



FEHLING THOREXPO Retractor System

Frame components

EEL-1STHOREXPO retractor frame arch side sections (pair)
EEL-1KTHOREXPO retractor frame arch centre section for table width 540 mm
EEL-1G.... THOREXPO retractor frame arch centre section for table width 580 mm

Table 1: List of components and extension modules for the THOREXPO Retractor System

Components

Fixations/guides

EEL-4FBlade guide, rotatable and pivotable 300 mm
EEM-2FTHOREXPO cross connector 16/8 mm
EEP-0Coupling rider
EEK-1FOperating table mounting clamp Ø 16 mm, angle-adjustable
EEK-1SOperating table mounting clamp Ø 16 mm, angle-adjustable

Manubrium hook

EEK-5THOREXPO manubrium hook 90° angled, 75 x 19 mm
EEK-8THOREXPO manubrium hook 90° angled, 75 x 24 mm
EEK-6THOREXPO manubrium hook 90° angled, 95 x 24 mm
EEK-7THOREXPO 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
EEM-1 THOREXPO retractor blade 90 x 130 mm
EEQ-1..... Blade for THOREXPO blade guide EEL-4F, 50 x 65 mm

Extension modules

Optional supplementary retractor systems

VENTREXPO Retractor System, see Instructions for Use G064



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 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

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 excludes retractors (as specified in the TD for Classes I and IIa retractors), hooks, vessel 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 THOREXPO 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 THOREXPO Retractor System with care during storage, transport and cleaning! Avoid impacts and point loading on the THOREXPO 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.
	The instruments must be handled with care during storage, transportation 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.



Limitations on reprocessing	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 marking, functional failure - also see "<i>Maintenance, Inspection and Testing</i>"). 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 ($< 40^{\circ}\text{C}$) 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, $< 40^{\circ}\text{C}$) 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, $< 40^{\circ}\text{C}$). • 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 "<i>General Information on Reprocessing</i>") 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, $< 40^{\circ}\text{C}$)



	• 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-



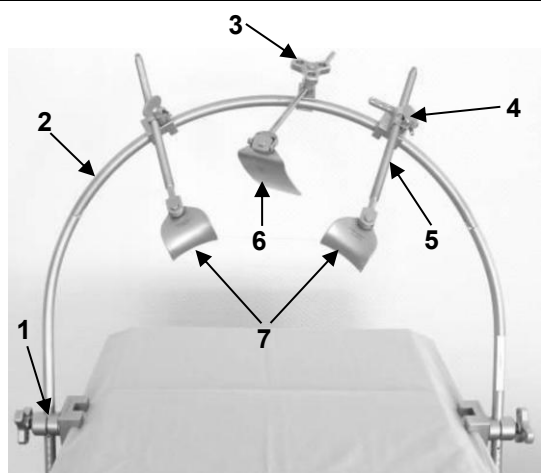
	ments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments.
Packaging	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated 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 basic component of the THOREXPO Retractor is a U-shaped frame assembled from two side arms (EEL-1S) and a continuously curved centre section (EEL-1K or EEL-1G). Two such centre sections are available to match the different operating table widths: Use centre section EEL-1K for operating tables measuring 52 or 54 cm in width (measured over the outer edges of the lateral T-rails) and centre section EEL-1G for operating tables measuring 58 cm in width. The frame can be disassembled to facilitate reprocessing and storage.

Figure 1 shows a configuration example for the THOREXPO Retractor System. The corresponding components are listed in Table 2.



1: Configuration example for the THOREXPO Retractor System

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

The THOREXPO Retractor is used to expose the upper abdominal and lower thoracic cavities and is compatible with all common brands of operating tables.

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

The coupling riders are moved along the frame concentrically about the patient's longitudinal axis. This allows the positions of the blade guide and blades to be optimised while minimising space requirements.

The blade guides can be pivoted laterally within a limited angular range and rotated continuously in the radial direction. This feature also helps to optimise the position of the retractor while minimising space requirements.

The retractor blades can be pivoted laterally in the blade-guide retainer. This ensures that the tissue load is distributed evenly across the entire width of the retractor blades, minimising the risk of necrosis or rib fractures.



