

97 – Form Reprocessing Instruction



Manufacturer Name:	Gebr. Zepf Medizintechnik GmbH & Co. KG	
Product(s):	All medical devices according to our product listing	
NOTE:	Due to product designs and materials used, it is not possible to determine a limit for the maximum amount of reprocessing cycles. Our medical devices may be reprocessed until their function is no longer guaranteed. Defect products must run through the complete reprocessing process before returning for repair.	
Reprocessing Instruction		
On-site	Products are to be soaked in cold (room temperature) water immediately after use. Do not use warm water or detergent as this may lead to fixation of residues on the product, which can influence the success of the following reprocessing steps.	
Preparing for decontamination:	If possible, products must be disassembled prior to the following reprocessing steps respectively go through the further reprocessing steps in open condition.	
Cleaning:	Manual Cleaning Process: <ol style="list-style-type: none"> Rinse products with cold mains water until all visible contamination has been removed. Persistent contamination can be removed using a soft brush; Soak products in an enzymatic detergent. Please follow the detergent manufacturer's instructions. Rinse products under running mains water in order to remove the detergent. 	Automatic Cleaning Process: <ul style="list-style-type: none"> Pre-clean with cold water for 4 minutes; Clean with 0.5% alkaline detergent at 55°C for 6 minutes; Neutralize with warm water (>40°C) for 3 minutes; Rinse with warm water (>40°C) for 2 minutes. Please follow special instructions of the cleaning machine's manufacturer.
Disinfection:	Manual Disinfection: <ol style="list-style-type: none"> Immerse products in an enzymatic detergent. Please follow the instructions of the disinfectant manufacturer. Rinse products in DS-Water. 	Automatic Disinfection: Automatic thermal disinfection with cleaning and disinfection machine considering the national A ₀ -Value.
Drying:	Manual drying with a lint-free cloth.	Automatic drying according to automated drying process of the cleaning and disinfection machine. If necessary, additional manual drying with lint-free cloth.
Maintenance, function check and inspection:	Check products for function and further decontamination. If necessary, perform cleaning and disinfection steps again in order to remove residual contamination.	
Packaging:	Pack products in suitable sterile packaging (e.g. Medipeel bag).	
Sterilization:	Recommended and validated method: Steam autoclave: Temperature = 121°C (250°F) with an exposure / holding time of at least 30 minutes and a drying time of 15 – 30 minutes or Autoclave with prevacuum: At least one prevacuum step, Temperature = 132°C – 135°C (270°F – 275°F), Pressure = 2 – 3 bar (27 – 30 psia), with an exposure / holding time of at least 4 to 10 minutes and a drying time of 20 – 30 minutes.	
Storage:	Store sterile products in a dry, clean and dust-free environment at 5°C to 40°C and protected from damage.	
Additional Information:	It is the responsibility of the user to achieve the required results by means of the actual performed reprocessing with the equipment, materials and human resources used in the reprocessing facility. In general, validation and routine monitoring of the methods and the used equipment is required for this.	
Contact of manufacturer:	Stamp	