

Processing Instructions

Manufacturer: Key Surgical GmbH

Product name:

Cable binder made of silicone

Please observe the reprocessing instructions in the following table. These instructions refer to cleaning, disinfection and sterilization. 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	
Recommendation: The cable binder must be replaced before each application	
Cleaning and Disinfection	
Manual or automated reprocessing without ultrasonic treatment	
Chemicals and Temperatures for Cleaning and Disinfection	
Acidic / neutral / alkaline > pH 10 with/without addition of surfactants, chemically at max. 60 °C or thermally with demineralized water at max. 93 °C	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	
Inspection, Maintenance and Testing	
Visual inspection for suitability for use and cleanliness of cable binder made of silicone.	
Sterilization	
A choice of one or several processes: validated steam sterilization process with 134 °C / 3.5 min, 5.3 min or 18 min programs or validated steam sterilization process with 121 °C / 15 min program	Sterilization and hold times are subject to national regulations and guidelines and, as such, 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 reference is generally made to steam sterilization using a validated steam sterilization process (see also DIN EN 554). There is therefore no need to use alternative sterilization processes, e.g. formaldehyde or ethylene oxide, for steam-tolerant products. However, each operator of a sterilization unit is free to have sterilization validation conducted using an alternative sterilization process.
Storage	
Requirements:	Cable binder made of silicone must be stored at room temperature. Do not expose to direct sunlight
Further Instructions	
<i>The reprocessing instructions given here are not a substitute for a detailed process description since it is not possible to elaborate in detail on the myriad reprocessing methods used worldwide. All information without guarantee.</i>	
Contact:	Key Surgical GmbH, Zum Windpark 1, D-23738 Lensahn Tel. +49 4363/905900, Fax +49 4363/90590590