

## **Instruction for Use – Non Sterile Multi-Use Diamond Dental Burs**

### **Description**

**Diamond dental burs** are made of a single piece of hardened stainless steel, coated with diamonds, for dental clinic applications.

The burs are provided sterile and non-sterile. Burs that are labeled as '**Sterile**' 

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 must be discarded after a single use. ☒

*The **Non-sterile*** burs can be reused following cleaning and sterilization instructions carefully.

### **SAFETY IN USE –Read precautions carefully:**

- The dental rotary instrument is intended for laboratory and dental applications in dental clinics and hospitals by licensed dentist (except for laboratory applications, where the instrument is used by licensed technician). Rx only
- Clean and sterilize the burs supplied in a non-sterile condition 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 aerosol or dust generated.
- Ensure that the bur is fully seated and gripped in the hand piece collet.
- Before each use, inspect the burs for excessive wear. Discard worn burs.
- Maintain hand piece in good working order and correctly lubricated.
- Do not exceed the recommended maximum operative speeds.
- Do not apply excessive pressure on the bur.
- Avoid using the bur at too high an angle in order to avoid leverage and breakage.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur.
- Do not use rusted burs.
- Read carefully the labels on the bur package.

### **APPLICATIONS**

MDT Diamond burs can be used for a wide variety of restorative procedures including but not limited to: removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, preparation of crowns, orthodontic device procedure and any other dental operation.

The bur pattern to be selected for specific application.

For best product performance, always match the bur to the task to be performed.

The following table provides recommended RPM

Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024- 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
080 - 100	45,000	10,000 - 20,000

## REPROCESSING INSTRUCTIONS FOR DENTAL ROTARY INSTRUMENTS

### SCOPE

The reprocessing instructions detailed below apply only to reusable burs. Burs shall be reprocessed prior to being reused.

### LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's dental burs. The end of bur's life is determined by wear and damage in use and the burs should be inspected for defects during the preliminary cleaning process.

Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean burs immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours.

Caution: Do not leave burs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

### WARNINGS

Used burs should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.

Used burs are also considered as bio-hazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according the above instructions.

### Preparation for Cleaning

There are no special requirements unless local infection controls require the use of a disinfectant immediately after use, in which case the selected disinfectant must be validated by the user

organization for reprocessing dental burs, and the disinfectant manufacturer's instructions must be followed.

### **CLEANING, DRYING AND INSPECTION PROCEDURE**

If manual cleaning is implemented, the burs should be cleaned in a sink reserved for the purpose.

- 1) Rinse the burs 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 burs or other similar types of reusable medical instruments, following the agent 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 burs, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.
- 5) Dry the burs using paper toweling or dry heat not exceeding 140°C.
- 6) Inspect the burs, with the aid of magnification if necessary and discard any damaged or corroded instruments.

Ultrasonic cleaning may also be used prior to sterilization, but only cleansing agents recommended for ultrasonic cleaning should be used and the user must validate the process.

Cleaning by means of an automated washer disinfectant is also possible, but the user should validate the process with the selected cleansing and disinfection agents. 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 disinfectant and the cleaning agent manufacturers' instructions must be followed.

### **STERILIZATION - USING STEAM**

#### **SCOPE**

These sterilization instructions applicable to burs initially provided non-sterile and to non-sterile burs that are being reused. No sterilization before first use is required for burs labeled 'Sterile'.

#### **PACKAGING FOR STERILIZATION**

If using an autoclave with a pre-vacuum cycle, pack the burs in appropriate instrument trays or pouches validated for steam sterilization.

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

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

### STERILIZATION

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

MDT 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 burs should be stored in the sterilization container (bur stand or pouch) until required. Containers or pouches must be dried before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.

### VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes have been validated to prepare MDT dental burs for reuse. It remains the responsibility of the user to ensure that the reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility achieve the required results. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

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