FEHLING CEBOTARI universal sternal retractor

Retractor frame MQL-1 CEBOTARI universal sternal retractor

Table 1: List of components and accessories for the CEBOTARI universal sternal retractor

Components

Sternal blades

MQL-4.....CEBOTARI sternotomy blade 34 x 50 mm (pair)
MQL-5.....CEBOTARI sternotomy blade 43 x 50 mm (pair)
MQL-6.....CEBOTARI sternotomy blade 34 x 100 mm (pair)
MQL-2.....CEBOTARI sternotomy blade 43 x 100 mm (pair)
MQL-7.....CEBOTARI sternotomy blade 50 x 100 mm (pair)
MQL-8.....CEBOTARI sternotomy blade 63 x 100 mm (pair)
MQL-9.....CEBOTARI sternotomy blade 34 x 120 mm (pair)
MQM-1.....CEBOTARI sternotomy blade 43 x 120 mm (pair)
MQM-2.....CEBOTARI sternotomy blade 50 x 120 mm (pair)
MQM-3.....CEBOTARI sternotomy blade 63 x 120 mm (pair)
MQL-4F ....CEBOTARI sternotomy blade (fixed) 34 x 50 mm (pair)
MQL-5F ....CEBOTARI sternotomy blade (fixed) 43 x 50 mm (pair)
MQL-6F ....CEBOTARI sternotomy blade (fixed) 34 x 100 mm (pair)
MQL-2F ....CEBOTARI sternotomy blade (fixed) 43 x 100 mm (pair)
MQL-7F ....CEBOTARI sternotomy blade (fixed) 50 x 100 mm (pair)
MQL-8F ....CEBOTARI sternotomy blade (fixed) 63 x 100 mm (pair)
MQL-9F ....CEBOTARI sternotomy blade (fixed) 34 x 120 mm (pair)
MQM-1F ...CEBOTARI sternotomy blade (fixed) 43 x 120 mm (pair)
MQM-2F ...CEBOTARI sternotomy blade (fixed) 50 x 120 mm (pair)
MQM-3F ...CEBOTARI sternotomy blade (fixed) 63 x 120 mm (pair)

IMA blades

MQL-3.....CEBOTARI IMA blade
MQL-3F ....CEBOTARI IMA blade (fixed)
MLC-2V ....Baykut IMA blade 15 x 90 mm

Accessories

LMT-4 .....Cardan screwdriver

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

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

⚠	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 CEBOTARI universal sternal retractor may only be used, reprocessed and disposed of by qualified medical personnel! The CEBOTARI universal sternal 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).

Anticipated 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 nickel, for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use	
The CEBOTARI universal sternal retractor is delivered unsterile 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 CEBOTARI universal sternal retractor with care during storage, transportation and cleaning! Avoid impacts and point loads on the CEBOTARI universal sternal 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!

⚠	Only assemble instruments with individual parts loosely before packaging and sterilization and do not screw them together tightly. For the CEBOTARI universal sternal retractor, this must be observed on the rotatable retractor arm (Fig. 1).  Fig. 1: CEBATORI universal sternal retractor with one retractor arm that is not firmly screwed in place
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. <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 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

The CEBOTARI universal sternal retractor is a U-shaped bar retractor with one rotatable and one movable retractor arm. The movable retractor arm is moved by a gear drive on the toothed rack. The retractor arm fixed to the toothed rack can be adjusted around the longitudinal axis of the arm. This allows the angle to the retractor level to be adjusted individually.

The CEBOTARI universal sternal retractor is intended in particular for the visualization of the thorax during total and partial sternotomy approaches for further surgically invasive treatment of the heart, including the visualization of IMA and mitral valves.

Figure 2 shows a configuration example for the CEBOTARI universal sternal retractor with an atrial hook attached to a ball adapter and a fastening element. Figure 3 shows another configuration example for the CEBOTARI universal sternal retractor with an IMA blade suspended in an IMA holding blade.

Figure 4 shows three variants of the fastening element and Figure 5 three variants of the ball adapter.

The corresponding components are listed in Table 2.

