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Schottlander Dental Diamond Burs

Instructions for Use

INTENDED USE

Schottlander Dental Diamond Burs are intended to drill or cut hard structures in the mouth such as teeth or surrounding tissue. It is also intended to cut hard metals, plastics, porcelains and similar materials intended for fabrication of dental devices. These uses include also applications in dental laboratories.

This IFU Leaflet refers to non-sterile provided burs which are intended for multiple uses.

CAUTIONS & PRECAUTIONS

- Read carefully these instructions for use leaflet before using the device.
- The device is intended for laboratory and dental applications in dental clinics and dental health facilities by licensed dentist or technicians when used in laboratories. The device is **Rx only**.
- For the safety of user and patient, only qualified dentists should work with the dental diamond burs.
- During clinical use, wear gloves and eye protection at all times. Do not contact contaminated instruments or the patient's tissue without gloves protection.
- Use surgical mask in order to avoid inhalation of aerosol or dust generated during application.
- Attention should be paid to speed of work (RPM – Rounds Per Minute). In particular when working with a large head diameter and coarse or super coarse grit size. Using a bur with too high RPM level, could generate undesirable heat. Please note the **FG mark** on the package, indicating the use in high speed turbine. See Max RPM table in the **instructions section below**.
- Do Not keep the bur still on one spot & keep constant movement during use.
- Do not force a bur into the turbine. In case of difficult access, check both turbine and bur. **Remember!** Schottlander Dental Diamond Burs are guaranteed and shall be replaced if found incompatible. However, special attention should be paid to instructions of use and maintenance of the turbine.
- **Note:** Single use labeled devices are **NOT** approved for re-use and are intended for single use only.
- Make sure to clean and sterilize non-sterile provided burs in accordance with the directions provided in Cleaning & Sterilization Instructions section below, before **first use and before each reuse**. **Note:** Sterile and single-use provided burs **Do Not** require cleaning and sterilization.
- Do not apply excessive force or pressure on the device. Feather touch (up to 150 gram) while working with the bur would be sufficient for proper use.

Please note that separate instructions for use are available for Sterile burs which are intended for single use only.

WARNINGS

- Used burs are considered to be contaminated. In order to avoid injuries associated with contamination, appropriate handling precautions should be taken during handling and/or reprocessing. Use gloves, mask and eye protection. Other measures may be required if there are specific infection or cross-contamination risks from the patient. These precautions are also necessary to avoid physical damage due to ejected particles during procedure.
- Used dental burs are considered as biohazard and need to be discarded as biohazard waste, according to applicable local laws and regulations or institutional protocol, unless reprocessing instruction has been performed by the user.
- Use eye protection to protect against ejected particles.
- In order to prevent too high drilling friction or heat, use the bur with sufficient water coolant.
- Constant movement during bur use is required in order to prevent overheating during drilling and burning of the bur.

CONTRA INDICATION

This product may contain nickel and should not be used on or by persons with known allergic reactions to nickel or nickel alloys.

GENERAL BURS' OPERATION INSTRUCTIONS

The diamond rotary dental burs are made of stainless steel which are coated with diamond particles on the working portion, in different roughness and shapes and are designed to fit into a dental handpiece. During cutting or drilling, the burs are exposed to friction. The bur rotation is generated using the handpiece connection, which allows the user to apply it on hard structures like teeth, bone, metal, plastics, porcelains and similar materials in the dental applications.

- After sterilization process, use aseptic technique.
- Performance of bur: Before use of the burs, consult the Max RPM (Rounds Per Minutes) for each bur type and always work within speed of work limits presented in the table below:

MAX. RPM

ISO Ø (1/10mm)	FG (RPM)	HP (RPM)
007-014	450,000	250,000
016-023	300,000	120,000
025-045	120,000	80,000
047-065	80,000	60,000
066-093	60,000	40,000

- Before drilling or cutting, verify firm connection of the bur and handpiece.
- Use the bur with sufficient water coolant.
- Apply no more than feather-like touch (up to 150 gram) while working with the bur.
- Schottlander Dental Diamond Burs can be used between **3 to 5 times**, depends on several parameters such as:
 - > Grits condition and shape. Do not use if wear signs or damage are seen.
 - > The user. Extra pressure or angulated drilling, might expedite the bur wear.
 - > The patient reaction. If the patient shows pain or discomfort.
 - > The handpiece connection (bad connection might affect bur wear).
 - > The coolant. Lack of coolant might increase friction & expedite bur wear.

