

PREPERATION (CLEANING, DISINFECTION AND STERILIZATION) OF REUSABLE ENDODONTIC DENTAL INSTRUMENTS.

1. PURPOSE

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable endodontic DIASWISS 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 endodontic DIASWISS instruments, in accordance with EN ISO 17664 requirements.

2. SCOPE

This instruction manual applies to all endodontic instruments manufactured by DIASWISS S.A. such as hand files and rotary instruments. These instruments can be reused several times unless they show visible wear or damage.

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). Because of the high number of products available on the market, please run a test with some of your instruments or contact the manufacturer of the chemical disinfectant. In case of uncertainty regarding the choice of the disinfectant please perform a test with your own instruments first or contact the manufacturer of the disinfectant.
- The sterilization 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 (H₂O₂) 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. CLEANING (PRETREATMENT)

Brush all dentinal debris off the instruments. Do not clean large amounts of instruments in an ultrasonic cleaner. Do not use chemical soda based or mercury salt based products, nor acid or alkaline solutions.

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 demineralized or distilled water to avoid corrosion during sterilization, or place it in a solution of water and neutral detergent. Dry with dry air. Sort out damaged instruments (broken, deformed, straightened instruments or those with marks which may lead to fracturing).

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

Only use products recommended specifically for disinfecting dental root canal instruments (do not use products containing phenol or hydrogen peroxide or soda or sodium hypochlorite and do not use the very aggressive disinfectants intended specifically for burs).

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

Manual cleaning / disinfection

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. Before immersing the instruments in the disinfectant bath, sort them according to their material composition to avoid corrosion and electrolysis reaction.
3. Completely immerse the device(s) in a cleaning/disinfecting solution, according to the instructions and observe concentrations (an excessive concentration may cause chemical deterioration of the instruments) given by the manufacturer (dilution, immersion time). Adhere to the immersion time (do not leave in the disinfectant overnight). 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.
4. Remove the device(s) from the solution and thoroughly rinse under purified running water for a minimum of 1 minute.
5. Dry with single use towelettes or filtered compressed air.

Automated cleaning / disinfection

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 A0-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 deformations (bent, twisted), damages (broken, corroded) or 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). Protect instruments from the environment during sterilization (in sterilization bags).

Exposure Time	The exposure time is 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. DIASWISS S.A. endodontic instruments are able to sustain such sterilization cycles.
Temperature	132-135°C (270-275 °F) / Broaches, Spring Paste Fillers, Gates, Peeso, DIAtaper 134°C (273 °F) / Files, Reamers
Pressure	2,2 bar
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.

