FEHLING VENTREXPO Retractor System

Body elements

EEN-2K	VENTREXPO body element bayonet, 11 x 420 mm
EEN-2V	VENTREXPO body element bayonet, 11 x 570 mm
EEN-3	VENTREXPO body element curved, 11/8 x 560 mm

Components

Fixations/guides

EEN-6	VENTREXPO blade guide 8 x 180 mm
EEN-5	VENTREXPO blade guide 8 x 260 mm
EEN-7	VENTREXPO blade guide, with adjustable angle, 8 x 260 mm
EEL-4F	Blade guide rotatable and swivelling 300 mm
EEK-1F	Operating table adapting clamp Ø 16 mm, adjustable angle
EEK-1S	Operating table adapting clamp Ø 16 mm, adjustable angle
EEN-4	VENTREXPO cross connector 11/8 mm
EEN-1	VENTREXPO cross connector 16/11 mm
EEP-0	Coupling rider

Abdominal spatula

EEN-8	VENTREXPO abdominal spatula 100 x 50 mm
EEM-8	VENTREXPO abdominal spatula 150 x 50 mm
EEN-9	VENTREXPO abdominal spatula 130 x 65 mm
EEN-0	VENTREXPO abdominal spatula 150 x 65 mm
EEO-6	VENTREXPO abdominal spatula 180 x 65 mm
EEM-4	VENTREXPO abdominal spatula 180 x 80 mm
EEO-5	VENTREXPO abdominal spatula 150 x 120 mm
EEM-9	VENTREXPO abdominal spatula 35 x 150 mm
EEO-8	VENTREXPO abdominal spatula 40 x 180 mm
EEM-5	VENTREXPO abdominal spatula, flexible 80 x 180 mm

Intestinal rake

EEM-6	Intestinal rake, flexible 160 x 80/120 mm

THOREXPO body elements

EEL-1S	THOREXPO retractor arch side parts (pair)
EEL-1K	THOREXPO retractor arch middle part for table width 540 mm
EEL-1G	THOREXPO retractor arch middle part for table width 580 mm

Manubrium hook

EEK-5	THOREXPO manubrium hook 90° angled, 75 x 19 mm
EEK-8	THOREXPO manubrium hook 90° angled, 75 x 24 mm
EEK-6	THOREXPO manubrium hook 90° angled, 95 x 24 mm
EEK-7	THOREXPO manubrium hook 90° angled, 95 x 30 mm

Retracting blade

EEL-5	THOREXPO retracting blade 41 x 44 mm
EEL-6	THOREXPO retracting blade 41 x 60 mm
EEL-7	THOREXPO retracting blade 46 x 75 mm
EEL-8	THOREXPO retracting blade 65 x 85 mm
EEL-9	THOREXPO retracting blade 85 x 85 mm
EEM-1	THOREXPO retracting blade 90 x 130 mm
EEQ-1	Blade for THOREXPO blade guide EEL-4F, 50 x 65 mm

Accessories

EEM-7	Fork wrench 8 mm for EEN-7

This instrument resp. medical device is non-sterile when delivered. It 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 VENTREXPO retractor system may only be used, reprocessed and disposed of by qualified medical personnel!

The VENTREXPO retractor system is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The VENTREXPO retractor system is intended for short-term application.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

The medical literature describes the following side effects, which may also possibly occur during the intended use of the VENTREXPO retractor system:

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses

⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use

The FEHLING INSTRUMENTS VENTREXPO retractor system is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before any further use (see 6) Reprocessing).

⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").

⚠	Handle the VENTREXPO retractor system with care during storage, transport and cleaning! Avoid striking and applying pressure to the VENTREXPO retractor system, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It 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.
⚠	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!
⚠	Do not clean instruments 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.
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").
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). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
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. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • 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 connectors of the instruments, if present, to the Luer lock rinsing 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	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • 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 using 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 for at least 20 seconds using a water spray gun (or similar). • 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. The instruments are rinsed for at least 30 seconds with deionized water. 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.
Assembly	See 9) Assembly
Maintenance, checking and testing	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 min. Drying time: 20 min. 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 MPBetreibV (Medical Devices Operator Ordinance) and the 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.
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.	
⚠	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The VENTREXPO retractor system is an optional enhacement of the THOREXPO retractor system and requires its EEK-1F operating table adapting clamps (1) as well as its EEL-1K or EEL-1G body arch and EEL-1S side parts (2) as an assembly base.

