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Reprocessing of resterilizable medical devices with assembly instructions in accordance with DIN EN ISO 17664-1

Risk assessment groups - Critical B

Manufacturer	FEHLING INSTRUMENTS GmbH
Products	All instruments or medical devices supplied by FEHLING INSTRUMENTS GmbH in the above risk assessment group and for which additional assembly instructions are available: Hook guides (for ball adapters) and guide clampsM 36 Somoha spreaderM 37
Warninge	Conoral information:
warnings	The instruments may only be used, prepared and disposed of by qualified medical personnel.
	Handle the instruments with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the instruments in order not to cause any possible consequential damage! Do not overload functional parts!
	The medical device must be prepared before use. Before reprocessing, the instru- ment must be risk-assessed in accordance with the RKI guidelines (non-criti- cal/semi-critical/critical A/B/C).
	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing must be com- plied with.
	The respective national regulations for the reprocessing of instruments that have been used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants must be observed.
	During surgery, rinse the instruments repeatedly using the Luer-Lock connection, if available, to prevent residues from drying.
	Place small parts in suitable containers (e.g. needle box) for storage and reprocessing!
	CERAMO [®] instruments and instruments with plastic components:
	Do not clean CERAMO [®] instruments (recognizable by their black-brown surface) using oxidative processes (processes using hydrogen peroxide H ₂ O ₂ , e.g. Or- thovario or Oxivario from Miele). The use of these procedures leads to the destruc- tion of the titanium-containing CERAMO [®] coating after some time due to the dis- solution of titanium.
	Similarly, do not clean instruments with plastic components using oxidative pro- cesses. These processes lead to oxidative aging of the material, which may not be recognizable by visible discoloration or embrittlement.
	SUPERPLAST instruments:
	Thermal disinfection and steam sterilization are used to activate the shape memory. Please note the following:
	• SUPERPLAST instruments must be stored in such a way that the recovery of the straight shape is not impaired by environmental influences (e.g. other instruments or limited space).
	 After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. Bending the instruments at temperatures above approx. 40 °C can impair their function.
Limitations of the reprocessing	Frequent reprocessing has little effect on the label of the instruments and does not impair the function of the instruments. The end of the product's life is normally determined by wear and damage caused by use (e.g. damage, illegible label, functional failure - see also <i>"Maintenance, inspection and testing"</i>).



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When used and reprocessed properly, the instruments have been shown to withstand at least 500 processing cycles.

Instructions				
General information on reprocessing	The reprocessing is based (manual pre-cleaning, aut lization) were validated wi "Validated procedure". F (cleaning agents: Neodist lex® med AF (Bode Chem and demineralized water quality) are used for clear Automated reprocessing better and safer cleaning It is also possible to clear cals that have been reco their material compatibility regarding concentration, agents and disinfectants. must be strictly adhered to material damage, such as	d on a validated procedure. All cleaning steps mentioned tomated/manual cleaning, manual disinfection and steri- th the parameters specified in each case and listed under for validation, the recommended reprocessing agents her® MediClean forte (Dr. Weigert); Disinfectant: Korso- nie GmbH)) is used. Both water of drinking water quality (demineralized, microbiologically at least drinking water ning. is preferable to manual cleaning because it provides a result. n our instruments with other tested and approved chemi- mmended by the chemical manufacturer with regard to y. Please always observe the manufacturer's instructions exposure time, temperature and renewal of cleaning All application instructions of the chemical manufacturer o. Otherwise, this can lead to optical material changes or a corrosion, fractures or premature ageing.		
Pretreatment at the place of use	Pre-cleaning: Care must be idues are removed from a mediately after completion machine cleaning. Once t must be carried out to ense The instruments must be cessing in such a way the medical devices are end proof containers and - if n	be taken to ensure that blood, tissue and medication res- the instruments with a disposable cloth/paper towel im- n of the procedure and that they are immediately sent for he instruments have been pre-treated, visual inspections sure that they are complete. transported from the place of use to the place of repro- nat neither users, third parties, the environment nor the langered or damaged (placement in closed, puncture- necessary - use of protective caps).		
Preparation before the cleaning	It is recommended that the dried residues are difficul NaCl solutions (otherwise Instruments that have bee again before cleaning. The to the corresponding asse	he instruments be reprocessed immediately after use, as It to remove from hard-to-reach places. Do not place in a risk of pitting or stress corrosion cracking). En connected to each other during use must be removed en disassemble the dismountable instruments according embly instructions.		
Manual pre-cleaning	 <u>Validated procedure:</u> Equipment: Cleaning agents: <u>Procedure/parameters:</u> If possible, rinse the i water (drinking water moved. Use a soft brue) Cavities, gaps, slits a cold water (drinking visimilar). Soak the products for odisher[®] MediClean for the second se	Basin Soft brush Water pressure gun (or similar) Neodisher [®] MediClean forte (Dr. Weigert) nstrument in disassembled condition under cold running r quality, < 40 °C) until all visible soiling has been re- ush (not a wire brush!) to remove stubborn dirt. nd lumen must be rinsed intensively (> 10 seconds) with water quality, < 40 °C) using a water pressure gun (or r 10 – 30 minutes in a solution containing 0.5 – 2 % Ne- orte with water (drinking water quality, < 40 °C).		



