


## **MDT's TC (Tungsten Carbide) Dental Burs- Sterile and Non-Sterile** **Instructions for Use**

### **DESCRIPTION:**

MDT's (Micro Diamond Technologies Ltd) **Tungsten Carbide** Dental Burs are manufactured from a single piece of Tungsten Carbide (TC) or from a TC tip brazed onto a surgical steel stem. The burs are provided sterile or non-sterile.

Burs that are labeled as 'Sterile'  are packed in a dedicated cleanroom facility and sterilized using Gamma Irradiation.

These burs are labeled as single-use   devices and should NOT be reused or re-processed

The *Non-sterile* burs can be **reused**, read the following cleaning and sterilization instructions carefully.

### **PRECAUTION:**

- **The device is to be used as per the following instructions by physician or licensed RxOnly practitioner.**
- **Always wear Gloves** when handling contaminated instruments.
- **Eye protection** must be worn to protect against ejected particles.
- **Surgical mask** must be worn to avoid inhalation of aerosol or dust generated.
- **Before each use**, inspect the burs for damaged blades or excessive wear. **Discard worn burs.**
- Ensure that the bur is **fully seated** and gripped in the handpiece collet.
- **Maintain headpieces** in good working order and correctly lubricated.
- **Do not exceed the maximum speeds** tabulated in this leaflet.
- **Do not activate excessive pressure** on the bur.
- **Move the bur continuously** when in use to avoid localized heating and/or damage to the bur.
- **Clean and sterilize** the burs supplied in a **non-sterile** condition in accordance with the directions below before first use and before each reuse.
- Don't use rust burs.
- 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 introduces undue stress.
- **Read carefully the labels on the bur.**

## APPLICATIONS - TC BURS

MDTs' TC burs can be used to cut, grind or polish 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 will be selected to cut a specific material in a specific application.

For best product performance, always match the bur to the task to be performed. The TC burs are task specific, each bur is designed for a particular area of use during endodontic access and canal exploration.

**For ALL TC burs, the following table provides guidance for M.O.S. selection:**

APPLICATION	TC BUR TYPE	MATERIAL	SIZE (mm)	MDT'S ID NUMBER	SPEED (RPM)
Cavity preparation	Standard	Enamel/Dentine	010-023	FG.TC0002-0008 / 0057 / 0556-0557	<450,000
Removal of fillings	Standard	Amalgam/Composite	010-018	FG.TC0330-0331	60,000-120,000
Excavation	Standard	Enamel/Dentine/Bone	010-023	FG.TC0002-0008 / 0035	<2,000
Finishing margins	Finishing	Enamel	010-016	FG.TC0057	10,000-20,000
Finishing restorations	Finishing	Amalgam	012-023	FG.TC0245	18,000-30,000
Finishing restorations	Finishing	Composite	012-023	FG.TC 557 / 057	10,000-20,000
Finishing restorations	Finishing	Glass ionomer	012-023	FG.TC 557 / 057	10,000-20,000
Cutting bone	Standard	Bone	018-027	FG.TC 0002-0008	500-3,000
Crown & bridge finishing	Finishing	C&B polymer	010-016	FG.TC 557 / 057	40,000-80,000
C&B metal trimming	Standard	Metals	018-027	FG.TC1157-1158 / 1557-1558	<30,000
Prosthetic polymer trimming	Standard	Polymer	018-027	FG.TC 1157 / 1158 / 330	<20,000

## REPROCESSING INSTRUCTIONS FOR NON STERILE LABELED TC BURS –

The **reprocessing instructions** detailed below apply **only** to the non-sterile reusable burs which are being processed prior to each use (both first use and reuses).

**Warning:** Sterile provided Tungsten Carbide dental burs are sold in a sterile microbial barrier packaging for single-use and should NOT be re-used or re-processed in order to avoid device malfunction or contamination.

## LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's TC dental burs. The end of bur's life is determined by wear and damage in use and the burs should be inspected for 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 the unclean burs immersed in the cleaning/disinfecting agent in accordance with its manufacturer instructions, but in any event **do not** exceed 12 hours.

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

## WARNINGS

Used burs should be considered as being 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.

## 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 organization for reprocessing 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 procedure detailed below has been fully validated:**

- 1) **Rinse** the 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 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.

*Note: for the purpose 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 clear.
- 7) After cleaning, **inspect** the burs for signs of damage and/or deterioration, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

- 8) Inspect the burs, with the aid of magnification if necessary and discard any damaged or corroded instruments.
- 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 the burs and dedicated bur block/stand (if applicable) into the washer-disinfector.
- 3) Start the program which will take you through the following pre-programmed cycles:  
**Flush** – removes any hard to clean contamination left over from the manual 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 reprocess,  
**Rinse** – removes traces of the detergent used during 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 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. Ant cleaning and disinfectant agents must be compatible with the material used in the burs.

#### STERILIZATION USING STEAM

These sterilization instructions are applicable to burs initially provided **non-sterile** and to **non-sterile** burs that are being **reused**. No sterilization before first use is required for burs labeled 'Sterile'.

#### PACKAGING FOR STERILIZATION

If using an autoclave with a pre-vacuum cycle, pack the burs in dedicated instrument trays or pouches validated for steam sterilization.

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 stands with perforated lids.

*NOTE: Local legislation may require that burs are wrapped in pouches for processing in either type of autoclave. If sterilization is unwrapped products are sterilized, use them immediately and **do-not** store them.*

#### STEAM STERILIZATION 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 that 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 moisture and the burs corroding.



### STORAGE

The burs should be stored in the sterilization 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 STERILIZATION

The above detailed processes have been validated as being capable of preparing MDT's dental 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, 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 results.

### STERILE PRODUCT SHELF-LIFE













- On the provision that appropriate storage and handling practices are applied to all unopened pouches, product sterility will be maintained for five (5) years unless sterile package is opened or damaged. **Do-not** use the product if the package is opened or damaged. 
- Sterile provided products are labeled with their expiry date. **Do-not** use the products after their stated expiration date 

### TRACEABILITY

Each package (sterile and non-sterile) includes **Lot number**  on its label. This number must be quoted in any correspondence regarding to the product.

### SYMBOLS INTERPRETATION

Symbols on the product package should be interpreted as follows:

	<i>Do not re-use</i>		<i>Do not re-sterilize</i>
	Consult operating instructions;		Manufacturer
	Catalogue number / Part Number (P/N)		<i>Sterilized using irradiation</i>
	Batch code/number		Use-by date (expiry date)
	Authorized Representative in the European Community		Do not use if package is open or damaged
	CE-Mark Symbol		Prescription device

## CONTACT INFORMATION

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