The VENTREXPO retractor consists of 2 cross connectors EEN-1 (8), 2 bayonet-shaped body elements EEN-2K or EEN-2V (9), a curved body element EEN-3 (10), 7 cross connectors EEN-4 (11), 5 blade guides EEN-5 (12), 3 blade guides EEN-6 (12), 2 blade guides EEN-7 (12) and a large selection of different retracting blades.

Figure 1 gives a configuration example for the VENTREXPO retractor system. Table 1 lists the corresponding components.

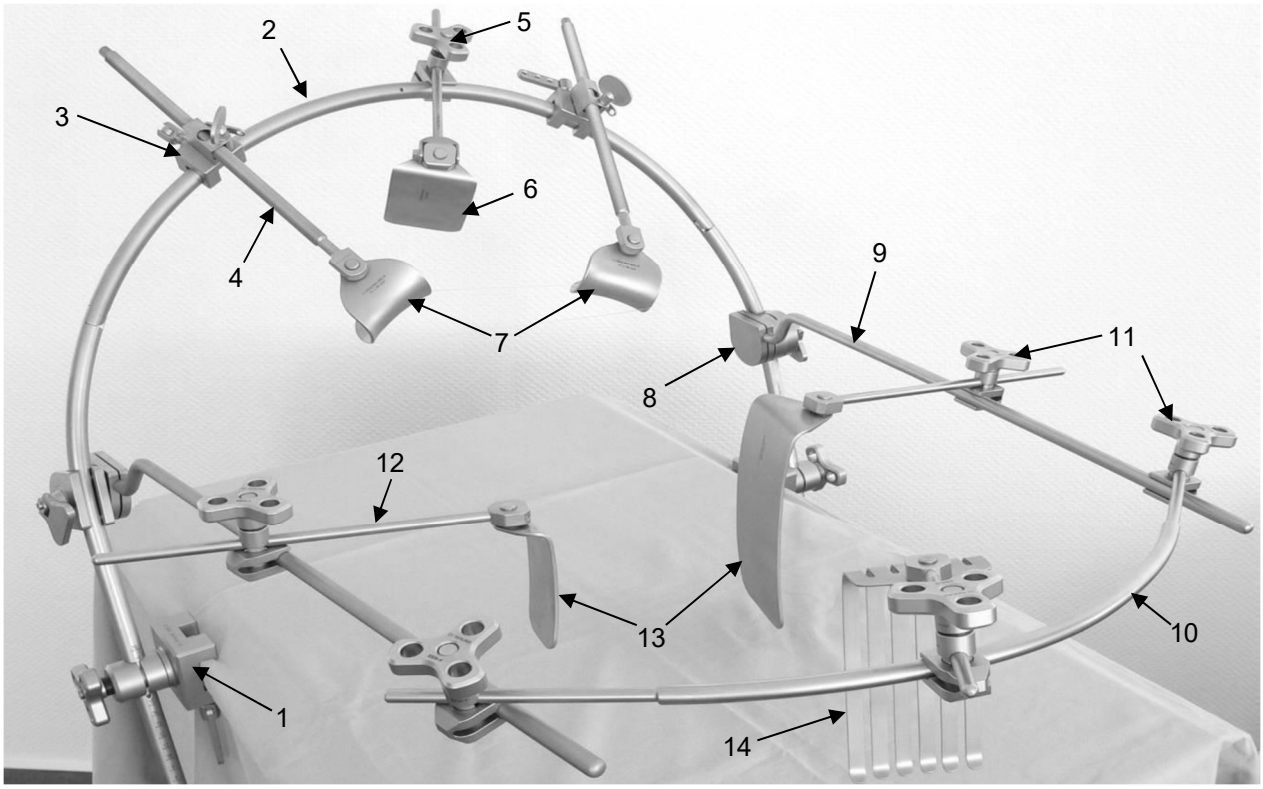


Fig. 1: Configuration example for the VENTREXPO retractor system

Table 1: List of the corresponding components

	Article no.	Description
1	EEK-1F/1S	Operating table adapting clamp Ø 16 mm, adjustable angle
2	EEL-1K or EEL-1G and EEL-1S	THOREXPO retractor arch and side parts
3	EEP-0	Coupling rider
4	EEL-4F	Blade guide rotatable and swivelling 300 mm
5	EEM-2F	THOREXPO cross connector 16/8 mm
6	EEM-4/5/8; EEO-5/6	VENTREXPO abdominal spatula
7	EEL-5/6/7/8/9; EEM-1	THOREXPO retracting blade
8	EEN-1	VENTREXPO cross connector for THOREXPO body
9	EEN-2K/2V	VENTREXPO body element bayonet, short/long
10	EEN-3	VENTREXPO body element curved
11	EEN-4	VENTREXPO cross connector for blade guide
12	EEN-5/EEN-6/EEN-7	VENTREXPO blade guide, long/short/with adjustable angle
13	EEN-0/EEN-8/EEN-9	VENTREXPO abdominal spatula
14	EEM-6	Intestinal rake

In combination with the THOREXPO retractor system, the VENTREXPO retractor system creates numerous advantages:

- The width of the body can be varied in its middle range between 550 and 580 mm.
- The height of the body can be varied as required up to a maximum of approx. 300 mm.
- The side parts of the body can be fixed parallel or at an angle to the plane of the operating table.
- The caudal curved body element can be fixed in the plane of the longitudinal elements or at any angle to these.
- The body dimension from cranial to caudal can be adjusted as required up to a maximum of approx. 540 mm.
- The retractor blades can be fixed to any point on the body elements with their blade guides. The blades are suspended rotatably and thus automatically align themselves with the tissue.
