

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














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General Instructions

1. 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.

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
	Non-sterile	ISO 15223-1:2012 / EN 980:2008
	Do not-reuse – Single Patient Use	ISO 15223-1:2012 / EN 980:2008
<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)
	Manufacturer/Legal Manufacturer	ISO 15223-1:2012 / EN 980:2008

