FEMAdent **SMART GERMAN ORTHODONTICS FOR SERIOUS PROFESSIONALS**

Pliers • Tweezers • Clamps • Measuring and Positioning Instruments

CE

Instructions for reconditioning of re-sterilisable orthodontic instruments
[DIN EN ISO 17664:2004]

General information:

Materials:
Stainless steel, cabide metall, titanium, partially with inlays from tungsten carbide

These instructions contain basic information and processes for the correct usage and the maintenance of functionality. The instruments may only be used by qualified professionals according to their purpose, which is evident from the specification of the instrument.

Using, treating and reconditioning the instruments in any other way may result in the instruments not being sterile, in the premature loss of their functionality and usability as well as the warranty and in jeopardising and impairing the health of the operator and the patient.

The described processes for the reconditioning have to be performed under consideration of the operating instructions of the utilised disinfection and cleaning agents and equipment. The utilised equipment and agents have to have the CE-mark. The equipment has to be serviced regularly and must be validated if required.

1. Warning messages

- **The usage and reconditioning of the instruments may only occur through qualified professionals.**
- **The instruments are supplied non-sterile. They have to undergo a complete reconditioning cycle and they have to be sterile before first use on a patient.**
- **Do not clean with steel or brass brushes. Please use nylon brushes.**
- **Please use only approved cleaners with a pH value of approx. 7-9 without organic, mineral or oxidising acids or halogens (chlorine, iodine, bromine) and do not use strong alkaline solutions, solvents, oxidants or heavy metal salts.**
- **The disinfection and cleaning solution has to be warm and may not be hot.**
- **Use demineralised water.**
- **Do not leave the instruments overnight in water or disinfecting and cleaning solution.**
- **Rinse and dry carefully after cleaning and before sterilisation. Maximum temperature for drying 90℃.**
- **Grease critical points (pliers-closures, locks, sliding surfaces, springs etc.) after drying and prior to sterilising with medicinal white oil.**
- **Steam sterilisation with fractionated vacuum process**
- **Maximum sterilisation temperature: 134℃**
- **Observe maximally permitted wire diameter ► Wire max. Ø ◄ when using pliers.**

2. Restriction and limitation during reconditioning

- No special requirements.

3. Preparation at place of application:

- It is recommended to clean the instruments soon after usage.
- During usage the instruments may come in contact with substances such as blood, tissue, secretions etc., which may dry, stick to them, seep into them or cause a chemical reaction with the metal (e.g. salts, acids).
- For this reason the instruments should be placed in warm demineralised water or in disinfection solution until the actual decontamination to prevent persistend contaminations, which would not or difficult to be remove.
- The instruments should not remain in the disinfection and cleaning solution too long (e.g. not overnight) because it may damage the material.
- **Recommended disinfection and cleaning agents:**

  Enzymatic cleaners or glutaraldehyde or other agents, which are designed and approved for this purpose an which possess an approximate pH level of 7-9 and which do not contain organic, mineral or oxidising acids or halogens, chlorine, iodine, bromine or strong alkaline solutions, solvents, oxidising agents or heavy metal salts.

  Demineralised water should be used for rinsing and to produce disinfection and cleaning solutions, because tap water may contain minerals, which may cause discolouration and rust. The amount, the concentration and/or dilution, the temperature, the duration of the application at the instruments, the total duration of the application of the disinfection and cleaning solution and the intervals of changing it are stipulated by the operating instructions of the disinfection and cleaning agent.

4. Preparation - prior to ultrasonic cleaning

- Pliers and instruments made of stainless steel should not be cleaned in one cycle together with those made from carbon steel and with metallic coatings.
- In order to increase the effectiveness of the ultrasonic cleaning process all visible coarse contamination should be removed from the pliers with a nylon or other plastic brush.

- prior to manual cleaning:

- Coarse and stubborn contamination on the instruments should be soaked in a warm, not hot disinfection and cleaning solution.

5. Cleaning

- A combined disinfecting cleaning with designated, approved disinfecting cleaning agents is to be performed as described in section 6.

6. Disinfection - ultrasonic, not automatic

- The disinfection and cleaning has to occur with the ultrasonic cleaning equipment. It is the most effective, non-automated method. The ultrasonic cleaning equipment has to be designed and approved for this purpose.
- A disinfection and cleaning solution has to be prepared in the basin of the equipment in accordance with the manufacturer's instructions.
- If the design requires and allows it, open the instruments so that joints and closures and locks are open and exposed and position them in the ultrasonic cleaning equipment and/or in a sieve basket in such a way that they do not touch.
- The adjustments of the ultrasonic equipment and the duration of the cleaning cycle are specified in the operating instructions of the equipment and the disinfection and cleaning agent.
- The instruments are to be checked for cleanliness particularly at joints and closure points and at locks after the disinfection and cleaning. The cleaning process is to be repeated manually or in the ultrasonic bath in the event of residues.
- Thoroughly rinse the cleaned instruments in clear, demineralised water.

Manual disinfection and cleaning

- If ultrasonic cleaning equipment is not available, the instruments may also be placed in a warm disinfection and cleaning solution and washed by hand.
- If the design requires and allows it, open the instruments so that joints and closures and locks are open and exposed.
- The instruments are to be repeatedly alternately rinsed, brushed with a nylon or other plastic brush and rinsed again in the disinfection and cleaning solution until all contamination has been removed.
- All gaps, grooves, drillings of joints and closure points and locks have to be cleaned and inspected particularly careful in the process.

