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Cleaning, disinfection and sterilisation of instruments and prosthodontic components.

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CLEANING, DESINFECTION AND STERILIZATION INSTRUCTIONS INSTRUMENTS AND PROSTHODONTIC COMPONENTS

1. GENERAL PRINCIPLES

Cleaning, disinfection, and sterilization protocol to be carried out by qualified personnel. The user is responsible for correctly following the instructions described in this document.

Phibo manufactures its instruments and prosthodontic components from high-quality materials and with high precision. Keeping surgical and prosthetic instruments clean and fit for use lies with the end user. Avoiding contamination from patient to patient is essential and important for treatment practices.

Phibo instruments and prosthodontic components are not supplied sterile and must be cleaned, disinfected, and sterilized before every use. This also applies for first-time use (when the product is first received by the end user).

Never let surgical residues (blood, secretion, tissue residues) dry on an instrument, clean immediately after use. Effective cleaning and disinfection are indispensable requirements for efficient sterilization.

Surgical and prosthetic parts that remain in the oral cavity directly after the surgery must be sterilized. Those classified as non-critical (only come into contact with intact skin) require cleaning and disinfection but do not require sterilization.

Instruments from different materials should never be placed together in a liquid bath (as this will result in an increased risk of contact corrosion).

Use only cleaning agents and disinfectants intended for the device's material, and follow their respective instructions for use, as provided by the manufacturers. You will find information about the material of a medical device in their respective instructions for use or product catalogue.

Only automatic cleaning and disinfecting processes can be used. Efficacy and correct biocompatibility of the processing step have been assessed under automatic process. Washer-disinfector equipment to be used must meet the requirements of the **ISO 15883** series.

The plastics used for Phibo devices can be sterilized at temperatures up to **134 °C (273 °F)**.

Do not sterilize instruments made of different materials together, except if the corresponding surgical box is used correctly.

Frequent processing has minor effects on the instruments. The end of the product life is normally determined by wear and damage during use (cutting instruments are an exception, see below). Therefore, instruments can be reused with appropriate care, provided they are undamaged and not contaminated. Do not use instruments beyond the effective product life cycle nor use damaged and/or contaminated instruments.

If appropriately cared for, and provided they are undamaged and not contaminated, cutting instruments can be reused up to a maximum of **10 times** (1 use = placement of 1 implant); any further use extending beyond this number or the use of damaged and/or contaminated

instruments is not allowed.

According to **EN ISO 17664**, it is the responsibility of the user/processor to ensure that processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the efficacy of the process.

It is the responsibility of the user to ensure the following:

- If alternative cleaning, disinfection, or sterilization methods are chosen, they must be sufficiently validated specifically for the equipment or device are used to conduct these processes.
- If alternative cleaning, disinfection, or sterilization methods are chosen, they must achieve the desired results without affecting the products that undergo processing.
- The equipment used (disinfector, sterilizer, …) must be regularly maintained, inspected, and calibrated.

In addition to these instructions, please observe the legal regulations valid in your country as well as the hygiene regulations of the dental practice.

NOTE:

- Follow the safety instructions indicated by the manufacturers of the equipment and products used.
- Exert extra caution when handling sharp and cutting instruments, to avoid injuries or damage to the instruments.
- Process contaminated instruments as quickly as possible for cleaning (**within two (2) hours after use, at the most**).
- Make sure that all contaminated instruments are collected separately to avoid contamination.
- Never use damaged or dirty material.
- Never reuse products indicated for single use.
- Never clean with metal brushes or steel wool.
- Never expose instruments, and surgical boxes and prosthodontic components to temperatures higher than **134 °C (273 °F)**.
- Rinse disinfectants and cleaning agents very thoroughly with water.
- Never leave or store instruments moist or wet.

2. PRETREATMENT

Neodisher® MediClean Forte (Dr. Weigert) can be used as pre-cleaning agent. Consult product instructions for use.

It is important to use protective clothing while cleaning contaminated instruments. Always wear protective glasses, face mask, gloves, etc. for your own safety during all activities.

Coarse impurities must be removed from the instruments directly after use (**within two (2) hours at the most**).

Sort the instruments into groups, according to material, and clean, disinfect and sterilize these groups separately. Never place instruments from different materials together.

Disassemble multi-piece instruments into their single parts according to their instructions for use.

Damaged and/or blunt instruments must be sorted out and disinfected, cleaned and disposed of separately. Cutting instruments should be replaced after a maximum of 10 uses.

Brush (soft) and rinse under running and cold water for between 20 and 30 seconds to remove excess dirt of instruments. Use only a soft brush or a clean, soft cloth that is used only for this purpose. Never use metal brushes or steel wool for the manual removal of impurities.

