and thereby making cleaning more difficult.

After cleaning inspect the burs to ensure any traces of contamination have been removed. Repeat cleaning if required.

DRYING: Dry the burs using either a paper towel, a non-shedding wipe or cloth, or dry heat not exceeding 140°C.

STERILISATION: If using a vacuum autoclave, pack the burs into a dedicated instrument tray or pouch validated for sterilisation. If using a non-vacuum autoclave, the burs shall be contained in a dedicated bur stand with perforated lid.

Use the following cycle times:

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

Warnings:

- 1/ ensure that the maximum load as stipulated by the manufacturer of the steriliser is NOT exceeded,
- 2/ 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.

Note: National legislation may require burs to be wrapped in pouches for processing in either type of autoclave system.

The instructions from the autoclave manufacturer must be followed.

STORAGE: The burs should be stored in the sterilisation container (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.

VALIDATION: The above processes have been validated and found appropriate and effective for preparing Prima Dental Group tungsten carbide burs 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.

LIMITATIONS of Re-PROCESSING: The life of the bur is normally determined by wear and tear and NOT through re-processing. Burs should be routinely inspected following preliminary cleaning and again after re-processing.

LOT NUMBER: The Lot or batch number is a seven (7) digit number printed on the label and the packaging. **This number must be quoted in any correspondence.**

POST MARKET FEEDBACK: As part of our documented QMS and continuing commitment to monitor and act on post market feedback, Prima Dental welcome any feedback regarding the appearance and performance of our products and packaging. If you have any comments you wish to make, please contact us by writing to or e-mailing us at the address given below. Please communicate the Lot No in all correspondence.

Rx ONLY (ref US FDA CDRH)



Prima Dental Group, Stephenson Drive, Gloucester, GL2 2HA, E-mail sales@primadental.com, Tel No +44 1452 729751 / Fax No +44 1452 307187

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