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| Products: | Surgical Instruments | |
| Warnings: | The cleaning of narrow lumens or holes requires special attention! In general, our products will be delivered unsterile. All instruments have to be completely cleaned, disinfected and sterilized before initial use according to following procedures. | |
| INDICATIONS: | It is very important to check each surgical instrument for visible damage and functions before use. Damaged products will be scrapped or sent back to the manufacturer for maintenance. Restrictions of reprocessing: Frequent reprocessing has minimal effect on our instruments. The end of the product life cycle is determined by waste and damage through use. Defect products have to be passed through the reprocessing process before reshipment. | |
| Instruction for use | | |
| Place of use: | Insert products in cold water immediately after each use (<40°C). Do not use cleaning agents or hot water (>40°C) as this may result in the fixation of residues and could reduce the cleaning success (risk of protein coagulation (denaturation)). Remove surface contamination with single-use towel/paper towel. | |
| Transport: | Save storage till and save transport for processing of products to avoid damages. | |
| Preparation for decontamination: | If possible, products have to be disassembled respectively introduced in open state to further processing steps. | |
| Manual cleaning: | <ul style="list-style-type: none"> • Insert products for 5 min. in cold water and brush it with nylon brush after. • Flush products with water pressure gun (with a static water pressure of at least 3.8 bar). • Clean products in an ultrasonic bath with a smooth alkaline cleaner (neodisher Mediclean, Dr. Weigert, Hamburg). | |
| Machine cleaning: | Machine cleaning process (Program Vario TD ; G 7735 CD Miele): <ul style="list-style-type: none"> ▪ Prerinse for 2 min. with cold water ▪ Discharging ▪ Clean for 5 min. at 55°C with 0,5% alkaline cleaning agent (neodisher Mediclean, Dr. Weigert, Hamburg) ▪ Discharging ▪ Neutralize for 3 min. with cold tap water ▪ Discharging ▪ Rinse for 2 min. with cold tap water Special manufacturer's instructions of the cleaning machine have to be considered. | |
| Disinfection: | Manual disinfection: 1. Immerse products in a RKI or VAH listed disinfectant. Please follow the manufacturer's instructions for use of the disinfectant. 2. Rinsing of products with fully demineralized water. | Automatic disinfection: Automatically thermic disinfection in cleaning and disinfection machine, in consideration of national requirements to the A ₀ -value. |
| Drying: | Manual drying is carried out using a lint free cloth. Heating the product over 140°C is not allowed. To avoid residual water in hollows, it is recommended to blow out with sterile compressed air. | Automatic drying in accordance to automatically drying process of the cleaning and disinfection machine. If necessary, subsequent manual drying with lint free cloth and blowing out of lumen by sterile, oil-free compressed air. |
| Service, control and review: | Performance of functional test and review of pollution. If necessary, perform cleaning and disinfection steps again in order to remove residual pollution. | |
| Packaging: | Products have to be packaged in suitable sterile packaging. | |
| Sterilization: | Sterilization of products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) in consideration of the respective national requirements. We recommend to perform a fractional pre-vacuum procedure with following parameters: <ul style="list-style-type: none"> • Fractional pre-vacuum (three times) • Sterilization parameter 132 °C • Holding period 3 min. (full cycle) • Drying time 10 min. | |
| Storage: | Sterilized products have to be stored in a dry, clean and dust-free area at moderate temperature from 5°C to 40°C. | |
| Additional information | | |
| The user has the responsibility that the effective performed processing with used equipment, materials and personnel achieves the desired results in the processing facility. | | |
| Manufacturer: | Rita Leibinger GmbH & Co. KG Griesweg 37 78570 Mühlheim/Do., Germany | |

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