FEHLING FALK sternum retractor

Retractor frame MQI-1 FALK sternum retractor with exchangeable blades, body only

Components

FALK retractor blades

MQI-2.....Retractor blade, 34 x 100 mm (pair)
MQI-3.....Retractor blade, 43 x 100 mm (pair)

Atrial hook

MRV-4V ....HOHE atrium retractor unflexible, 30 x 20 x 150 mm, Ø 6.35 mm
MRV-4H ....HOHE atrium retractor unflexible, 65 x 20 x 150 mm, Ø 6.35 mm
MRV-3H ....HOHE atrial hook unflexible, 65 x 30 x 150 mm, Ø 6.35 mm
MRV-4L ....HOHE atrium retractor unflexible, 65 x 20 x 200 mm Ø 6.35 mm
MRV-3L ....HOHE atrium retractor unflexible, 65 x 30 x 200 mm, Ø 6.35 mm
MPF-1H ....HOHE atrium retractor unflexible, 65 x 40 x 200 mm, Ø 6.35 mm
MRV-2H ....HOHE Tricuspid retractor unflexible, 45 x 45 x 150 mm, Ø 6.35 mm
MRV-2L ....HOHE Tricuspid retractor unflexible, 45 x 45 x 200 mm, Ø 6.35 mm
MQG-1 .....Atrial hook small, 20 mm with ball connector Ø 7 mm
MQG-2 .....Atrial hook medium, 30 mm with ball connector Ø 7 mm
MQG-3 .....Atrial hook large, 40 mm with ball connector Ø 7 mm

Other retaining elements

MRR-3V....Myocardial stabilizer with ball connector Ø 7 mm
MQG-5.....Zenker hook with ball connector Ø 7 mm

Fastening elements

MZZ-1N ....Clamping element f. ball joint adapter movable, small clamping range
MZZ-1Q ....Clamping element f. ball joint adapter movable, flat
MZZ-2 .....Clamping element f. ball joint adapter movable with gear wheel

Ball adapter

MRV-0F ....Ball joint adapter bayonet Ø 6.35 mm, length and height variable
MRV-0J ....Ball joint adapter bayonet w.artic. Ø 6.35 mm, length and height variable
MRV-0R....Ball joint adapter bayonet w.artic. Ø 6.35 mm, length and height variable
MRV-1F ....Ball joint adapter Ø 6.35 mm, length and height variable

Accessories

LMT-4 .....Cardan screwdriver

This instrument or medical device is supplied non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).
The FALK sternum retractor must only be used, prepared, and disposed of by qualified medical personnel!
The FALK sternum retractor is intended for reuse.

1) Intended purpose

The purpose of holding and guiding instruments is to hold products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drainage tubes, holding rods, handles, retractor blades, etc.).

- to hold or fix in a certain position

- to move into or to a certain position

This does not apply to retractors (according to TD retractor class I and class IIa), hooks, vessel and tissue clamps, forceps and needle holders.

Supplementary information on 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 for all patients where products and tissue have to be held or fixed in or at a certain position and/or moved in or at a certain position.

User profile: Holding and guiding instruments may only be used by medically trained specialists (e.g. medical specialists).

Application environment: Holding and guiding instruments are only used under controlled environmental conditions (e.g. operating theater).

Target patient population: No restrictions

2) Indications

Treatment methods that require products and tissues to be held and guided.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual holding and guiding instrument model are considered contraindicated. There are no generally valid contraindications for the use of holding and guiding instruments.
Nevertheless, attention must be paid to increased risks that could arise from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible side effects

The following side effects are described in the medical literature, which may also occur during the intended purpose of the instruments:

- Bone fractures such as spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischemia of other organs due to compression of blood vessels

⚠	Medical devices may contain PEEK, chromium, and/or nickel for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use

The FALK sternum retractor is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before each subsequent use (see chap. *6) Reprocessing*).

⚠	A safety inspection must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see chap. *6) Reprocessing* under *"Maintenance, inspection and testing"*).

⚠	Handle the FALK sternum retractor with care during storage, transport and cleaning! Avoid blows and localized stress on the FALK sternum retractor to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!

