


## Sterisafe Carbide Toller Surgical Burs (sterile)

### INSTRUCTIONS FOR USE

**DESCRIPTION:** Prima Dental Group carbide Toller Surgical burs are manufactured from a tungsten carbide tip, brazed to a surgical grade stainless steel stem. The range include round 2.3mm and taper fissure 1.6mm heads in both right angle (RA) latch and straight hand piece (HP) shanks.

The shank has a blood ring designed to throw off blood and other fluids preventing ingress into the hand piece mechanism. The shanks are long and tapered in such a way so as to allow deep penetration with good visibility but without prejudicing the burs intrinsic strength. The fissure version has a reversed spiral to the teeth which facilitates passage of irrigating fluid to the bur tip.

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 carbide Toller Surgical dental burs.

**INDICATIONS FOR USE:** Prima Dental Group sterisafe carbide Toller Surgical burs are designed for endodontic access and dental bone surgery particularly to facilitate removal of impacted wisdom teeth.

**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.

**CONTRAINDICATIONS:** *Prima Dental's range of 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:** 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.

Prima Dental Group carbide Toller Surgical burs can be used at speeds ranging between 10,000 and 50,000 rpm. **It is recommended to use a hand piece incorporating a torque limiting device. It is also worth noting that electric hand pieces may continue to run at full speed even when excess pressure is applied.** Ensure that there is a constant feed of lubricant to the cutting surface and move the bur continually to avoid localised heating caused by friction. To avoid the burs 'snatching' during use, apply steady, firm pressure to achieve penetration. Material should be removed in stages and the bur withdrawn periodically to prevent clogging. In the event of the hand piece slowing down significantly, this indicates excessive cutting force has been used and the pressure applied must be reduced. Avoid excessive lateral forces and do **NOT** allow the shank to contact the outer margins of the cavity and/or incision.

**Sterisafe carbide Toller Surgical 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 speed of 50,000 rpm 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.**

### **Sterisafe Carbide Toller Surgical Burs (sterile)**

**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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