FEHLING THOREXPO Retractor System

EEL-1G	Frame arch, center section for table width 580 mm
EEL-1K	Frame arch, center section for table width 540 mm
EEL-1L	Frame arch, center section for table width 610 mm
EEL-1S	Frame arch, side sections (pair)
EEL-4F	Blade guide, rotatable and slewable, 300 mm
EEM-0	Blade guide, radially fixable, 300 mm
EEM-2F	Cross connector, 16/8 mm
EEM-3	Spare transport pinion
EEP-0	Connecting slide
EEK-5	Manubrium retractor, 90° offset, 75 x 19 mm
EEK-6	Manubrium retractor, 90° offset, 95 x 24 mm
EEK-7	Manubrium retractor, 90° offset, 95 x 30 mm
EEK-8	Manubrium retractor, 90° offset, 75 x 24 mm
EEL-5	Retracting blade 41 x 44 mm
EEL-6	Retracting blade 41 x 60 mm
EEL-7	Retracting blade 46 x 75 mm
EEL-8	Retracting blade 65 x 85 mm
EEL-9	Retracting blade 85 x 85 mm
EEM-1	Retracting blade 90 x 130 mm
ZKD-7	Langenbeck liver retractor 30 x 150 mm

Warning: Prior to processing, a risk assessment on the instrument must be performed.

Retractor systems may only be used, processed and disposed of by competent medical personal!

Intended use:

The THOREXPO retractor is used for the exposition of the upper abdominal and the lower thoracic cavity.

Before use:

FEHLING INSTRUMENTS retractor systems are delivered non-sterile and must be cleaned and sterilized by the user before their first and any further use (see reprocessing).

Handle retractors with care during storage, transport and cleaning! Avoid impacts and selective loads!

Perform a safety check before each use. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing).

The THOREXPO retractor can be adapted to all common operation tables.

Height and angle of the THOREXPO frame are adjustable. Thus the frame takes into account the different anatomic requirements.

The slides are moved on the frame concentrically to the patient's axis. Thus the position of the blade guide and the blades can be optimized with minimum space required.

The blade guides are slewable laterally within a limited angle range as well as continuously rotatable in radial direction. This feature adds to the optimization of the retractor position with minimal space required.

The retractor blades are laterally slewable in the socket of the blade guide. Thus the tissue load is evenly distributed over the entire width of the retractor blades and the risk of necroses or rib fractures is minimized.

Assembly:

Geometry

The basic component of the THOREXPO retractor is a U-shaped frame that is assembled from two lateral legs (EEL-1S) and a continuously curved center section. There are two such centre parts to fit the different widths of operation tables. Use the center section EEL-1K for operation tables with a width of 52 and 54 cm (measured at the outer edges of the lateral T-shaped rails), and center section EEL-1G for operation tables with a width of 58 cm. The frame can be disassembled for easier processing and storage.

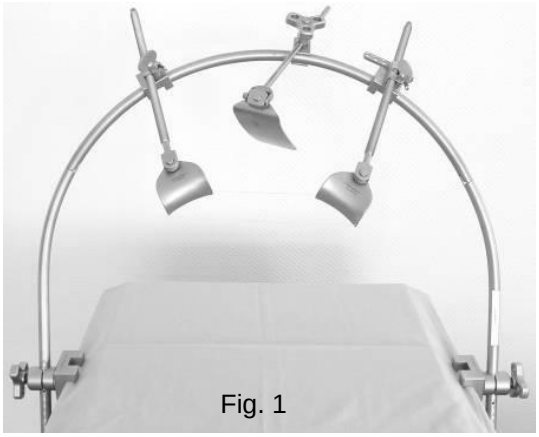


Fig. 1

The frame section is round and has a diameter of 16 mm. Thus it fits in the commercial operation table adapters (e.g. Maquet). The two U-shaped legs have a stretch of app. 60 mm just before the beginning of the bend, over which the frame diameter is tapered to 14 mm (fig. 2). In these areas the slides EEP-0 (see fig. 3) are slid on. Depending on the requirements, 2, 3 or 4 slides can be placed on the frame.

Fig. 2

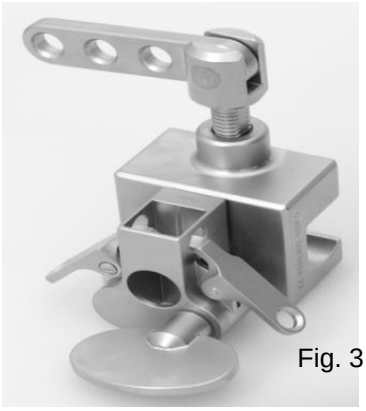


Fig. 3

The aforementioned connecting slides take up the blade guide EEL-4F (fig. 4). The blade guides can be rotated and slewed in the connecting slide and their effective length can be varied. At the distal end of the blade guide, the socket for the retracting blades EEL-5 to EEL-9 as well as EEM-1 is located.

Assembly and fastening at the operation table

The two straight legs of the U-shaped frame section have a scale from 5 – 20 cm on the outside of their open end (fig. 5). This graduation enables the frame ends to be fixed in the operation table fixing claw at the same height on both sides. In addition, it is to be observed that the frame is mounted with the same distance to both ends of the operation table.