6) Reprocessing	
⚠	The medical device must be prepared before use. Before reprocessing, it must be risk-assessed according to the RKI guidelines (non-critical/semicritical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for preparation must be complied with.
⚠	The respective national regulations for the treatment of instruments used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants must be observed.
⚠	The instruments may only be used, prepared and disposed of by qualified medical personnel.
⚠	Handle the instruments with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the instruments in order not to cause any possible consequential damage! Do not overload functional parts!
⚠	Do not clean containers with plastic components using oxidative processes (process with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative aging of the material, which may not be recognizable by visible discoloration or embrittlement.
Limitations during reprocessing	Frequent reprocessing has little effect on the label of the instruments and does not impair the function of the instruments. The end of the product's life is normally determined by wear and damage caused by use (e.g. damage, illegible labeling, functional failure - see also *"Maintenance, inspection and testing"*). When used and reprocessed properly, the instruments have been shown to withstand at least 500 processing cycles.

General information on reprocessing	Reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". For validation, the recommended reprocessing agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Automated preparation is preferable to manual cleaning because it provides a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical material changes or material damage, such as corrosion, fractures or premature aging.
Pre-treatment at the point of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and medication residues are removed from the instruments with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for machine cleaning. Once the instruments have been pre-treated, visual inspections must be carried out to ensure that they are complete. The instruments must be transported from the place of use to the place of preparation in such a way that neither users, 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 before cleaning	It is recommended that the instruments be cleaned immediately after use, as dried residues are difficult to remove from hard-to-reach places. Do not place in NaCl solutions (otherwise risk of pitting or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See chap. *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse the instrument in disassembled condition under cold running water (drinking water quality, < 40 °C) until all visible soiling has been removed. Use a soft brush (not a wire brush!) to remove stubborn dirt.

	• Cavities, gaps, slits and lumen must be rinsed intensively (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Soak the products for 10 – 30 minutes in a solution containing 0.5 – 2 % Neodisher® MediClean forte with water (drinking water quality, < 40 °C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be observed. • Make sure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). • Rinse the instrument for 1 minute under cold demineralized water (see *"General information on reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ disinfection	If possible, a washer-disinfector that uses thermal disinfection and complies with DIN EN ISO 15883 is preferable.
Cleaning: Machine	Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. • If applicable, relax springs • Make sure that all cavities are completely flushed out, including the inside. • Make sure that no areas are left unwashed. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector. <u>Procedure/parameters:</u> • 3 minutes pre-rinse with cold water (drinking water quality, < 40 °C) • Emptying • 10 minutes cleaning with a solution of 0.5 – 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C • Emptying

	• 2 minutes rinsing with water (drinking water quality, < 40 °C) • Emptying • 1 minute rinse with cold demineralized water (< 30 °C) • Emptying • 5 minutes thermal disinfection with demineralized water (> 90 °C) • 30 minutes drying (90 °C) After machine cleaning, cavities, blind holes, etc. in particular have to be inspected for visible dirt. If necessary, repeat the cycle or clean manually.
Cleaning: Manual	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. • Operate moving parts, if any, through their full range of movement. • Clean the instruments with a soft brush (not a wire brush!) until no visible contamination remains. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). <u>Ultrasonic cleaning:</u> • 10 minutes sonication at < 40 °C with 0.5 – 2 % detergent solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments with water (drinking water quality, < 40 °C) for at least 10 seconds. • Deionized water (< 40 °C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • After cleaning, immerse the products for 5 minutes in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med

	AF). Ensure that all surfaces are wetted with the disinfectant. If necessary, move mobile 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 necessary, move mobile parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Then dry with suitable compressed air in accordance with RKI recommendations. Pay particular attention to drying areas that are difficult to access.
Assembly	See chap. *9) Assembly*
Maintenance, inspection and testing	For instruments with moving components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such points may also be indicated by an oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to stiffness and impair the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). If applicable, check the locking mechanisms. All instruments: Visually inspect for damage and wear using a magnifying lamp. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments whose labeling is no longer legible must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or workshops authorized 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 in the standard hospital scrap metal disposal system. In this case, especially for surgical instruments with pointed or sharp edges, it is important to ensure safe storage in a closed, puncture- and break-proof disposable container. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into trays provided for this purpose or place them on all-purpose sterilization trays. A suitable method must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance according to DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended

