


**Hasharon Dental TC (Tungsten Carbide) Dental Burs-**  
**Sterile and Non-Sterile**  
**Instructions for Use**

**DESCRIPTION:**

Hasharon Dental **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 practitioner.**

RxOnly

- **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.
- **Read carefully the labels on the bur.**

**APPLICATIONS - TC BURS**

Hasharon Dental 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)	HD'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 Hasharon Dental 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.

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

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

**The procedure detailed below has been validated by Hasharon Dental:**

- 1) **Rinse** the burs under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent labeled for use on dental burs or other similar types of reusable medical instruments, following the agent manufacturer's instructions.

*Note: for the purpose of Hasharon Dental reprocessing validation "DrillActive" cleaner/disinfectant by ad-Arztbedarf GmbH was used.*

- 2) Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process.
- 3) **Wire brushes** must be used with caution, as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.
- 4) After cleaning, **inspect** the burs, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.
- 5) **Dry** the burs using paper toweling or dry heat not exceeding 140°C.
- 6) **Inspect** the burs, with the aid of magnification if necessary and discard any damaged or corroded instruments.

**Ultrasonic cleaning** may also be used prior to sterilization, but the user organization should use only cleansing agents recommended for ultrasonic cleaning and validate the process.

Cleaning by means of an automated washer disinfectant is also possible, but the user organization should validate the process with the selected cleansing and disinfection agents. Any cleansing and disinfecting agents used must be compatible with the materials used in the dental burs; otherwise accelerated corrosion or other damage may occur. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed.

## 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

Follow the autoclave manufacturer's instructions to sterilize the burs. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.

Hasharon Dental has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of six (6) minutes at a temperature of 134°C. The holding time is the **minimum time** for which the minimum temperature is sustained.

Post sterilization allow drying time of 30 minutes.

***NOTE:** Local infection control practice may recommend a different combination of holding time and temperature.*

## 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 Hasharon Dental dental burs for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing as 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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