Processing Instructions

Manufacturer: Key SurgicalGmbH

Product name: Container for Kirschner wires

Please observe the reprocessing instructions in the following table. These instructions refer to cleaning, disinfection and sterilization. This is the only way to ensure that your products retain their value. The manifold reprocessing possibilities available derive from the material compatibility of this product. The operator bears sole responsibility for assuring a successful reprocessing outcome.	
Preparation at the site of use	
wet or dry	Dry means the instruments are transferred to CSSD without any disinfectant or other additional fluids immediately after the operation. Wet means the instruments are immersed in a non-fixating active cleaning disinfection solution immediately after operation. Please observe the manufacturer's instructions for the cleaner.
Cleaning and disinfection	
manual or mechanical reprocessing **with** or **without** ultrasound treatment	Clean and disinfect all removable parts separately and without contents.
Chemicals and Temperatures for Cleaning and Disinfection	
Acidic / neutral / alkaline with or without tenside additives, chemically at max. 60° C / 140° F or with demineralized water, thermally, at max. 93° C / 199° F	It is assumed that commercially available products that have been approved for cleaning and disinfection will be used. Likewise, it is assumed that the recommended concentrations, exposure times and temperatures will be observed. It must be ensured that no residues remain on the products. Demineralized water must be used for the final rinse.
Drying	
Max. 100 °C / 212° G	
Inspection, Maintenance and Testing	
Visual inspection for suitability for use and intactness	
Package	
Packaging materials according to EN 868 and ISO 11607 standards approved for the specified sterilization process	
Sterilization	
A choice of one or several processes: validated steam sterilization process with 134 °C / 3.5 min, 5.3 min or 18 min	Sterilization and hold times are subject to national regulations and guidelines and, therefore, cannot be stipulated in general terms. The operator bears responsibility for ensuring that reprocessing and sterilization, as actually conducted with the equipment, materials and personnel used for reprocessing and sterilization, achieve the required results. Validation and routine monitoring of the process are needed to that effect.
Alternative sterilization processes*	*Note on alternative sterilization processes: Steam sterilization has become established worldwide as a very safe and reliable sterilization method and is thus the method of choice for temperature- and humidity-resistant sterile supplies. Here, steam sterilization using a validated steam sterilization process (see also DIN EN ISO 17665) is generally referenced. Therefore, there is no need to sterilize steam sterilizable products with alternative sterilization processes, e.g. low-temperature plasma sterilization, formaldehyde and ethylene oxide. However, each operator of a sterilization unit is free to have sterilization validation conducted using an alternative sterilization process.
Storage	
No special requirements.	Please observe the general principles and requirements when handling

	sterile goods and sterile goods packaging.

Further Instructions

Observe the manufacturer's instructions for the washer-disinfectors and sterilizers. The reprocessing instructions given here cannot replace detailed process descriptions, as the multitude of reprocessing methods used worldwide cannot be described in detail. All information is without guarantee. The scope of application and the resulting consequences are the sole responsibility of the operator.

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