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	Machine cleaning alkaline pH >10; Manual cleaning neutral enzymatic; with pre-cleaning	


 WARNINGS	<u>The following vCJD prion-specific protective measure is indicated when processing instruments.</u> <u>In the event of diagnosis of a definite or probable case of vCJD.</u> If it is not possible to use disposable products, the instrument used, which has been contaminated or where contamination cannot be ruled out, must be disposed of as incinerated waste . <u>If prion contamination is suspected:</u> In the event of suspected prion contamination, incineration of the instrument is recommended according to the vCJD task force final report. <u>If vCJD is excluded:</u> Continue to use after instrument processing is completed. Otherwise, the instrument, which has been contaminated or where contamination cannot be ruled out, must be disposed of as incinerated waste . <u>In the case of a non-identifiable vCJD illness.</u> Even if nothing is known about the presence of a prion disease, two processing procedures should be used with at least partial efficacy against prions – e.g. mechanical alkaline cleaning combined with steam sterilization. If mechanical alkaline cleaning or another cleaning procedure with proven efficacy against prions is not used and the medical devices in question are in contact with risk tissues (CNS, eyes, lymphatic tissue), the RKI recommends a prolonged sterilization time of 18 minutes at 134°C.
	Instruments made of stainless steel must not be placed in physiological saline solution (NaCl solution) as prolonged contact leads to corrosion such as pitting and stress-corrosion cracking.
	Only cleaned and disinfected instruments may be sterilized.
	Reprocessing restrictions Frequent reprocessing has few effects on these instruments. The end of their working life is normally determined by wear and damage through use. If there are any reprocessing restrictions, this is noted in the instructions for use of the specific product.

Reprocessing instructions:


Location of use:	<ol style="list-style-type: none"> 1. Directly after use, gross contamination should be removed from the instruments with a disposable cloth/paper. 2. Fixing agents or hot water (>40°C) must not be used as this leads to fixation of residues and can affect cleaning outcome. 3. The instruments should be conveyed promptly to processing. 4. Dry disposal preferred.
Preparation for decontamination:	Articulated instruments must be processed in open position. For rinsing, the instruments must be placed in instrument holders suitable for machine cleaning. The instrument holders (e.g. wire trays) must allow subsequent cleaning in an ultrasonic bath or in the cleaning and disinfection device (CDD) where they are not impeded by acoustic or rinsing shadows.
Pre-cleaning	<ol style="list-style-type: none"> 1. Place the instruments in cold water for 5 minutes; 2. Brush the instruments (plastic brushes) under cold water until all visible soiling is removed; 3. Internal spaces, threads, and holes are each rinsed with the water pistol for 10 seconds and brushed again;
Cleaning: machine	The cleaning and disinfection device (CDD) must meet DIN EN ISO 15883-1 requirements. <ol style="list-style-type: none"> 1. Pre-rinse 1: 1 minute with cold demineralised water, without additive; 2. Emptying; 3. Pre-rinse 2: 3 minutes with cold demineralised water, without additive; 4. Emptying; 5. Cleaning: with demineralised water, heat to 55°C and wash / clean for 10 minutes, add cleansing agent at 45°C, alkaline cleansing agent, strength 0.5%; 6. Emptying. 7. Neutralization: 3 minutes with warm water (>40°C) with addition of neutralizer, strength 1ml / l;

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Disinfection:	8. Emptying; 9. Final rinse: 2 minutes with warm deionised water (>40°C) (without any additive); 10. Emptying "Thermal Disinfection A0 value 3000: Completely desalinated water, the thermal disinfection is carried out at temperatures > 80 °C and corresponding application time according to the A0 concept, DIN EN ISO 15883 (e.g. A0 3000 = 90°C and 5 minutes application time). The operator is responsible for the implemented A0 value."
Drying:	Complete drying must be ensured by the CDD. The instruments must be removed from the CDD promptly once the cleaning and disinfection program has finished. If necessary, compressed-air drying is recommended because of its good and rapid action (recommendation by the German RKI).
Cleaning / disinfection: manual	The cleansing agents and disinfectants employed must be suitable for manual cleaning and disinfection of instruments and must be compatible with each other. The disinfectant must be of tested efficacy. When selecting the disinfectant agent and method, the relevant lists and recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (DGHM) should be noted.
Pre-cleaning:	<ol style="list-style-type: none"> Place the instruments in cold water for 5 minutes; Brush the instruments (plastic brushes) under cold water until all visible soiling is removed; Internal spaces, threads, and holes are each rinsed with the water pistol for 10 seconds and brushed again; Thorough rinsing with demineralised water
Cleaning / disinfection:	<ol style="list-style-type: none"> Place the instruments in a bath with a tested cleansing and disinfectant agent; The instruments must be completely covered with the solution; The application times, temperatures, and concentration stated by the manufacturer of the cleansing/disinfectant agent must always be observed; Remove the instruments and rinse for 2 minutes with cold deionised water; Repeat the cleansing process if visible contamination is still present on the instrument; If necessary, clean and disinfect the instruments in an ultrasonic bath. <p>Fresh solutions must be prepared daily. In case of severe soiling, the solution must be changed sooner.</p> <p>A high contamination load in the ultrasonic bath impairs the cleansing action and promotes the risk of corrosion. The cleansing solution must be renewed regularly according to the conditions of use. The criterion is visibly apparent soiling. In any case, a frequent change of bath is necessary, at least once a day.</p> <p>National guidelines must be observed.</p>
Drying:	Dry manually with compressed air and a lint free cloth. Compressed-air drying is recommended because of its good and rapid action (recommendation by the German RKI).
Maintenance, inspection, and testing:	<p>After cleaning / disinfection the instruments must be macroscopically clean, i.e., free from visible residues and soiling. Inspection is performed visually.</p> <p>Insufficiently clean instruments must be cleaned again and then adequately rinsed and dried.</p> <p>Before functional testing, instruments with movable parts must have cooled down and been lubricated with instrument maintenance oil (Medicon REF. 46.00.40). Instruments such as clamps and needle holders, which have a detent, should only be closed up to the first detent (risk of stress cracking).</p> <p>Defective instruments (hairline cracks, deformation or wear) must be replaced as they no longer fulfil their function or do so without adequate safety. Corroded instruments must also be replaced as they may corrode intact instruments by extraneous rust.</p>
Packing:	<p>The instruments must be placed in a suitable sterile barrier system. The sterile barrier system must meet the following criteria:</p> <ul style="list-style-type: none"> DIN EN 868, DIN EN ISO 11607,

