

Sterisafe Tungsten Carbide Dental Burs (sterile)

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: Prima Dental Manufacturing's 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.

The burs are packed in a PET/PE laminate pouch in a dedicated cleanroom facility and terminally sterilised using Gamma Irradiation by a contract steriliser. These burs are identified as single-use devices ⁽²⁾ and should NOT be re-processed and/or re-used.

2.0 SCOPE: These instructions are applicable to the safe use of Prima Dental Manufacturing's range of sterisafe tungsten carbide dental burs.

3.0 INDICATIONS FOR USE: Prima Dental Manufacturing's sterisafe tungsten carbide burs can be used to cut 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
Cuffing 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 Trimming	Standard	Metals	018 to 027	< 30,000
Prosthetic Polymer Trimming	Standard	Polymer	018 to 027	< 20,000

4.0 WARNINGS: Used burs shall be considered as contaminated and as such, appropriate handling and disposal procedures must be followed when discarding used burs. In the event of damage too and/or breaches in the sterile barrier, do NOT use the product, in such cases please return the product in its packaging to Prima Dental Manufacturing.

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

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

6.0 STORAGE: Store in a dry and clean environment at ambient temperature. Store out of direct sunlight and away from other sources of heat.

7.0 DIRECTIONS FOR USE: Prior to use, carefully inspect the pouch for signs of damage and/or deterioration and check that the expiry date has not expired. Refrain from opening the pouch until you are ready to use the bur. Holding the bur in the pouch by its operative end, carefully push the shank through the film of the pouch far enough to insert into the collet of the hand piece. Once the shank has sufficiently engaged with the collet, tighten, before releasing the grip on the operative end and discarding the empty pouch. Following use dispose of the used bur in a sharps bin or in accordance with other national/international disposal procedures.

Sterisafe tungsten carbide dental burs are sold in a sterile condition for single-use only and should NOT be re-processed and/or re-used.

8.0 PRECAUTIONS:

Eye protection shall be worn to protect against ejected particles.

Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.

Prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs.

Follow the hand piece manufacturer's instructions for use and maintenance and service all hand pieces appropriately.

Ensure the bur is fully seated and gripped in the hand-piece collet.

Before use run the hand piece to check for any abnormalities including overheating.

Ensure hand-pieces are maintained in good working order and remain correctly lubricated at all times.

Move the bur continuously when in use so as to avoid localised heating.



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Never exceed the maximum speeds as shown in the above table as this may generate undesirable heat. Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.

9.0 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.**

10.0 PRODUCT SHELF LIFE: On the proviso that appropriate storage and handling practices are applied to all unopened pouches, product sterility will be maintained for five (5) years as indicated on the pouch.

11.0 POST MARKET FEEDBACK: As part of our documented QMS and continuing commitment to monitor and act on post market feedback, Prima Dental Manufacturing Ltd 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 Mfg Ltd, Stephenson Drive, Gloucester, GL2 2HA, E-mail sales@primadental.com, Tel No +44 1452 729751 / Fax No +44 1452 307187



Explanation of Symbols Shown on the Labelling/Packaging



Lot/Batch Number



Consult with the Instructions for Use (IFU)



Sterilised with Gamma Irradiation



For single-use only, do NOT re-use



Do NOT Re-sterilise



Use by Date, expressed as yyyy-mm-dd



Manufactured by

Rx ONLY *Device for Professional use Only (ref US FDA)*



Medical Device