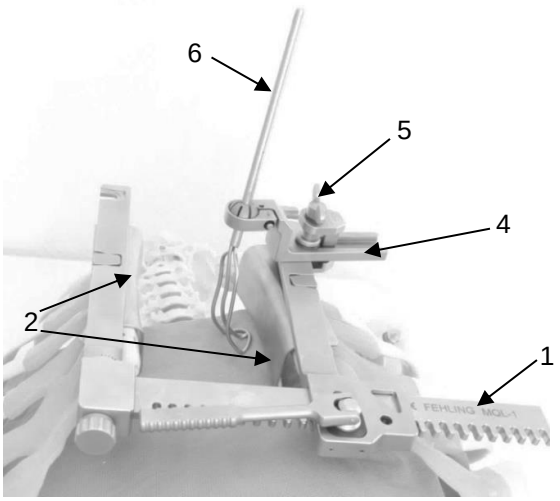


Fig. 2: Configuration example for the CEBOTARI universal sternal retractor with atrial hook

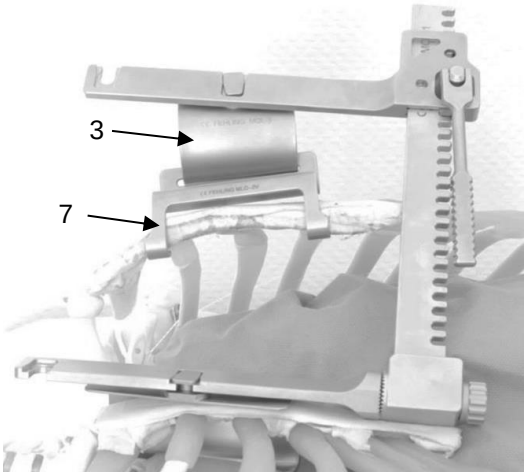


Fig. 3: Configuration example for the CEBOTARI universal sternal retractor with IMA blade

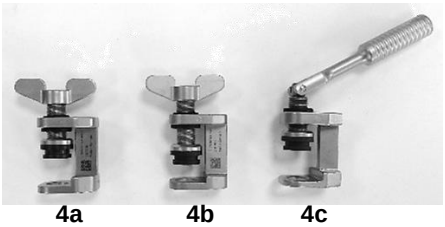


Fig. 4: Variants for clamping elements MZZ-1Q (4a), MZZ-1N (4b) and MZZ-2 (4c)

Table 2: List of the corresponding components

	Item No.	Designation
1	MQL-1	CEBOTARI universal sternal retractor
2		Sternotomy blades
	MQL-2/2F	Sternotomy blades 43 x 100 mm / fixed
	MQL-4/4F	Sternotomy blades 34 x 50 mm / fixed
	MQL-5/5F	Sternotomy blades 43 x 50 mm / fixed
	MQL-6/6F	Sternotomy blades 34 x 100 mm / fixed
	MQL-7/7F	Sternotomy blades 50 x 100 mm / fixed
	MQL-8/8F	Sternotomy blades 63 x 100 mm / fixed
	MQL-9/9F	Sternotomy blades 34 x 120 mm / fixed
	MQM-1/1F	Sternotomy blades 43 x 120 mm / fixed
	MQM-2/2F	Sternotomy blades 50 x 120 mm / fixed
	MQM-3/3F	Sternotomy blades 63 x 120 mm / fixed
3	MQL-3/3F	CEBOTARI IMA blade/fixed
4		Clamping element
4a	MZZ-1Q	with wing screw
4b	MZZ-1N	with wing screw, small clamping range
4c	MZZ-2	with crank
5		Ball adapter, Ø 6.35 mm, adjustable length and height
5a	MRV-0F	Bayonet
5b	MRV-0J	with joint, hexagon screw
5c	MRV-0R	with joint, wing screw
5d	MRV-1F	Straight, hexagon screwdriver
6		HOHE atrial retractor
	MRV-2H	Tricuspid 45/45/150 mm
	MRV-2L	Tricuspid 45/45/200 mm
	MRV-3H	Fixed 65/30/150 mm
	MRV-3L	Fixed 65/30/200 mm
	MRV-4V	Fixed 30/20/150 mm
	MRV-4H	Fixed 65/20/150 mm
	MRV-4L	Fixed 65/20/200 mm
	MPF-1H	Fixed 65/40/200 mm
7	MLC-2V	Baykut IMA blade 15 x 90 mm

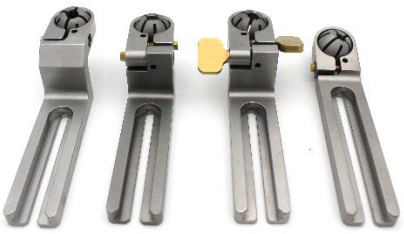


Fig. 5: Variants for ball adapter MRV-0F (5a), MRV-0J (5b), MRV-0R (5c) and MRV-1F (5d)

⚠ For the application of the ball adapters MRV-0F (5a), MRV-0J (5b) and MRV-1F (5d) (Fig. 5), an external hexagon screwdriver, e.g. the LMT-4 Cardan screwdriver (see chap. *8) Required accessories*), is required.

