

"Strauss & Co." Degranulation set - Instructions for use (IFU)

Introduction

Use the "Degranulation Set" to remove elements that can potentially inhibit healing or promote infection.

The set is supplied with three specially designed burs (1mm, 2.5mm, 3.1mm, 3.5mm) a cleaning brush and a extension tube.

Indications for Use

The Degranulation Set is indicated for the removal of elements present following tooth extraction such as soft tissue, tooth root debris and bone fragments that could potentially impair the healing process.

Contraindications

The device is contraindicated for patients who are contraindicated for dental implantation

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.

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.
- Before drilling or cutting, verify firm connection of the bur and handpiece.
- These Strauss & Co's reusable dental diamond burs can be used between **80-100 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).

Use of the Device

1. Perform an atraumatic tooth extraction while preserving the integrity of the socket walls.
2. Using a surgical curette debride the soft tissue in the socket.
3. Use the dedicated extension to remove blood from within the socket to allow direct visualization of the socket walls, and identify regions that still harbor soft tissue that penetrates the bone
4. Attach the burr to the physio-dispenser and operate it at drilling speeds of 2000-2500 rpm to scrape the defect walls. Scrape initially with no water and then use in conjunction with water to rinse the drill and the socket and defect while employing the dedicated extension.
5. Repeat the procedure until complete removal of the soft tissue and cleaning of the defect is accomplished.

Note:

There is no need to sterilize or disinfect the site with chlorhexidine or antibiotic solutions. The cleaning under direct visualization employing the dedicated drill and extension should be sufficient to secure the site to remain infection-free.

In case the extension tube becomes obstructed perform the following steps:

1. Disconnect the extension from the hand piece and inject sterile water into the extension using a sterile syringe.
2. Insert the brush to clean out any debris.
3. Repeat the process till full cleaning of the extension tube is achieved.
4. Finish the cleaning process by injecting of sterile water into the extension tube.
5. Return the extension on the hand piece to continue the treatment.

Warnings

- The set should be used by qualified, trained dental professionals only.
- Read instructions for use before using the set
- Sterilize burs and extension tube before initial use and between patients
- Inspect all components before use. If any damage is observed discard the component.
- Do not exceed the maximum speeds indicated in this leaflet.
- Ensure that the bur is fully seated and gripped before use
- Always wear Gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Surgical mask must be worn to avoid inhalation of aerosol or dust generated.

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: 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

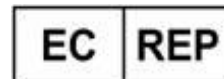
- Symbols on the product package should be interpreted as follows:

• 	• Batch code number	• 	• 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
• 	• Medical device symbol	•	•

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



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