



FEHLING VENTREXPO Retractor System

Frame components

EEN-2K VENTREXPO bayonet-shaped frame element, 11 x 420 mm
EEN-2V VENTREXPO bayonet-shaped frame element, 11 x 570 mm
EEN-3 VENTREXPO frame 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 angle-adjustable, 8 x 260 mm
EEL-4F Blade guide, rotatable and pivotable 300 mm
EEK-1F Operating table-mounting clamp Ø 16 mm, angle-adjustable
EEK-1S Operating table mounting clamp Ø 16 mm, angle-adjustable
EEN-4 VENTREXPO cross connector 11/8 mm
EEM-2F VENTREXPO cross connector 16/8 mm
EEN-1 VENTREXPO cross connector 16/11 mm
EEP-0 Coupling rider

Abdominal blade

EEN-8 VENTREXPO abdominal blade 100 x 50 mm
EEM-8 VENTREXPO abdominal blade 150 x 50 mm
EEN-0 VENTREXPO abdominal blade 150 x 65 mm
EEO-6 VENTREXPO abdominal blade 180 x 65 mm
EEO-5 VENTREXPO abdominal blade 150 x 120 mm
EEM-5 VENTREXPO abdominal blade flexible 80 x 180 mm

Intestinal fan retractor

EEM-6 VENTREXPO Intestinal fan retractor flexible 160 x 80/120 mm

THOREXPO frame components

EEL-1S THOREXPO retractor frame arch side sections (pair)
EEL-1K THOREXPO retractor frame arch centre section for table width 540 mm
EEL-1G THOREXPO retractor frame arch centre section 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

Retractor blade

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

Accessories

EEM-7 VENTREXPO open-ended spanner 8 mm for EEN-7



This instrument or 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

The purpose of holding and guiding instruments is to hold or fix products and tissue (e.g. sizers, 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 to move them into or to a specific position

This does not apply to retractors (as specified in the TD for Classes I and IIa retractors), hooks, vascular and tissue clamps, forceps and needle holders.

Additional information regarding the intended purpose

Duration of application: Holding and guiding instruments are intended for short-term use.

Field of application: Holding and guiding instruments are used in all patients where products and tissue must be held or fixed in or to a specific position and/or moved to or in a specific position.

User profile: Holding and guiding instruments may only be used by medically trained personnel (e.g. specialist surgeons).

Application environment: Holding and guiding instruments are only to be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions.

2) Indications

Treatment methods requiring the holding and guiding of products and tissue.

3) Contraindication

All applications that are inconsistent with the physical and/or mechanical properties of the specific holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding and guiding instruments.

Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.

4) Possible side effects

The following side effects are described in the medical literature and may also occur during the intended use of holding and guiding instruments:

- Bone fractures, e.g. ribs, sternum, spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Injury to structures (tissues, organs, nerves, vessels)
- Necrosis
- Ischaemia
- Hernia formation
- Haematoma



	Medical devices may contain, for example, PEEK, chromium, nickel and/or titanium. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.
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5) Before use

The VENTREXPO Retractor System is supplied non-sterile and must be cleaned and sterilised by the user before initial use and before each subsequent use (see Section 6) Reprocessing).

	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section 6) <i>Reprocessing</i> under " <i>Maintenance, Inspection and Testing</i> ").
	Handle the VENTREXPO Retractor System with care during storage, transport and cleaning! Avoid impacts and point loading on the VENTREXPO Retractor System to prevent any possible secondary damage! Do not overload functional parts!
	Use only intact and sterilised products!

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 mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts!
	Do not clean instruments with plastic components using oxidative processes (processes with hydrogen peroxide H ₂ O ₂ , e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative ageing of the material, which may under certain circumstances not be detectable by visible discolouration or embrittlement.



Reprocessing limitations	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible labels or marking, functional failure – also see "Maintenance, inspection and testing"). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.
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 sterilisation) 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 deionised water (deionised water, demineralised, 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 of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-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 automated 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	Instruments should be reprocessed 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 that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section 10) <i>Disassembly</i>
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 may be 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 deionised water (see “General Information on Reprocessing”) and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, preference should be given to a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilisation 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 so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the 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 washer/disinfector. <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 deionised water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionised 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 contamination is no longer visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • 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). • Deionised water (< 40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.



Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • 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 deionised 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 section 9) <i>Assembly</i>
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), apply a biocompatible, steam sterilisable, steam-permeable paraffin-/white oil-based instrument oil (according to the valid European or United States Pharmacopoeias) before sterilisation. 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 impair the effectiveness of steam sterilisation. 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 looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. 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 authorised by the manufacturer. A confirmation 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 instru-



	ments 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	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation using a fractionated vacuum process in a steriliser complying with DIN EN 285 and DIN EN ISO 17665. 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 Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, 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 loss of 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. They must be cleaned prior to disposal. They can be disposed of 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 result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy 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 extension to the THOREXPO Retractor System and requires its EEK-1F operating-table mounting clamps (1), EEL-1K or EEL-1G frame arch and EEL-1S side sections (2) as a mounting base.

The VENTREXPO retractor consists of two EEN-1 cross connectors (8), two EEN-2K or EEN-2V bayonet-shaped frame elements (9), one EEN-3 curved frame element (10), seven EEN-4 cross connectors (11), five EEN-5 blade guides (12), three EEN-6 blade guides (12), two EEN-7 blade guides (12) and a wide selection of different retraction blades.

Figure 1 shows an example configuration of the VENTREXPO Retractor System. The corresponding components are listed in Table 1.

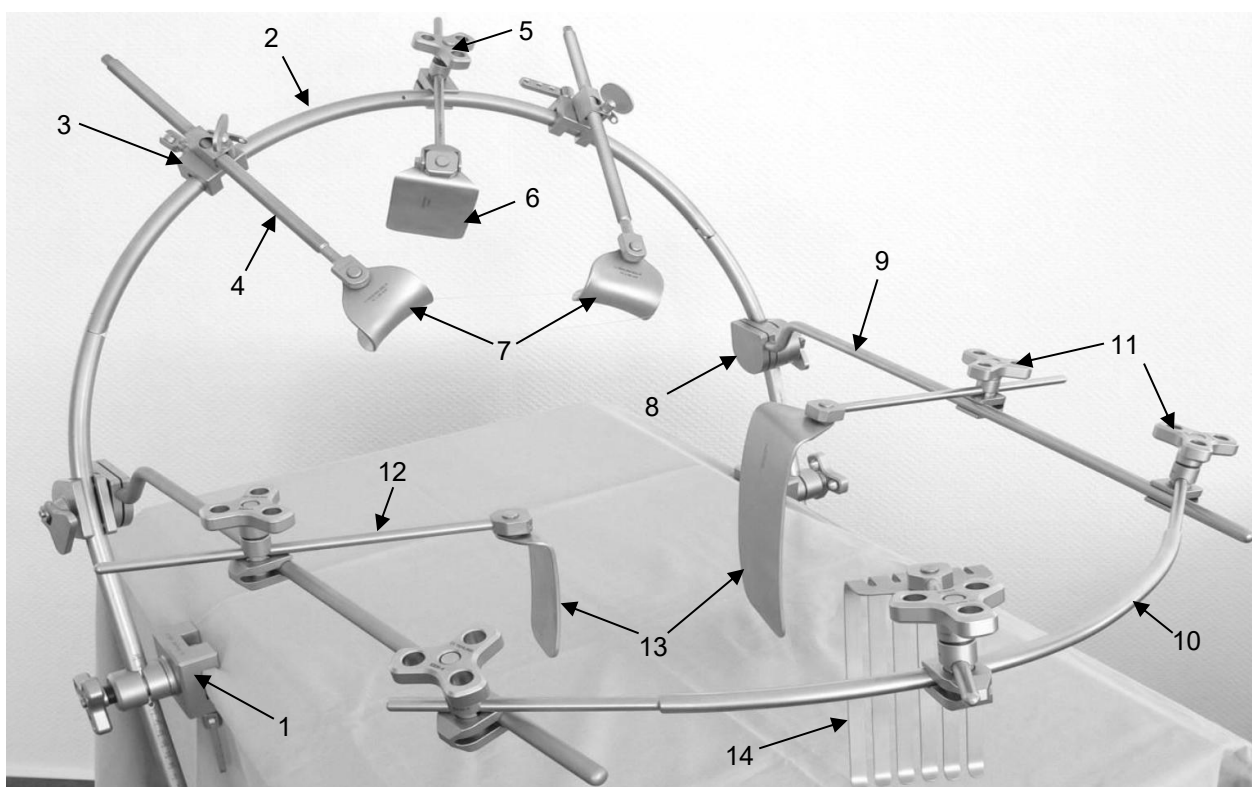


Fig. 1: Example configuration of the VENTREXPO Retractor System



Table 1: List of the corresponding components

	Item no.	Description
1	EEK-1F/1S	Operating table mounting clamp Ø 16 mm, angle-adjustable
2	EEL-1K or EEL-1G and EEL-1S	THOREXPO frame arch and side sections
3	EEP-0	Coupling rider
4	EEL-4F	Blade guide, rotatable and pivotable, 300 mm
5	EEM-2F	THOREXPO cross connector 16/8 mm
6	EEM-5/8; EEO-5/6	VENTREXPO abdominal blade
7	EEL-5/6/7/8/9	THOREXPO retractor blade
8	EEN-1	VENTREXPO cross connector for THOREXPO frame
9	EEN-2K/2V	VENTREXPO bayonet-shaped frame element short/long
10	EEN-3	VENTREXPO frame element curved
11	EEN-4	VENTREXPO cross connector for blade guide