⚠	Only use flawless and sterilized products!
⚠	Before inserting the spreaders (retractors) and retractor components, ensure that the surgical site has been properly prepared.
⚠	Before using the spreaders (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	
⚠	For **partial sternotomy**, use narrower sternal blades. Risk of injury! When performing a **Z sternotomy**, ensure that the retractor does not twist. Risk of injury!
Inserting the sternal blades	

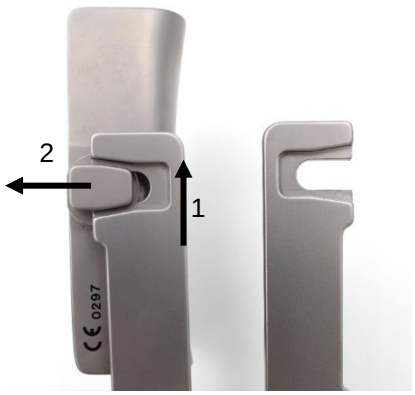


Fig. 6

⚠ **Note the direction of the clamping profile!**

The blade suspension must be inserted with the narrow side first.

A slight click of the cylindrical pin on the underside of the blade suspension indicates the correct end position of the blade.

If the blades are mounted incorrectly, the sternal blades can no longer be rotated at an angle.

To unhook the blades, slight pressure in the direction of the distal end of the retractor arm is required to overcome the blade lock (arrow 1, Fig. 6). The blades can then be removed laterally (arrow 2, Fig. 6).

⚠	Ensure correct orientation of the sternal and IMA blades! Risk of injury!

Depending on the purpose of the operation and the available assembly space, the sternal blades can be connected to the retractor either before (A) or after (B) insertion into the sternal saw gap.

(A) The blades are first secured by inserting the cylindrical pins into the holders of the retractor arms and then inserted into the saw cut.

(B) First insert the blades into the saw cut. Then insert the two retractor arms one after the other into the space between the blade pivots and slide the respective holders of the retractor arms over the blade pivots. This can be done either with the retractor closed or slightly open.

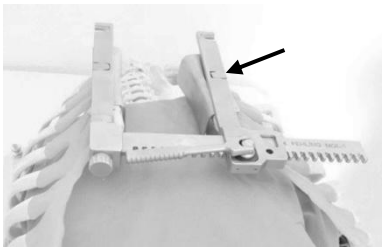


Fig. 7a

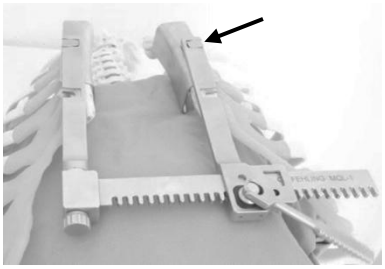


Fig. 7b

The sternal blades can be positioned on both holders of the retractor arms depending on the requirements of the operating field.

Figure 7a shows the image of the sternal blades closer to the proximal end of the retractor arm and Figure 7b shows the image of the sternal blades at the distal end of the retractor arm.

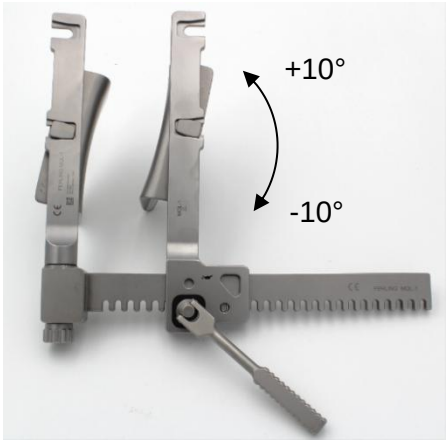


Fig. 8

Angular rotatability of the sternal and IMA blades:

The design of the blade suspension makes it possible to rotate the blades at an angle of up to ±10° (Fig. 8). This allows the sternal blade to rest against the edge of the sternum during retraction (better load distribution compared to rigid suspension) and the sternum to retract safely.

⚠	If the blades are mounted incorrectly, the sternal blades and IMA blades can no longer be rotated at an angle.
⚠	Sternal blades and IMA blades with the additional letter "F" are fixed and therefore do not have the property of angular rotatability.

To expose the thorax, open the retractor as far as necessary using the toothed drive.