CLEANING & STERILIZATION INSTRUCTIONS

General Instructions:

- Schottlander Dental Diamond Burs are designed for several uses and are eligible for both cleaning and autoclave sterilization.
- Clean and sterilize the burs before first use and before each reuse.
- Use only a natural pH cleaning / disinfecting solution which is approved for this use (through CE Marking or FDA approval/clearance) and compatible with Stainless-Steel and Nickel.
- The cleaning/disinfecting solution should be aldehyde free (to avoid blood impurities fixation) & without di- or triethanolamines as corrosion inhibitor.
- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the instruments.
- Cleaning may be performed using Manual Cleaning or Automated cleaning. Sterilization should be conducted using steam sterilization, per the instructions below for each method.

Manual Cleaning:

- Immediately after use, immerse all instruments in a disinfection solution compatible with stainless steel and Nickel, according to manufacturer's instructions (this product has been validated by Strauss using Cidex OPA in concentration of 0.3%). Use the lowest recommended concentration and lowest recommended temperature (an excessive concentration may cause corrosion or others defects on instruments).
- Immerse the products for 5 minutes.
- While soaked scrub the device thoroughly with a soft nylon brush for 5 minutes.
- Allow drying for at least 10 minutes. Make sure that the product is completely dry.
- Observe the device to assure that no discoloration or corrosion signs or other visual contamination appeared.
- Move forward to the steam sterilization process.

Automated Cleaning:

- As **manual pre-cleaning**, soak all instruments immediately after use in a detergent and disinfecting natural pH solution combined with proteolytic enzyme for 5 minutes or as specified by the cleaning agent manufacturer. Use the lowest recommended concentration by the manufacture. Endozime® Premium with APA (Advanced Proteolytic Action) detergent was utilized for this product's validation by Strauss & Co at 0.1% equal to 1ml/liter in lukewarm water.
- Follow instructions and observe concentrations and immersion times given by the specific cleaning agent's manufacturer (an excessive concentration may cause corrosion or others defects on instruments).
- Under running water, scrub the device thoroughly with a soft nylon brush to remove any remaining blood or debris.
- Rinse under tap water for one (1) minute.
- Place the burs in the automatic washer (until they are placed in the washer avoid contact between them).
- **Utilize the automated process:** Run the automatic wash cycle according to automated washer manufacturer's instructions.
- **The following parameters were utilized to validate this product:**
 - > Two (2) Minutes prewash at 30±5°C (86±41°F) with tap water.
 - > Ten (10) Minutes main wash with the natural pH detergent and tap water at 45±5°C (113±41°F).
 - > One (1) Minute rinse with tap water at 30°C (86°F).
 - > Ten (10) Minutes distilled water rinse at 30°C (86°F).
 - > Twenty (20) Minutes air drying phase at high temperature of 100°C (212°F).
- Observe the device to assure that no discoloration or corrosion signs or other visual contamination appeared.
- Move forward to the steam sterilization process.

Steam Sterilization Instructions:

- Follow the autoclave manufacturers instruction to sterilize the products. Do not exceed the maximal load allowed by the manufacturer.
- Note: Local infection control practice may recommend a different combination of holding time and temperature.
- Place the products into the steam sterilizer into a sterile barrier pouch.
Note: Use microbial barrier pouch that is cleared by the US FDA (US users) and CE-Marked approved (EU users).
- Use an Autoclave that is cleared by the US FDA (US users) and CE-Marked approved (EU users)
Note: Consult the autoclave's manufacturer instructions for use.
- Method validated by Strauss & Co:
 - > Wrapped instruments, Gravity Displacement.
 - > Temperature: 135°C/275°F.
 - > Exposure Time: 10 minutes.
 - > Drying Time: 30 minutes.
- After drying, make sure the product is completely dry.
- Use maximal loaded autoclave with wrapped products.
- After sterilizing the device, do not remove burs from sterile pouch until used. If burs are being sterilized unwrapped, use them immediately after sterilization. **Use aseptic technique.**

STORAGE

- After sterilization, keep the devices in sterilization packaging in a dry and clean environment, under room temperature.

SYMBOLS INTERPRETATION

- Symbols on the product package should be interpreted as follows:



Batch code number



Catalogue number



Consult operating instructions



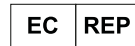
Do not use if package is opened or damaged



Non-Sterile (to distinguish between similar devices that are provided as non-sterile from sterile labeled devices)



Manufacturer



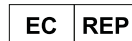
Authorized Representative in the European Community



CE-Mark Symbol



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