12	EEN-5/EEN-6/EEN-7	VENTREXPO blade guide long/short/angle-adjustable
13	EEN-0/EEN-8	VENTREXPO abdominal blade
14	EEM-6	Intestinal fan retractors

The VENTREXPO Retractor System offers a number of advantages when combined with the THOREXPO Retractor System:

- The width of the central section of the frame can be adjusted between 550 and 580 mm.
- The height of the frame can be freely adjusted up to a maximum of approx. 300 mm.
- The lateral frame elements can be fixed parallel or at an angle to the plane of the operating table.
- The caudal, curved frame element can be attached in the same plane as the longitudinal elements or at any angle to them.
- The cranial-to-caudal dimension of the frame can be freely adjusted up to a maximum of approx. 540 mm.
- The retraction blades can be secured by their blade guides at any position on the frame elements. The blades are mounted so that they can rotate and thus automatically align themselves with the tissue.
- The angle-adjustable EEN-7 blade guides also allow the retraction blades to be angled upwards or downwards in the axial direction. This allows the pressure exerted by the blade tips to be increased or decreased as required.
- The wide range of blade sizes and shapes allows optimal soft-tissue retraction, thereby providing optimal exposure of the surgical field.
- The combination with the THOREXPO Retractor System allows the lower thoracic cavity and the entire abdominal cavity to be exposed to meet all surgical requirements.

	Use only intact and sterilised products!
	Before inserting the VENTREXPO Retractor System, ensure that the surgical site has been prepared accordingly beforehand.
	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.



	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
	The choice of components depends on the anatomical and physiological conditions and the field of application. Care must be taken to ensure that the components used have the correct size and geometry, as well as sufficient stability.

8) Required accessories

No accessories are required for using the VENTREXPO Retractor System.
An EEM-7 open-ended spanner (8 mm) is required to use the EEN-7 angle-adjustable VENTREXPO blade guide.

9) Assembly

9.1) Coupling rider

No assembly of the EEP-0 coupling rider is necessary.

9.2) Operating table mounting clamp

Please follow the instructions below to assemble the operating table mounting clamp.



Figures 2–4 are for illustrative purposes only and do not correspond to the EEK-1F/1S operating-table mounting clamp, as the clamping section of the operating-table mounting clamp shown is diamond-shaped rather than round.

Figure 2 depicts an example of an EEJ-1 operating-table mounting clamp.
It consists of a star grip handle (1), upper (2) and lower (3) clamping jaw sections, and a base (4).
The operating table mounting clamp must be assembled as follows before use.