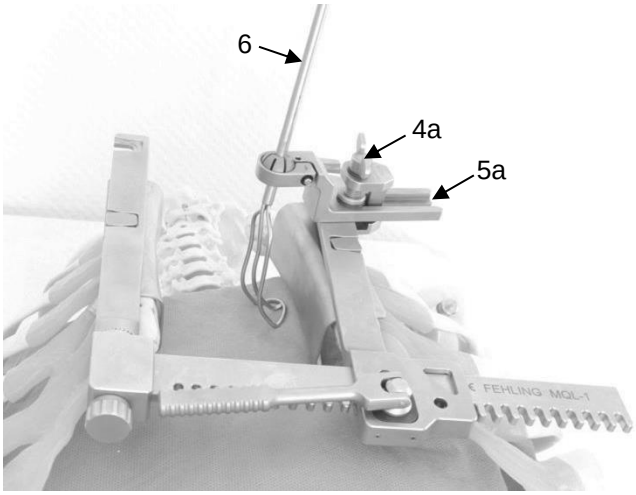


Fig. 9: Configuration example for the CEBOTARI universal sternal retractor with atrial hook

To position the atrial hooks (6) (see Table 2, page 10), these are attached to the retractor arms at any point (including in the area of the blades) using the MZZ-1Q clamping element (4a) and a suitable ball adapter (5a) (Fig. 9).
The mounting element and ball adapter are installed in accordance with instruction manual G 217.

Application in sternotomy for IMA visualization

To use the CEBOTARI universal sternal retractor in total sternotomy for exposure and dissection of the internal mammary arteries (IMA), the following combination of the retractor system must be used:

CEBOTARI universal sternal retractor	MQL-1
Sternal blade	e.g. MQL-2
IMA blade	MQL-3/3F
IMA holding blade	MLC-2V

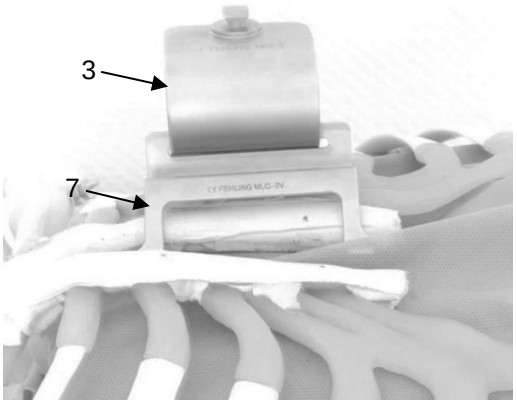


Fig. 10

1. Insert the IMA blade (3) in conjunction with the IMA retaining blade (7) into the sternal saw gap (Fig. 10).

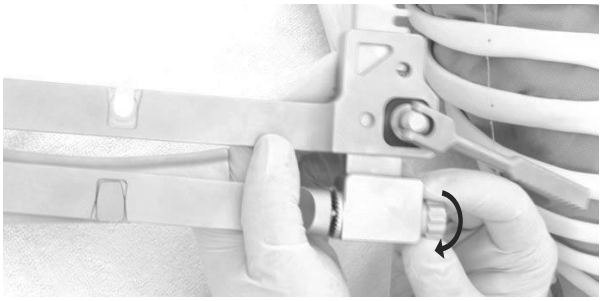


Fig. 11

2. Turn the rotatable retractor arm by loosening the fastening screw until the interlocking teeth no longer engage.
   Turn the rotatable retractor arm counterclockwise as far as it will go (the interlocking teeth also allows less rotation).
   Tighten the fastening screw by hand (Fig. 11).

⚠ The toothing profiles must interlock securely and must not tilt (see chap. *9) Assembly,* fig. 19e)! Risk of injury!

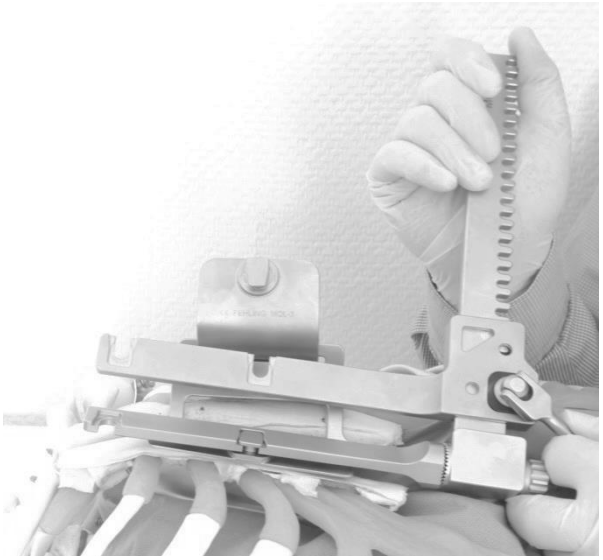


Fig. 12

3. Insert the sternal retractor with the mounted sternal blade into the saw gap and position it at the desired retraction point (Fig. 12).

