

Instructions for Use

BRASSELER USA BRIOPREP™ STERILE DIAMOND BURS

BRIOPREP™ STERILE DIAMOND BURS are available in Sterile models with numerous head diameters, shapes and working lengths.

Description

The BRIOPREP™ STERILE 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.

Intended Use

BRIOPREP™ STERILE 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. BRIOPREP™ STERILE DIAMOND BURS can also be used to abrade hard metals, plastics, porcelains and similar materials.



Warnings and Precautions

- BRIOPREP™ STERILE DIAMOND BURS are Single use. **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.
- 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.
- BRIOPREP™ STERILE DIAMOND BURS are labeled "Sterile" and require no further action prior to first use.
 - If the packaging for "Sterile" labeled devices is opened or damaged, the device must be thoroughly cleaned and steam sterilized prior to use to prevent the risk of infection or cross-contamination.
 - Do not use chemical or dry heat to sterilize BRIOPREP™ STERILE DIAMOND 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.
- Use a rubber dental dam while using BRIOPREP™ STERILE DIAMOND BURS to avoid possible aspiration or swallowing of the device.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause 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 BRIOPREP™ STERILE DIAMOND BUR.

Contraindications

- BRIOPREP™ STERILE DIAMOND BURS contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.

Precautions

- Always inspect the burs before use. Use of dull burs could cause undesirable heat or may cause the device to fail.
- 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 and 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 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 disc into a handpiece as this could cause damage to the handpiece collet.
- Eye protection must be worn to protect against eject particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.



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- BUSA Bur Blocks used to hold the devices for storage and steam sterilization are not intended to maintain sterility of the device.

General Instructions

1. Clean and sterilize non-sterile burs (only if the packaging for "Sterile" labeled devices is opened or damaged) in accordance with the validated procedures provided below prior to first use.
2. 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 BRIOPREP™ STERILE DIAMOND BURS. They are applicable before initial use (only if the packaging for "Sterile" labeled devices is opened or damaged).
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 BRIOPREP™ STERILE DIAMOND BURS. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.
Reprocessing Limitations	The BRIOPREP™ STERILE DIAMOND BURS are single use medical devices and should not be reprocessed.
Point of Use	BRIOPREP™ STERILE DIAMOND BURS should be immediately used upon opening the primary package (pouch).
Containment/ Transportation	Diamond Burs and Discs 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, the Diamond Bur 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 cleaning 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	<p>Prepare a fresh pH-neutral cleaning solution; place the Diamond Bur or Disc 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 are missing or worn diamond particles. c. Do not use if there is evidence of corrosion.
Packaging	<p>Singly: Pack the Diamond Bur or Disc in pouches validated for sterilization</p> <p>In Sets: Place the Diamond Bur or Disc in the dedicated instrument block.</p>



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Sterilization	Use the following cycle for steam sterilization			
	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
	Ensure that the sterilizer manufacturer's maximum load is not exceeded. 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 bur that could result in corrosion.			
Storage	The Diamond 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 Diamond Burs for use only if sterile packing was compromised. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.			

Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1:2012 / EN 980:2008
	Batch Code	ISO 15223-1:2012 / EN 980:2008
	Quantity	N/A
	Revolution (RPM)	ISO 21531:2009
	Sterile using irradiation	ISO 15223-1:2012 / EN 980:2008
	Use-by date	ISO 15223-1:2012 / EN 980:2008
	Consult instructions for use	ISO 15223-1:2012 / EN 980:2008
	Caution	ISO 15223-1:2012 / EN 980:2008
	Do not use if package is damage	ISO 15223-1:2012 / EN 980:2008
	Do not re-use	ISO 15223-1:2012 / EN 980:2008
Rx Only	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)
	Manufacturer/Legal Manufacturer	ISO 15223-1:2012 / EN 980:2008