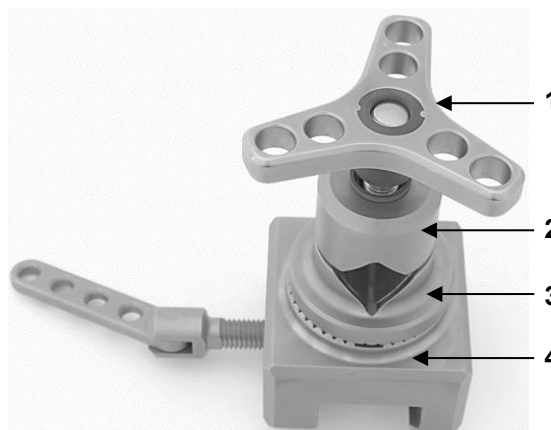


Fig. 2: EEJ-1 operating table mounting clamp (example)

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

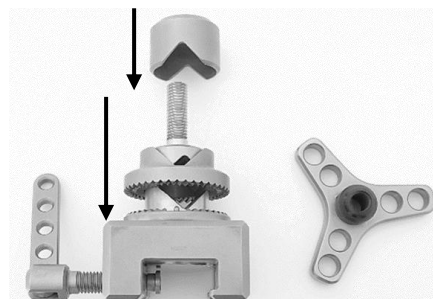


Fig. 3



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

After performing a functional test, the assembled instrument is ready for use again.



Fig. 4

9.3) Cross connector

Cross connector EEN-4

Figure 5 shows the EEN-4 cross connector. It consists of a star grip handle (1), a clamping sleeve (2), a clamping piece (3) and a threaded rod (4).

The cross connector must be assembled as follows before use.

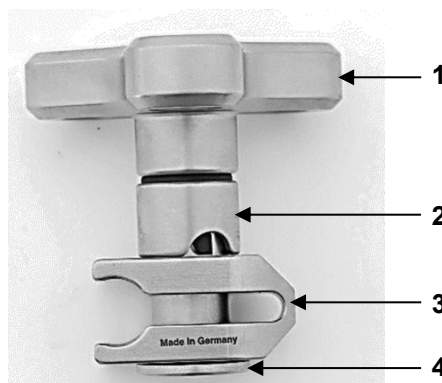


Fig. 5: Cross connector EEN-4

As shown in Figure 6, first insert the clamping piece (3) and then the clamping sleeve (2) over the threaded rod (4).

Please observe the following instructions!

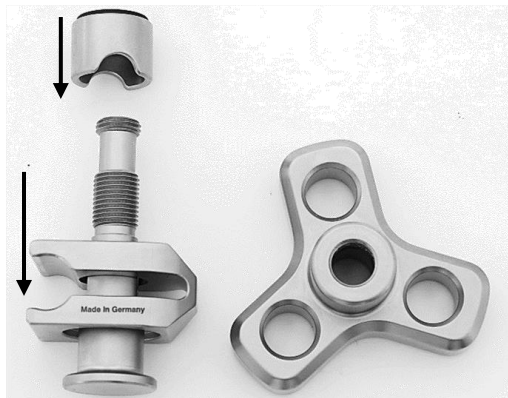


Fig. 6



When inserting the clamping piece onto the threaded rod, ensure that the recess faces downwards (Fig. 7a) so that the head of the threaded rod (4) is flush with the clamping piece (3) (Fig. 7b). If this instruction is not followed, the blade guide cannot be inserted through the clamping sleeve (2).

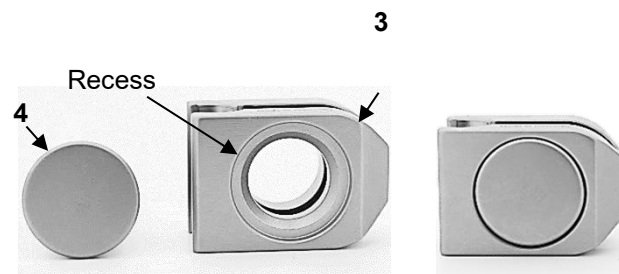


Fig. 7a

Fig. 7b



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

After performing a functional test, the assembled instrument is ready for use again.



Fig. 8

Cross connector EEN-1

Figure 9 shows the EEN-1 cross connector. It consists of a star grip handle (1), an upper (2) and a lower (3) clamping piece and a threaded rod (4).

The cross connector must be assembled as follows before use.