Use only intact and sterilised products!



Before inserting the THOREXPO 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 as well as the field of application. Ensure that the components used have the correct size and geometry, as well as sufficient stability.

7.1) Configuration

The THOREXPO Retractor System can be extended using the frame components and other 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

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 operating table mounting clamp (EEJ-1).

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.

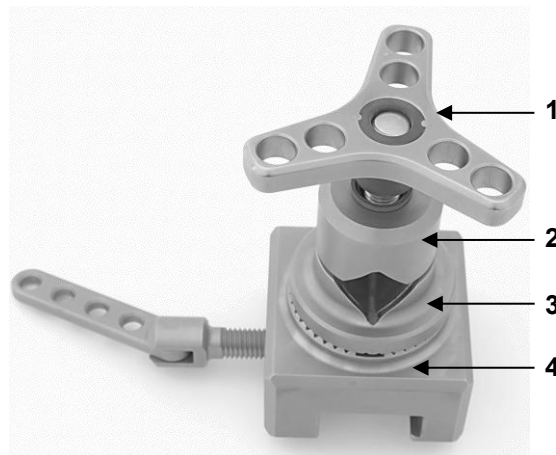


Fig. 2: EEJ-1 operating table mounting clamp (example)

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).

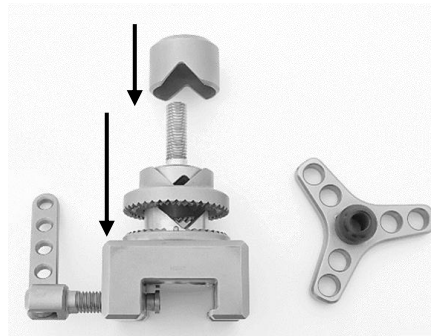


Fig. 3

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

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



Fig. 4



9.3) Cross connector

Please follow the assembly instructions below when assembling the cross connector.

Figure 5 shows the EEM-2F 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.

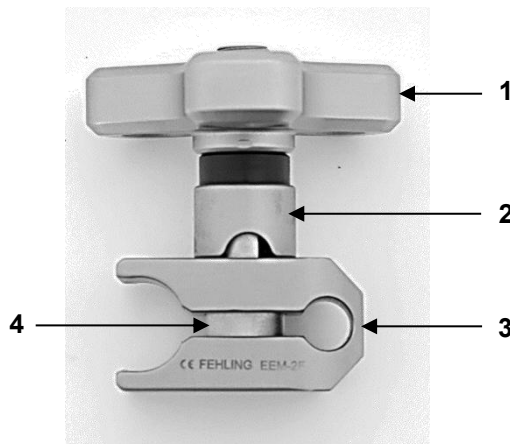


Fig. 5: Cross connector EEM-2F

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!

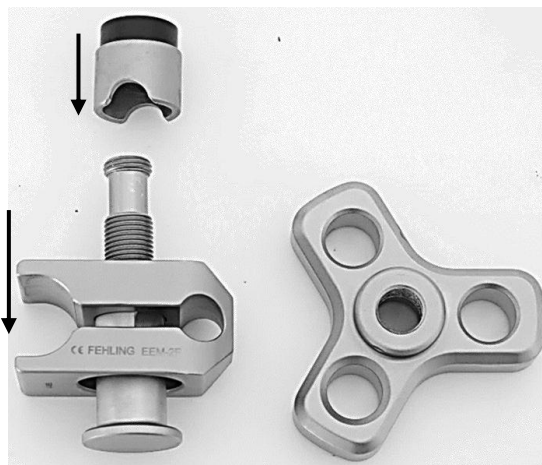


Fig. 6



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).

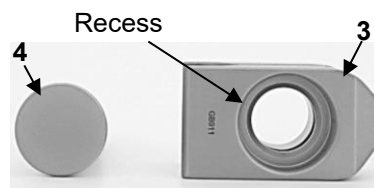


Fig. 7a



Fig. 7b

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

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



Fig. 8



9.4) Frame elements and components

Please follow the instructions below to assemble the frame elements and components.

