Reprocessing of resterilizable medical devices according to DIN EN ISO 17664-1 Risk assessment group - Critical B

Manufacturer	FEHLING INSTRUMENTS GmbH
Products	All containers or medical devices supplied by FEHLING INSTRUMENTS GmbH risk assessment group for which no specific instructions are available.
Warnings	Do not clean containers with plastic components using oxidative processes (process with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative aging of the material, which may not be recognizable by visible discoloration or embrittlement. The containers may only be prepared and disposed of by qualified medical personnel or by trained AEMP personnel. Handle the containers with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the containers 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 container 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 applicable national regulations must be observed when reprocessing containers that have been used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
Limitations of the reprocessing	Frequent preparation has little effect on these containers. 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"*).

Instructions

General information on reprocessing	The reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated cleaning and sterilization) were validated according to the parameters specified in each case and listed under "Validated procedure". For validation, the recommended preparation agent Neodisher® MediClean forte (Dr. Weigert) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. It is also possible to clean our containers 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.
Transport to the place of reprocessing	The containers 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 compromised or damaged.
Pre-treatment at the place of reprocessing	Pre-cleaning: Care must be taken to ensure that immediately after removing the instruments from the containers, residues of blood, tissue and medication are removed from the containers with a disposable cloth/paper towel and that they are

	immediately sent for automated cleaning. Once the containers have been pre-treated, visual inspections must be carried out to ensure that they are complete.
Preparation before the cleaning	It is recommended that the containers 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). The container should be disassembled as much as possible, i.e. the lid should be removed and only inserts that have been placed inside should be taken out.
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 container 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 container come into contact with the solution. • If necessary, moving parts on the container 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 container for 1 minute under cold demineralized water (see "*General information on reprocessing*") and move any moving parts on the container back and forth.
Cleaning/disinfection	A washer-disinfector with thermal disinfection in accordance with DIN EN ISO 15883 must be used for cleaning/disinfection.
Cleaning: **Machine**	Containers must not be cleaned and disinfected when closed. The tray must be placed in the washing machine with the opening facing downwards in order to prevent water from collecting and to ensure sufficient drainage of the media used. The container lid must be cleaned with the inside facing downwards and, if necessary, the latches must be folded outwards. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine PG 8535 (Miele) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • If possible, containers should be disassembled before being put into the machine to ensure that water can drain out of hollow spaces and blind holes. • Ensure that all cavities are completely flushed. • 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. Repeat cycle, if necessary.
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	For containers with moving components that are subject to friction (e.g. locking hinges, handles), an instrument oil based on paraffin/white oil (according to the current European or United States Pharmacopoeia), which is biocompatible, steam sterilizable and vapor permeable, must be applied before sterilization. Containers 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 containers must be carried out before each use. Check for sharp edges, damage, cracks, mechanical malfunctions and missing components on fasteners, handles, lids, silicone mats, stacking corners and instrument holders as well as possible signs of wear. The container must not have any deformations that impair its function and the closures must be functional. Check containers with moving parts for ease of movement (avoid excessive play). If applicable, check the locking mechanisms. Pay particular attention to critical points on moving parts. Defective, damaged containers or containers whose labeling 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. Containers that cannot be repaired are to be disposed of in the usual hospital manner for scrap metal or plastic. In this case, especially for containers 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 containers!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort the instruments into the designated container and pack the loaded container into a standard hospital sterilization container. A suitable procedure must be used for this purpose. The containers may be loaded with a maximum of twice the load capacity (according to the standard DIN 58952-3).

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: Equipment: Lautenschläger ZentraCert Procedure/parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilizing several containers 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. Unloaded containers should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of 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.
Waste disposal	These products are mainly made of steel and/or plastic. These must be cleaned before disposal. They can be disposed of at a scrap metal or plastic 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.