

Instructions For Use



#### INTENDED USE

Beves\*

Beyes Dental Bur is designed to fit into a dental handpiece that provides the rotation allowing the user to cut hard structures in the mouth, such as teeth or bone.

### DESCRIPTION

Beyes Dental Burs instruments are made of a single piece of hardness stainless steel, coated with diamonds, for dental clinic applications.

# SAFETY IN USE

#### . Read precautions carefully

• The device is to be used on the instruction of and by a dentist or other licensed practitioner. Rx only.

 Clean and sterilize burs in accordance with the directions below before first use and before each reuse.

- Always wear gloves when handling contaminated instruments.
- · Eye protection must be worn to protect against ejected particles.

 Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.

- Ensure that the bur is securely gripped in the handpiece collet.
- Do not use worn-out diamonds.
- Maintain handpieces in good working order and correctly lubricated.
- Do not exceed the maximum speeds tabulated in this leaflet.
- Do not apply excessive pressure on the diamond.

 Avoid removing the diamond at too sharp an angle to avoid leverage and breakage.

 Move the diamond continuously when in use to avoid localized heating and/or damage to the diamond.

Read carefully the labels on the packaging.

#### DIAMOND INSTRUMENT guidance for maximum RPM:

Instrument head diameter 01/10 (mm) - ISO	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007- 010	450,000	100,000-220,000
012 -014	450,000	70,000 - 220,000
016 -018	450,000	55,000 - 160,000
021 -023	300,000	40,000 - 120,000
025-027	160,000	35,000 - 110,000
029 -031	140,000	30,000 - 95,000
033-040	120,000	25,000 - 75,000
042-050	95,000	15,000 - 60,000

#### INSTRUCTIONS FOR CLEANING AND STERILIZING DENTAL ROTARY INSTRUMENTS

Multi-Use Diamonds are available non-sterile. Non-sterile burs are recommended to be cleaned and sterilized before first use and each subsequent use.

# CONTAINMENT AT THE POINT OF USE

Delay between use and reprocessing must be kept to a minimum.
Keep the unclean diamonds immersed in the cleaning/disinfecting agent in accordance with its manufacturer's instructions, but in any event do not exceed 12 hours.

•  $\triangle$  Caution: Do not leave diamonds immersed in disinfectants that have a fixative action (such as aldehyde based products) unless the diamonds have been thoroughly cleaned first.

# CLEANING, DRYING AND INSPECTION PROCEDURE MANUAL CLEANING:

1) Rinse the diamond under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent labeled for use on dental diamond or other similar types of medical instruments, following the manufacturer's instructions.

2) Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process.

3) Wire brushes must be used with caution, as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel.

4) After cleaning, inspect the diamonds, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

5) Dry the diamonds using paper toweling or dry heat not exceeding 140°C. 6) Inspect the diamonds with the aid of magnification if necessary and discard any damaged or corroded instruments.

# **AUTOMATED CLEANING**

Cleaning by means of an automated washer disinfector: Any cleansing and disinfecting agents used must be compatible with the materials used in the dental burs, otherwise accelerated corrosion or other damage may occur. The washer disinfector and the cleaning agent manufacturers' instructions must be followed if using an autoclave with a pre-vacuum cycle, pack the diamonds in dedicated instrument trays or pouches validated for steam sterilization.

If using an autoclave without a pre-vacuum cycle, the diamonds should not be packed or wrapped but should be contained in dedicated diamonds stands with perforated lids.

**NOTE:** Local legislation may require that diamonds are wrapped in pouches for processing in either type of autoclave.

### STERILIZATION

Follow the autoclave manufacturer's instructions to sterilize the diamonds. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.

Manufacturer has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of six minutes at a temperature of 134 °C. The holding time is the minimum time for which the minimum temperature is sustained.

**NOTE:** Local infection control practice may recommend a different combination of holding time and temperature.

# STORAGE

The diamonds should be stored in the dry sterilization container (bur stand or pouch) until required. Storage should be in dry, clean conditions and at ambient temperature.

# VALIDATION OF CLEANING AND STEAM STERILIZATION

Any deviation from these instructions should be properly evaluated by the user for effectiveness and potential adverse results.

Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the states in which he or she practices to use or order the use of this device. Beyes Dental Canada Inc. is not responsible for any typographical errors. Subjects to technical changes which our hold:

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