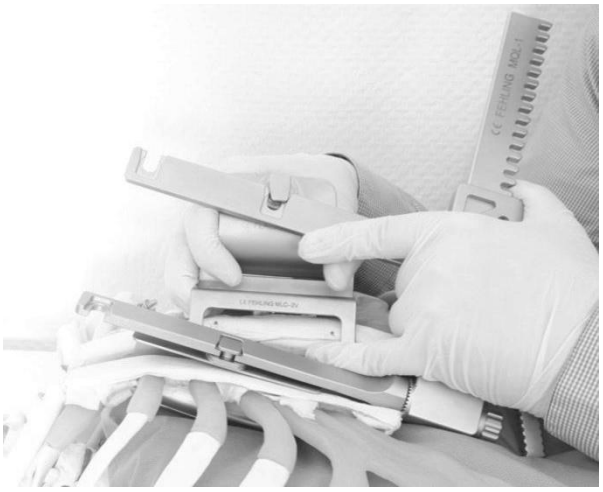


Fig. 13

4. Spread the movable retractor arm using the drive lever until the IMA retaining blade can be hooked in (Fig. 13).

⚠ Ensure that the blade is mounted securely! Risk of injury!

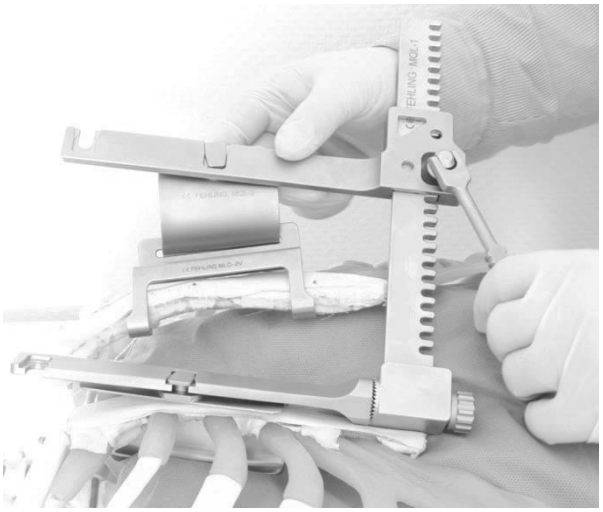
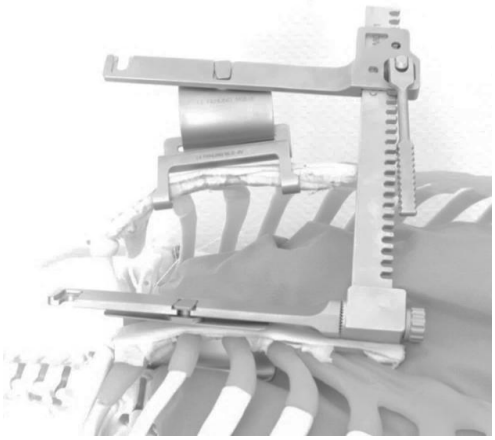
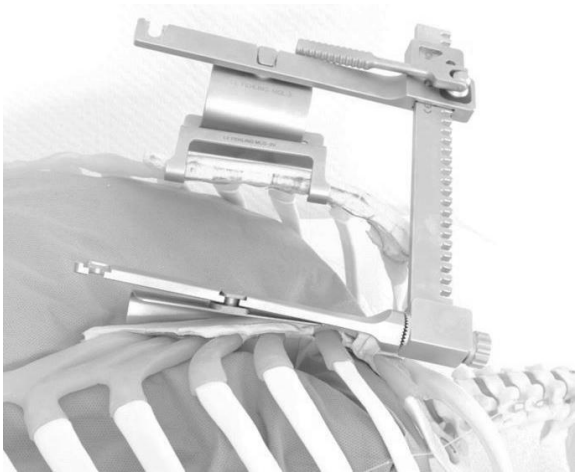


Fig. 14

5. Spread the retractor to the desired exposure of the thorax (Fig. 14).

Set-up for exposure and preparation of the LIMA: The toothed rack is located caudally (Fig. 15).  Fig. 15	Set-up for exposure and preparation of the RIMA: The toothed rack is located cranially (Fig. 16).  Fig. 16

⚠	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 retractor components from the operating field, ensure that the retractor arms are slowly pushed together again.

