FEHLING THOREXPO Retractor System

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

Table 1: List of the components, the extension modules for the THOREXPO retractor system

Components

Fixations/guides

EEL-4F	Blade guide rotatable and swivelling 300 mm
EEM-2F	THOREXPO cross connector 16/8 mm
EEP-0	Coupling rider
EEK-1F	Operating table adapting clamp Ø 16 mm, adjustable angle
EEK-1S	Operating table adapting clamp Ø 16 mm, adjustable angle

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

Extension modules

Possible supplementary retractor systems

VENTREXPO retractor system see Instructions for Use G064

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 THOREXPO retractor system may only be used, reprocessed and disposed of by qualified medical personnel!

The THOREXPO 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 THOREXPO 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 THOREXPO 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 THOREXPO 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 THOREXPO retractor system with care during storage, transport and cleaning! Avoid striking and applying pressure to the THOREXPO 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). <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). • 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). <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 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 basic component of the THOREXPO retractor is a U-shaped body composed of two lateral branches (EEL-1S) and a continuous curved central part (EEL-1K or EEL-1G). Two such center parts are available to accommodate different operating table widths: the EEL-1K center part is to be used for operating tables with a width of 52 and 54 cm (measured over the outer edges of the lateral T-rails), and the EEL-1G center part is to be used for operating tables with a width of 58 cm. The disassembly option of the body provides for better reprocessing and storage.

Figure 1 gives a configuration example for the THOREXPO retractor system. Table 2 lists the corresponding components.

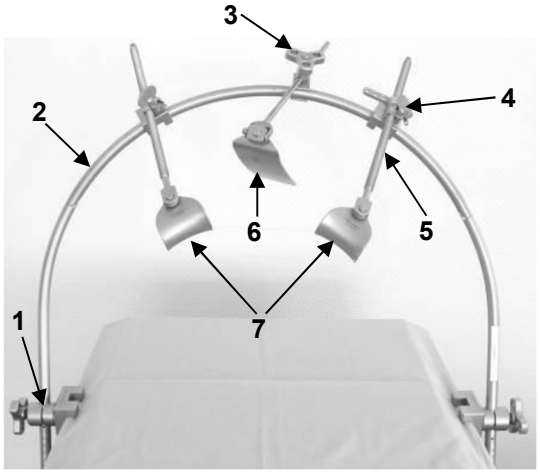


Fig. 1: Configuration example for the THOREXPO retractor system

Table 2: 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	EEM-2F	THOREXPO cross connector 16/8 mm
4	EEP-0	Coupling rider
5	EEL-4F	Blade guide rotatable and swivelling 300 mm
6	EEN-0/8/9; EEM-4/5/8; EEO-5/6	VENTREXPO abdominal spatula
7	EEL-5/6/7/8/9; EEM-1	THOREXPO retracting blade

The THOREXPO retractor is used to expose the upper abdominal and lower thoracic cavity and can be adapted to all common brands of operating tables.

The THOREXPO body is adjustable in height and angle. Thus, the body can accommodate the different anatomical requirements.

The coupling riders are moved on the body concentrically to the patient axis. This allows the position of the blade guide and the blades to be optimized necessitating only minimal space requirements.

The blade guides can be swiveled laterally over a limited angular range as well as rotated infinitely in a radial direction. This feature also helps to optimize the position of the retractor while requiring minimal space.

The retractor blades can be swiveled laterally in the mounting of the blade guide. This distributes the tissue load evenly across the entire width of the retractor blades and minimizes the risk of necrosis or rib fractures.

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the THOREXPO 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.

7.1) Extension module

The THOREXPO retractor system can be extended with the body elements and components of the VENTREXPO retractor system (see "Extension modules" in Table 1, Page 1).

8) Required accessories

No accessories are required for using the THOREXPO retractor system.

9) Assembly

9.1) Coupling rider

Assembly of the coupling rider 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.