	limit values for the ingredients of feed water and steam condensate are defined in DIN EN 285. Validated procedure: Equipment: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert Procedure/parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see appliance manufacturer's instructions).
Storage	In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage). If applicable, always store instruments in a tension-free state. This helps to prevent premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are mainly made of steel. These must be cleaned before disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care should be taken to ensure that any pointed or sharp edges are protected.
The instructions listed above have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The person carrying out the preparation is responsible for ensuring that the preparation actually carried out with the equipment, materials and personnel used in the preparation facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for effectiveness and possible adverse consequences.	
⚠	Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

Together with the components, the MQI-1 retractor frame forms the FALK sternum retractor.

This is a U-shaped bar retractor with one fixed and one movable retractor arm. The movable retractor arm is moved by a gear drive using the drive lever and pinion on the toothed rack. The blades are attached to the distal end of the retractor arms.

The Falk sternum retractor is intended in particular for exposing the thorax during total and partial sternotomy approaches for further surgically invasive treatment of the heart.

Figure 1 shows a configuration example for the FALK sternum retractor with an atrial hook attached to a ball adapter and a clamping element. The corresponding components are listed in Table 1.

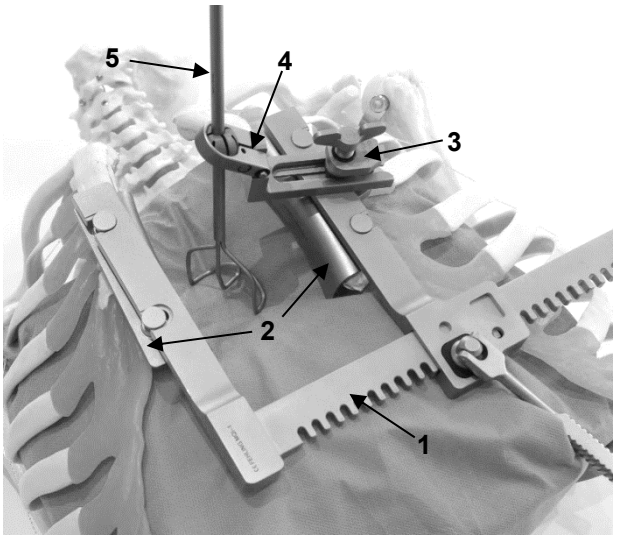


Fig. 1: Configuration example of a FALK sternum retractor with an atrial hook attached to a ball adapter with clamping element

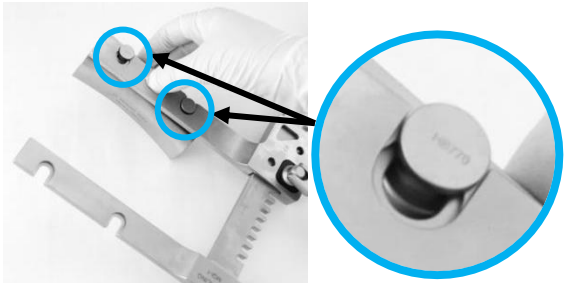
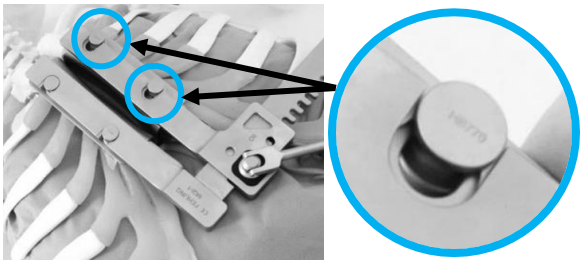
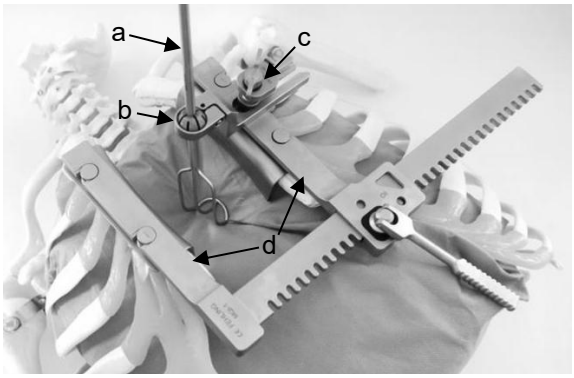
Table 1: List of the corresponding components