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	<ul style="list-style-type: none"> • suitable for steam sterilization (vapor permeable), • adequate temperature resistance up to 138°C. <p>Sterilization equipment and sterilization wrapping must match both the wrap contents and the employed sterilization method.</p>																				
Sterilization:	<p>Taking into account the respective national regulations, the following method must be employed for sterilization:</p> <ul style="list-style-type: none"> • Vacuum autoclave with triple vacuum and adequate drying of the products (Vacuum minimal 15 Minutes) • Steam sterilizer complying with DIN EN 13060 or DIN EN 285 and validated in accordance with DIN EN ISO 17665-1. • Sterilization time and temperature: at least 5 minutes hold time at 134°C <p>It is essential to attain a Sterility Assurance Level of 10⁻⁶.</p>																				
Storage:	<p>Reprocessed sterile instruments must be stored in a suitable reusable sterilization container in a dry, dark, cool, and semi-sterile place, protected from dust and free from vermin. To avoid the development of condensation, major temperature fluctuations should be avoided during storage. Chemicals must not be stored together with instruments.</p> <p>The walls, floors, and ceilings of the storage room should be smooth and easy to clean and disinfect. Shelves must be at least 30 cm off the floor.</p> <p>The duration of storage permitted depends on the type of sterile barrier system employed and the storage conditions. This storage period must be established by the operating authority.</p>																				
Further information on reprocessing:	<p>Validated machine cleaning and disinfection is always preferred over manual cleaning because of the greater certainty of the method. Good cleaning helps to preserve value and is a precondition of successful sterilization.</p> <p>During machine processing, the following points should be noted:</p> <ul style="list-style-type: none"> • Correct loading of the trays for rinsing is a precondition for effective machine processing. Trays must not be overloaded. • Rinsing shadows due to large instruments must be avoided. • The instruments must be placed or stored based on their susceptibility to mechanical damage in order to prevent them from becoming damaged. <p>The times and temperatures specified in these reprocessing instructions are minimum requirements and must not be less than those stated here. If they are to be reduced for technical reasons, this must be validated by the operating authority. Exceeding the stated times and temperatures is always possible but leads to increased stress on the material, which may result in premature ageing of the instruments.</p> <p>The use of other sterilization methods is outside our responsibility.</p>																				
Information on validation of the processing	<p>Validation was performed with the following equipment, materials, and chemicals:</p> <table border="0"> <tr> <td>Cleaning and disinfection device:</td> <td>Type Miele Disinfector G 7735 CD and 7836 CD compartmented cart for surgical instruments</td> </tr> <tr> <td>Cleaning agent alkaline:</td> <td>neodisher® FA, Dr. Weigert GmbH & Co. KG</td> </tr> <tr> <td>Cleaning agent enzymatic:</td> <td>Endozime, Ruhof (enzymatic)</td> </tr> <tr> <td>Neutraliser:</td> <td>Decondex 23 Neutrazym, Borer, Switzerland</td> </tr> <tr> <td>Water pistol:</td> <td>neodisher® Z, Dr. Weigert GmbH & Co. KG</td> </tr> <tr> <td>Cleaning brush:</td> <td>Selecta</td> </tr> <tr> <td>Ultrasonic bath:</td> <td>Plastic / nylon brushes</td> </tr> <tr> <td>Steriliser:</td> <td>Sonorex</td> </tr> <tr> <td></td> <td>MMM Vaculab 969 S 3000, MMM Selectomat S 3000,</td> </tr> <tr> <td></td> <td>Stiefenhofer KS 666-2ED, H+P Varioclav 400E</td> </tr> </table>	Cleaning and disinfection device:	Type Miele Disinfector G 7735 CD and 7836 CD compartmented cart for surgical instruments	Cleaning agent alkaline:	neodisher® FA, Dr. Weigert GmbH & Co. KG	Cleaning agent enzymatic:	Endozime, Ruhof (enzymatic)	Neutraliser:	Decondex 23 Neutrazym, Borer, Switzerland	Water pistol:	neodisher® Z, Dr. Weigert GmbH & Co. KG	Cleaning brush:	Selecta	Ultrasonic bath:	Plastic / nylon brushes	Steriliser:	Sonorex		MMM Vaculab 969 S 3000, MMM Selectomat S 3000,		Stiefenhofer KS 666-2ED, H+P Varioclav 400E
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Note:	<p>The user is responsible for the actual processing achieving the desired results with the equipment, materials, and staff employed in the processing facility. Usually, this requires validation and routine monitoring of the method.</p> <p>If the previously described equipment, materials, and chemicals are not available, it is the responsibility of the user to validate his method accordingly.</p> <p>Please note the instructions and regulations of the relevant national regulations and standards and any instructions for use accompanying the medical device.</p>																				

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	Please note that all instruments sent to the Medicon Repair Service (MRS) for repair must be cleaned and sterilized prior to dispatch. Medicon eG reserves the right to modify these instructions whenever new information is obtained.
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To contact manufacturer:

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