


**Hasharon Dental**  
**Instructions for Reprocessing *Non-Sterile* - Tungsten Carbide ('TC') Dental burs**

**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 grade stainless-steel stem. The Dental TC burs are part of Hasharon Dental Rotary instruments portfolio available to the clients including diamond coated burs, discs and dental polishers.

The TC dental burs are provided non-sterile (multi-use) 

**SCOPE**

These instructions are applicable to the cleaning of the multi-use TC dental burs prior to initial use, and there after every subsequent re-use. The multi-use dental rotary instruments are supplied mechanically clean, but NOT sterile.

For reprocessing instruction for the diamond coated burs/discs or the dental polishers please follow their specific instruction provided separately.

**INDICATIONS FOR USE**

The products prescribed are used by dentists in dental clinics and hospitals for dental and periodontal applications. The Rotary Instruments can be used to cut or polish a wide variety of materials, including enamel, dentine and bone, amalgam, composite, glass-ionomer cements, polymer/ceramic veneers, zirconia and precious/non-precious metals. Therefore, they are also being used in dental laboratories in addition to the actual clinical use in the patient mouth or chair-side. The Rotary instrument pattern/type is selected in order to cut/grind/polish a specific material in a specific application.

Professional use - Dental Rotary Instruments are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these instruments and its reprocessing procedures based on their training and experience. Therefore, user training is not needed to ensure specified performance, safe use and reprocessing of the medical device.

- a) Used TC dental burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, gloves and a mask should be worn when re-processing.
- b) In the event of TC dental burs being returned to **Hasharon Dental**, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned and sterilized and are appropriately packaged for return.

**STORAGE (pre-use):** Store in a dry and clean environment at ambient temperature.

**GENERAL PRECAUTIONS - PLEASE READ CAREFULLY**

- a) The device is to be used as per the following instructions by physician or licensed practitioner.
- b) Carefully read package labels to ensure appropriate use of the device. Failure to do so may cause procedural delays or patient or user injury.
- c) Failure to follow these instructions can result in cross-contamination that may lead to infection for the patient or user.
- d) Clean and sterilize the device supplied in a non-sterile condition in accordance with the directions below before initial use and after each subsequent use to avoid any risk of contamination.
- e) Wear gloves, mask and eye protecting gear when handling contaminated instruments.
- f) Prior to use inspect the device for broken and/or damaged flutes, rust, or any other visible damage. Discard any potentially defective instrument. Do not use worn- out or dull devices.
- g) Observe the manufacturer's reprocessing materials information in order to ensure material compatibilities for cleaning, disinfection and sterilization
- h) The reprocessing materials exposure time and concentration specified by the manufacturer must be followed.
- i) Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilization.
- j) Strong acids and strong bases may oxidize the stainless-steel shank.

**REPROCESSING INSTRUCTIONS FOR TC DENTAL BURS**

**SCOPE**

The reprocessing instructions detailed below apply only to reusable TC dental burs. instruments shall be reprocessed prior to being reused and upon initial use.

**LIMITATIONS OF RE-USE**

Reprocessing will have little effect on **Hasharon Dental** 's dental TC dental burs. The end of the device life is determined by wear and damage in use and the device 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 instruments immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

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

**WARNINGS**

Used TC dental 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. Used instruments are also considered as bio-hazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done in accordance with these instructions.

<p><b>PREPARATION FOR CLEANING</b></p>	<p>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 for cleaning dental rotary devices shall be used and the manufacturer’s instructions followed.</p>
<p><b>MANUAL CLEANING AND DISINFECTION</b></p>	<p>If manual cleaning is implemented, the instruments should be cleaned in a sink reserved for the purpose</p> <p>MANUAL CLEANING</p> <ol style="list-style-type: none"> <li>1. Rinse the burs and dedicated bur block/stand (if applicable) under cool running water for at least 60 seconds</li> <li>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 the cleaning agent/manufacturer’s instructions. Soak for at least 10 minutes.</li> <li>3. After soaking and keeping the burs immersed, using a soft bristle brush, brush away from the body in a slow controlled manner so as to avoid spreading contaminants by spraying and/or splashing</li> <li>4. Take the burs out of the bath and rinse under warm running water for at least 60 seconds and until visibly clean</li> <li>5. Inspect the burs thoroughly for any signs of damage and/or deterioration such as corrosion, pay particular attention to the flutes, teeth and shanks for any chips/cracks, chatter marks, distortion and general wear &amp; tear. Any found in condition which causes concern, must be immediately discarded.</li> </ol> <p>MANUAL DISINFECTION</p> <ol style="list-style-type: none"> <li>1. Immerse the burs in a disinfection bath adhering to the manufacturer’s instructions, ensure all burs are sufficiently submerged</li> <li>2. After disinfecting, rinse the burs thoroughly with running water to remove all remaining chemicals</li> <li>3. Dry the burs using either a paper towel, a non-shredding wipe or using filtered pressurized air.</li> </ol> <p>Note: Validated using cleaning agent Nedisher MediClean Forte (Dr Weigert GmbH &amp; Co. KG Hamburg) and 80% Ethanol as the Disinfectant.</p>
<p><b>AUTOMATED CLEANING (DIAMOND BURS AND TC)</b></p>	<p><b>PRE-CLEANING –</b>          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.</p> <p><b>Automated Cleaning Procedure – Tungsten Carbide dental burs</b></p> <ol style="list-style-type: none"> <li>1. Load the burs and dedicated bur block/stand (if applicable) into the washer-disinfector</li> <li>2. Start the program which will take you through the following programmed cycles:           <ul style="list-style-type: none"> <li>• <b>Flush</b> – removes any hard to clean contamination left over from the manual pre-clean,</li> </ul> </li> </ol>

