FKG swiss endo	**INSTRUCTIONS FOR PROCESSING OF FKG DEVICES**	EN

1. PURPOSE

These instructions are recommended to ensure cleaning, disinfection, and sterilization of FKG devices before first use for non-sterile devices and before each reuse for reusable devices. This document aims to help healthcare professionals handle FKG devices in a safe manner as well as (re)process and maintain them in an appropriate manner, in accordance with the requirements of EN ISO 17664.

2. SCOPE OF APPLICATION

These instructions apply to all devices for which FKG is the manufacturer. Refer to the information on the label or marking on the blister to determine the processing applicable to the device(s):

Sterility	Single use device	Processing required before first use	Processing required after each use
		Yes	No
	No		Yes
		No	No
	No		Yes

The following devices are not covered by this document. Where necessary, refer to the instructions for use specific to these devices:

- Motors: Rooter® Universal and Rooter® X3000.
- Filling materials: TotalFill® range as well as Gutta Percha and Paper Points.

3. WARNINGS AND PRECAUTIONS

Warnings and precautions for the user:

- The devices covered by these instructions are intended for use in medical or hospital environments by qualified healthcare professionals.
- Use a dental dam when using the device(s) to avoid, for example, aspiration or ingestion by the patient.
- For your own safety, use personal protective equipment required during processing of the devices.
- For your own safety, wear surgical masks, gloves, and safety goggles.
- Carefully read the label or marking on the packaging to ensure you are using the correct device.

Warnings and precautions for the processing of devices:

- Use approved cleaning and disinfecting agents (e.g., approved by the VAH/DGHM or FDA, or bearing the CE marking) and use them according to the recommendations in their respective instruction manual.
- It is the user's responsibility to check the devices before each use in order to identify any possible defects.

Cracks, deformations, signs of corrosion, loss in color or marking are signs that the device is no longer able to achieve the required performance level and should be discarded.

- Do not use hydrogen peroxide (H_2O_2), as it degrades nickel-titanium instruments.
- Do not soak the active part of nickel-titanium devices for more than 5 minutes in a NaOCl solution at more than 5 %.
- Do not exceed a sterilization temperature of 135 °C.

In case of incident:
All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority according to local regulations.

4. LIMITATIONS ON REPROCESSING

Generally speaking, any device showing visible signs of wear and tear or damage should be discarded (see sections 10 and 14).

Single use devices:

Devices labeled for single use only must not be reprocessed for reuse, as they are not designed to perform as intended after first use. Changes in mechanical, physical or chemical characteristics occurring with repeated use and/or (re)processing may compromise the integrity of the design and/or material, thus reducing the safety, performance and/or compliance of the device(s). When single use devices are supplied non-sterile and require sterilization before use, the relevant sections of these instructions are applicable.

Reusable devices with indicator of possible remaining uses:

These devices can be reused and reprocessed up to 8 times depending on the complexity of the canal to be treated. Where necessary, refer to the instructions in the device's instructions for use.

Other reusable devices:

Due to the design of the devices and/or materials used and in the absence of contrary indications in the labeling or instructions for use of the device, the total number of uses is 10 (maximum). The only exception is the endo stands, for which there is no specific limitation.

5. INITIAL PROCESSING AT THE POINT OF USE FOR REUSABLE DEVICES

After use, follow the steps below:

1. Disassembly: Remove the SMD(s) and/or endo stop(s) from the instrument(s).
2. Pre-cleaning: Within a maximum of 30 minutes after use, remove excess soiling from the device(s) with disposable, lint-free wipes or a soft brush. Immerse the device(s) in a solution of water and neutral detergent.
3. Rinsing: Thoroughly rinse the device(s) with plenty of running water for at least 1 minute.

6. PREPARATION BEFORE CLEANING

Precautions:

- The device(s) should be reprocessed as soon as possible after use.
- The user should observe the concentrations and soaking times indicated in these instructions. An excessive concentration may cause corrosion or other defects on the devices.
- The disinfectant solution should not contain aldehyde so as to avoid fixation of blood residue.
- Do not use a disinfectant solution containing phenol, aldehyde or substances not compatible with the devices.
- The washer/disinfector must comply with EN ISO 15883 and undergo regular maintenance and calibration.

7. CLEANING/DISINFECTION

Follow one of the two methods described below (manual or automated) for cleaning and disinfection:

- Manual and mechanized devices before first use (if applicable, see section 2) and before each reuse (if applicable, see section 2)
- Matrixes and matrix bands before first use
- SMDs and endo stops before first use and before each reuse
- See sections 8 and 9 for specific instructions applicable to endo stands and calcinable pins.

Manual cleaning/disinfection:

Equipment: Cleaning/disinfectant solution (Helvemed Instrument Forte: 2 % concentration for 15 minutes), brush, ultrasonic bath, purified running water, absorbent cloth.

