FEHLING VENTREXPO Retractor System

EEN-2	Frame element, bayonet, 11 x 570 mm
EEN-3	Frame element, curved, 11/8 x 560 mm
EEK-9	Blade guide, adjustable angle, 8 x 450 mm
EEN-5	Blade guide 8 x 260 mm
EEN-6	Blade guide 8 x 180 mm
EEN-7	Blade guide, adjustable angle, 8 x 260 mm
EEO-7	Blade guide, adjustable angle, 8 x 180 mm
EEN-1	Cross connector, 16/11 mm
EEN-4	Cross connector, 11/8 mm
EEM-7	Open-end wrench 8 mm for EEN-7
EEM-4	Abdominal spatula 180 x 80 mm
EEM-5	Abdominal spatula, malleable, 80 x 180 mm
EEM-6	Intestinal rake, malleable, 160 x 80 / 120 mm
EEM-8	Abdominal spatula 150 x 50 mm
EEM-9	Abdominal spatula 35 x 150 mm
EEM-0	Abdominal spatula 150 x 65 mm
EEN-8	Abdominal spatula 100 x 50 mm
EEN-9	Abdominal spatula 130 x 65 mm
EEO-5	Abdominal spatula 150 x 120 mm
EEO-6	Abdominal spatula 180 x 65 mm
EEO-8	Abdominal spatula 40 x 180mm

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 VENTREXPO retractor is used for the exposition of the entire abdominal area.

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!

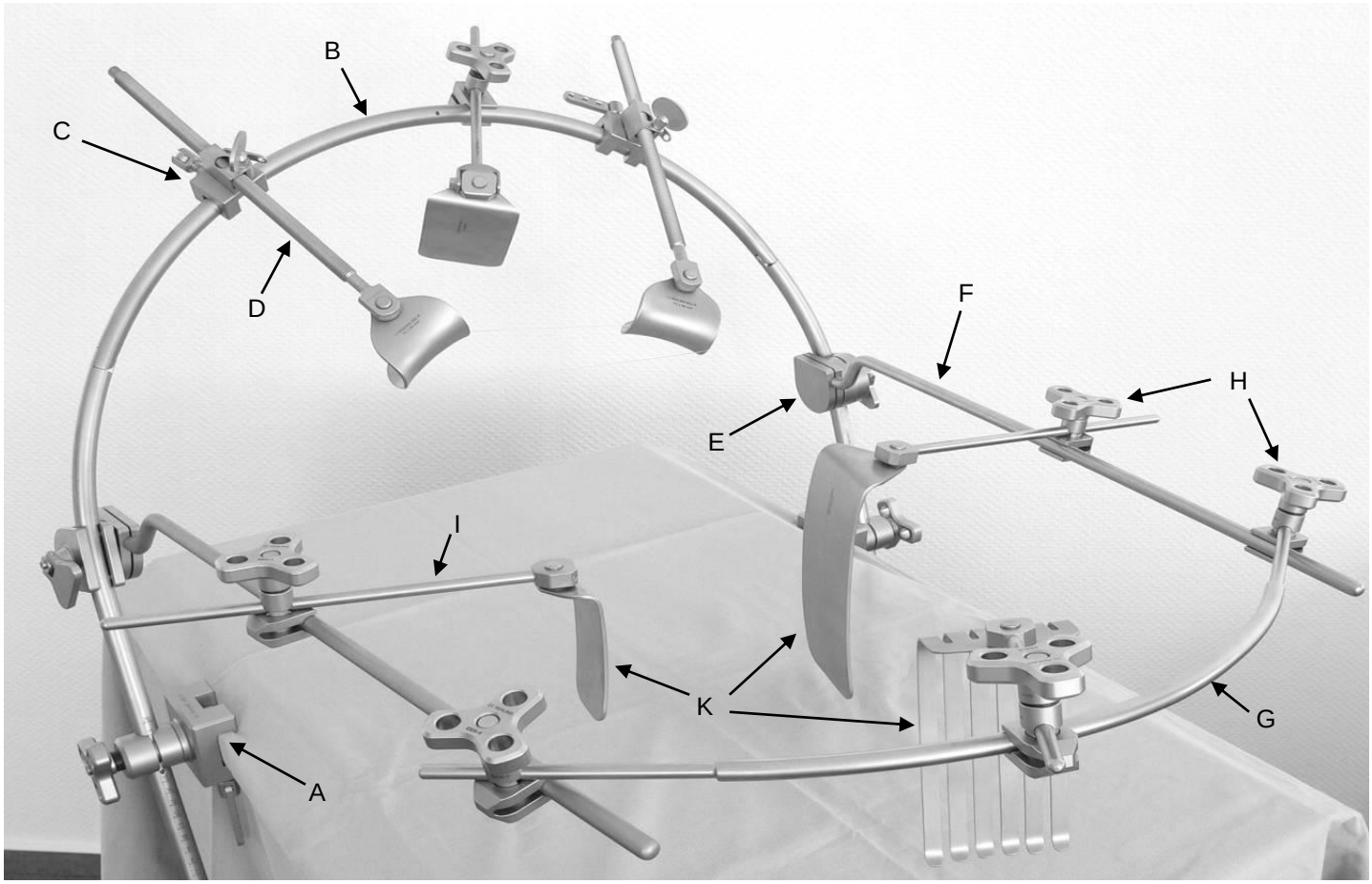
Perform a safety check before each use. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing).

