



## **Disinfection, Cleaning and Sterilization**

### **Reprocessing procedure for dental instruments and implantable radicular devices**

#### **Foreword**

For hygiene and sanitary safety purposes, all instruments not marked “sterile” must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent ones.

#### **Area of application**

Disinfection and sterilization before first usage and reprocessing procedures concerning.

#### **Instruments**

Cutting instruments (hand and engine driven)  
Endodontic instruments (files, reamers, endodontic burs)  
Rotary cutting instruments (diamond burs, stainless steel reamer and drills)  
Root canal filling instruments (reverse spirals)

#### **Implantable devices**

Dentinal and radicular posts made of steel, titanium and glass fibers.

#### **Exclusion**

Equipment such as Hand Pieces, Contra Angles, Air Motors with reprocessing procedures included in the individual Directions for Use.

#### **General Recommendation**

Single use marked products are not approved for re-use.

The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damage or dirty instruments.

For your own safety, please wear personal protective equipment (gloves, safety glasses, etc).

Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.

For all metal instruments, it is recommended to use anticorrosion disinfecting and cleaning agents.

#### **Limitations and restrictions on reprocessing**

The individual DFU indicates if the useful life of a device might be reduced by the number of reprocessing cycles. Furthermore, the appearance of defects such as cracks, deformations (bent, twisted), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfill the intended use with the required safety level.

The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

Hand instruments and NiTi instruments are degraded by Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) solution.

NiTi Instruments are degraded if immersed more than 5 minutes in a solution of NaOCl at more than 5%.

## **1 Pre-disinfection or Decontamination**

### **Operating Mode**

Soak immediately just after usage all instruments in a disinfectant solution.

### **Warning**

- \* Following instructions and observe concentrations and immersion time given by the manufacturer (an excessive concentration may cause corrosion or other defects on instruments).
- \* The disinfectant solution should be aldehyde free (to avoid blood impurities fixation).
- \* Do not use disinfectant solution containing Phenol or any products which are not compatible with the instruments (see general recommendation).
- \* For visible impurities observed on instruments a pre-cleaning is recommended with a soft material.

## **2 Automated Cleaning Disinfection**

### **Operating Mode**

- \* Disassemble the device (silicone stops removed).
- \* Put them in a kit, support or container to avoid contact between other instruments.
- \* Put them in the thermo disinfectant (for at least 5 min at 200° F or 93° C).

### **Warning**

- \* Discard any instruments with large obvious defects (bent, broken, etc).
- \* Avoid contact between instruments, drills or posts when placing in the thermo disinfectant.
- \* Follow instructions and observe concentrations given by the manufacturer (see general recommendations).
- \* The thermo disinfectant is not recommended for instruments made of aluminum, tungsten carbide or carbon steel. In case of chemical disinfection, there is a danger of remnants of the disinfectant on the instruments.
- \* Sufficient rinsing step should be available in purified water (max 10 germs/ml and max 0.25 endotoxin units/ml).
- \* Use filtered air for drying the instruments, reamers, drills and posts.
- \* Use only approved thermo disinfectants according to EN ISO 15883. Maintain and calibrate regularly.
- \* If possible and automated procedure is preferred.

## **3 Manual Cleaning Disinfection**

### **Operating Mode**

- \* Disassemble the device (silicone stops removed).
- \* Rinse the device under cool tap water for a minimum of 3 minutes while rotating the device to ensure access to all surfaces.
- \* Prepare detergent batch per manufacturer's recommendation.
- \* Fully immerse the devices into the prepared detergent bath. Ensure there is no contact between the devices. Allow devices to soak for 10 minutes.
- \* After 10 minutes soak time, vigorously brush devices for 3 minutes each while rotating. Ensure device is fully immersed during brushing.
- \* Remove the device from the detergent and rinse under running tap water for 2 minutes.

#### **Second Cleaning:**

- \* Prepare detergent per manufacturer's instructions in an ultrasonic unit.
- \* Fully immerse the device into the prepared detergent. Ensure there is no contact between the articles.
- \* Allow the device to sonicate for 10 minutes.
- \* Remove the device from the ultrasonic unit and rinse under running tap water for 5 minutes.
- \* Visually inspect each device for visible soil. If soil is noticed repeat the cleaning process or discard device.

### **Warning**

- \* No visible impurities should be observed on the instrument.
- \* Discard any instruments with large obvious defects (broken, bent or twisted, etc.).
- \* Avoid any contact between instruments, reamers, drills or posts when placing in the solution. Use kits, supports, trays or containers.
- \* Follow instructions and observe concentrations given by the manufacturer (see general recommendations).
- \* If a disinfectant solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before autoclaving.

## **4 Inspection**

### **Operating Mode**

- \* Inspect devices and discard those with defects.
- \* Assemble the devices (silicone stops).

### **Warning**

- \* Dirty instruments must be cleaned and disinfected again.
- \* Discard instruments which show any deformation or defects (bent, twisted, broken, corroded, etc.) affecting the resistance, safety or the performance of the instruments, reamers, drills or posts.

## **5 Packaging**

### **Operating Mode**

- \* Place the device in a kit, support or container to avoid any contact between instruments, reamers, drills or posts and pack the device in a sterilization pouch.

### **Warning**

- \* Avoid any contact between instruments, reamers, drills or posts during sterilization. Use kits, supports or containers.
- \* Check the validity period of the pouch given by the manufacturer to determine the shelf life.
- \* Use the packaging which are resistant up to a temperature of 141° C or 286° F and in accordance with EN ISO 11607.

## **6 Sterilization**

### **Operating Mode**

- \* Steam sterilization at 134° C or 273° F for 20 minutes. Drying time minimum 30 minutes.

### **Warning**

- \* The instruments, reamers, drills or posts must be sterilized according to the packaging labeling.
- \* Use only autoclaves that are matching the requirements of EN ISO 13060, EN 285.
- \* Use a validated sterilization procedure according to ISO 17665.
- \* Follow the maintenance procedure of the autoclave device given by the manufacturer.
- \* Control the efficiency of the sterilization (packaging, integrity, no humidity, color change of sterilization indicators, physico-chemical integrators and digital records of cycle parameters).
- \* Traceability of procedure records.

## **7 Storage**

### **Operating Method**

- \* Keep devices in sterilization packaging in a dry clean environment.

### **Warning**

- \* Sterility cannot be guaranteed if packaging is open, damaged or wet.
- \* Check the packaging and the medical devices before using them (packaging integrity, no humidity and validity period).