

TC Burs

Instructions for Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for use by dental professionals only.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Perfection Plus Non-sterile TC Burs are manufactured from either from a single piece of tungsten carbide (TC) or from TC tip brazed onto a surgical steel stem. They are supplied in a non-sterile state.



Product Name	TC Bur
Company Name	Perfection Plus Ltd
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PRODUCT CODE - REF

PP001/9308	TC Bur Round HP
PP001/9401 -PP001/9408	TC Bur Round RA 1-8
PP001/9411-PP001/9420	TC Bur Round FG 1/4 - 8
PP001/9430-PP001/9433	TC Bur Inverted Cone FG 34 -37
PP001/9440-PP001/9445	TC Bur Flat Fissure 57 - 558
PP001/9450-PP001/9454	TC Bur Taper Fissure Cross Cut FG 170 - 1171
PP001/9460-PP001/9464	TC Bur Domed Fissure Cut FG 1156 – 1558
PP001/9470-PP001/9473	TC Bur Pear FG 329 – 332
PP001/9480	TC Bur Amalgam Prep 245
PP001/94701-PP001/9703	TC Bur Taper Fissure Cross Cut HP 701 - 703

INDICATIONS FOR USE

They are intended for use by professionals only, in dental applications. They can be used to cut, grind or polish a wide variety of materials including enamel, dentine and bone, dental materials such as amalgam, composite, glass ionomer cements, polymer and ceramic veneers and precious and non-precious alloys. Each bur is task specific and so the bur pattern will be selected to cut a specific material and for a specific task. TC Burs are task specific, each bur is designed for a particular area of use during endodontic access and canal exploration.

<u>Application</u>	<u>TC BUR Type</u>	<u>Material</u>	<u>Speed</u>
Cavity preparation	Standard	Enamel/ Dentine	450,000
Removal of fillings	Standard	Amalgam/ Composite	60,000-120,000
Excavation	Standard	Enamel/ Dentine/ Bone	<2,000
Finishing margins	Finishing	Enamel	10,000-20,000
Finishing restorations	Finishing	Amalgam	18,000-30,000
Finishing restorations	Finishing	Composite	10,000-20,000
Finishing restorations	Finishing	Glass Ionomer	10,000-20,000
Cutting bone	Standard	Bone	500-3,000
Crown & Bridge finishing	Finishing	C&B polymer	40,000-80,000
C&B metal trimming	Standard	Metals	<30,000
Prosthetic polymer trimmer	Standard	Polymer	<20,000

PRECAUTIONS

1. Always wear gloves when handling contaminated instruments.
2. Eye protection and a surgical face mask should be worn
3. Before each use, inspect the burs for damaged blades or excessive wear. Discard any worn/damaged burs.
4. Ensure the bur is fully seated and gripped in the hand piece collet.
5. Ensure the hand piece is in good working order and correctly lubricated.
6. Do not exceed the maximum speeds as advised above in this IFU.
7. Do not apply excessive pressure to the bur.
8. Move the bur continuously when in use to avoid localised heating and or damage to the bur.

INSTRUCTIONS FOR USE

Before first and every subsequent use inspect the bur for signs of damage or deterioration, clean and sterilise the bur.

MANUAL CLEANING

If manual cleaning is implemented, the burs should be cleaned in a sink reserved for the purpose.

To Reprocess:

1. Rinse burs under running cold water for at least 60 seconds.
2. Place the burs in a fresh bath using a neutral pH cleaning solution, ensuring all burs are sufficiently immersed, follow cleaning agent manufacturer's instructions. Soak for at least 10 minutes.
3. After soaking and keeping the burs immersed, using a soft bristle brush, brush away from the body in a slow controlled manner.
4. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process
5. Wire brushes must be used in caution, as brass particles may result in galvanic corrosion and steel particles may cause discolouration of stainless steel.
6. After cleaning inspect the burs using magnification, if necessary, to ensure all contamination has been removed and for signs of damage and/or deterioration. Repeat cleaning process if necessary. Rusted burs should be discarded as bio-hazardous waste.
7. Dry the burs with paper toweling or non-shredding wipe or using filtered pressurized air.

AUTOMATED CLEANING

For the removal of extensive contamination, prior to loading the burs into the washer-disinfector, rinse under warm running water for at least 60 seconds.

Load burs into the washer-disinfector.

Start the program which will take you through the following pre-programmable cycles:

- Flush – removes any hard to clean contamination left over from the pre clean
- Wash – removes and remaining contamination, detergents used must be specified by the manufacturer as suitable for use in washer disinfectors and the instruments being reprocessed
- Rinse – removes traces of the detergent used in the washing process
- Thermal Disinfection – The temperature of the load is held at the pre-set disinfection temperature for the required holding time, refer to the manufacturers recommendations.
- Drying – purges the load and chamber with heated air to remove residual moisture. Dry heat should not exceed 140°C.

When using an automated washer-disinfector, the user should ensure that the process has been validated with the selected cleaning and disinfectant agents. Any cleaning and disinfectant agents must be compatible with the material used in the burs.

STEAM STERILISATION

These sterilisation instructions are applicable to burs initially provided non-sterile.

If using an autoclave with a pre-vacuum cycle, pack the burs in dedicated instrument trays or pouches validated for steam sterilisation. If using an autoclave without a pre-vacuum (gravity displacement) cycle, the burs should to be packed or wrapped but should be contained in dedicated bur stand with perforated lids.

Note: local legislation may require that burs are wrapped in pouches for processing in either type of autoclave. If legislation is that unwrapped products are sterilised, use immediately after sterilisation and do not store.

STEAM STERILISATION INSTRUCTIONS

Use the following cycle times:



Cycle Time	Exposure Times (Min)	Temperature	Drying Times (Min)
Pre-vacuum (4 pulses)	3	134°C	30
Gravity Displacement	10	134°C	30

Warnings;

1. Ensure the maximum load as stipulated by the manufacturer of the steriliser is not exceeded.
2. Ensure the minimum drying time (30 mins) is not compromised as failure to achieve this could result in a build-up or moisture and the burs corroding.

STORAGE

The burs should be stored in the sterilisation container (bur stand or Protect+ Self Seal Sterilisation Pouch PP002/5000) until required. Containers or pouches must be dried before opening to avoid recontamination of the contents. Storage should be in dry, clean conditions and at ambient temperature.

SHELF LIFE

The burs should be stored in the sterilisation container (stand or pouch) until required. Storage should be in dry, clean conditions and at ambient temperature.

Reprocessing will have little effect of Prefection Plus Dental burs. The end of life is determined by wear and damage in use and the burs should be inspected for any defects before use.

WARNING!

Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore keep unclean burs in a cleaning/ disinfecting solution for a maximum of 12 hrs in accordance with manufacturer's instructions. Cleaning agents with chlorine or Chloride as the active ingredient are corrosive to stainless steel and must therefore NOT be used. Cleaning agents with a neutral pH are recommended.

Do not soak in a solution that has a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

Hazard and precautionary statements:

Used burs should be considered as bio-hazard and should be discarded as bio-hazard waste unless reprocessing as above. Appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.

Caution



Should a serious incident in relation to the product occur, it should be reported to the manufacturer and the competent authority.

Batch code/Expiry Date

See packaging for batch and expiry date. Do not use after expiry date. Please quote this batch number in all correspondence.



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