8) Required accessories

No accessories are required to use the CEBOTARI universal sternal retractor. An external hexagon screwdriver, e.g. the Cardan screwdriver LMT-4, is required to use the ball adapters MRV-0F, MRV-0J, and MRV-1F (Fig. 17), is required.	 Fig. 17: Cardan screwdriver LMT-4

9) Assembly

To fit the CEBOTARI universal sternal retractor, please observe the following assembly instructions.

To install the sternal blades or IMA blades, please refer to chap. *7) Configuration and application*.

Figure 18 shows the individual parts of the CEBOTARI universal sternal retractor that are required for assembly. Table 3 lists the corresponding designations of the individual parts.

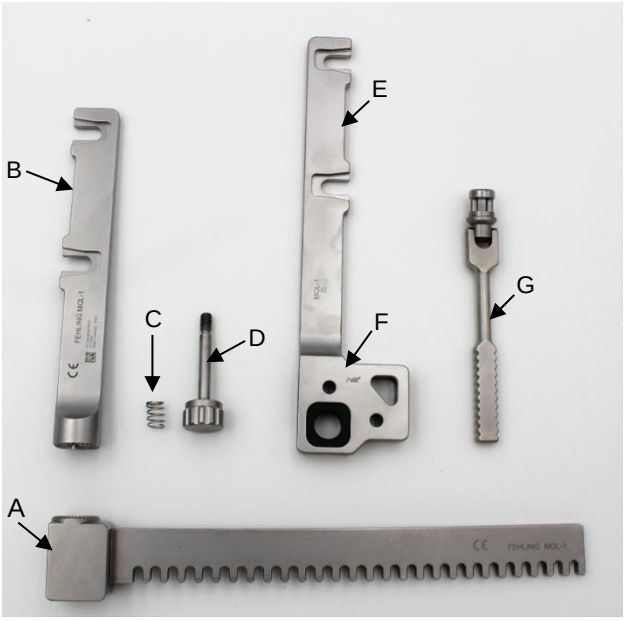


Fig. 18: Individual parts of the CEBOTARI universal sternal retractor

Table 3: Designation of the individual parts

	Designation of the individual parts
A	Toothed rack
B	Rotatable retractor arm
C	Spring
D	Fastening screw
E	Movable retractor arm
F	Box with recess for the movable retractor arm
G	Drive lever

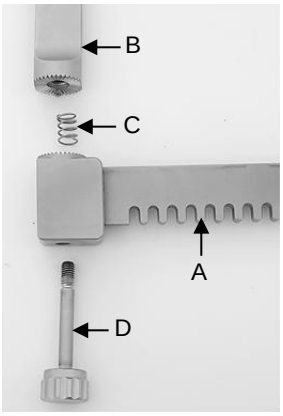


Fig. 19a

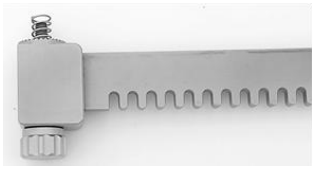


Fig. 19b

Figure 19a shows the individual parts required to attach the rotatable retractor arm B to the toothed rack A.

To attach the rotatable retractor arm B to the toothed rack A, first push the fastening screw D through the hole in the toothed rack A. Slide the spring C over the protruding thread of the fixing screw D (Fig. 19b).

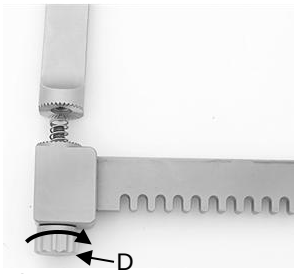


Fig. 19c

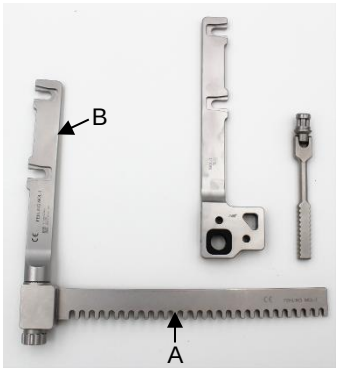


Fig. 19d

Then bring the rotatable retractor arm B and the fastening screw D together and screw them together (Fig. 19c). To do this, turn the fixing screw D clockwise.