- In addition, the angle-adjustable EEN-7 blade guide allows the retractor blades to be angled up or down in axial direction. This can be used to accentuate or relieve the tips of the blades as required.
- The wide range of sizes and shapes of the blades allow for perfect retraction of the soft tissues, thus creating optimal exposure of the surgical field.
- Combined with the THOREXPO retractor system, the lower thoracic cavity as well as the entire abdominal cavity can be visualized for all surgical requirements.

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the VENTREXPO retractor system, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of body elements and components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the body elements and components used are of the correct size and provide sufficient stability.

8) Required accessories

No accessories are required for using the VENTREXPO retractor system.
A fork wrench (8 mm) EEM-7 is required for the use of the VENTREXPO blade guide with adjustable angle EEN-7.

9) Assembly

9.1) Coupling rider

Assembly of the coupling slider EEP-0 is not necessary.

9.2) Operating table adapting clamp

To assemble the OR table adapting clamp please observe the following assembly instructions.

⚠ Figures 2 - 4 are only examples and do not correspond to the EEK-1F/1S OR table adapting clamp, as the clamping area of the illustrated OR table adapting clamp is rhombic instead of round.

Figure 2 depicts an example of an OR table adapting clamp (EEJ-1).
This consists of a star grip (1), the upper (2) and lower (3) parts of the clamping jaw and a base (4).
The OR table adapting clamp is to be assembled as follows prior to application.

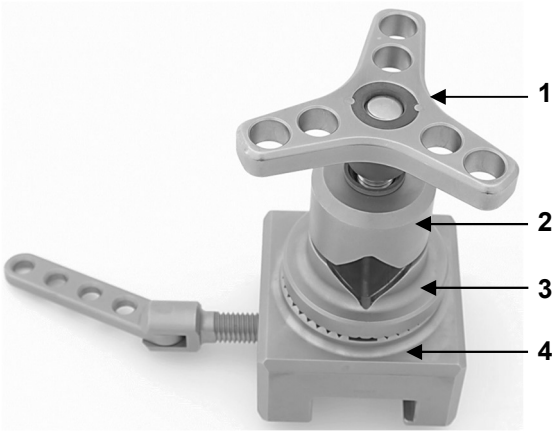


Fig. 2: OR table adapting clamp EEJ-1 (exemplary)

As shown in Figure 3, place the lower part of the clamping jaw (3) on the base (4), then insert the upper part of the clamping jaw (2) over the thread of the base (4).

