










Products:	General 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: 	<p>Limitation of the reprocessing: Frequent reprocessing has minimal effects on our instruments. The end of the product life time is usually given by damage or wear.</p> <p>Defect products have to be passed through the reprocessing process before reshipment.</p> <p>The used town water has to comply with the GUIDELINE 98/83/EG OF THE COUNCIL from 3. November 1998 about the quality of the water for human use.</p> <p>The cleaning and deinflection agents for the validation are stated in this instruction manual. When using an alternative cleaning or deinflection agent (RKI or VAH listed) the responsibility is with the reprocessor.</p>	
Instruction for use		
Place of use:	<p>Insert products in cold water immediately after each use (<40°C). Do not use hot water (>40°C) or fixing disinfection agents as this may result in the fixation of residues and could reduce the cleaning success (risk of protein coagulation (denaturation)).</p> <p>Remove surface contamination with single-use towel/paper towel.</p>	
Transport:	<p>Save storage till and save transport for processing of products to avoid damages.</p> <p>The products have to be disposed in a wet condition immediately after use. This means, the products have to be transported in wet condition in a closed container so that no surface drying will happen.</p>	
Preparation for decontamination:	<p>If possible, products have to be disassembled respectively inserted in open state to further processing steps. Dead zones have to be avoided. The products have to be reprocessed in appropriate wire baskets or drainage bowls (choose size according to product). The instruments have to be fixed with a minimum distance one to another. An overlap one to another has to be avoided in order to avoid damage to the product due to the cleaning process.</p>	
Pre-cleaning:	<p>Rinse products with cold (<40°C) town water, as long until all visible contamination have been removed. Adhering contamination has to be removed with a soft brush or enclosed cleaning mandrel. Cavities and lumen have to be flushed by a water pistol (or similar) intensively (>30 sec) with cold town water (<40°C).</p>	
Cleaning:	<p>Manual cleaning process</p> <ul style="list-style-type: none"> • Insert products in an ultrasonic bath with a smooth alkaline cleaner (0.5% neodisher Mediclean forte, Dr. Weigert, Hamburg) with a sonication time of 10 min. and a frequency of 35 kHz. The instruction of the cleaning agent manufacturer has to be followed. • Post-clean the products completely with a soft brush. If existing, flush cavities and lumen with a water pistol (or similar) intensively (>30 sec) • Flush the products under town water to remove the cleaning agent (>15 sec). 	<p>Automatic cleaning process (Miele G7735 CD):</p> <ul style="list-style-type: none"> ▪ Pre-clean with cold town water (< 40°C) for 1 min. ▪ Discharging ▪ Pre-clean with cold town water (< 40°C) for 3 min. ▪ Discharging ▪ Clean with 0,5% alkaline cleaning agent (0.5% neodisher® Mediclean forte, Dr. Weigert, Hamburg) for 5 min. at 55°C±5°C ▪ Discharging ▪ Neutralize for 3 min. (0,1% neodisher® Z) with cold town water <40°C ▪ Discharging ▪ Rinse for 2 min. with cold demineralized water <40°C <p>Special manufacturer's instructions of the cleaning machine have to be considered.</p>
Disinfection:	<p>Manual disinfection:</p> <ol style="list-style-type: none"> 1. Immerse products in a RKI or VAH listed disinfectant. Please follow the disinfectant manufacturer's instructions for use of the disinfectant. It has to be ensured that the disinfectant reaches all spots of the product 2. The process is validated with the disinfectant 3% Korsolex® plus, 15 min. 3. Rinsing of products (complete flooding on the inside, outside and cavities) with fully demineralized water >60 sec. 	<p>Automatic disinfection (Miele G7735 CD):</p> <p>Automatically thermic disinfection in cleaning and disinfection machine, in consideration of national requirements to the A₀-3000value: >5min at 92°C±2°C.</p>

Drying:	Manual drying is carried out using a lint free single use cloth. To avoid residual water in hollows, it is recommended to blow out with sterile compressed air. If necessary further drying in drying cabinet for at least 20 min. The product must never be heated over 140°C.	Automatic drying in accordance to automatically drying process of the cleaning and disinfection machine 30 min at 60°C±5°C. 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 contamination. If necessary, perform cleaning and disinfection steps again in order to remove residual contamination.	
Packaging:	Products have to be packed conform to the standards for sterilization ISO 11607 and EN 868.	
Sterilization:	Sterilization of products with fractional pre-vacuum procedure (in accordance to DIN EN ISO 17665-1) in consideration of the respective national requirements. The sterilization has to be performed with a fractional pre-vacuum procedure with following parameters: 134°C / 273,2°F, 3 ±0,5 bar, ≥5 min detention time, 3 pre-vacuum-cycles Flash sterilization is not suitable for products with lumen!	
Storage:	Sterilized products have to be stored in a dry, clean and dust-free area, protected from damage, at moderate temperature.	

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. Therefore it is usually required to have validations and routine monitoring of the process and the used equipment.

Erläuterung verwendeter Symbole

	Batch name
	Manufacturing date
	Name and address of the manufacturer
	ATTENTION!
	Non-sterile
	CE-Mark
 Rita Leibinger GmbH & Co. KG Griesweg 37 78570 Mühlheim /Do., Germany	