Reprocessing of resterilizable medical devices with assembly instructions in accordance with DIN EN ISO 17664:2018
Risk assessment groups Critical B

Manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG
Products:	All instruments or medical devices of the above mentioned risk assessment group supplied by FEHLING INSTRUMENTS GmbH & Co. KG, for which the following additional assembly instructions are available: Flexible holding device MNU-1V .....M27 Bar retractor with pinion .....M29 Bar retractor with sprocket/lock.....M30 Vascular retractor.....M31 LEYLA titanium holding device .....M32 Operating table adapting clamp .....M33 Handle for CERAMO® FI Micro Set.....M35 Blade guides (for ball adapters) and guide forceps M36
Warnings:	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time. Similarly, instruments with components of plastics should not be cleaned with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement. The instruments may only be used, reprocessed and disposed of by qualified medical personnel. Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts! The medical device is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing. The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with. The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants. **SUPERPLAST instruments:** Thermal disinfection and steam sterilization should be used to activate the shape memory. The following should be observed here: • SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e.g., other instruments or restricted space). • After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of 40°C.
Limitations on reprocessing:	Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").

Instructions

General information on reprocessing:	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
Initial treatment at the place of use:	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, 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 prior to cleaning:	It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking). Instruments which were connected to each other during use must be disassembled again before cleaning. Then disassemble take-apart instruments according to the corresponding assembly instructions.
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40°C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40°C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2% Neodisher® MediClean forte with water (potable water quality, <40°C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution.

	• If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • During the exposure time, use appropriate brush (not a wire brush) to remove coarse contamination. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/Disinfection:	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer-disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40°C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2% Neodisher® MediClean forte in water (potable water quality) at 55°C • Emptying • Rinse for 2 minutes with water (potable water quality, <40°C) • Emptying • Rinse for 1 minute with cold deionized water (<30°C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90°C) • Dry for 30 minutes (90°C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.

Cleaning: Manually

Validated procedure:

Equipment:	Basin
	Soft brush
	Water spray gun (or similar)
	Bandelin Sonorex Digitec
Detergent:	Neodisher® MediClean forte (Dr. Weigert)

Procedure/Parameters:

- Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40°C) for 10 minutes.
- Move any movable parts, if present, back and forth over the entire range of movement.
- Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible.
- Rinse the instruments for at least 20 seconds with a water spray gun (or similar).

Ultrasonic cleaning:

- Clean for 10 minutes at < 40 °C with 0.5 - 2% cleaning solution at 35 kHz
- After ultrasonic cleaning, rinse the instruments with a water spray gun (or similar) for at least 20 seconds.
- Rinse the instruments for at least 10 seconds with water (potable water quality, <40°C).
- Deionized water (<40°C) is to be used for the final rinse. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.

Disinfection: Manually

Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information).

Validated procedure:

Equipment:	Basin
	Bandelin Sonorex Digitec
Disinfectant:	Korsolex® med AF (Bode Chemie GmbH)

Procedure/Parameters:

- After cleaning, place the products in an ultrasonic bath (35 kHz, <40°C) with a suitable disinfectant solution (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving 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 applicable, move the moveable parts of the instrument back and forth.
- Ensure that no residues remain on the products.
- Dry with sterile, oil-free compressed air.

Drying:

If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120°C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.

Maintenance, checking and testing:	Assemble the disassembled instruments according to the corresponding assembly instructions. For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging:	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization:	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by 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 more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

Storage:	In accordance with §4 of the German Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal:	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
Obligation to report serious incidents:	The user is obliged to report serious incidents relating to the medical device to the manufacturer per e-mail to vigilance@fehling-instruments.de or via the report form at https://www.fehling-instruments.de/en/complaint/ and the competent authority of the Member State where the user is registered.
To contact the manufacturer: 	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de

Symbols

In as far as the medical device or medical device label or reprocessing instructions are labeled, the symbols represent the following meaning:


Manufacturer

Article number

Batch code

Serial number


Instructions for Use are to be observed

CE labeling


Warning


Oil can for points to be lubricated

Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.