GUIDELINE FOR CLEANING, DISINFECTION AND STERILIZATION

87 Rev.1

Guideline for Cleaning, Disinfection and Sterilization

1. PURPOSE OF THIS DOCUMENT

This document gives general guidance on how medical devices manufactured by Valoc AG that are suitable for cleaning, disinfection and sterilization may be processed to prepare them for use.

2. GENERAL INFORMATION / PRINCIPLES

The applicability of these guidelines for Valoc AG devices is indicated in the Instructions for Use (IFU). Where required, disassembly and assembly of the device components shall be performed in accordance with the applicable IFU.

All instruments / prosthetic components must be cleaned, disinfected and, if required, sterilized before every use. This applies for first-time use of multiple-use components after delivery, as well as for single-use devices that are delivered non-sterile and might have to be disinfected or sterilized prior to use.

Cleaning and disinfection and/or sterilization is performed after removal of the protective transport packaging. Effective cleaning and disinfection are mandatory requirements for efficient sterilization.

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

- only procedures that are sufficiently and specifically validated for the equipment or the devices are used for cleaning, disinfection and sterilization.
- the equipment used (disinfector, sterilizer) is regularly maintained, checked and calibrated.
- the instructions regarding Valoc AG product components, the equipment, disinfectants and cleaning fluids must be observed at all time.

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

3. SCOPE OF THE GUIDELINE

These instructions apply to all Valoc AG instruments (for multiple use) and prosthetic components of Valoc AG products.
The instructions apply only to products from Valoc AG and not products that are only distributed by and not manufactured by Valoc AG.

4. CLEANING AND DISINFECTION

For cleaning and disinfection, the prosthetic components must be separated in accordance to their material composition. Components from different materials should never be placed together in one bath, especially components made from different metals (as this will result in an increased risk of contact corrosion). Information regarding the material of the devices can be found on the label and in the respective instructions for use or in the Valoc product catalog.

4.1 Disinfectant used during validation

Revital-OX Resert® HLD (Steris)

Notes:

- If the used disinfectant is not commercially available in your market, use an equivalent one and follow the instructions of the manufacturer.
- Suitability of the alternative disinfectant should be checked by referencing the details from manufacturer and the material of Valoc AG product components.
- Valoc AG does not recommend any specific disinfection agent. However, it is recommended to use disinfectants with approved efficacy (for example VAH/DGHM or FDA approval or CE marking).

4.2 Cleaning / Preparation

Step 1: Place the device / device components to be disinfected in tap water for 5 minutes.

Step 2: Clean the device / device components by brushing with suitable cleaning brush.

Step 3: Rinse the device / device components under running tap water for 30 seconds.

4.3 Disinfection

Step 1: Prepare a bath with disinfection solution at the concentration and temperature specified in the manufacturer's instructions. (*The disinfectant solution for validated method of disinfection, Revital-Ox Resert® from Steris Corporation (REF 4445 AWEC) is a ready-to-use solution).*

Step 2: Completely immerse the device / device components in the disinfection bath for at least the time specified in the manufacturer's instructions. Ensure that all lumina are filled with the disinfection solution and all surfaces are wetted with it.

Note: The disinfectant solution Revital-Ox Resert® from Steris Corporation was used according to the manufacturer's instructions during validation and samples were immersed for 8 minutes.

Step 3: Remove the device / device components from disinfection bath at the end of specified exposure time and rinse the device / device components at least five times (5x) with freshly prepared purified water or sterile water.

Step 4: Dry the device / device components using clean compressed air or single use sterile wipes.

Step 5: Inspect the disinfected device / device components and if necessary (if not to be used immediately), pack in sterilization bags as quickly as possible after removal.

5. STERILIZATION

The sterilization methods listed below may be used for sterilization.

Steam sterilization (fractionated vacuum method)

Step 1: Seal the devices in suitable autoclave foil / bag.

Step 2: Steam sterilization with fractionated vacuum procedure with at least 3 vacuum steps (with adequate product drying time: at least 20 minutes) with maximum sterilization temperature of 138 °C (280 °F; plus tolerance) in compliance with EN ISO 17665.

Sterilization time, exposure time at sterilization temperature, of at least 4 minutes at 132 °C (270 °F) or 18 minutes for prion inactivation.

Method	**Moist heat sterilization according to ISO 17665**	
Cycle	Saturated steam with fractional forced air removal	Saturated steam
Temperature	132 °C (270 °F)	
Temperature Max	138 °C (280 °F)	
Exposure time	4 minutes	15 minutes
Pre- vacuum	3 times < 60 mbar	N.A.
Drying time	Minimum 20 minutes, up to 30 minutes	

Step 3: After sterilization, store the product in dry conditions if not to be used immediately. Follow the instructions of the manufacturer of the sterile pouches regarding storage conditions.

All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with DIN EN 13060, EN 285, EN ISO 17665-1, AAMI ST79 or your national standards.

Note: According to EN ISO 17664, the user is responsible for ensuring that the equipment and materials used, as well as the staff employed in the processing facility, achieves the required results. The user is responsible for validation of equipment used. The devices/sterile containers used must be serviced and inspected regularly and the validated parameters must be complied with on every cycle.

6. REFERENCES

- AAMI ST-81: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re- sterilizable medical devices.
- FDA-June 09. 2017: Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.
- VAH – Verbund für Angewandte Hygiene E.V http://www.vah-online.de/ ”Association for Applied Hygiene”.
- DGHM – Deutsche Gesellschaft für Hygiene und Mikrobiologie http://www.dghm.org/ ”German Association for Hygiene and Microbiology”.
- CE – Conformité Européenne http://ec.europa.eu/ ”European Conformity”.
- DIN EN 13060: Test method to demonstrate the suitability of a medical device simulator during steam sterilisation – Medical device simulator testing.
- DIN EN 285 Sterilization – Steam sterilizers – large sterilizers.
- DIN EN ISO 17665, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- EN ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the preparation of re-sterilizable medical devices (ISO 17664:2004).