



Interproximal Reduction Burs

Sterilization Guide

This document summarizes cleaning and sterilization instructions derived from the manufacturer's Instructions for Use (IFU). Refer to the full manufacturer IFU for complete device information, including indications, warnings, and limitations of use.

General Instructions

Cleaning and sterilization parameters referenced in this document are based on validation performed by Strauss & Co., the contract manufacturer.

- Garrison'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 neutral 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 the cleaning agent manufacturer's instructions (this product has been validated by the Manufacturer using Cidex OPA in concentration of 0.3%). Use the lowest recommended concentration and lowest recommended temperature (an excessive concentration may cause corrosion or other 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 neutral 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 the Manufacturer 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 other defects on instruments).

Sterilization Guide (Cont.)

- 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 by the contract manufacturer (Strauss & Co.) to validate this product:**
 - Two (2) Minutes prewash at $30\pm5^{\circ}\text{C}$ ($86\pm41^{\circ}\text{F}$) with tap water.
 - Ten (10) Minutes main wash with the neutral pH detergent and tap water at $113\pm41^{\circ}\text{F}$ ($45\pm5^{\circ}\text{C}$).
 - One (1) Minute rinse with tap water at 86°F (30°C).
 - Ten (10) Minutes distilled water rinse at 86°F (30°C).
 - Twenty (20) Minutes air drying phase at high temperature of 212°F (100°C).
- 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 meets applicable regulatory requirements for the intended market (e.g., FDA-cleared for U.S., CE-marked for EU).
- **Note:** Consult the autoclave's manufacturer instructions for use.
- Method validated by the Manufacturer:
 - Wrapped instruments, Gravity Displacement.
 - Temperature: 275°F / 135°C .
 - 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.

For additional information, refer to the Strauss & Co. Instructions for Use for reusable dental burs.