Figure 19d shows the mounted rotatable retractor arm B on the toothed rack A.

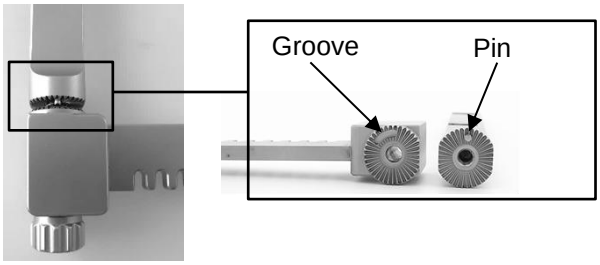


Fig. 19e

When fitting the rotatable retractor arm, make sure that the pin located on the front of the rotatable retractor arm B engages in the groove provided on the toothed rack A (Fig. 19e).
This pin limits the rotation of the rotatable retractor arm B.

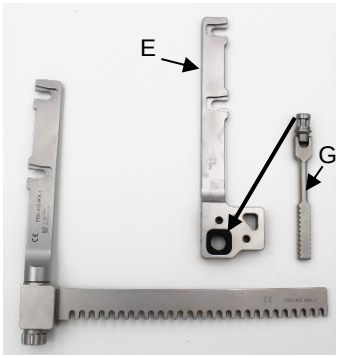


Fig. 20a

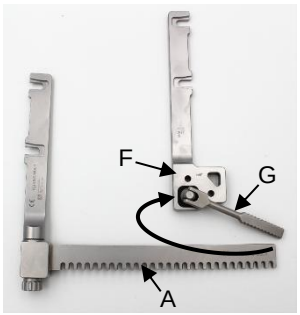


Fig. 20b

To attach the movable retractor arm E to the toothed rack A, first insert the drive lever G into the recess provided in the box at the end of the retractor arm E (Fig. 20a).

Insert the toothed rack A into the recess in the box F until the pinion of the drive lever G engages in the gear rack A (Fig. 20b).

Make sure that both retractor arms (B and E) point in the same direction, as shown in Figure 20c.

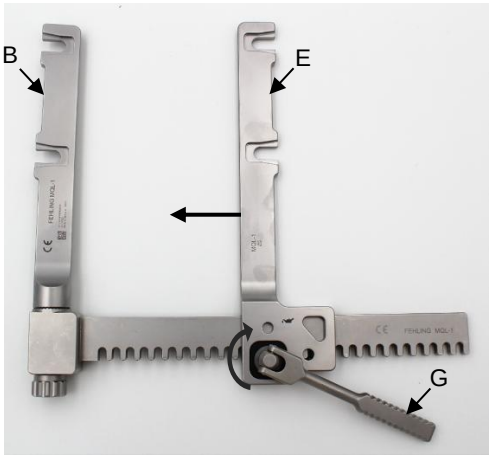


Fig. 20c

Turn the drive lever G clockwise to move the movable retractor arm E on the toothed rack A inwards towards the rotatable retractor arm B (Fig. 20c).

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

10) Disassembly

For reprocessing, the CEBOTARI universal sternal retractor must be disassembled as follows.

To remove the sternal blades or the IMA blades, please refer to chap. *7) Configuration and application*.

Figure 21 shows the CEBOTARI universal sternal retractor with the individual parts disassembled. Table 4 lists the corresponding designations of the individual parts.

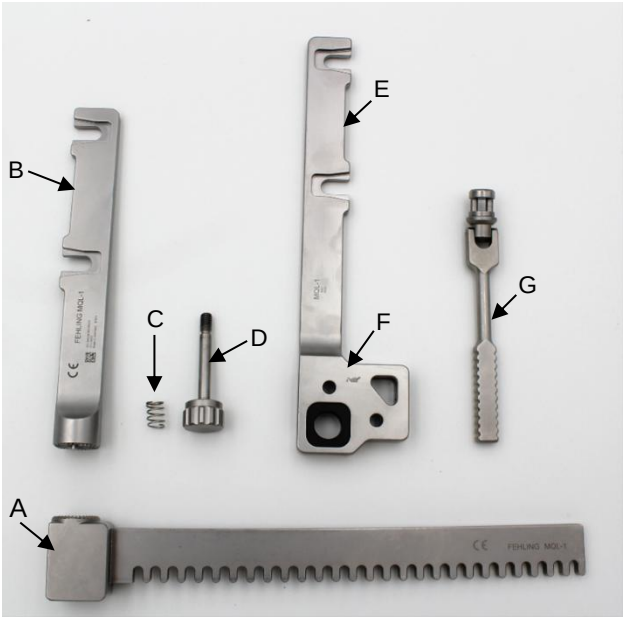


Fig. 21: Individual parts of the CEBOTARI universal sternal retractor

Table 4: Designation of the individual parts

	Designation of the individual parts
A	Toothed rack
B	Rotatable retractor arm
C	Spring
D	Fastening screw
E	Movable retractor arm
F	Box with recess for the movable retractor arm
G	Drive lever