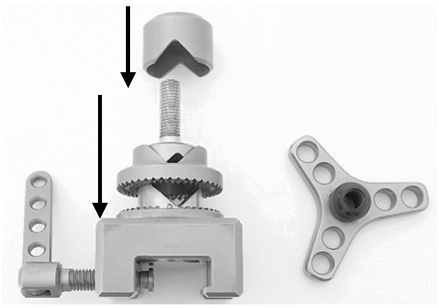


Fig. 3

Place the star grip (1) on the thread of the base (4) as shown in Figure 4 and tighten clockwise.

Following a functional test, the assembled instrument is now ready for use again.


Fig. 4

9.3) Cross connector

Cross connector EEN-4

Figure 5 depicts the cross connector EEN-4.
This consists of a star grip (1), a clamping sleeve (2), a clamping piece (3) and a threaded rod (4).
The cross connector is to be assembled as follows prior to application.

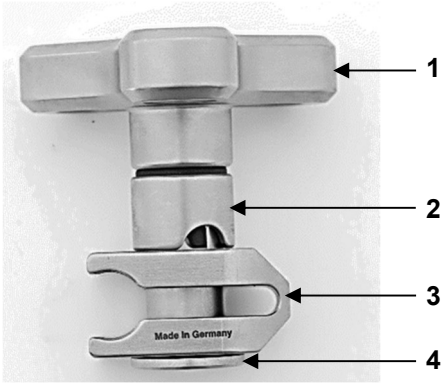


Fig. 5: Cross connector EEN-4

As illustrated in Figure 6, first insert the clamping piece (3) and then the clamping sleeve (2) over the threaded rod (4).
Please observe the following note!

Fig. 6

⚠ The clamping piece must be inserted onto the threaded rod with the recess facing downwards (Fig. 7a) so that the head of the threaded rod (4) is flush with the clamping piece (3) (Fig. 7b). If this is not observed, then a blade guide cannot be inserted through the clamping sleeve (2).

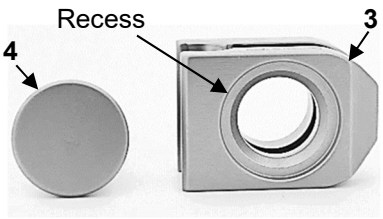


Fig. 7a

Fig. 7b

Place the star grip (1) on the threaded rod (4) as shown in Figure 8 and tighten clockwise.

Following a functional test, the assembled instrument is now ready for use again.

Fig. 8

Cross connector EEN-1

Figure 9 depicts the cross connector EEN-1.
This consists of a star grip (1), an upper (2) and a lower (3) clamping piece and a threaded rod (4).
The cross connector is to be assembled as follows prior to application.

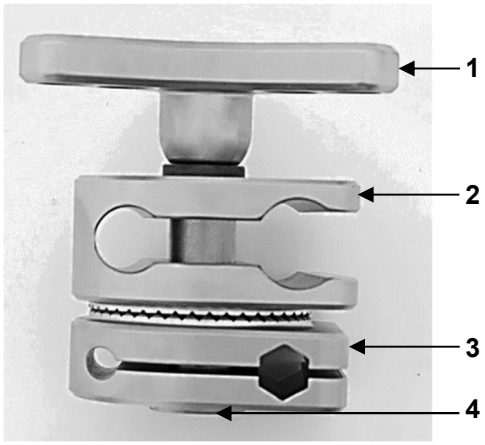


Fig. 9: Cross connector EEN-1

As illustrated in Figure 10, first insert the lower clamping piece (3) and then the upper clamping sleeve (2) over the threaded rod (4).
Please observe the following notes!

⚠ Both clamping pieces (2, 3) are serrated on one side. When inserting onto the threaded rod (4), ensure that the two serrations of the clamping pieces can engage with each other.

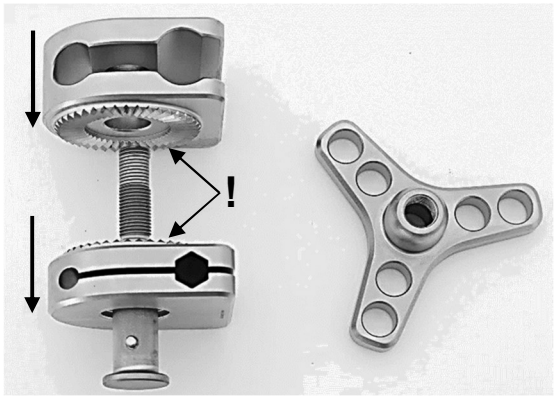


Fig. 10

⚠ When mounting the cross connector, ensure that the pins of the threaded rod (4) engage in the grooves of the lower clamping piece (3) (Fig. 11).

