NOBAMED Paul Danz AG

Reprocessing instructions of NOBAMED Paul Danz AG for the reusable accessory device **APPLIKATOR** for tubular bandages e. g. NOBATRIKOT®

The device is intended for reuse and requires reprocessing to bring it from its post-clinical use state to a cleaned, disinfected and/or sterilised state ready for reuse.

Instructions	
Initial Treatment at the place of use (storage and transport)	The storage and transport conditions and the shelf-life of the non-sterile product are indicated on the package In accordance with general reprocessing rules, the APPLICATOR should not lie dry and dirty for longer than 6 hours after use, as otherwise machine cleaning can no longer be reliably carried out
Preparation of Cleaning	Preclean if necessary
Cleaning/ Disinfection	Validated mechanically in commercially available washer-disinfectors for surgical instruments according to ISO 15883 or validated manually with the prescribed clinical detergents/disinfectants depending on the contamination. Saline solution and detergents/disinfectants containing aldehyde, chloride, bromine, bromide, iodine or iodide are corrosive and must not be used.
Drying	Verified process for machine or manual drying. Drying can be achieved as part of the machine cleaning or disinfection process
Control and Verification	The Product must be clean, dry, and free of residues
If sterilisation is required, preparation for sterilisation	Remove and discard the packaging of the product
Packaging	Suitable validated sterile barrier system or cleanable screen basket
Sterilization	Validated sterilization process for example • with moist heat according to DIN EN ISO 17665 or as per requirements of the European Pharmacopoeia with 15’ to 20’, 121°C to 134°C, 2 bar
Control and Verification	The validation of the sterilization process and the product fall under the responsibility of the processor
Storage and Transport	For the product the storage and transport conditions indicated on the original packaging are applicable.
Additional Information	Material: Stainless Steel Limitations for reprocessing are normally determined by wear and damage due to intended use

The above-mentioned instructions have been compiled in accordance with EN ISO 17664 and have been validated as SUITABLE for the reprocessing of **APPLIKATOR**. It falls under the processor’s responsibility to make sure that the actual process (with the equipment, materials, and staff in the processing department) is adequate to achieve the desired results. This necessitates a validation and routine monitoring of the process on site.

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