CLEANING – DISINFECTION – STERILIZATION

SIGNUS PRODUCTS

Manufacturer: SIGNUS Medizintechnik GmbH, Industriestr. 2, 63755 Alzenau/Germany

Classification regarding RKI*-directive: At user´s responsibility

Pre-cleaning Class A: if needed, Class B+C direct after use
Disassembly of the products, if possible.
Immerse the products in cold regular tap water without any bubbles for a minimum of 5 minutes.
Depending on the severity of contamination all moveable components have to be moved several times under regular running tap water; free accessible sections have to be brushed.
Products with cavities as well as connections, threads, joints, hinges and springs have to be soaked in an ultrasonic bath for 10 minutes at 40°C with 0.5% solution of alkaline cleaner (e.g. neodisher FA) and then rinsed from the inside and outside with a water spray gun at 4 bar static power for minimum 20 sec. with cold regular tap water.
Surfaces have to be brushed with a soft brush until visable contaminations are removed completely.

Automated cleaning (Preparation in a purifier/disinfector)
Products have to be placed in the tray of the purifier/disinfector (e.g Miele G7735). Products with a cannula have to be placed in the MIS-tray and have to be connected to the wash up system [MIS = minimal invasive surgery].
Clean the products e.g. with the Vario TD program as follows: 1. Minimum 2 minutes pre-washing with cold regular tap water 2. Drain 3. Dose the cleaning agent (e.g. neodisher FA Dr. Weigert, Hamburg) 4. 5 minutes cleaning with neodisher FA 0.5% at 55°C or equal cleaning agent 5. Drain 6. 3 minutes neutralization with warm water (> 40°C) 7. Drain 8. 2 minutes intermediate rinsing with warm water (> 40°C) 9. Drain

Disinfection
Automated operation: Automatique thermal disinfection, maximum 93°C in the a purifier/disinfector (part of the Vario TD programm) following the national requirements regarding the A0 value. [In the standard EN DIN ISO 15883-1:2009, appendix A the definition A0 is as a measuring unit of time and kinetik regarding the killing of microorganisms at the procedure with moist heat].

Drying
Automated operation: Dry the products in the purifier/disinfector (one drying cycle, part of the Vario TD program) if necessary the products can be dryed with a lint-free fabric.

Function check maintenance package
Visual auditing of results of the previous steps; assembling of all disassembled products; function check
Maintenance and care measures: Maintenance or care means targeted application of care agents to moving parts, the joints, hinges, locks, threads etc. or friction surfaces of products after they have been carefully cleaned and disinfected. This prevents metal-on-metal friction and therefore constitutes a preventive measure against corrosion caused by such friction. In this way, the products are kept functional and hinge action maintained. Requirements for care agents: Paraffin/white oil basis, in accordance with the current European or United States Pharmacopoeia, suitable for steam sterilization, vapor-permeable and biocompatible. Single products have to be double-packed in sterile bags, Trays have to be wrapped in sterile fabric.

Sterilization	
Operation:	Steam sterilization (fractionated prevacuum-operation)
Temperature:	minimum 132°C, maximum 137°C
Cycles:	minimum 4 times pre-vacuum
Sterilization duration:	minimum 4 minutes. ATTENTION: DIANA Tray (SH01AY, one piece synthetic inlay SH01AZ) 10 minutes
Drying duration:	Drying time in accordance to the setting of the sterilizer, sterile products have to be dry. ATTENTION: DIPLOMAT Tray AC01AY and AC02AY 30 minutes

Storage
The sterilized products have to be stored by ambient temperature in a dry, clean and non-fuzzing environment.

*The instructions are based on the respective validation, conducted by an external test laboratory according to the relevant standards DIN EN ISO 17664:2004 and RKI-directive (Robert-Koch-Institution): "Hygiene requirements for the reprocessing of medical devices; 2012"

Comment if necessary:

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