The frame has a round profile and a diameter of 16 mm. This means that it is compatible with commercially available operating table adapters (e.g. Maquet). Immediately before the bend, both U-shaped arms have a section approximately 60 mm long over which the frame diameter tapers to 14 mm (Fig. 9). The EEM-2F cross connectors (Fig. 10) and/or EEP-0 coupling riders (Fig. 11) are slid onto these sections. Depending on requirements, 2, 3 or 4 coupling riders or cross connectors can be fitted on the frame.



Fig. 9



Fig. 10

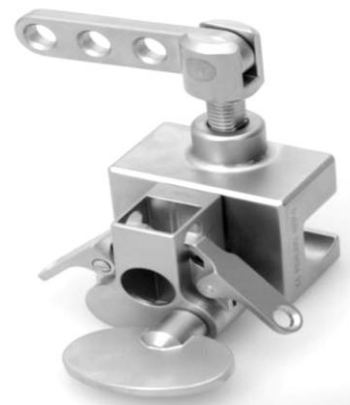


Fig. 11

The coupling riders mentioned above accommodate the blade guides EEL-4F (Fig. 12). The blade guides can be rotated and pivoted in the coupling riders, and their operating length can be adjusted. The retainer for the EEL-5 to EEL-9 and EEM-1 retractor blades is located at the distal end of the blade guide.



Fig. 12



Fig. 13

Assembly and attachment to the operating table

The two straight arms of the U-shaped frame profile have a scale from 5 to 20 cm on the outside at their open ends (Fig. 13). This scale allows the frame ends to be attached at the same height on both sides in the operating table mounting clamp. It must also be ensured that the frame is mounted at the same distance from the end of the operating table on both sides.

The EEM-1F operating table mounting clamp (Fig. 14) is used to attach the frame to the rails of the operating table. It allows the frame to be mounted on the table at variable angles and heights under sterile conditions over the drape. The operating table mounting clamp is secured to the operating table rail by a threaded bolt with a toggle lever, while the frame is secured in the operating table mounting clamp using a large screw.



Fig. 14



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 15 and 16 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. 15).



Fig. 15

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. 16).

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

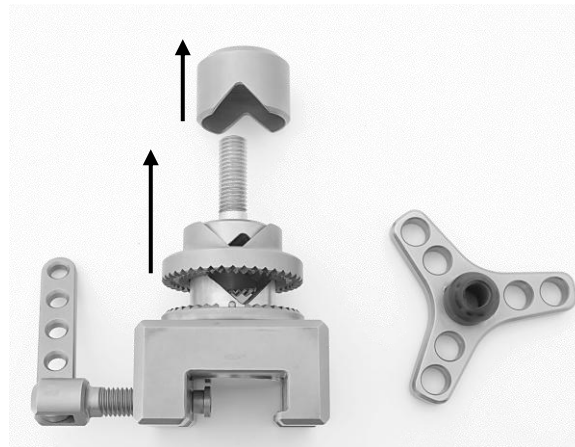


Fig. 16



10.3) Cross connector

For reprocessing, the cross connector must be disassembled as follows.

Turn the star grip handle (1) anticlockwise until it can be removed (Fig. 17).



Fig. 17

First, pull the clamping sleeve (2) off the threaded rod (4), then remove the clamping piece (3) (Fig. 18).

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

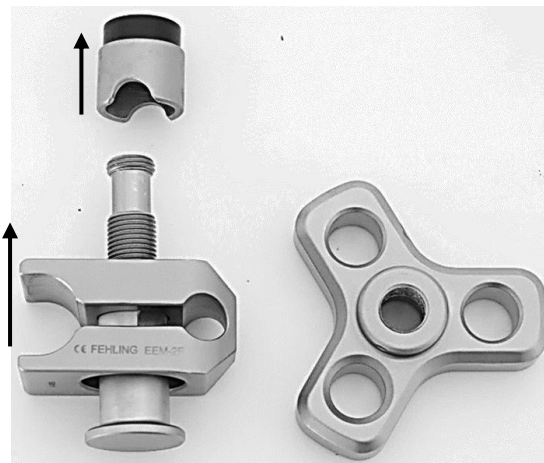


Fig. 18

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

	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 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	
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