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

Indications
Diseases and conditions requiring dental restorative procedures such as (non-exhaustive list) removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, preparation of crowns and orthodontic devices.

Intended use

Grinding hard structures in the mouth, such as teeth or bone, and cutting and polishing hard metals, plastics, porcelains, and similar materials used in fabrication of dental devices.

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

Material introduce into the human body:
The burs are composed from stainless steel AISI-420F and are coated with diamond grits and Nickel acting as a bond.

Cautions and Precautions
The Strauss & Co – industrial diamonds ltd. Dental burs should only be used by dentists adequately qualified and trained in dental restorative procedures; dental laboratory use should be limited to adequately qualified and trained technicians.

Precautions:
Dentists must consider all comorbidities, past and present, medications, previous treatments.

- Burs must be disposed/discarded according to local authority regulations and environmental requirements or returned to the manufacturer, if so instructed. Manufactured must be contacted for recommendations on safe return of devices.
- Gloves must be worn at all times when handling contaminated burs.
- Eye protection must be worn to protect against ejected particles.
- Surgical mask must be worn to avoid inhalation of aerosol or generated dust.
- Avoid excessive duration of uninterrupted drilling and cutting to prevent overheating and associated complications.
- Move the bur continuously when in use to avoid localized heating.

Warnings

- Ensure that the burs are fully seated and gripped in the handpiece collet before use. Do not force burs into handpiece.
- Do not exceed the maximum rotation speed indicated in the instructions for use, to prevent breakage, overheating, and associated complications.
- Re-use and/or re-sterilization of single-use burs is strictly forbidden.
- Reusable burs must not be used beyond the number of repeat uses indicated in the instructions for use.
- Use only specifically formulated cleaning and disinfectant agents.

- Make sure to clean and sterilize non-sterile provided burs outside of the box 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.

Please notice that separate instructions for use are available for Strauss & Co Sterile provided burs which are intended for single use only.

Use of the dental burs is associated with a general dental restorative procedure, which may include, according to local practice, administration of anesthetic agents, preceding the procedure, and antibiotic prophylaxis, administered prior to or after the procedure. Consequently, the following contraindications apply to the procedure:

- Pregnancy
- Renal failure
- Steroid use
- Systolic pressure above 170 and/or diastolic pressure above 110 mmHg
- Patients receiving corticosteroid, anticonvulsive, or immunosuppressive therapy
- Organ transplantation
- Abnormal values for blood urea nitrogen or creatinine
- Abnormal liver function
- Anticoagulation therapy
- Granulocytopenia
- Hemophilia

Aside of hypersensitivity to the dental burs components, ie, stainless steel, nickel and nickel alloys there are no contraindications that apply to use of the dental burs for dental restorative procedures.

Patient populations

Children, adolescents, and adults.
NOTE ON THE DEFINITION OF "CHILDREN" FOR THE PURPOSES OF THIS EVALUATION
Considering the apparent dissonance in terminology, with "children" and "pediatric patients" oftentimes used interchangeably, and the fact that definitions of these populations vary in different jurisdictions, it is important to note the differences for regulatory purposes.
In the European Union, MDD and MDR lack definitions on pediatric patients. MDR also does not discern between a "minor" and a "child" in Article 65 and does not contain definitions for either. Title 1 Chapter 1 Article 2.1) of Regulation (EC) No 1901/2006 on medicinal products for pediatric use defines 'paediatric population' as part of the population aged between birth and 18 years, while Regulation 536/2014 (Article 2(2.18)) defines a "minor" (and unlike the ICH E11 guideline, does not discern between a "minor" and a "child"[1]) as: "a subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent." The age of legal competence differs across national laws, for example adolescents from 16 years of age may not be regarded as minors in some Member States.
In the United States, 21 CFR 56.111 refers to children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons as vulnerable populations. Children are defined in 21 CFR 50.3(o) as persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted[2]. This definition differs from the definition of children provided in the ICH E11 *Note for Guidance on Clinical Investigation of Medicinal Products in The Paediatric Population* (CPMP/ICH/2711/99), in which "children" is a term defining a

[1] § 5.3 of the "*Ethical considerations for clinical trials on medicinal products conducted with minors Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use*" Revision 1, 18 September 2017.
[2] 45 CFR Subparts B, C, and D defines vulnerable populations as patients who are racial or ethnic minorities, children, elderly, socioeconomically disadvantaged, underinsured

subgroup of pediatric patients aged 2-11 years. In the drug regulations, namely in 21 CFR 201.57(c)(9)(iv)(A) and 201.80(f)(9)(i), the terms pediatric population(s) and pediatric patient(s) are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents. However, 21 U.S.C. § 360j(m)(6)(E)(i) and (ii) (incorporating Section 520m(6)E(i) and (ii) of the Food, Drug, and Cosmetic Act) define pediatric patients as age 21 years or younger at the time of diagnosis or treatment and specify categories of pediatric subpopulations:

- (I) Neonates.
- (II) Infants.
- (III) Children.
- (IV) Adolescents.

Further, 21 U.S.C. § 360e-1(a) (Section 515A of the FD&C Act) uses the same definition of "pediatric subpopulations." Accordingly, for medical device, the US FDA interprets the statutory definition of pediatrics as individuals who are 21 years of age or younger, that is, from birth through the 21st year of life, up to but not including the 22nd birthday (21 CFR 814.3(s)).
Consequently, dental burs are not intended to be used in "newborns" (or neonates), ie, pediatric patients from birth to 1 month of age, and in "infants", until the first tooth eruption.

Intended users

Dentists adequately qualified and trained in dental restorative procedures; and certified dental technicians, when used in laboratory settings.

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.

- 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 (1/10 mm)	FG (RPM)	HP (RPM)
007-014 016-023	450,000 300,000	250,000 120,000
025-045 047-065 066-093	120,000 80,000 60,000	80,000 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.
- These Strauss & Co's reusable 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 or damage signs are visible.
  - The user: Extra pressure or angulated drilling may 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 and expedite bur wear.

Cleaning & Sterilization Instructions

General Instructions:

- Strauss & Co.'s 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) and 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:

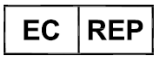
- Follow the autoclave manufacturer's instruction to sterilize the products. Do not exceed the maximal load allowed by the manufacturer.
- ***Note:*** *Local infection control practice may recommend a different combination of holding time and temperature.*
- Place the products into the steam sterilizer 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: 135ºC/275ºF.
  - 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			Non-Sterile (to distinguish between similar devices that are provided as non-sterile from sterile labeled devices)
	Catalogue number			Manufacturer
	Consult operating instructions			Authorized Representative in the European Community
	Do not use if package is opened or damaged			CE-Mark Symbol

MD	Medical device symbol			

For any questions or report any adverse event - please contact the Strauss & Co team

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IFU-0001 Rev. 03 2.8.22