	<ul style="list-style-type: none"> <li>• <b>Wash</b> – removes any remaining contamination, detergents used must be specified by the manufacturer as suitable for use in washer-disinfectors and the instruments being reprocess,</li> <li>• <b>Rinse</b> – removes traces of the detergent used during the washing process,</li> <li>• <b>Thermal Disinfection</b> – The temperature of the load is held at the pre-set disinfection temperature for the required holding time, refer to manufacturer's recommendations,</li> <li>• <b>Drying</b> – purges the load and chamber with heated air to remove residual moisture. Dry heat should not exceed 140°C.</li> </ul> <ol style="list-style-type: none"> <li>3. On removal from the washer-disinfector, visually inspect to confirm removal of debris, repeat cycle if required</li> <li>4. Inspect the burs thoroughly for any signs of damage and/or deterioration such as corrosion, pay particular attention to the flutes, teeth and shanks for any chips/cracks, chatter marks, distortion and general wear &amp; tear. Any found in condition which causes concern, must be immediately discarded.</li> </ol> <p>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 dental rotary instruments.</p>
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### STERILIZATION - USING STEAM

#### SCOPE


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

<b>PACKAGING FOR STERILIZATION</b>	<p>If using a vacuum autoclave with a pre-vacuum cycle, pack the burs in dedicated instrument trays or pouches validated for steam sterilization.</p> <p>If using a non-vacuum autoclave, the burs shall be contained in a dedicated bur stands with perforated lid, or pouch validated for sterilization.</p> <p>Assure Plus sterilization pouches were validated for the TC dental burs.</p> <p><b>NOTE:</b> Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave.</p>												
<b>STEAM STERILIZATION</b>	<p>Follow the autoclave manufacturer's instructions to sterilize the instrument. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.</p> <ol style="list-style-type: none"> <li>1) Place the packaged products in the sterilization chamber</li> <li>2) Start the program</li> </ol> <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Program</th> <th>Exposure time</th> <th>Cycle temperature (°C)</th> <th>Drying time (Min.)<sup>1</sup></th> </tr> </thead> <tbody> <tr> <td>Pre-vacuum (4 pulses)</td> <td>3</td> <td>134 °C</td> <td>30</td> </tr> <tr> <td>Gravity displacement</td> <td>10</td> <td>135 °C</td> <td>30</td> </tr> </tbody> </table> <p><sup>1</sup>Ensure the minimum drying time is not compromised as failure to achieve this could result in a build-up moisture and the burs corroding.</p> <ol style="list-style-type: none"> <li>3) Remove the instruments at the end of the program and allow to cool down</li> <li>4) check the packaging for possible damage and screening effects</li> <li>5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.</li> </ol> <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature.</p>	Program	Exposure time	Cycle temperature (°C)	Drying time (Min.) <sup>1</sup>	Pre-vacuum (4 pulses)	3	134 °C	30	Gravity displacement	10	135 °C	30
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<b>STORAGE</b>	<p>The burs should be stored in their sterilized pouches until required for use.</p> <p>Pouches must be dry before opening to avoid recontamination of the contents with water.</p> <p>Storage should be in dry, clean conditions and at ambient temperature.</p>												

#### VALIDATION OF CLEANING AND STEAM STERILIZATION












The above detailed processes *have been validated* as being capable of preparing Hasharon Dental's TC 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. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

### TRACEABILITY



Each package includes **Lot number**  on its label.

This number must be quoted in any correspondence regarding to the product.

### GLOSSARY OF SYMBOLS

	Catalogue number / Part Number (P/N)
	Batch code/number
	Manufacturer
	Date of manufacturing
	Consult Instruction for use
	Non-Sterile Product
	Keep Dry
	Medical Device
	Wear mask and eye protection gear while operating
	Maximum speed
	(ref US FDA CDRH) DEVICE for professional use only

### CONTACT INFORMATION

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