

BRASSELER USA CARBIDE Burs

BRASSELER USA Carbide Burs are available in Sterile and Non-Sterile models under various trade names with numerous head diameters and working lengths. The devices are reusable and can be sterilized using steam sterilization in a gravity or prevacuum cycle.

Description

The BRASSELER USA CARBIDE Dental Bur family includes Clinical Carbides and Laboratory Carbides. A CARBIDE dental bur is a rotary cutting device made of stainless steel, the working end of which is made from tungsten carbide, and which is designed to fit into a dental handpiece. Alternatively, the device may be constructed wholly from tungsten carbide. BRASSELER USA CARBIDE Burs are reusable devices.

Intended Use

BRASSELER USA CARBIDE Burs fit into a dental handpiece, which provides the rotation, allowing the user to cut hard structures in the mouth, e.g., teeth or bone. BRASSELER USA CARBIDE Burs can also be used to cut hard metals, plastics, porcelains and similar materials.

Contraindications

- CARBIDE Burs contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.



WARNINGS AND PRECAUTIONS

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Attention should be paid to the speed of work (RPM)
 - Always refer to the product packaging for the Maximum RPM. Use of the bur beyond the RPM range may cause the bur to break and result in patient or user harm.
 - Operating a bur with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Proper irrigation is required while using the device. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Do not apply excessive pressure on the bur as this could cause undesirable heat or may cause the bur to fail and cause patient or user injury.
- ② Devices marked as single use are not intended to be used on more than one patient. Use on more than one patient may lead to decreased cutting efficiency which could result in device failure or generation of undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- CARBIDE Burs must be thoroughly cleaned and steam sterilized prior to the first use and each subsequent reuse to prevent the risk of infection or cross-contamination.
- CARBIDE Burs labeled “Sterile” require no further action prior to first use but must be thoroughly cleaned and steam sterilized prior to each subsequent reuse to prevent the risk of infection or cross-contamination.
 - If the packaging for “Sterile” labeled devices is opened or damaged or is past its expiration date, the device must be thoroughly cleaned and steam sterilized prior to use and each subsequent reuse to prevent the risk of infection or cross-contamination.
- Do not use chemical or dry heat to sterilize CARBIDE Burs, as these processes have not been validated for use. Use of these processes may be corrosive to the device and could result in premature device failure.
- Proper cleaning is required after use of the device to prevent cross-contamination. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.

- Use a rubber dental dam while using CARBIDE Burs to avoid possible aspiration or swallowing of the device.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Eye protection must be worn to protect against eject particles which could cause user injury.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated that could cause possible infection/cross-contamination.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.
- Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the CARBIDE Burs.
- Always inspect the burs before use:
 - Use of worn-out or dull burs could cause undesirable heat or may cause the device to fail.
 - Use of bent burs could cause vibration that may cause patient discomfort or damage to the preparation site.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
- Never force a bur (or converter) into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- Ensure that the bur is properly assembled to the converter before operation of the device. Failure to do so may lead to injury of the patient or user or aspiration or swallowing of the device.
- Bur Blocks used to hold the devices for storage and steam sterilization are not intended to maintain sterility of the device. Burs should be stored in the sterilization pouch to prevent cross-contamination.
- Do not force CARBIDE Burs into Bur Blocks as this could cause damage to the bur or cause it to become lodged in the Bur Block.
- This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm. For more information go to www.p65Warnings.ca.gov.

General Instructions

1. Clean and sterilize non-sterile burs in accordance with the validated procedures provided below prior to first use and prior to each reuse.
2. Do not force a bur into the handpiece. In case of difficult access, check both handpiece turbine and bur and refer to handpiece instructions for troubleshooting.










