Carbide Toller Surgical Burs (non-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 includes 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.

SCOPE: These instructions are applicable to the cleaning of the carbide Toller Surgical bur prior to its initial use ONLY. These burs are supplied mechanically clean, but NOT sterile.

Prima Dental Group recommend that these burs are only ever used ONCE. However, if reuse is unavoidable, clean and sterilise in accordance with the below recommendations following each subsequent use.

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

DIRECTIONS FOR USE: 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 Material should be removed in stages and the bur withdrawn periodically to prevent clogging.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.

CONTRAINDICATIONS & 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. 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. Move the bur continuously when in use so as to avoid localised heating caused by friction. 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.

LIMITATIONS: Repeated use and re-processing may result in a reduction in the burs mechanical strength through damage and/or corrosion.

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 discoloration.

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.
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DRYING: Burs must be dried using either a paper towel 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.

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

Autoclave the burs for a holding time of not less than 3 minutes at a temperature between 134 and 137°C. The holding time is the minimum time for which the minimum temperature is sustained.

The instructions from the autoclave manufacturer must be followed. In particular, care shall be taken not to exceed the maximum recommended load for the autoclave.

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.

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.

Rx ONLY (ref US FDA CDRH)

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