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	 Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be observed. Make sure that all areas of the instrument come into contact with the solution. If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). Rinse the instrument for 1 minute under cold demineralized water (see "General information on reprocessing") and move any moving parts on the instrument back and forth. 	
Cleaning/disinfection	If possible, a washer-disinfector that uses thermal disinfection and complies with DIN EN ISO 15883 is preferable.	
Cleaning: Machine	 Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. If applicable, relax springs Make sure that all cavities are completely flushed out, including the inside. Make sure that no areas are left unwashed. 	
	 Procedure/parameters: 3 minutes pre-rinse with cold water (drinking water quality, < 40 °C) Emptying 10 minutes cleaning with a solution of 0.5 – 2% Neodisher® MediClean forte in water (drinking water quality) at 55 °C Emptying 2 minutes rinsing with water (drinking water quality, < 40 °C) Emptying 1 minute rinse with cold demineralized water (< 30 °C) Emptying 5 minutes thermal disinfection with demineralized water (> 90 °C) 30 minutes drying (90 °C) After machine cleaning, cavities, blind holes, etc. in particular are inspected for visible dirt. If necessary, repeat the cycle or clean manually. 	



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Cleaning:	Validated procedure:		
Manual	Equipment:	Basin	
		Soft brush	
		Water pressure gun (or similar)	
		Bandelin Sonorex Digitec	
	Cleaning agents:	Neodisher [®] MediClean forte (Dr. Weigert)	
	Procedure/parameters:		
	 If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. 		
	Operate moving parts, if any, through their full range of movement.		
	Clean the instrument tamination remains.	s with a soft brush (not a wire brush!) until no visible con-	
	Rinse the instrument similar).	ts for at least 20 seconds using a water pressure gun (or	
	Ultrasonic cleaning:		
	 10 minutes sonication 	n at < 40 °C with $0.5 - 2\%$ detergent solution at 35 kHz	
	After solication, fins pressure gun (or sim	ilar).	
	Rinse the instrument 10 seconds.	ts with water (drinking water quality, < 40 °C) for at least	
	Deionized water (< 4 are rinsed with deion that no residues rem	40 °C) must be used for the final rinse. The instruments nized water for at least 30 seconds. It must be ensured ain on the products.	
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions).		
	Validated procedure:		
	Equipment:	Basin	
	• •	Bandelin Sonorex Digitec	
	Disinfectant:	Korsolex [®] med AF (Bode Chemie GmbH)	
	Drocoduro (noromotoro)		
	Procedure/parameters:	area the products for 5 minutes in an ultrasonic both (25	
	 After cleaning, immerse the products for 5 minutes in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex[®] med AF). Ensure that all surfaces are wetted with the disinfectant. If necessary, move mobile parts in the disinfection bath before switching on the ultrasonic cleaner. 		
	• After disinfection, rinse all products thoroughly with deionized water (< 40 °C) for at least 1 minute to remove the disinfectant and, if necessary, move mobile parts back and forth on the instrument.		
	It must be ensured the second se	nat no residues remain on the products.	
	Drying with sterile, o	Il-free compressed air.	
Drying	If drying is achieved as p be exceeded. Then dry v ommendations. Pay part	part of the cleaning/disinfection cycle, 120 °C should not with suitable compressed air in accordance with RKI rec- icular attention to drying areas that are difficult to access.	



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Maintenance, inspection and testing	Assemble the disassemble instructions.	d instruments according to the corresponding assembly
	For instruments with movin an instrument oil based of European or United States able and steam-permeable also be indicated by an oil products containing silicon- tiveness of steam sterilizat	ing components that are exposed to friction (e.g. joints), in paraffin/white oil (in accordance with the applicable is Pharmacopoeia) that is biocompatible, steam-steriliz- e must be applied before sterilization. Such points may can symbol. Instruments must not be treated with care e. These can lead to sluggishness and impair the effec- ion.
	A safety check of the instrusharp edges, cracks, fraction nents.	uments must be carried out before each use. Check for tures, mechanical malfunctions and missing compo-
	Check instruments with mo If applicable, check the loc	ving parts for ease of movement (avoid excessive play). king mechanisms.
	All instruments: Visually ins Pay particular attention to o	spect for damage and wear using a magnifying lamp. critical points on moving parts and in the work area.
	Defective, damaged instru- out and cleaned and disin- pairs may only be carried o manufacturer. A confirmati- turer.	ments whose label is no longer legible must be sorted fected before being returned to the manufacturer. Re- but by the manufacturer or workshops authorized by the on form for this process is available from the manufac-
	Instruments that can no lo hospital scrap metal dispo ments with pointed or sha closed, puncture- and brea struments!	nger be repaired must be disposed of in the standard sal system. In this case, especially for surgical instru- arp edges, it is important to ensure safe storage in a ak-proof disposable container. Do not use damaged in-
Packaging	Individually: in accordance and DIN 58953 series.	with standards of the DIN EN 868, DIN EN ISO 11607
	Sets: Sort instruments into purpose sterilization trays.	o trays provided for this purpose or place them on all- A suitable method must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance according to DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended limit values for the ingredients of feed water and steam condensate are defined in DIN EN 285.	
	Validated procedure:	Tuttnauer autoclave type B 3870 FHS /
		Lautenschläger ZentraCert
	Procedure/parameters:	
	Cycle type:	3 pre-vacuum phases
	Sterilization temperature:	132 – 134 °C
	Holding time:	4 – 5 minutes
	Drying time:	20 minutes
	of the sterilizer must not be	exceeded (see appliance manufacturer's instructions).





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Storage	In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage). If applicable, always store instruments in a tension-free state. This helps to prevent premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are mainly made of steel or titanium. These must be cleaned be- fore disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care should be taken to ensure that any pointed or sharp edges are protected.
Obligation to report Serious Incidents	The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.
Contact the manufacturer	FEHLING INSTRUMENTS GmbH Hanauer Landstrasse 7A D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 Email: info@fehling-instruments.de www.fehling-instruments.de







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Symbols

If displayed on the medical device, the label of the medical device or the reprocessing instructions, the symbols according to DIN EN ISO 15223-1 have the following meaning:



Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.

The instructions listed above have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The person carrying out the reprocessing is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for effectiveness and possible adverse consequences.