To dismantle the CEBOTARI universal sternal retractor, the movable retractor arm E is first moved completely out of the toothed rack A using the drive lever G (Fig. 22a and 22b).
The drive lever G can be easily pulled out of the movable retractor arm E (Fig. 22b and 22c).

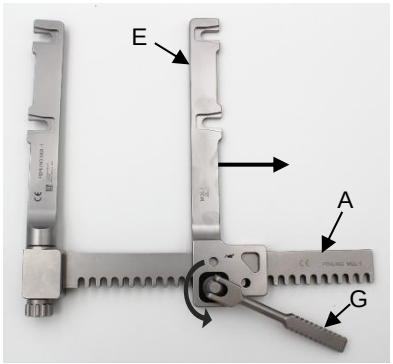


Fig. 22a

Fig. 22b

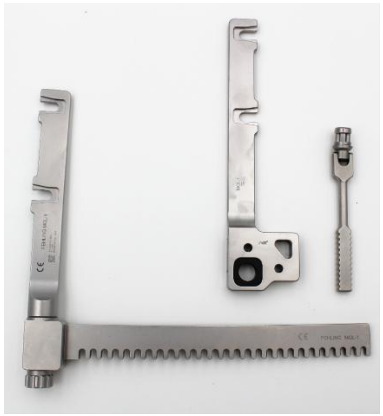


Fig. 22c

The fixing screw D must be completely unscrewed from the toothed rack A (Fig. 23a and 23b). To do this, turn the fastening screw D counterclockwise. The rotatable retractor arm B and the spring C are thus released (Fig. 23c).

Fig. 23a

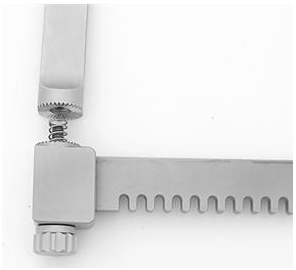


Fig. 23b

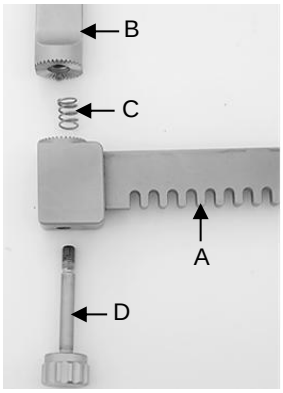


Fig. 23c

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

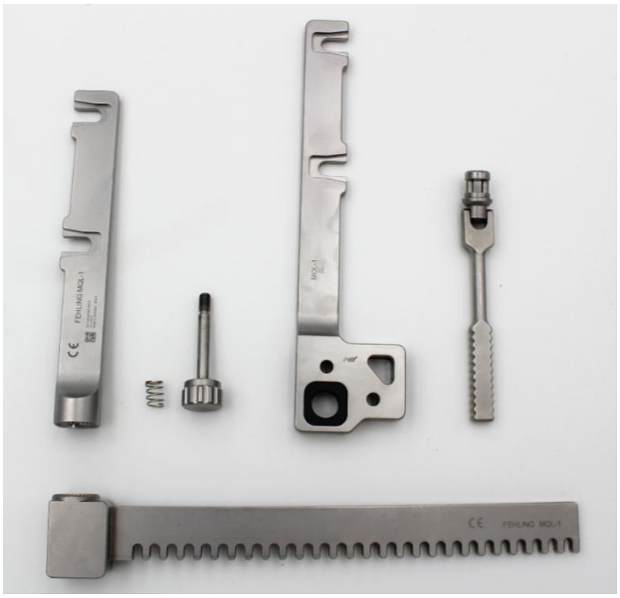


Fig. 24

⚠ 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 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
REF Catalog number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points that require lubrication	CE CE marking	

Contact the manufacturer		
	FEHLING INSTRUMENTS GmbH Hanauer Landstr. 7A D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 E-Mail: info@fehling-instruments.de www.fehling-instruments.de	CE