	Item No.	Designation
1	MQI-1	FALK sternum retractor with exchangeable blades, body only
2	MQI-2	Retractor blade, 34 x 100 mm (pair)
3	MZZ-1Q	Clamping element f. ball joint adapter movable, flat
4	MRV-0J	Ball joint adapter bayonet w.artic. Ø 6.35 mm, length and height variable
5	MRV-2H	HOHE Tricuspid retractor unflexible, 45 x 45 x 150 mm, Ø 6.35 mm

⚠	Only use flawless and sterilized products!
⚠	Before inserting the retractors and retractor components, ensure that the surgical site has been properly prepared.
⚠	Before using the retractors and retractor components, make sure that their functionality is not impaired and that there is no damage!
⚠	Medical devices made of ferromagnetic materials must not be exposed to 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 holding and guiding instruments depends on the anatomical and physiological conditions as well as the area of application. It is important to ensure that the holding and guiding instruments used are the right size and geometry and have sufficient stability.

During the application

Depending on the purpose of the operation and the available mounting space, the blades can either be mounted in front of (Fig. 2) or also according to (Fig. 3) be connected to the retractor frame after insertion into the sternum saw gap.

1	By inserting the cylindrical pins into the two holes in the retractor arms, the blades are first connected to the retractor frame and then inserted into the saw cut (Fig. 2).	 Fig. 2
2	The blades are inserted into the saw cut first. Then insert the two arms one after the other into the space between the blade pivots and slide the respective holes in the arms over the blade pivots. This can be done either with the retractor frame closed or slightly open (Fig. 3).	 Fig. 3
3	To expose the thorax, open the retractor as far as necessary by the tooth drive (Fig. 4). To position the atrial hooks (a), e.g. MRV-3H, ball adapters (b) (see components) can be attached anywhere on the retractor arms (d) using the MZZ-1Q fastening element (c) - even in the area of the blades. Installation is carried out in accordance with instructions for use G 217.	 Fig. 4

⚠	When inserting the retractor blades, make sure that no tissue structures are unintentionally injured (especially nerves and blood vessels)!
⚠	Excessive and prolonged pressure on the tissue can cause necrosis, ruptures, fractures and other lesions!
⚠	Overloading can cause plastic deformation or breakage of the spreaders (retractors) and retractor components!
⚠	Before removing the spreaders (retractors) and spreader components from the surgical field, ensure that the spreader arms are slowly brought back together.

8) Required accessories

No accessories are required to use the FALK sternum retractor.

To use the ball adapters MRV-0F, MRV-0J and MRV-0F, an external hexagon screwdriver, e.g. the cardan screwdriver LMT-4 (Fig. 5), is required.

Fig. 5: Cardan screwdriver LMT-4

9) Assembly

To fit the FALK sternum retractor, please observe the following fitting instructions.

To install the retractor blades, please refer to chap. *7) Configuration and application* under *"During the application"*.

Figure 6 shows the FALK sternum retractor, which is a U-shaped bar retractor with pinion. The bar retractor consists of a fixed retractor arm (1), a toothed rack (2) and a movable retractor arm (4).
The proximal end of the movable retractor arm is the box (5) in which the drive lever (3) is located.

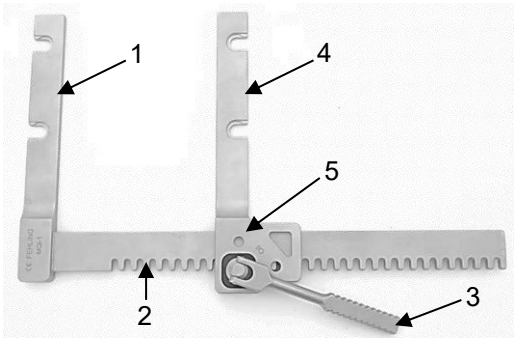


Fig. 6

First insert the drive lever (3) into the recess provided in the box (5) (Fig. 7).