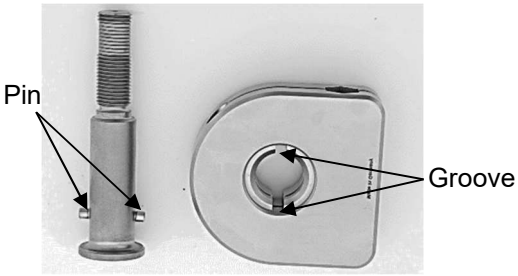


Fig. 11

Place the star grip (1) on the threaded rod (4) as shown in Figure 12 and tighten clockwise.

Following a functional test, the assembled instrument is now ready for use again.

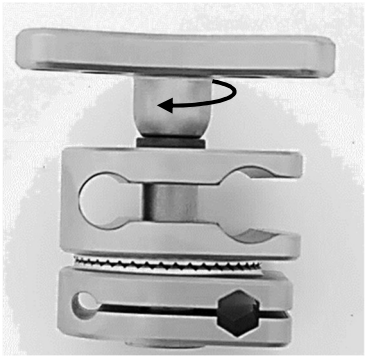


Fig. 12

9.4) Body elements and components

The bayonet-shaped body elements EEN-2K and EEN-2V have a standard container-compliant length of 420 mm and 570 mm, respectively, which, in conjunction with the curved caudal body element EEN-3 (length of 560 mm), allows full exposure of the abdominal cavity in patients of any size.

The body elements running alongside the patient have a hexagonal profile at their cranial end, which is connected to the body arch EEL-1K or EEL-1G of the THOREXPO retractor by means of a cross connector. The mechanics of the cross connectors allow the body elements to be attached to the outside (Fig. 13a) or the inside (Fig. 13b) of the THOREXPO body. In combination with the 6 positions defined by the hexagonal profile, this therefore results in 12 degrees of freedom for configuring the body width on each side of the body. Added across both sides, this results in a variable width of approx. 200 mm, within which the retractor system can be adapted to the patient's anatomy in a stable manner.

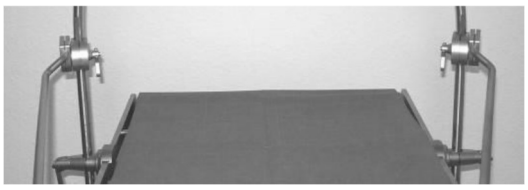


Fig. 13a: Fixing the cross connectors to the outside of the body element

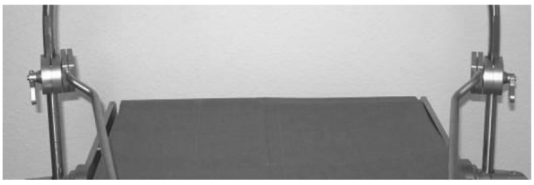


Fig. 13b: Fixing the cross connectors to the inside of the body element

The two bayonet-shaped body elements EEN-2K and EEN-2V are connected to an arc-shaped body element EEN-3 at their caudal end. The joints of the small EEN-4 cross connectors allow this body element to be positioned at any width and angle (Figs. 14a and 14b).

Any number of small cross connectors EEN-4 can be placed at any position of the bayonet-shaped body elements EEN-2K or EEN-2V and the curved part of the body element EEN-3 and fitted with long (EEN-5) or short (EEN-6) blade guides. The blade guides are then locked at any desired working length and angle using the star grip.

The retaining blades are inserted into the distal holes of the blade guides. These are available in various sizes for all conceivable anatomical requirements. The blades are each fixed in their holders with 2 ball snap locks (Fig. 15).

Fig. 14a: small angle

Fig. 14b: large angle

Fig. 15: Blade guide fixed with the cross connector at the proximal end and the blade mount is located at the distal end

10) Disassembly

⚠ Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning and reprocessing!

10.1) Coupling rider

Disassembly of the coupling slider EEP-0 is not necessary.

10.2) Operating table adapting clamp

The OR table adapting clamp must be disassembled as follows for reprocessing.