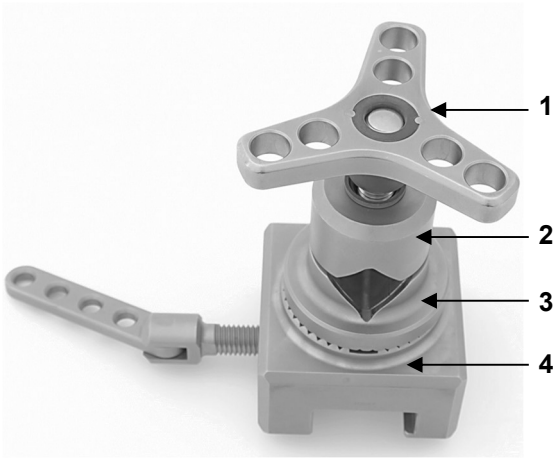


Fig. 2: OR table adapting clamp EEJ-1 (exemplary)

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).

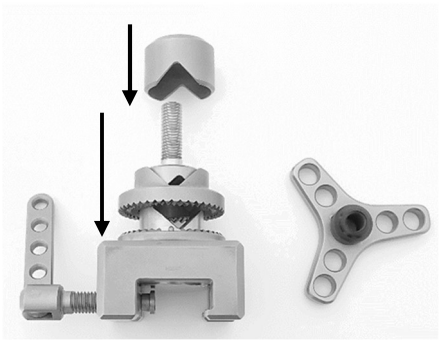


Fig. 3

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

For assembly of the cross connector please observe the following assembly instructions.

Figure 5 depicts the cross connector EEM-2F.
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.

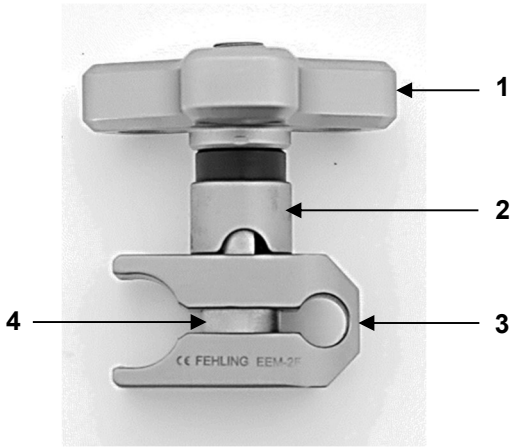


Fig. 5: Cross connector EEM-2F

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 notes!

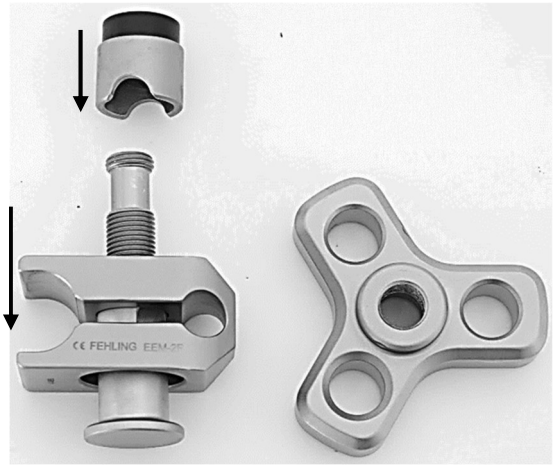


Fig. 6

⚠ 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).

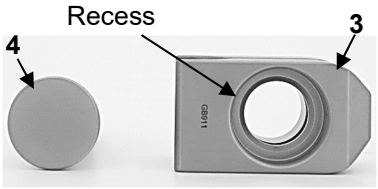


Fig. 7a

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

9.4) Body elements and components

For assembly of the body elements and components, please observe the following assembly instructions.