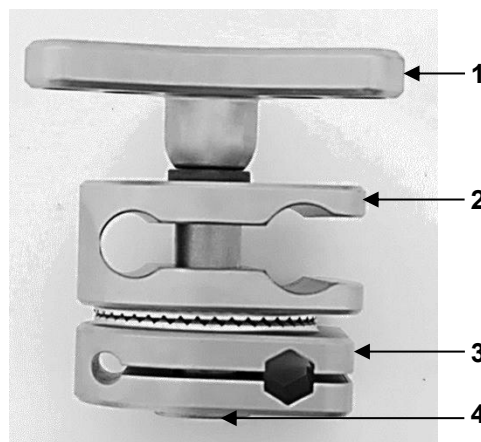


Fig. 9: Cross connector EEN-1

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



Both clamping pieces (2, 3) are serrated on one side. When inserting the clamping pieces onto the threaded rod (4), ensure that their serrated surfaces can engage with one another.

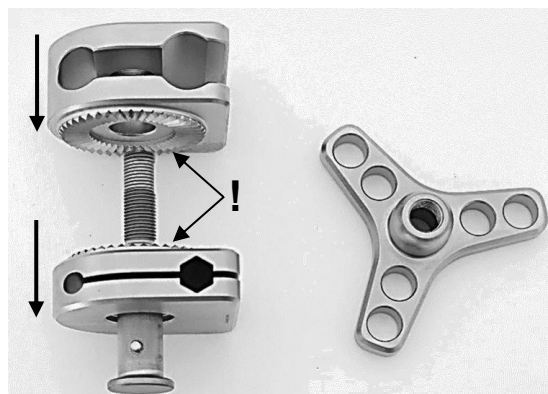


Fig. 10



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

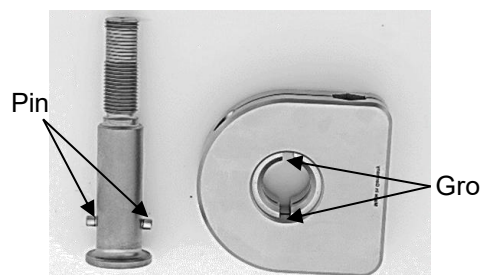


Fig. 11



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

After performing a functional test, the assembled instrument is ready for use again.

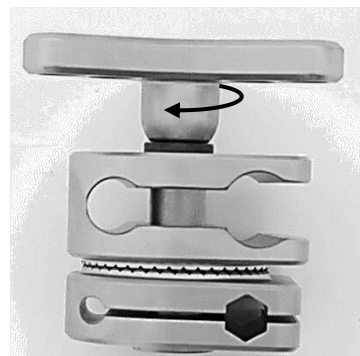


Fig. 12

9.4) Frame elements and components

The bayonet-shaped frame elements EEN-2K and EEN-2V have standard-container-compatible lengths of 420 mm and 570 mm, respectively, which, in combination with the curved caudal frame element EEN-3 (length: 560 mm), allow complete exposure of the abdominal cavity in patients of all sizes.

The longitudinal frame elements running alongside the patient have a hexagonal profile at their cranial end, which is connected to the EEL-1K or EEL-1G frame arch of the THOREXPO Retractor by means of a cross connector. The cross-connector mechanism allows the frame elements to be attached to either the outer side (Fig. 13a) or the inner side (Fig. 13b) of the THOREXPO frame arch. In combination with the six positions defined by the hexagonal profile, this provides 12 adjustment options on each side of the frame for configuring the frame width. Taken together, the two sides provide a width adjustment range of approx. 200 mm, within which the retractor system can be stably adapted to the patient's anatomy.

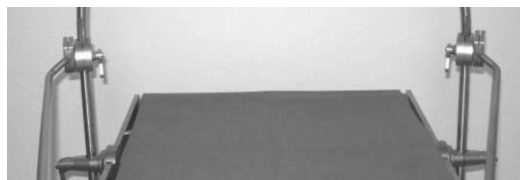


Fig. 13a: Attachment of the cross connectors to the outer side of the frame element

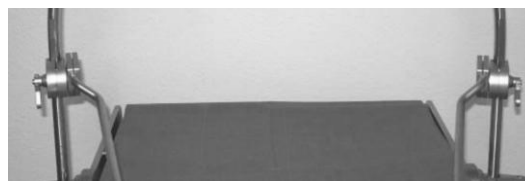


Fig. 13b: Attachment of the cross connectors to the inner side of the frame element

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

Any number of small EEN-4 cross connectors can be attached at any position on the EEN-2K or EEN-2V bayonet-shaped frame elements and the curved section of the EEN-3 frame element, and equipped with long EEN-5



Fig. 14a: Small angle



Fig. 14b: Large angle



or short EEN-6 blade guides. The blade guides are then locked at the required working length and angle using the star grip handle. Insert the retraction blades into the distal bores of the blade guides. The retraction blades are available in various sizes for all conceivable anatomical requirements. Each blade is secured in its holder by two ball catches (Fig. 15).



