Reprocessing of resterilizable medical devices in accordance with DIN EN ISO 17664:2018
Risk Assessment Group Critical B

Manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG
Products:	All containers or medical devices of the above mentioned risk assessment group supplied by FEHLING INSTRUMENTS GmbH & Co. KG, for which no specific instructions are available.
Warnings:	Do not clean containers containing plastic components with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement. The containers may only be reprocessed and disposed of by qualified medical personnel of the RUMED. Containers must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to containers, so as not to cause any consequential damage! Do not overstrain functional parts! The medical device is to be reprocessed prior to use. The container 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 containers used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
Limitations on reprocessing:	Frequent reprocessing has little impact on these containers. 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 cleaning and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agent Neodisher® MediClean forte (Dr. Weigert) was 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. There is also the option of cleaning our containers 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.
Transport to the place of reprocessing	The containers 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.

Initial treatment at the place of reprocessing:

Pre-cleaning: ensure that blood, tissue and drug residues are removed immediately after removing the instruments from the containers with a disposable cloth/paper wipe and that they undergo mechanical cleaning immediately. After completion of initial treatment of the containers, visual inspections must be performed to ensure that the containers are complete.

Preparation prior to cleaning:

It is recommended to reprocess the containers immediately after use because it is very difficult to remove dried residues from parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion cracking).

Disassemble the container as much as possible, i.e. remove the lid and only take out inserts that have been inserted.

Manual pre-cleaning

Validated procedure:

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

Procedure/Parameters:

- Rinse container, 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 container come into contact with the solution.
- If necessary, the moving parts of the container 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 container for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts of the container back and forth.

Cleaning/Disinfection:

A washer/disinfector with thermal disinfection according to DIN EN ISO 15883 is to be used.

Cleaning: Automated

Containers must not be cleaned and disinfected in a closed state.

The tray must be placed in the washing machine with the opening facing downwards to avoid the accumulation of water and to ensure sufficient drainage of the media used.

The container lid should be cleaned with the inside facing downwards and, if necessary, the latches should be folded outwards.

Validated procedure:

Equipment:	Washer/Disinfector
	PG 8535 (Miele)
Detergent:	Neodisher® MediClean forte (Dr. Weigert)

	Preparation: • If possible, containers should be disassembled before being placed in the unit to ensure that water can drain out of cavities and blind holes. • Ensure that all cavities are also completely rinsed. • Ensure that no areas are left unwashed. Procedure/Parameters: • 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.
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:	For containers with movable components that are exposed to friction (e.g. locking hinges, handles), 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. Containers 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 containers prior to each use. When doing so, check for sharp edges, damage, cracks, mechanical malfunctions and missing components on closures, handles, lids, silicone mats, stacking corners and instrument holders as well as for possible signs of wear. The container must not exhibit any deformations which could impair its function and the closures must be in working order. Check containers with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. In particular, inspect the critical points on moving parts. Defective or damaged containers, 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. Containers that can no longer be repaired must be disposed of in the usual hospital waste for scrap metal or plastic. In the case of containers 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 containers!

Packaging:	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: Sort instruments into the designated container and pack the loaded container into a sterilization container commonly used in the hospital. A suitable procedure is to be employed here. The containers may be loaded with a maximum of 2 times the load capacity (according to standard DIN 58952-3).
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. Validated procedure: Equipment: Lautenschläger ZentraCert Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one container 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. Empty containers are be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). The sterilization containers with the loaded containers must be stored under suitable conditions after sterilization and transported to the place of use in a closed state.
Disposal:	These products largely consist of steel and/or plastic. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal or plastic 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 which have occurred in connection with the medical device to the manufacturer by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.
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.