The body has a round profile and a diameter of 16 mm. It therefore fits the commonly available OR table adapters (e.g. Maquet). Just before the bend starts, the two U-limbs have a distance of approx. 60 mm over which the body diameter is tapered to 14 mm (Fig. 9). The EEM-2F cross connectors (Fig. 10) and/or the EEP-0 coupling riders (Fig. 11) are pushed on in these areas. Depending on requirements, 2, 3 or 4 coupling riders or cross connectors can be mounted on the body.

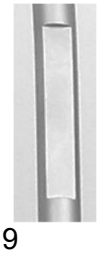


Fig. 9

Fig. 10

Fig. 11

The aforementioned coupling riders accommodate the EEL-4F blade guides (Fig. 12). The blade guides can be rotated and swiveled in the coupling rider and their effective length can be varied. The mounting for the retracting blades EEL-5 to EEL-9 as well as EEM-1 is located at the distal end of the blade guide.

Fig. 12

Fig. 13

Assembly and attachment to the operating table

The two straight limbs of the U-shaped body profile feature a graduation of 5 - 20 cm at their open end on the outside (Fig. 13). This graduation enables the body ends to be secured at the same height on both sides in the OR table adapting clamp. It should also be kept in mind that the body is mounted at the same distance from the end of the operating table on both sides.

The EEK-1F OR table adapting clamp (Fig. 14) is used to attach the body to the rails of the operating table. It allows variable mounting angles and heights of the body to the table - sterile above the cover. The OR table adapting clamp is fixed to the rail of the operating table via a threaded bolt with a toggle lever, while the body is fixed in the OR table adapting clamp using a large-sized screw.

Fig. 14

10) Disassembly

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

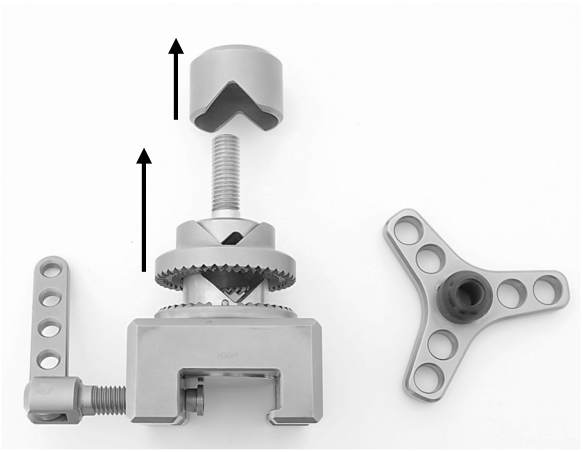
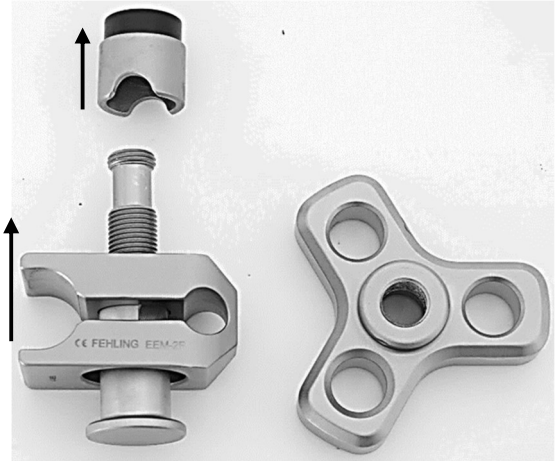
10.1) Coupling rider

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

10.2) Operating table adapting clamp

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

⚠ Figures 15 and 16 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. 15).	 Fig. 15
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. 16). The instrument is now disassembled and can be reprocessed.	 Fig. 16
10.3) Cross connector	
The cross connector must be disassembled as follows for reprocessing.	
Turn the star grip (1) counterclockwise until it can be removed (Fig. 17).	 Fig. 17
First pull the clamping sleeve (2) from the threaded rod (4), then remove the clamping piece (3) (Fig. 18). The instrument is now disassembled and can be reprocessed.	 Fig. 18

10.4) Body elements and components
For reprocessing, the body elements and 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