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 clamps.....M 36 Somoha spreader.....M 37
Warnings	**General information:** 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 instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/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 complied 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_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these procedures leads to the destruction of the titanium-containing CERAMO® coating after some time due to the dissolution of titanium. Similarly, do not clean instruments with plastic components using oxidative processes. 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 *"Maintenance, inspection and testing"*).

	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 on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". For validation, the recommended reprocessing agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); Disinfectant: Korsolex® med AF (Bode Chemie GmbH)) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning because it provides a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical material changes or material damage, such as corrosion, fractures or premature ageing.
Pretreatment at the place of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and medication residues are removed from the instruments with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for machine cleaning. Once the instruments have been pre-treated, visual inspections must be carried out to ensure that they are complete. The instruments must be transported from the place of use to the place of reprocessing in such a way that neither users, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation before the cleaning	It is recommended that the instruments be reprocessed immediately after use, as dried residues are difficult to remove from hard-to-reach places. Do not place in NaCl solutions (otherwise risk of pitting or stress corrosion cracking). Instruments that have been connected to each other during use must be removed again before cleaning. Then disassemble the dismountable instruments according to the corresponding assembly instructions.
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse the instrument in disassembled condition under cold running water (drinking water quality, < 40 °C) until all visible soiling has been removed. Use a soft brush (not a wire brush!) to remove stubborn dirt. • Cavities, gaps, slits and lumen must be rinsed intensively (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Soak the products for 10 – 30 minutes in a solution containing 0.5 – 2 % Neodisher® MediClean forte with water (drinking water quality, < 40 °C).

	• 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. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector. <u>Procedure/parameters:</u> • 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.

Cleaning:
Manual

Validated procedure:

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 instruments with a soft brush (not a wire brush!) until no visible contamination remains.
- Rinse the instruments for at least 20 seconds using a water pressure gun (or similar).

Ultrasonic cleaning:

- 10 minutes sonication at < 40 °C with 0.5 – 2% detergent solution at 35 kHz
- After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar).
- Rinse the instruments with water (drinking water quality, < 40 °C) for at least 10 seconds.
- Deionized water (< 40 °C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain 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)

Procedure/parameters:

- 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 that no residues remain on the products.
- Drying with sterile, oil-free compressed air.

Drying

If drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Then dry with suitable compressed air in accordance with RKI recommendations. Pay particular attention to drying areas that are difficult to access.

Maintenance, inspection and testing	Assemble the disassembled instruments according to the corresponding assembly instructions. For instruments with moving components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such points may also be indicated by an oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to sluggishness and impair the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). If applicable, check the locking mechanisms. All instruments: Visually inspect for damage and wear using a magnifying lamp. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments whose label is no longer legible must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or workshops authorized by the manufacturer. A confirmation form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of in the standard hospital scrap metal disposal system. In this case, especially for surgical instruments with pointed or sharp edges, it is important to ensure safe storage in a closed, puncture- and break-proof disposable container. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into trays provided for this purpose or place them on all-purpose sterilization trays. 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. <u>Validated procedure:</u> Equipment: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see appliance manufacturer's instructions).

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 before 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

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:

Manufacturer

Follow the instructions for use or use electronic
follow the electronic instructions for use

Caution

Unique Device Identifier

Catalog number

Batch designation

Serial number

Medical device

Oil can for areas to be lubricated

CE marking

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.