1. Place the device(s) in a container, limiting any contact between the parts as much as possible.
2. Immerse the device(s) in the recommended cleaning/disinfectant solution. If necessary, use a soft nylon brush to gently scrub the device(s) until all visible soiling has been removed. If needed, use ultrasonic equipment as well.
3. Remove the device(s) from the solution and container and thoroughly rinse them under purified running water for at least 1 minute.
4. Dry the device(s) with single use absorbent cloth.

Automated cleaning/disinfection:

Equipment: Washer/disinfector, purified water, cleaning/disinfectant solution:
- Washing: Neodisher® Mediclean Forte (0.5 % concentration)
- Thermal disinfection: Neodisher® Mediklar Special (0.03 % concentration)

1. Place the device(s) in a washer/disinfector basket, limiting any contact between the parts as much as possible.
2. Process using a standard washer/disinfector cleaning cycle for at least 10 minutes at 93 °C or A_0 value > 3000 and complete with a hot air drying cycle for at least 15 minutes at 110 °C.

8. CLEANING/DISINFECTION OF ENDO STANDS

Precautions:

- Do not place the endo stands in an ultrasonic bath.
- Aluminum endo stands are colored by an anodizing process. Anodizing and aluminum can be damaged by certain cleaning agents.
- Do not use highly alkaline/acidic substances, ideal pH between 4 and 9.
- Do not use substances containing soda, mercury salt or potash.

Manual cleaning/disinfection:

Equipment: Cleaning/disinfectant solution (Helvemed Instrument Forte: 2 % concentration for 15 minutes), brush, purified running water, absorbent cloth.

1. Place the device(s) in a container, limiting any contact between the parts as much as possible.
2. Immerse the device(s) in the recommended cleaning/disinfectant solution.
3. Remove the device(s) from the solution and container and thoroughly rinse them under purified running water for at least 1 minute.
4. Dry the device(s) with single use absorbent cloth.

9. COLD DISINFECTION OF CALCINABLE PINS

Precautions:

- Do not use a disinfectant solution containing phenol or any other chemical product that may damage restorative materials used in combination with these devices.
- Do not sterilize calcinable pins.

1. Before use, immerse the plastic calcinable pins in a NaOCl solution (concentration between 2.5 % and 5 %) at room temperature for 5 minutes.

10. INSPECTION AND MAINTENANCE

1. Before sterilization, discard any device(s) that has/have the following defects:
    - Plastic deformation
    - Bent device
    - Untwisted device
    - Damaged or blunt cutting edges
    - No marking
    - Corrosion
    - Discoloration
    - Other visible defects
2. Reassemble the SMD(s) and/or endo stop(s) on the appropriate device(s).
3. Thoroughly inspect each device to check that all visible contamination has been eliminated. In case of contamination being observed, repeat the cleaning/disinfection process described above.

11. PACKAGING

Precautions:

- Check the use-by date of the sterilization pouch stated by the manufacturer.
- Use packaging that can withstand temperatures up to 141 °C and complies with EN ISO 11607 and EN 868.

1. The device(s) should be packed in a medical grade sterilization pouch (compliant with EN ISO 11607-1). Limit any contact between the devices and seal the pouches in accordance with the manufacturer's recommendations.

12. STERILIZATION

Precautions:

- Autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended.
- Place the pouches in the sterilizer in accordance with the recommendations of the sterilizer's manufacturer.
- The autoclaves should comply with the requirements of the applicable standards (EN 13060 and EN 285) and should be approved, maintained and checked in accordance with these standards and the manufacturer's recommendations.
- Before any sterilization cycle, make sure that the maximum load indicated by the sterilizer's manufacturer is not exceeded.

Device class	Class B
Exposure time	Min. 3 minutes. The exposure time can be extended to 18 minutes to comply with the recommendations of the World Health Organization (WHO), the Robert Koch Institute (RKI), etc. FKG Dentaire medical devices are able to withstand such sterilization cycles.
Temperature	134 °C
Drying time	Recommended: 20 minutes (minimum, in chamber)
Visual inspection	Check the device(s) in accordance with section 10 and verify proper performance of the sterilization cycle (packaging integrity, no humidity, color change of sterilization indicators, physical and chemical integrators, and digital records of various cycle parameters).

13. STORAGE

Precautions:

- If the packaging has been opened, damaged or become wet, the sterile state of the devices inside the packaging is not guaranteed. Perform a new complete (re)processing cycle or discard the device(s).

1. Store the device(s) in sterile packaging in a well-ventilated area, protected from dust, moisture, insects and temperature/humidity extremes, and at the temperature specified by the paper-plastic pouch by the manufacturer of the steam sterilizer.
2. The packaging of the sterile devices should be carefully examined before opening (packaging integrity, no humidity, and expiry date) to ensure that the packaging's integrity has not been compromised during storage.

14. DISPOSAL

When a device reaches the end of its life, make sure that it is discarded in accordance with the applicable laws and regulations.

EC REP
EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

CE (For Class I product only)

CE 1639

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