Continuation →

- The instruments are to be checked for cleanliness particularly at joints and closure points and at locks after the disinfection and cleaning. The cleaning process is to be repeated in the event of residues.
- The cleaned instruments have to be subsequently rinsed thoroughly in clear, demineralised water until all residue has been removed.

Automatic cleaning and disinfection

- If an automatic cleaning and thermal disinfection (according to EN ISO 15883) in a steriliser (thermo-steriliser) is possible, this procedure should be given preference.
- The manufacturer's instructions regarding the usage of the equipment and the disinfection and cleaning function are to be observed.

  Principally applicable:
- The equipment has to be loaded according to the manufacturer's instructions. If the design requires and allows it, open the instruments so that joints and closures and locks are open and exposed.
- Only non-foaming cleaners should be used.
- The equipment has to be set for disinfection, cleaning and rinsing (and drying if possible) according to the manufacturer's instructions and the full cycle of the process and/or cleaning program has to be executed.
- The equipment has to be checked whether the process was really completely executed.
- The instruments are to be checked for cleanliness particularly at joints and closure points and at locks after the disinfection and cleaning and rinsing. The cleaning process is to be repeated in the event of residues.

7. Drying, automatic drying

- If a thermo-steriliser with drying function is available, this procedure should be given preference and should be conducted directly following the disinfection and cleaning.
- The manufacturer's instructions regarding the usage and the operation of the equipment and the drying function are to be observed.
- A temperature of 90°C may not be exceeded during the drying process.
- The instruments are to be checked for cleanliness particularly at joints and closure points and at locks after the disinfection and cleaning rinsing and drying. The cleaning process is to be repeated in the event of residues.

Non-automatic, manual drying

- Only touch the instruments with disinfected hands or rubber gloves.
- Large amounts of water on the surfaces are to be absorbed with a low-germ lint-free cloth or paper towel.
- Residual moisture on the surfaces and moisture in gaps, grooves, drilling of joints and closure points and locks are to be carefully blasted and dried with dry, oil-free compressed air.

8. Control, maintenance, verification, selection

- Pliers-closures, locks, sliding surfaces, springs and other critical points have to be greased with approved and sterilisable oil after drying and prior to sterilising, such as e.g. with so-called medicinal white oil.
- The instruments have to be inspected prior to sterilisation and usage.
- The instruments have to be complete and may not show any adhesions, contaminations, soluble discolouration, rust, cracks or other damages.
- Material discolouration may also be unproblematic, e.g. if a passive layer has formed. The operator and/or controller has to assess this (see hereto: red AKI brochure under http://www.a-k-i.org). The equipment is to be segregated in case of doubt.
- Tips, blades, cutters, jaws, joints, locks and springs have to be form-locking, functional and easy to operate.
- Damaged, defect instruments may not be reused.
- Battered, worn or blunt instruments can be repaired or restored by a qualified and approved company or specialist.
- Used instruments, which are sent for maintenance or processing or for inspection have to be disinfected and packaged according to regulations.

9. Packaging

- Before sterilization the instruments have to be packaged in opened condition in a sterilisation cassette made of steel or aluminium with disposable filters in the lid or in the floor or
- in a sterilisation packaging (according to DIN EN 868 and DIN EN ISO 11607), designed and approved for this purpose.

10. Sterilisation with damp heat, steam sterilisation in the autoclave

- Sterilisation has to be performed via steam sterilisation in a steam steriliser (autoclave) (according to DIN EN 13060 and/or DIN EN 285), preferably in a fractionated vacuum process (according to DIN EN ISO 17665).
- If fractionated vacuum is not available, it may also be performed in a gravitation process.
- Other sterilisation procedures, such as e.g. flash or quick sterilisation or sterilisation with hot air, radiation, formaldehyde, ethylene oxide and plasma are not permissible.
- The instruments are to be loaded into the autoclave according to manufacturer's instructions.
- The following temperatures and exposure times have to be adhered to for the sterilisation in the autoclave at approx. 2-3 bar chamber pressure:

at	115 °C	to	118 °C	for at least	30	minutes
at	121 °C	to	124 °C	for at least	20	minutes
at	126 °C	to	134 °C	for at least	10	minutes

- Subsequent drying time approx. 15 minutes.
- The specifications of the manufacturer of the steam steriliser are to be considered.

11. Storage

- The shelf life depends on the environmental conditions.
- Single packed (in only one packaging) instruments should be stored under normal protected, aseptic conditions in a dry, dust-free environment without direct sunlight and heavy vibrations (e.g. in cupboards, drawers, etc.).
- The instructions of the manufacturer of the sterile goods packaging are to be observed regarding the shelf life.
- For storage suitability an shelf life a benchmark of 6 months at proper, protected storage is generally recommended for practical reasons and to ensure operational safety.

Further information and references regarding reconditioning of medical devices:

- The recommendation of the Robert Koch Institute and the BfArM (Federal Institute for Drugs and Medical Devices)

  "Requirements for the reconditioning of medical devices"

  in the Internet under **http://www.rki.de**

- **Yellow AKI-brochure "Correct instrument reconditioning in the dental surgery"** and

  Red AKI-brochure "Correct instrument reconditioning"

  of theWorkshop/Committee Instrument Reconditioning

  in the Internet under **http://www.a-k-i.org**

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