Cleaning and Sterilization Instructions

Scope	These instructions are applicable to all Carbide Dental Burs. They are applicable before initial use and after each subsequent use. Carbide Burs are provided mechanically clean, but are not sterile (unless labeled “STERILE”). Therefore, Carbide Burs should be sterilized before first use.
Warnings	<ol style="list-style-type: none"> 1. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended. 2. Do not use Cold Sterilizing Methods for the sterilization of Carbide Burs. These agents often contain strong oxidizing chemicals that may dull or weaken Carbide Burs.

Reprocessing Limitations	The end of life is determined by wear and damage in use. Carbide Burs should be inspected for defects (i.e. broken tips, broken sections on flutes, etc.) during the cleaning process.
Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.
Containment/ Transportation	Carbide Burs can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in degradation of the product and must be avoided.
Manual Cleaning Procedure	<p>If hand cleaning is the only available option, Carbide Burs should be cleaned in a sink reserved for cleaning instruments.</p> <p>Rinse the Carbide Bur (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute.</p> <p>Prepare a fresh bath of neutral-pH cleaning solution (such as Enzol). Follow the cleaning agent's manufacturer's instructions. Immerse the Carbide Bur (and instrument block) and soak for at least ten (10) minutes.</p> <p>After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.</p> <p>Special care should be taken to clean crevices and other hard-to-reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p> <p>Thoroughly rinse the Carbide Bur (and instrument block) under running warm water for at least one (1) minute and until visibly clean.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>
Ultrasonic Cleaning Procedure	<p>Prepare a fresh pH-neutral cleaning solution (such as Enzol); place the Carbide Bur in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the cleaning agent manufacturers' instructions for correct concentration, exposure time, temperature, and water quality. Completely submerge the device in the cleaning solution and sonicate for at least fifteen (15) minutes.</p> <p>Perform a final thorough rinse of the device and instrument block (if applicable) under running warm tap water for at least (1) minute.</p> <p>Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>
Inspection Testing	<ol style="list-style-type: none"> 1. Carefully inspect each device to ensure that all debris has been removed. 2. Visually inspect the device for damage/ wear that would prevent proper operation. <ol style="list-style-type: none"> a. Do not use if the tip is broken. b. Do not use if there is a broken section of a flute. c. Do not use if there is evidence of corrosion.
Packaging	<p>Singly: Pack the Carbide Bur in pouches validated for sterilization</p> <p>In Sets: Place the Carbide Bur in the dedicated instrument block.</p>

Sterilization	Use the following cycle for steam sterilization												
	<table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Minimum Sterilization Exposure Time (minutes)</th> <th>Minimum Sterilization Exposure Temperature</th> <th>Minimum Dry Time (minutes)</th> </tr> </thead> <tbody> <tr> <td>Gravity</td> <td>10</td> <td>135°C (275°F)</td> <td>30</td> </tr> <tr> <td>Pre-vacuum (4 Pulses)</td> <td>3</td> <td>134°C (273°F)</td> <td>30</td> </tr> </tbody> </table>	Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)	Gravity	10	135°C (275°F)	30	Pre-vacuum (4 Pulses)	3	134°C (273°F)	30
Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)										
Gravity	10	135°C (275°F)	30										
Pre-vacuum (4 Pulses)	3	134°C (273°F)	30										
	<p>Ensure that the sterilizer manufacturer’s maximum load is not exceeded.</p> <p>The minimum dry time has been validated to ensure that the devices will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the burs that could result in corrosion.</p>												
Storage	The Carbide Bur should be stored in the sterilization pouch (or instrument block) until required.												
Additional Information	These processes have been validated as being capable of preparing Carbide Burs for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.												

Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Revolution (RPM)	ISO 21531
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
	Do not re-use – Single Patient Use	ISO 15223-1
<i>Rx Only</i>	Caution: Federal law restricts this device to sale by or on the order of a “dentist/physician” licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
<i>Made in</i>	Made in	N/A
	Manufacturer/Legal Manufacturer	ISO 15223-1



Brasseler U.S.A. Dental, LLC
 One Brasseler Blvd.
 Savannah, GA 31419 USA
 Telephone 912-925-8525