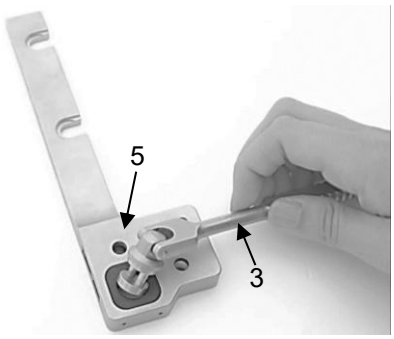


Fig. 7

Insert the toothed rack (2) into the recess in the box (5) until the pinion of the drive lever (3) engages in the toothed rack (2) (Fig. 8).

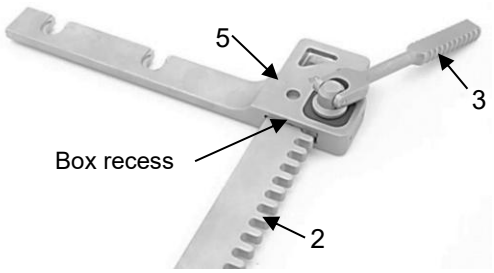


Fig. 8

⚠ Make sure that both retractor arms point in the same direction, as shown in Figure 9.

Turn the drive lever (3) clockwise to move the movable retractor arm (4) on the toothed rack (2) inwards towards the fixed retractor arm (1) (Fig. 9).

The assembled instrument is now ready for use again after a functional test.

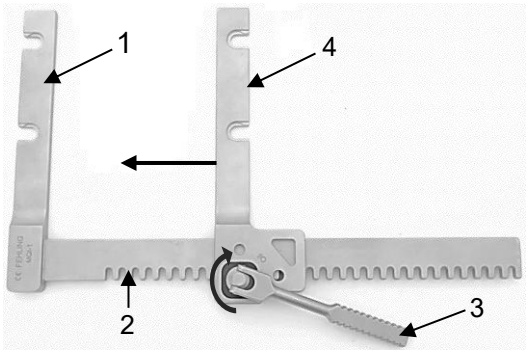


Fig. 9

10) Disassembly

The FALK sternum retractor must be disassembled as follows for reprocessing.

To remove the retractor blades, please refer to chap. *7) Configuration and application* under *"During the application"*.

Turn the drive lever (3) counterclockwise to move the movable retractor arm (4) outwards on the toothed rack (2) until it can be removed.

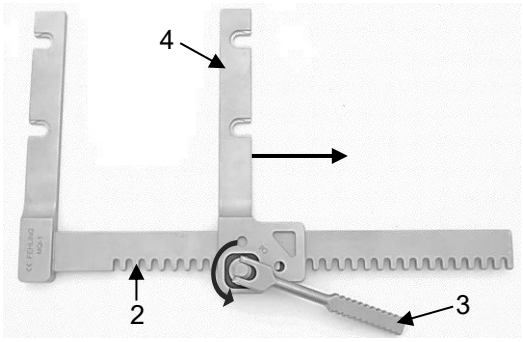


Fig. 10

In the second step, remove the drive lever (3).

The instrument disassembled into its three individual parts (Fig. 11) can now be processed.

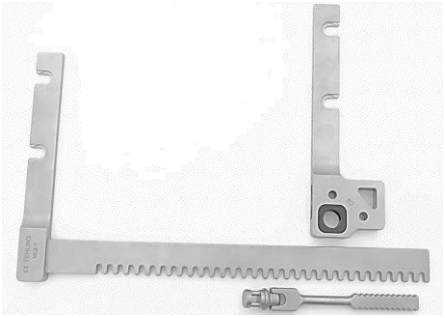


Fig. 11

11) Obligation to report serious incidents

The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.

Symbols		
If displayed on the medical device, the label of the medical device or the instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meaning:		
 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalog number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 0297 CE marking
 Oil can for points that require lubrication	 CE marking	

Contact the manufacturer		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 E-Mail: info@fehling-instruments.de www.fehling-instruments.de