

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. The bur pattern will be selected to cut a specific material in a specific application. For best performance always match the bur to the task to be performed. TC Burs are task specific, each bur is designed for a particular area of use during endodontic access and canal exploration.

Application	TC BUR Type	Material	Size (mm)	Bur Pattern	Speed
Cavity preparation	Standard	Enamel/ Dentine	010-023	2-8, 57, 556, 557	450,000
Removal of fillings	Standard	Amalgam/ Composite	010-018	330-331	60,000-120,000
Excavation	Standard	Enamel/ Dentine/ Bone	010-023	2-8, 35	<2,000
Finishing margins	Finishing	Enamel	010-016	57	10,000-20,000
Finishing restorations	Finishing	Amalgam	012-023	245	18,000-30,000
Finishing restorations	Finishing	Composite	012-023	557, 57	10,000-20,000
Finishing restorations	Finishing	Glass Ionomer	012-023	557, 57	10,000-20,000
Cutting bone	Standard	Bone	018-027	2-8	500-3,000
Crown & Bridge finishing	Finishing	C&B polymer	010-016	557, 57	40,000-80,000
C&B metal trimming	Standard	Metals	018-027	1157-1158, 1557-1558	<30,000
Prosthetic polymer trimmer	Standard	Polymer	018-027	1157-1158, 330	<20,000

PRECAUTIONS

1. **Always wear gloves** when handling contaminated instruments.
2. **Eye protection must be worn** to protect against ejected particles
3. **Surgical face mask must be worn** to avoid inhalation of aerosol or dust generated
4. **Before each use** inspect the burs for damaged blades or excessive wear. **Discard any worn/damaged burs.**
5. **Ensure the bur is fully seated** and gripped in the hand piece collet.
6. **Maintain handpieces** in good working order and correctly lubricated.
7. **Do not exceed the maximum speeds** as advised above in this IFU.
8. **Do not apply excessive pressure** to the bur.
9. **Move the bur continuously** when in use to avoid localized heating and or damage to the bur.
10. **Clean and sterilize the burs** supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse.
11. Don't use rusted burs
12. When removing burs from a blister pack, always utilize the Solo-Peel tab mechanism. Never use the burs to pierce the rear foil strip as this subject the bur to adverse side loading and introduce undue stress.
13. **Read carefully the labels on 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.

LIMITATIONS OF RE-USE

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

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.

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 in accordance with manufacturer's instructions, but in any event **Do Not** exceed 12 hours.

Caution: Do not leave burs immersed disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

PREPARATION FOR CLEANING

There are no special requirements unless local infection controls require the use of a disinfectant immediately after use, in which case the selected disinfectant must be validated by the user organisation for reprocessing of dental burs, and the disinfectant manufacturer's instructions must be followed.

CLEANING DRYING AND INSPECTION PROCEDURE

MANUAL CLEANING

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

The below procedure has been fully validated:

1. **Rinse** burs and dedicated bur block/stand (if applicable) under cool running water for at least 60 seconds.
2. Place the burs (and bur block/stand) in a fresh bath using a pH-neutral 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.

NOTE: For the purposes of reprocessing validation 'Neodisher MediClean Forte' cleaner/disinfectant by Dr Weigert GmbH & Co. was used.

4. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process
5. Wire brushes must be used with caution, as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.
6. Take the burs out of the bath and rinse under warm running water for at least 60 seconds and until visibly clean.
7. After cleaning **inspect** the burs signs of damage and/or deterioration, with the aid of magnification if necessary, to ensure all that all contamination has been removed. Repeat cleaning process if necessary.
8. Inspect the burs, with the aid of magnification if necessary and discard any damaged or corroded burs.
9. Only relevant burs that are cleaned manually can be dried using either a paper towel, a non-shredding wipe or using filtered pressurized air.

AUTOMATED CLEANING

1. 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.
2. Load burs and dedicated bur block/stand (if applicable) into the washer-disinfector.
3. 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 any 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 manufacturer’s recommendations.
 - **Drying** – purges the load and chamber with heated air to remove residual moisture. Dry heat should not exceed 140°C.
4. On removal from the washer-disinfector, visually inspect to confirm removal of debris, repeat cycle if required.
5. Check all burs for signs of damage and/or deterioration.

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

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 not 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	135°C	30

Warnings;

1. Ensure the maximum load as stipulated by the manufacturer of the sterilizer 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 of moisture and the burs corroding.

STORAGE

The burs should be stored in the sterilisation container (bur stand or pouch) until required. Containers or pouches must be dried before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.

VALIDATION OF CLEANING AND STEAM STERILISATION

The above detailed processes have been validated as being capable of preparing these burs for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing is actually performed, using the equipment, materials and personnel in the reprocessing facility, to achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse events.

WARNING!

Hazard and precautionary statements:

Used burs should be considered as contaminated and 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.

EXPLANATION OF SYMBOLS

For professional use only



LOT NUMBER AND TRACEABILITY

See packaging for Lot. Please quote this lot number in all correspondence.

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