

## BRASSELER USA DIAMOND Burs

BRASSELER USA LGI DIAMOND Burs are available in Sterile models with numerous head diameters, shapes and working lengths. The devices are reusable and can be reprocessed using steam sterilization in a gravity or prevacuum cycle.

### Description

The BRASSELER USA LGI DIAMOND Dental Bur family includes Clinical Diamond Burs. A DIAMOND dental bur is a rotary abrading device made of stainless steel which is coated with diamond particles on the working end, and which is designed to fit into a dental handpiece. BRASSELER USA LGI DIAMOND Burs are reusable devices.

### Intended Use

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

### Warnings and Precautions

Warning: Attention should be paid to the speed of work (RPM)

- Always refer to the product packaging for the Maximum RPM
- Operating a bur with too high of an RPM may generate undesirable heat
- Operating a bur with too high of an RPM may cause the bur to fail

- LGI DIAMOND Burs are labeled “Sterile” and require no further action prior to first use but must be thoroughly cleaned and steam sterilized prior to each subsequent reuse
  - If the packaging for “Sterile” labeled devices is opened or damaged, the device must be thoroughly cleaned and steam sterilized prior to use and each subsequent reuse
- Do not use chemical or dry heat to sterilize BRASSELER USA LGI DIAMOND Burs, as these processes have not been validated for use
- Do not use worn-out or dull burs
- Do not apply excessive pressure on the bur as this could cause undesirable heat or may cause the bur to fail
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage
- Carefully read package labels to ensure use of the appropriate device
- Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device
- Use a rubber dental dam while using LGI DIAMOND Burs to avoid possible aspiration or swallowing
- Always wear gloves when handling contaminated instruments
- Eye protection must be worn to protect against eject particles
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated
- BRASSELER USA Bur Blocks used to hold the devices for storage and steam sterilization are not intended to maintain sterility of the device

## General Instructions

1. The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
2. Clean and sterilize non-sterile burs in accordance with the validated procedures provided below prior to first use and prior to each reuse.
3. Do not force 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 BRASSELER USA LGI Diamond Dental Burs. LGI Diamond Burs are provided STERILE, but should be cleaned and sterilized before subsequent reuse. These instructions should also be followed if the STERILE packaging has been compromised.
Warnings	<ol style="list-style-type: none"> <li>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.</li> <li>2. Do not use Cold Sterilizing Methods for the sterilization of Diamond Burs. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.</li> </ol>
Reprocessing Limitations	The end of life is determined by wear and damage in use and Diamond Burs should be inspected for defects (i.e. broken tips, missing diamond particles, 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	Diamond 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, Diamond Burs should be cleaned in a sink reserved for cleaning instruments.</p> <p><i>Optional step: Insert the Diamond Bur into a handpiece and operate at the Maximum RPM. Insert the Diamond Bur head fully into a wet diamond cleaning stone for at least 2 seconds. Remove Diamond Bur from handpiece.</i></p> <p>Rinse the Diamond 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. Follow the agent's manufacturer's instructions. Immerse the Diamond 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 Diamond 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	Prepare a fresh pH-neutral cleaning solution; place the Diamond Bur in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the agent manufacturers' instructions for correct

	<p>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"> <li>1. Carefully inspect each device to ensure that all debris has been removed.</li> <li>2. Visually inspect the device for damage/ wear that would prevent proper operation. <ol style="list-style-type: none"> <li>a. Do not use if the tip is broken.</li> <li>b. Do not use if there are missing or worn diamond particles.</li> <li>c. Do not use if there is evidence of corrosion.</li> </ol> </li> </ol>												
Packaging	<p>Singly: Pack the Diamond Bur in pouches validated for sterilization</p> <p>In Sets: Place the Diamond Bur in the dedicated instrument block.</p>												
Sterilization	<p>Use the following cycles for steam sterilization</p> <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> <p>Ensure that the sterilizer manufacturer's maximum load is not exceeded.</p>	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
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Storage	<p>The Diamond Bur should be stored in the sterilization pouch (or instrument block) until required.</p>												
Additional Information	<p>These processes have been validated as being capable of preparing LGI Diamond Burs for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.</p>												

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