Fixing claw EEK-1F (fig. 6) serves to fix the frame at the rails of the operation table. It allows for variable fixing angles and heights of the frame at the table – sterile across the cover. The claw is fixed at the operation table using a threaded bolt with rocker arm, while the frame is fixed in the fixing claw using a large-sized screw.

Fig. 4

Fig. 5

Fig. 6

Reprocessing:

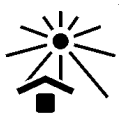
Restriction for reprocessing:
Frequent reprocessing has only minor effects on these instruments.
Usually the end of the product service life is determined by wear and damage due to utilization.

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage: acc. to § 4 MPBetreibV (regulation on the operation of medical devices)	Store instruments in dry rooms to avoid condensation. It is recommended to start reprocessing the instruments directly after use, as dried residues located in areas with limited access are quite difficult to remove.
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	Make sure that traces of blood, tissue and medication are removed from the instruments directly after termination of the surgery and that they are immediately forwarded to mechanical cleaning. To do so, clean these instruments with soft brushes under running water until all visible contaminatin is removed. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use an approved solution of a combined cleaning and disinfecting agent without protein fixing effect (observe the recommendation of the chemicals producer when mixing the solution). Avoid overfilling of instrument trays and washing trays – use appropriate instrument carriers only. Be particularly careful that the mouths/points do not get stuck in the mesh when placing

	and removing the instruments into/from the screen baskets. Disassemble dismountable instruments according to the appropriate assembly instructions.
Cleaning/Disinfection acc. to DIN EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfection are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.
Cleaning: Mechanically acc. to DIN EN ISO 15883-1:2009	Validated procedure: Equipment: Washer/disinfector G 7836 CD (Miele) Process: 2-component process alkaline/enzymatic Cleaning agents: deconex® TWIN PH10 and deconex® TWINZYME (Borer Chemie, Switzerland) Preparation: • Make sure that all cavities are completely flushed on the inside as well. • Make sure that no flushing shadows arise. Parameter: • 3 min pre-cleaning with tap water • Drain • 10 min cleaning with tap water 0,3 % dosing TWIN PH10 at 35 °C and 0,2 % dosing TWINZYME at 40 °C • Drain • 2 min rinsing with deionized water > 30 °C • Drain • 1 min rinsing with deionized cold water • Drain • 5 min thermal disinfection at 93 °C, • After mechanical cleaning, check cavities, blind holes, etc. for visible dirt. Repeat cycle or clean manually if required.
Cleaning/Disinfection: Manually Manual cleaning should be avoided as it cannot be validated.	Equipment: Detergent (active and non protein-fixing cleaner, with or without anti-microbial effect and/or enzymes), compressed-air cleaning gun, soft cloths/sponges, running water. 1. Thoroughly rinse dirt from the surface of the instrument. 2. Apply detergent solution on all surfaces using a soft cloth/sponge. Make sure that joint instruments are cleaned in open as well as in closed position. 3. Thoroughly rinse all cavities and blind holes with a sufficient amount of detergent solution (min. 200 ml) using a syringe. Take special care that enough solution flows to the distal end. 4. Hold the instrument under running water. The running water must flow through the cavities, and blind holes must be filled and emptied several times. Use demineralized water for the final rinsing. For manual cleaning the detergent solution should not be warmer than room temperature. Disinfection: Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (min. 5 minutes at 93 °C). (Thermal disinfector, see indications of the device manufacturer.) Demineralized water has to be used for the final rinsing. Make sure that no residues remain on the products.
Drying:	If the drying is achieved as part of the cleaning/disinfection cycle 120 °C should not be exceeded.
Maintenance:	Assemble the instruments according to the assembly instructions. Apply a small amount of high-grade, water-soluble instrument spray on the hinges.

Control and function test:	Check instruments for easy operation (avoid too much play). Check locking mechanisms. Using a magnifying lamp visually inspect for damage and wear. Edges should not show nicks and should be even. Sort out defective instruments and return them to the manufacturer for repair. Clean and disinfect instruments before sending them to be repaired. A confirmation form for this procedure can be obtained from the manufacturer.
Packaging:	Separate: acc. to standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments in trays provided for that purpose or place them on universal sterilization trays. Use an appropriate procedure to pack the trays.
Sterilization:	Steam-sterilize using the fractional vacuum process at 134 °C (min. 5 minutes holding time) with equipment acc. to DIN EN 285, validated sterilization processes! To avoid formation of stains and corrosion, the steam must be free of components. The recommended limit values of the components for feed-water and steam condensation are defined in DIN EN 285. Validated process: Equipment: Selectomat HP (MMM) 1. Three times pre-vacuum 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: min. 10 minutes
Storage:	Acc. to § 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.
Additional information:	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).
Contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: +49 (0) 6188-957440 Fax: +49 (0) 6188-957445 E-mail: info@fehling-instruments.de

Storage / Symbols

					
Protect from excessive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Attention	Observe instructions for use	Article number	

! Each modification to the product or deviation from these instructions of use results in exclusion of liability!
Subject to change without notice.

Manufacturer:
FEHLING INSTRUMENTS GmbH & Co. KG, Hanauer Landstr. 7A, 63791 Karlstein/Germany, www.fehling-instruments.de

The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.