


Sterisafe Steel Dental Burs (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. The burs are packed in a tough laminate/paper pouch in a dedicated cleanroom facility and terminally sterilised using Gamma Irradiation by a contract steriliser. These burs are identified as single-use devices  and should **NOT** be re-processed and/or re-used.

SCOPE: These instructions are applicable to the safe use of Prima Dental Groups range of sterisafe steel dental burs.

INDICATIONS FOR USE: Prima Dental Group sterisafe 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
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. Do not use if the packaging has been damaged and/or opened.

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.

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 the operative end, push the stem end through the paper far enough to insert into the hand piece collet. Immediately insert the stem into the hand piece collet and 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 steel dental burs are sold in a sterile condition for single-use only and should NOT be re-processed and/or re-used.

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.
 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.

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.**

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.

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)



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