⚠ Figures 16 and 17 are only examples and do not correspond to the EEK-1F/1S OR table adapting clamp, as the clamping area of the illustrated OR table adapting clamp is rhombic instead of round.

Turn the star grip (1) counterclockwise until it can be removed (Fig. 16).

Fig. 16

First pull the upper part of the clamping jaw (2) from the thread of the base (4), then remove the lower part of the clamping jaw (3) (Fig. 17).

The instrument is now disassembled and can be reprocessed.

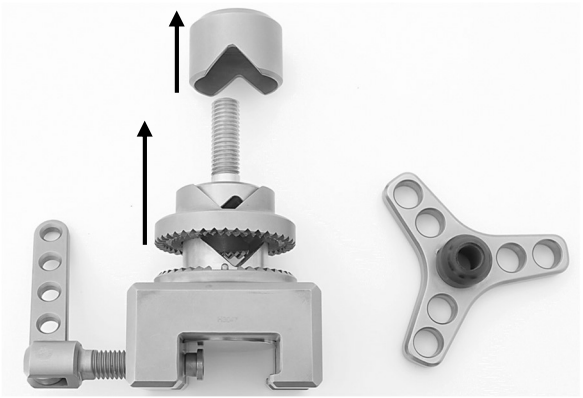


Fig. 17

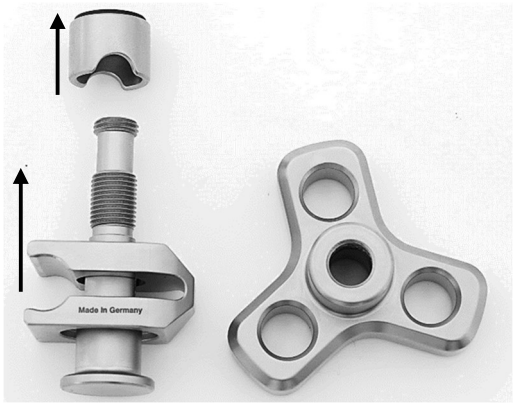
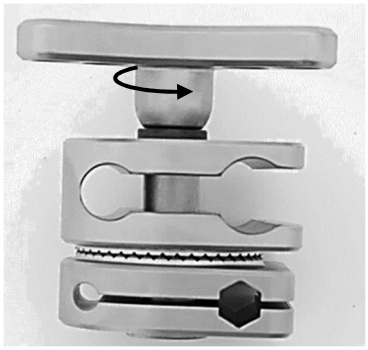
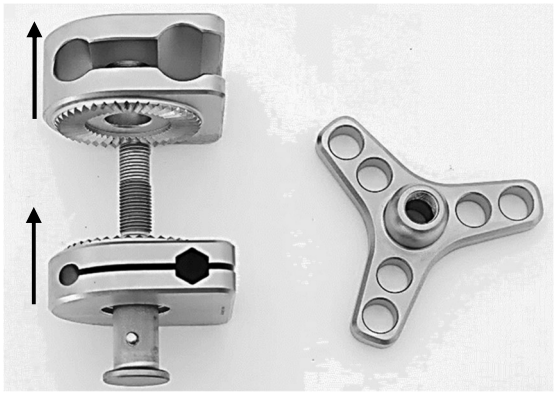
10.3) Cross connector

The cross connectors EEN-4 and EEN-1 must be disassembled as follows for reprocessing.

Cross connector EEN-4

Turn the star grip (1) counterclockwise until it can be removed (Fig. 18).

Fig. 18

First pull the clamping sleeve (2) from the threaded rod (4), then remove the clamping piece (3) (Fig. 19). The instrument is now disassembled and can be reprocessed.	 Fig. 19
Cross connector EEN-1	
Turn the star grip (1) counterclockwise until it can be removed (Fig. 20).	 Fig. 20
First pull the upper clamping sleeve (2) from the threaded rod (4), then remove the lower clamping piece (3) (Fig. 21). The instrument is now disassembled and can be reprocessed.	 Fig. 21

10.4) Body elements and components

For reprocessing, the body elements and the components need to be disassembled again. Therefore, please observe the corresponding assembly instructions (see 9.4) Body elements and components).

11) 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.

Symbols		
In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:		
Manufacturer	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

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