Reprocessing of Risk Class I medical devices made by Kögel GmbH:

CE

Applies to: Kögel medical devices, MEDSolutions V211, article no. 22.216.*****, 28.216.*****;
product name: Wistainer, small-parts trays, instrument trays, endoscopy baskets, sterile goods baskets and components.

By purchasing one of the above devices, you have acquired a high-grade Kögel product.
Please follow the reprocessing instructions given in the table below.
The instructions cover cleaning, disinfection, drying and sterilisation. This is the only way to ensure that your medical devices will remain in good condition. The success of reprocessing is the sole responsibility of the operator. Prior to first use of Kögel medical device, these must complete a full machine reprocessing cycle.

Preparation at the site of use	
Procedure	Explanation
Dry/wet	Note: Handle used devices with care! Dry means: the devices (MD) are set aside after use without a disinfectant or any other additional liquids and transported to CSSD/SPD (reprocessing unit). Wet means: the devices (MD) are placed into a non-fixating, cleansing disinfecting solution immediately after use. Note: Please see the detergent manufacturer information!
Cleaning and disinfection	
Procedure	Explanation
Manual and machine reprocessing **with** and **without** ultra sound	Validated machine reprocessing is always preferable! Manual reprocessing is always at the sole responsibility of the reprocessing individual. The requirements published by the RKI (Robert Koch Institute) and the methods published by the AKI (Instrument Reprocessing Working Group) apply. Note: Drilling/K-wire dispenser sets, article no. 22.216.1162 to 22.216.1171, must be dismantled and have to complete the reprocessing cycle prior to being equipped with drilling wires.
Chemicals & temperatures for cleaning and disinfection	
acidic/neutral/alkaline; pH between 5.5 and 10.5, with/without surfactants, chemically at no more than 60 °C or thermally using purified water at no more than 93 °C.	It is assumed that commercially available reprocessing products suitable for the intended use are used for cleaning and disinfection and that recommended concentrations, exposure times and temperatures are complied with. It must also be ensured that no residue remains on the devices (MD)! In a last step, the device must be rinsed with purified water. Note: Handle reprocessed devices (MD) with care!
Drying	
by machine: max. 115 °C; manually: protected from ambient air;	Automated process, part of the validated process; the reprocessing individual is solely responsible for validation! Note: Handle reprocessed devices (MD) with care! The MD are subject to high temperatures during machine-based reprocessing.

Checks, servicing and controls	
Procedure	Explanation
Functional checks must always be performed by trained and qualified personnel. The requirements published by the Deutsche Gesellschaft für Sterilgutversorgung (DGSV) and the Instrument Reprocessing Working Group (AKI) must be complied with!	Visual inspection of devices and components for suitability for use and integrity. Note: Processes must be selected at the reprocessing entity's own responsibility! The reprocessing entity is responsible for ensuring that reprocessing with the selected equipment, materials and personnel in the reprocessing unit yields the desired results. Visual inspection of wire mesh for breaks and frames for integrity, if necessary batch check for the devices; visual inspection of instrument holders for surface damage.
Packaging	
Packaging materials in line with standards EN 868 and ISO 11607 approved for the specified sterilisation process by the MD manufacturer.	
Sterilisation	
Several steam sterilisation processes available: Validated steam sterilisation process at 134 °C for 3.5 minutes or Validated steam sterilisation process at 121 °C for 15 minutes Note: The MDs are exposed to high temperatures.	Sterilisation and exposure times are subject to national regulations and guidelines. No general information can therefore be provided. The reprocessing entity is responsible for ensuring that reprocessing and sterilisation with the selected equipment, materials and personnel in the reprocessing and sterilisation unit yields the desired results. This requires validation and routine monitoring of methods and processes!
Alternative sterilisation processes	Note: Steam sterilisation has globally been shown to be very safe and reliable and should therefore be preferred for temperature- and moisture-sensitive sterilisation goods. Usually, reference is made to steam sterilisation using a validated steam sterilisation process (see DIN EN ISO 17665:2006-11). As a result, there is no need to sterilise MDs that can be steam-sterilised using other means, e.g. low-temperature plasma sterilisation, formaldehyde or ethylene oxide. Nevertheless, those operating sterilisation equipment are free to use alternative processes to validate sterilisation of the medical devices that are to be sterilised.
Storage/transport	
Storage: Only store in clean, dry, well-ventilated rooms that are easy to clean and disinfect. Protect against direct sunlight. Transport: Transport carts, open or closed, must be easy to clean and disinfect.	Please comply with the basic requirements and rules for handling sterile goods and sterile goods packaging.
Additional information	
The reprocessing information provided herein cannot be a substitute for independent, detailed process descriptions. We accept no liability for the information provided herein. Please label damaged products (MDs and components) clearly, reprocess and return them to Kögel using the return form. Only the manufacturer may make repairs. Only dispose of devices once decontamination is verified.	
Contact:	**Kögel GmbH,** Hagenfeldstraße 4, 75038 Oberderdingen, Germany T: +49 (0) 7045 / 982-0 F: +49 (0) 7045 / 982-22 med@mk-koegel.de

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