Rinse out all cavities of the instruments many times using a disposable syringe (minimum volume 20 ml). Shift movable parts forwards and backwards several times during pre-cleaning. Please observe that the disinfectant used in pretreatment serves only for your own protection and cannot replace the disinfection step to be performed later after cleaning.

NOTE:

- Use tap water to rinse the products.

3. CLEANING AND DESINFECTION

Use only an automatic method.

The procedure described has been validated in a Washer-disinfector compliant to **EN ISO 15883 series** and using Neodisher® MediClean Forte (Dr. Weigert) as a cleaning/disinfecting agent. Consult product instructions for use.

It is important to use protective clothing while cleaning contaminated instruments. Always wear protective glasses, face mask, gloves, etc. for your own safety during all activities.

Immerse the instruments in an adequate disinfectant bath, strictly following the manufacturer's instructions regarding dose/concentration, immersion time and temperature. The instruments should not be in contact with one another.

The disinfectant should have tested effectiveness, i.e., it should be suitable for disinfection of surgical instruments and be compatible with the instrument's materials: Stainless Steel, Titanium, and plastic polymeric compounds.

The process parameters are described in table 1.

Table 1 – Cleaning and Disinfecting Process Parameters.

Detergent	**Neodisher MediClean Forte ®**		
Program Parameters	**Temperature (°C)**	**Duration (minutes)**	**Concentration of detergent**
Prewashing I	10	10	N/A
Washing	55	5	0,3% to 1,0 % detergent
Neutralization	10	2	N/A
Rinsing II	10	1	N/A
Thermic Disinfection	93	5	N/A
Drying	110	25	N/A

NOTE:

- Neodisher® MediClean Forte (Dr. Weigert), is a cleaning and disinfecting medical device (93/42EEC) intended for reprocessing of surgical instruments.
- Neodisher® MediClean Forte (Dr. Weigert) has been used in the validation of the cleaning and disinfecting process and its use is recommended. Validation covers the range of concentrations of Neodisher® MediClean Forte, and temperatures pointed in table 1. The following equipment was used for the validation: Miele Unit G 7836 CD.
- Use purified water for cleaning and disinfection steps (bioburden <100 CFU/mL, and endotoxins <0.25 EU/mL, according to Ph. Eur. 04/2018:0008).

4. INSPECTION, MAITENANCE, FUNCTIONAL TEST

Check all instruments for corrosion, damaged surfaces, chipping and contamination, and sort out damaged instruments. Critical areas such as handle structures, joints, or blind holes must be inspected carefully. You can use a magnifying glass and direct lighting to improve visibility. Instruments with illegible markings/labelling must also be replaced.

If the instruments still look contaminated, the cleaning and disinfection processes must be repeated. Damaged, corroded or worn instruments should not come into contact with intact instruments, to avoid contact corrosion.

Verify that the instruments and surgical boxes are perfectly dry before assembling them and proceeding with sterilization.

The instruments must be subjected to a functional test. Multi-piece instruments are assembled for this purpose. Further contamination must be absolutely avoided in assembly.

5. STERILIZATION

- For sterilization of single items: place the material individually in sterilization pouches and seal them.
- For co-sterilization: assemble the instruments in their corresponding surgical box, place the box inside a sterilization pouch and seal it.
- Place the pouches to be sterilised in the steam autoclave and sterilise them using a cycle at 134ºC (273 °F) with fractional pre-vacuum, for 6 minutes, and 20 minutes for drying.

The usage of a **sterilisation control** is recommended, recording the date and expiry date, in addition to performing periodic controls of the sterilisation process using biological indicators.

NOTE:

- Respect all the phases of the sterilizer.
- Check the materials and pouches at the end of the sterilisation cycle ensuring that they are dry.
- Follow the instructions of the manufacturer of the sterilisation pouches.
- Sterility cannot be guaranteed if the sterilization pouch is open, damaged, or wet.
- Corroded and rusty instruments can contaminate the water circuit of the sterilizer with rust particles. These rust particles will cause initial rust on intact instruments in all future sterilization cycles. It is important to regularly inspect and clean the unit.
- Instruments presenting corrosion and/or rust must be discarded and not used.
- The instruments must be stored dry after sterilization.
- Do not use dry heat sterilisers.
- Disposable sterilization packaging must meet **EN ISO 11607**, be suitable for steam sterilization, and provide sufficient protection for the devices that it will contain.
- Steam sterilizer must fulfil **EN 13060** and/or **EN 285**.
- Steam sterilization validated according **EN ISO 17665**.

6. CONSERVATION

The instruments must be stored dry and free of dust in the sterilization packaging after sterilization. Never exceed the expiration dates determined by the manufacturer of the sterilisation pouches.

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