maxill

Instructions For Use

OHIO FORGE EDGE™

DIAMOND BURS

MULTI-PATIENT-USE







The product can be reused if it is properly cleaned and sterilized.
LIMITATION OF USE: Recommended to reprocess no more than 5 times.

Indication for Use

For professional use only. Ohio Forge EDGE Diamond Burs are a cutting device for use in dental procedures with a high-speed rotary handpiece. They can be used on a variety of materials, such as bone, enamel, dentin, and restorative materials such as hard metals and composites.

Sterile Diamond Burs

Do not use if the package is open or damaged. The sterile diamond bur does not require prior cleaning and sterilization. If you choose to reuse, follow the cleaning and sterilization guidelines outlined above.

Non-Sterile Diamond Burs

The non-sterile diamond dental burs require prior cleaning and sterilization. Follow the cleaning and sterilization guidelines outlined above **before** use.

Cleaning Instructions

Manual Cleaning

- Use area specifically reserved for cleaning devices.
- Rinse the burs in running water and keep them immersed in a bath of enzymatic detergent solution, following the manufacturer's instructions.
- After soaking and keeping submerged, brush well away from the body with the neutral cleaning agent. Care should be taken to avoid spreading contaminants from the spray during brushing actions. Do not use wire brushes.
- Special care should be taken to clean cracks and other hard-to-reach areas. Inspect visually to confirm debris removal, repeat the cycle if necessary.
- Wash the device with running water until it is visibly clean.
- Dry the device with clean compressed air or paper towels.

Ultrasonic Cleaning

- Prepare an enzymatic detergent solution by following the agent manufacturer's instructions for the correct concentration, exposure time, temperature and water quality.
- Completely immerse the device in the cleaning solution and program the ultrasonic bath for at least fifteen (15) minutes.
- Wash the device with running water until it is visibly clean
- Dry the device with clean compressed air or paper towel

Spaulding's Classifications

maxill inc.

Canadian Head Office
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Rev.0: 2024-12-05
MP-REF-DMFG0143D

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Sterilization Requirements For Diamond Burs (sterile and non-sterile)

- This applies to Ohio Forge EDGE Diamond Burs purchased in non-sterile packaging for reuse.
- It is recommended that Ohio Forge EDGE Diamond Burs be sterilized by steam autoclave properly packaged in its own autoclave packaging or the sterilization parameters must be followed in accordance with the relevant policies/regulations of the country where the device is being used.
- it is the full responsibility of the professional to keep the autoclave equipment updated to ensure the correct sterilization of the device.

	GRAVITY DISPLACEMENT (STEAM)	PRE-VACUUM (STEAM)
TEMPERATURE	121°C (250°F)	132°C (270°F)
STERILIZATION TIME	15 minutes	4 minutes
DRYING TIME	15-30 minutes	20 minutes

DESCRIPTION	QTY	SKU	Device Identifier on Health Canada Lics. 110254/170197	MAX RPM
Ohio Forge EDGE Diamond MU, 392-016F	100	DMFG0143	1378F	450,000
Ohio Forge EDGE Diamond MU, 830-010C	100	DMFG0144	1143C	450,000

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Precautions

- Prolonged immersion of Ohio Forge Diamond burs in disinfectant solutions can cause corrosion and should therefore be avoided.
- Do not use cold sterilization methods (chemical process) to sterilize the diamond burs. These chemical agents can cause corrosion of the products.
- Do not use sodium hypochlorite as a cleaning agent, as it may cause corrosion.
- Do not use the device in patients allergic to any tungsten carbide component.
- Respect the working speed (max RPM) to prevent excess friction heat or possible fracturing of the diamond bur.
- Wear personal protective equipment such as masks, gloves, and protective eyewear.
- Ensure patients are also wearing protective eyewear during the use of diamond burs.
- The disposal of the material must follow the relevant local guidelines.

Storage

- For sterile-supplied products: sterilization will only be guaranteed if the packaging is not open or damaged.
- The product must be stored in an airy, dry, and protected from light place to maintain optimal storage and transport conditions, as well as physical and chemical integrity.

Additional Information

- The aforementioned sterilization processes described have been validated and are suitable and effective for the use of diamond cutters. maxill is not responsible if the instructions for use are not followed correctly, generating results not intended for the efficacy and safety of the product/patient.

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132 +/- 2°C

NON STERILE

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