

Steel Dental Burs (non-sterile)

INSTRUCTIONS FOR USE

DESCRIPTION: Prima Dental Group steel burs are manufactured from a single piece of heat treated carbon steel. 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 steel bur prior to its initial use ONLY. Steel burs are supplied mechanically clean, but NOT sterile.

② **Steel burs are single-use devices and should therefore NOT be re-processed.**

INDICATIONS FOR USE: Prima Dental Group steel 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)
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

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

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.
Ensure the bur is fully seated and gripped in the hand-piece collet.
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.
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.
Prior to use clean the bur in accordance with the instructions below.

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.

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. 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.

Cleaning by auto-claving is NOT recommended due to a propensity for rusting.

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

DRYING: Burs must be dried using either a paper towel or, dry heat not exceeding 140°C.

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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