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Cleaning, disinfection and sterilization

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Index

1. General principles

The following procedure applies to:

- Phibo® Implantable Attachments: Attachments are single-use products and therefore, must not be reused.
- Phibo® Dental Instruments: Instruments are reusable devices that must be cleaned, disinfected, and sterilized before every use.

Phibo® Attachments and Instruments **are not supplied sterile** and must be cleaned, disinfected, and sterilized before their use.

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 process. Any deviation from the following instructions should be validated by the user/processor to ensure the efficacy of the process.

This procedure is based on automatic cleaning and disinfecting process. Efficacy and biocompatibility of the reprocessing have been assessed under these instructions. If alternative cleaning, disinfection, or sterilization methods are chosen, they must be sufficiently validated, specifically for the equipment or device used to conduct these processes and, they must achieve the desired results without affecting the products that undergo reprocessing.

Use only cleaning agents and disinfectants intended for the device's material, and follow their respective instructions for use, as provided by the manufacturer. Information about the material of each medical device could be found in their respective instructions for use:

- **IFU-00002** Implantable attachments.
- **IFU-00003** Dental instruments Class IIa.
- **IFU-00004** Non-implantable attachments.
- **IFU-00005** Dental instruments Class I.

The equipment used (disinfector, sterilizer, etc.) must be regularly maintained, inspected, and calibrated. Washer- disinfector equipment to be used must meet the requirements of the ISO 15883 series.

It is important to use personal protective equipment (PPE) while handling contaminated products, and executing the cleaning, disinfection and sterilization steps. Always wear protective glasses, face mask, gloves, etc. for your own safety during all activities.

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

Notes for Instruments

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.

2. Warnings

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.

Never let surgical residues (blood, secretions, tissue residues) dry on an instrument. 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.

Do not place instruments from different materials together in a liquid bath, as this will result in an increased risk of contact corrosion.

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

Do not mix instruments and attachments during the stages of cleaning, disinfection, and sterilization.

Never use damaged or dirty material.

Never reuse products indicated for single use.

Never expose instruments, surgical boxes and attachments to temperatures higher than 134 °C (273 °F).

Never leave or store moist or wet parts.

3. Pretreatment

Devices first time being used do not require this first step, is only intended for used dental instruments.

Neodisher MediClean Forte (Dr. Weigert) can be used as pre-cleaning agent. Consult product instructions for use. The disinfectant used in pretreatment serves only for your own protection and cannot replace the disinfection step to be performed later after cleaning.

First, 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.

Use tap water to rinse the products. 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 disinfectants and cleaning agents very thoroughly with water. Rinse out all cavities of the instruments e.g. using a disposable syringe.

Shift movable parts forwards and backwards several times during pre-cleaning.

4. Cleaning and disinfection

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 before use.

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

The process parameters are described in table 1.

Table 1 – Validated parameters for the Cleaning and Disinfecting Process.

Detergent	Neodisher MediClean Forte		
Program Parameters	**Temperature (ºC)**	**Duration (minutes)**	**Reagent**
Prewashing I	10	10	Tap water
Washing	55	5	0,3% to 1,0 % detergent in tap water
Neutralization	10	2	Purified water
Rinsing II	10	1	Purified water
Thermic Disinfection	93	5	Purified water
Drying	110	25	N/A

NOTE: 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).

5. Inspection and maintenance

Check all parts; attachments or instruments for corrosion, damaged surfaces, chipping and contamination, and sort out damaged ones. Critical areas such as handle structures, joints, or blind holes must be inspected carefully. Magnifying glass and direct lighting can be used 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 avoided during assembly.

6. Sterilization

For sterilization of single items: place the material, attachments or instruments individually in sterilization pouches and seal them following manufacturer's instructions.

The packaging system must enable sterilization and guarantee sterility until use under proper storage conditions;

Care must be taken to ensure that the sterilant has access to all external and internal surfaces of the medical device within the sterile packaging.

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 sterilized in the steam autoclave and sterilize them using a cycle at 134ºC (273 °F) with fractional pre-vacuum, for 6 minutes, and 20 minutes for drying.

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

Note:

- Respect all the phases of the sterilizer.
- Check the materials and pouches at the end of the sterilization cycle ensuring that they are dry.
- Follow the instructions of the manufacturer of the sterilization 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.
- Do not use dry heat sterilizers.
- 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 must be validated according to **EN ISO 17665**.

7. Labelling

Packaged, reprocessed medical devices are to be accompanied by information that enable safe use. It must be possible at all times for the user to recognise:

- the name of the medical device; this must allow for use-relevant identification (e.g. model, size) if this is not immediately obvious;

- information on the labelling of released medical devices; as well as

- the release decision and, where applicable, process indicators;

as well as information that enables a decision to be taken on time-related aspects of safe use of the medical device, such as:

- date of sterilization (batch number of the sterilisation, sterilisation date);
- where appropriate, an expiry date understood as the manufacturer-indicated date until which safe use is proven to be possible;
- Specifications for technical-functional testing and safety, safety instructions, warnings and other information, which is exclusively present on the original packaging and is relevant for safe use and traceability;
- the name of the manufacturer and batch.
- the number and type of completed reprocessing cycles.

8. Release and Storage

The reprocessing of medical devices ends with their documented release for use. This is authorized if the process parameters measured during the reprocessing cycle comply with those stated in Table 1. Any deviation must be documented and approved.

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