1. PURPOSE

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable FKG instruments and for the processing of non-sterile devices before the first use. This document is intended to assist health care professionals in safe handling practices, effective (re)processing and maintenance of FKG instruments, in accordance with EN ISO 17664 requirements.

2. SCOPE

This instruction manual applies to all endodontic instruments manufactured by FKG Dentaire SA such as hand files and rotary instruments. This document does not pertain to the Rooter, obturation material (paper points and gutta percha) or any other implantable devices.

3. WARNINGS AND PRECAUTIONS

- Do not exceed 135°C.
- Use approved cleaning and disinfecting agents (e.g. VAH/DGHM or FDA approved or CE marked).
- The sterilisation of the product before first use and reuse is the responsibility of the user. Similarly, if the latter should use dirty and/or damaged instruments, they will assume full responsibility herewith.
- For your own safety, use the required personal protective clothing and equipment (gloves, eye protection).
- Do not use Hydrogen peroxide (H_2O_2) as it degrades instruments in nickel-titanium and hand instruments.
- Do not soak nickel-titanium instruments more than 5 minutes in a solution of NaOCl at more than 5%.

4. LIMITATIONS ON REPROCESSING

Single use devices 

Devices labelled for single use only must not be reprocessed for re-use as they are not designed to perform as intended after the first usage. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use and/or (re)processing may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. When single use devices are supplied non-sterile and require sterilization before use, the appropriate sections of this instruction may be applied.

Re-usable devices with SafetyMemoDisk (SMD) 

These devices can be reused 2 to 8 times depending on the complexity of the canal to treat. Refer to the product's specific instructions for further details.

Other re-usable devices

These devices can be reused several times unless they show visible wear or damage.

5. CARE AT THE POINT OF USE (PRE-DESINFECTION)

Within a maximum of 1 hour after use, remove excess soil with disposable, non-shedding wipes or a soft brush. Thoroughly rinse the device with running water or place it in a solution of water and neutral detergent.

6. PREPARATION FOR DECONTAMINATION AND CLEANING

Device(s) should be reprocessed as soon as is reasonably practical following use. All cleaning agents should be prepared according to the use-dilution recommended by the manufacturer. Purified water may be used to prepare cleaning agents.

7. CLEANING / DISINFECTION

Follow one of the two methods provided below (Manual or Automated):

Manual cleaning / desinfection

Equipment: cleaning/disinfecting solution, brush, ultrasonic bath, purified running water, drying towelettes.
Cleaning agent used during the validation of this processing instruction: Helvemed Instrument Forte (2% - 15 min.).

1. Disassemble the device(s), (e.g. endo stop(s) should be removed, when applicable).
2. Completely immerse the device(s) in a cleaning/disinfecting solution, according to the manufacturer's instructions (dilution, immersion time). If appropriate, use a soft-bristled nylon brush to gently scrub the device(s) until all visible soil has been removed or use ultrasonic equipment.
3. Remove the device(s) from the solution and thoroughly rinse under purified running water for a minimum of 1 minute.
4. Dry with single use towelettes or filtered compressed air.

Automated cleaning / desinfection

Equipment: Washer/disinfector (compliant to EN ISO 15883), cleaning/disinfecting solution, purified water.
Cleaning agent used during the validation of this processing instruction: Neodisher® Mediclean Forte (washing - 0.5%) and Neodisher® Mediklar Special (thermal disinfection - 0.03%).

Disassemble the device(s), (e.g. endo stop(s) should be removed, when applicable) and place them in a suitable washer/disinfector basket and process using a standard washer/disinfector cleaning cycle for at least 10 minutes at 93°C or A_0-value > 3000 completed by hot air drying for at least 15 min. at 110°C.

8. INSPECTION

Assemble device(s) (e.g. endo stop(s), when applicable) and carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Discard device(s) which show any deformation (bent, twisted), damages (broken, corroded) or any other visible defect.

9. PACKAGING

Device(s) should be packed in a medical grade sterilization pouch (compliant to EN ISO 11607-1) or wrapped suitably for the recommended specifications for steam sterilization provided in the section below.

10. STERILIZATION

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained and checked in accordance with applicable standards (EN 13060 or EN 285).

Exposure Time	3 minutes at a minimum. Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. FKG Dentaire SA medical devices are able to sustain such sterilization cycles
Temperature	132°C-135°C (270°F-275°F)
Drying Time	Recommended: 20 minutes (minimum, in chamber)

11. STORAGE

Sterile packaged device(s) should be stored in a well ventilated area and protected from dust, moisture, insects and temperature/humidity extremes. Sterile device(s) packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

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