Combined with the THOREXPO retractor system, the VENTREXPO retractor system develops a multitude of advantages:

- The frame width can be adjusted between 550 and 580 mm in its middle section.
- The frame height can be adjusted at will to a maximum of app. 300 mm.
- The lateral frame elements can be fixed in parallel or angular to the plane of the operation table.
- The curved caudal frame element can be fixed in the plane of the longitudinal elements or in any angle to that plane.
- The frame dimension from cranial to caudal can be adjusted at will up to a maximum of app. 540 mm.
- The retracting blades can be fixed at any position on the frame elements by means of with their blade guides. The blades are pivoted and thus align themselves automatically to the tissue.
- In addition, the blade guides with hinge (EEN-7) allow to place the retracting blades in axial direction in any upward or downward angle. Thus an accentuation or reduction of the strain of the blade tips can be caused, if required.
- The manifold sizes and shapes of the blades allow for a perfect retraction of the soft tissue and thus provide for an optimum exposition of the field of operation.
- By combination with the THOREXPO retractor system the lower thoracic area as well as the entire abdominal area can be exposed for all surgical requirements.

Components:

The system is an optional complement to the THOREXPO retractor system and needs its operation table fixing claws EEK-1F (A) as well as its frame arch EEL-1K or EEL-1G and the side sections EEL-1S (B) as the mounting base.



A EEK-1F
Operation table fixing claw

B EEL-1K or EEL-1G
THOREXPO frame arch and EEL-1S side sections

C EEP-0
THOREXPO connecting slide

D EEL-4F
THOREXPO blade guide

E EEN-1
VENTREXPO cross connector for frame

F EEN-2
VENTREXPO frame element, bayonet-shaped

G EEN-3
VENTREXPO frame element, curved

H EEN-4
VENTREXPO cross connector for blade guide

I EEN-5/EEN-6/EEN-7
Blade guide, long and short, with hinge

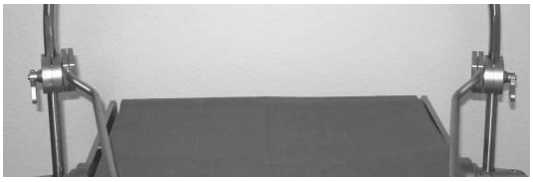
K EEN-8/EEN-9/EEM-6
VENTREXPO retracting blades

The VENTREXPO retractor consists of 2 cross connectors EEN-1 (E), 2 bayonet-shaped frame elements EEN-2 (F), one curved frame element EEN-3 (G), 7 cross connectors EEN-4 (H), 5 blade guides EEN-5 (I), 3 blade guides EEN-6 (I), 2 blade guides EEN-7 (I), and a wide selection of different retracting blades.

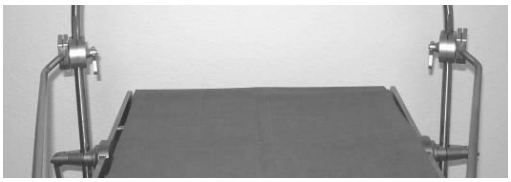
Geometry:

The bayonet-shaped frame elements EEN-2 have a length in conformity with standard containers of 570 mm that, in conjunction with the curved caudal frame element EEN-3, allows for the complete exposition of the abdominal cavity of patients of any size.

The frame elements running alongside the patient have a hexagonal section at their cranial end, which is connected to the frame arch EEL-1K or EEL-1G of the THOREXPO retractor by means of a cross connector. The mechanics of the cross connector allows to fix the frame elements on the outside or the inside of the THOREXPO frame. Together with the 6 positions given by the hexagonal section there are therefore 12 degrees of freedom for the configuration of the frame width on each side of the frame. Added across both sides this provides a variable width of app. 200 mm within which the retractor system can be adapted to the patient's anatomy in a stable manner.



inside



outside

The two bayonet-shaped frame elements EEN-2 are connected to a curved frame element EEN-3 at their caudal end. The hinges of the small cross connectors EEN-4 allow to position these frame elements in any width and any angle.

Any number of small cross connectors EEN-4 can be added at any position of the bayonet-shaped frame elements EEN-2 and the curved part of the frame element EEN-3, and equipped with long (EEN-5) or short (EEN-6) blade guides. Then the blade guides are locked in any required working length and angle using a large-format screw.

The retaining blades are inserted in the distal holes of the blade guides. Those are available in different sizes for every possible anatomic requirements. The blades are fixed in their holders using 2 ball snap locks.

Reprocessing:

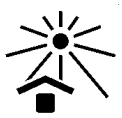
Restriction for reprocessing:
Frequent reprocessing has only minor effects on these instruments.
Usually the end of the product service life is determined by wear and damage due to utilization.

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