

Strauss & Co. Sterile Dental Burs **Instructions for Use (IFU)**

Intended use

Strauss & Co Dental Burs are intended to drill or cut hard structures in the mouth such as teeth or surrounding tissue. They are also intended to cut hard Metals, Plastics, Porcelains and similar materials and are intended for fabrication of dental devices. These uses also include applications in dental laboratories.

This IFU Leaflet refers to **sterile provided** burs which are intended for **single use only**.

Cautions and Precautions

- Please read instructions carefully on the instructions for use leaflet before using the device.
- The device is a prescription device, intended for dental applications in dental clinics and dental health facilities by licensed dentist The device is **Rx only**.
- For the safety of both 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 a surgical mask in order to avoid inhalation of Aerosol or dust generated during application.
- Attention should be paid to operating speed (RPM – Rounds Per Minute). In particular when working with a large head diameter and coarse or super coarse grit sizes. Using a bur at a higher RPM level than recommended 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 - maintain constant movement during use.
- Do not force a bur into the turbine. In case of difficult access, check both turbine and bur. **Remember!** Strauss & Co 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.
- Do not use if package is opened or damaged.
- **Note:** The device is single use labeled and is **NOT** approved for re-use. It is intended for single use only.
- **Note:** Sterile provided burs may be used without additional cleaning or sterilization process. Do **not** reuse and do **not** attempt to re-sterilize after use.
- Discard the sterile provided burs after one use.

- Do not apply excessive force or pressure on the device. A feather touch (up to 150 gram) would be sufficient while working with the bur for proper use and reaching desirable optimum results.

Please notice that separate instructions for use are available for Strauss & Co Non-Sterile provided burs which are reusable and suitable for multiuse after cleaning and sterilization 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.
- In order to avoid patient contamination, biohazard infection or product malfunction, **do not reuse** the device, **do not** perform any re-cleaning or re-sterilization after use!
- In case the sterile packaging is opened, damaged or otherwise breached, the bur is not sterile. In such a case **DO NOT** use the bur.
- Use eye protection to protect against ejected particles.
- In order to prevent generating undesirable local heating and general overheating during drilling friction, use the bur with sufficient water coolant.
- Constant movement while bur is in use is required in order to prevent overheating during drilling and burning of the bur.

Contraindication

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 burs 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. Make sure that the handpiece connection is properly firmed.

- Remove sterile device from packaging. 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 (1/10 mm)	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











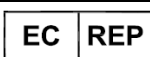

- Before drilling or cutting, verify firm connection of the bur and handpiece.
- Use the bur with sufficient water coolant.
- Apply no more than feather-like touch (up to 150 gram) while working with the bur.

Storage

- Keep the devices in their sterile original packaging in a dry and clean environment, at room temperature.

Symbols Interpretation

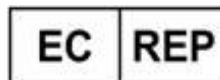
- Symbols on the product package should be interpreted as follows:

	Use-by date (expiration date)		Batch code number
	Consult operating instructions		Catalogue number
	Do not use if package is opened or damaged and/or if sterile barrier is compromised		Single use, Do not re-use
	Sterilized using irradiation		Manufacturer
	Non-Sterile (to distinguish between similar devices that are provided as non-sterile from sterile labeled devices)		Date of manufacture
	Authorized Representative in the European Community		CE-Mark Symbol

For any questions please contact the Strauss & Co



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