

EthOss[®] Degranulation Kit – Instructions For Use

Introduction

Use the “Degranulation Kit” to remove elements that can potentially inhibit healing or promote infection.

The kit is supplied with four specially designed burs (1mm, 2.5mm, 3.1mm, 3.5mm) a cleaning brush and a suction tube.

Indications for Use

The Degranulation Kit 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.

Warnings

- The kit should be used by qualified, trained dental professionals only.
- Read the Instructions For Use before using the kit.
- Sterilize burs and suction 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.

Sterilization

The burs and suction tube are supplied non-sterile and must be sterilized before initial use and after use on each patient.

Sterilization should be performed in an autoclave under the following conditions:

Temperature: 270 F to 275 F (132 °C to 135 °C), Pressure: 2 atmospheres, Time: 20 minutes,

Dry: 15 minutes

After use the burs should be cleaned:

- Soak the burs in a 3% Hydrogen Peroxide solution for 5 minutes.
- Clean the bur with a metal brush.
- Soak the burs in Dakin's solution for 5 minutes.
- Clean the bur with soap and a soft brush.
- Soak the bur in an ultrasonic bath for 15 minutes.
- Sterilize again as stated above.

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 suction 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 800 - 1200 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 suction.
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 suction should be sufficient to secure the site to remain infection-free.

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

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

Storage

The user must avoid all acts that could affect the product marking or shelf-life, the burr surface or the burr geometry such as unnecessary force, heat, UV radiation, moisture, etc..

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