Fig. 15: The blade guide is attached to the cross connector at its proximal end and has a blade holder at its distal end.

10) Disassembly

10.1) Coupling rider

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

10.2) Operating table mounting clamp

For reprocessing, the operating table mounting clamp must be disassembled as follows.



Figures 16 and 17 are for illustrative purposes only and do not correspond to the EEK-1F/1S operating table mounting clamp, as the clamping section of the operating table mounting clamp shown is diamond-shaped rather than round.

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

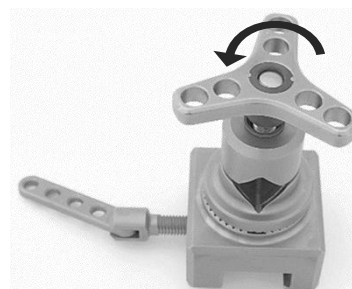


Fig. 16

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

The instrument, disassembled into its individual components, can now be reprocessed.

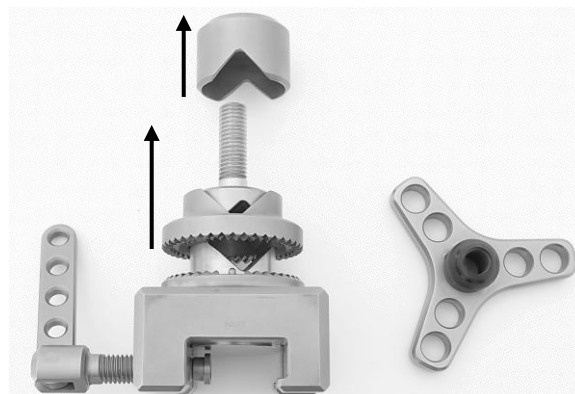


Fig. 17



10.3) Cross connector

For reprocessing, the cross connectors EEN-4 and EEN-1 must be disassembled as follows.

Cross connector EEN-4

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



Fig. 18

First, pull the clamping sleeve (2) off the threaded rod (4), then remove the clamping piece (3) (Fig. 19).

The instrument, disassembled into its individual components, can now be reprocessed.

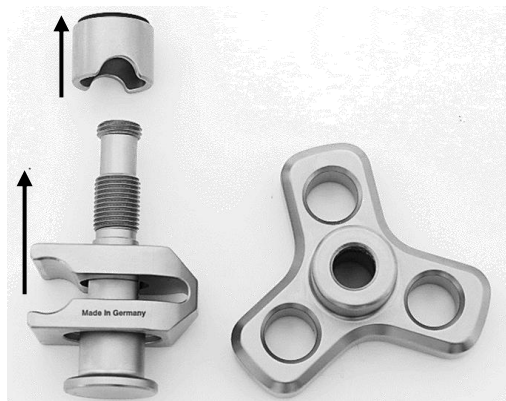


Fig. 19

Cross connector EEN-1

Turn the star grip handle (1) anticlockwise until it can be removed (Fig. 20).

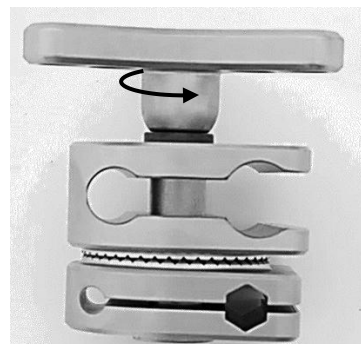


Fig. 20



First, pull the upper clamping piece (2) off the threaded rod (4), then remove the lower clamping piece (3) (Fig. 21).

The instrument, disassembled into its individual components, can now be reprocessed.



Fig. 21

10.4) Frame elements and components

The frame elements and components must be disassembled again for reprocessing. Therefore, please observe the relevant assembly instructions (see 9.4, Frame elements and components).



Place small parts in suitable containers (e.g., needle box) for storage and reprocessing!

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 either 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

Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:

 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 CE marking
 Oil can for points to be lubricated	 CE marking	

Manufacturer's contact information

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