FEHLING CEBOTARI universal sternal retractor

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

Clamping elements

MZZ-1Q	Clamping element for length and height adjustable ball adapter, flat
MZZ-1N	Clamping element for length and height adjustable ball adapter, small clamping range
MZZ-2	Clamping element for length and height adjustable ball adapter, with crank

Ball adapter

MRV-0F	Ball adapter bayonet Ø 6.35 mm, adjustable length and height
MRV-0J	Ball adapter bayonet with joint Ø 6.35 mm, adjustable length and height
MRV-0R	Ball adapter bayonet with joint Ø 6.35 mm, adjustable length and height
MRV-1F	Ball joint adapter straight Ø 6.35 mm, adjustable length and height

Atrial retractor

MRV-4V	HOHE atrial retractor fixed 30 x 20 x 150 mm
MRV-4H	HOHE atrial retractor fixed 65 x 20 x 150 mm
MRV-3H	HOHE atrial retractor fixed 65 x 30 x 150 mm
MRV-4L	HOHE atrial retractor fixed 65 x 20 x 200 mm
MRV-3L	HOHE atrial retractor fixed 65 x 30 x 200 mm
MPF-1H	HOHE atrial retractor fixed 65 x 40 x 200 mm
MRV-2H	HOHE atrial retractor tricuspid fixed 45 x 45 x 150 mm
MRV-2L	HOHE atrial retractor tricuspid fixed 45 x 45 x 200 mm

⚠	This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing. The 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

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The CEBOTARI universal sternal retractor is intended for short-term application.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

The medical literature describes the following side effects, which may also possibly occur during the intended use of the CEBOTARI universal sternal retractor:

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses
- Ischemia of other organs due to compression of blood vessels

⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
The FEHLING INSTRUMENTS CEBOTARI universal sternal retractor is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before any further use (see 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Handle the CEBOTARI universal sternal retractor with care during storage, transport and cleaning! Avoid striking and applying pressure to the CEBOTARI universal sternal retractor, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Do not clean instruments containing plastic components with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.
Limitations on reprocessing	Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing").

General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilization) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionized water (deionized water, demineralized, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
Initial treatment at the place of use	Pre-cleaning: ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo mechanical cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	It is recommended to reprocess the instruments immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar).

	• Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (potable water quality) at 55 °C • Emptying • Rinse for 2 minutes with water (potable water quality, <40 °C) • Emptying • Rinse for 1 minute with cold deionized water (<30 °C)

	• Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: Manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner.

	• After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly
Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
	Only loosely assemble instruments with individual parts before packaging and sterilization and do not screw them tightly. Observe the following for the CEBOTARI universal sternal retractor's rotatable retractor arm (Fig. 1).  Fig. 1: CEBATORI universal sternal retractor with a retractor arm which is not firmly screwed together

Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.

Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability!
Subject to change without notice.

7) Configuration and application

The CEBATORI universal sternal retractor is a U-shaped bar retractor with one rotating and one movable retractor arm. A gear control is used to move the flexible retractor arm along the toothed rack. The rotating retractor arm is axially adjustable due to its ability to rotate, so that the retractor arm can be adjusted individually.
The CEBOTARI universal sternal retractor is intended specifically for exposure of the thorax in total and partial sternotomy accesses for further surgically invasive treatment of the heart including the exposure of IMA and mitral valves.

Figure 2 gives a configuration example for the CEBOTARI universal sternal retractor with an atrial retractor attached to a ball adapter and a clamping element. Figure 3 gives a further configuration example for the CEBOTARI universal sternal retractor with an IMA blade suspended from an IMA retaining blade.
Figure 4 illustrates three variants of the clamping element and Figure 5 three variants of the ball adapter.
Table 2 lists the corresponding components.

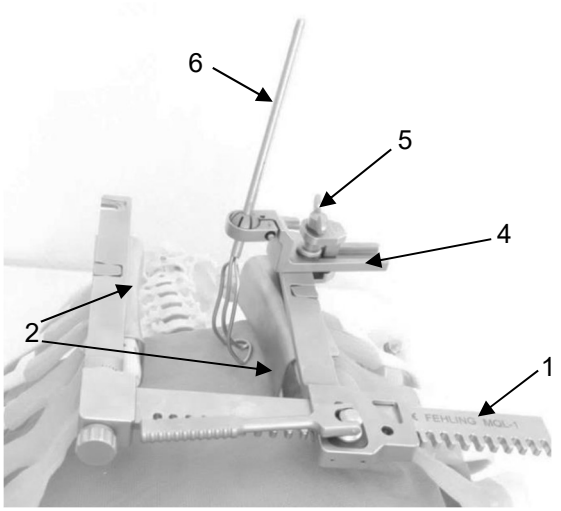


Fig. 2: Configuration example for the CEBOTARI universal sternal retractor with an atrial retractor

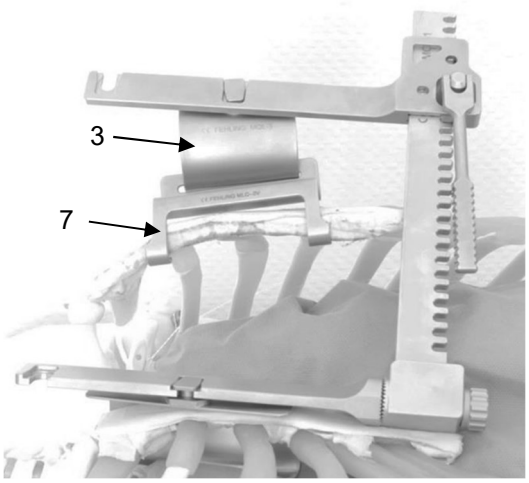
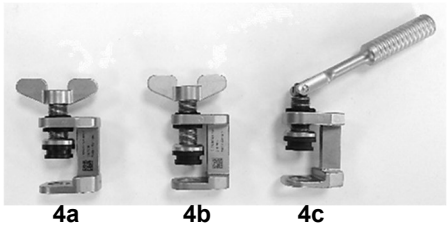


Fig. 3: gives a configuration example for the CEBOTARI universal sternal retractor with IMA blade

Table 2: List of the corresponding components

	Article no.	Description
1	MQL-1	CEBOTARI universal sternal retractor
2		Sternal blades
	MQL-2/2F	Sternal blades 43 x 100 mm/fixed
	MQL-4/4F	Sternal blades 34 x 50 mm/fixed
	MQL-5/5F	Sternal blades 43 x 50 mm/fixed
	MQL-6/6F	Sternal blades 34 x 100 mm/fixed
	MQL-7/7F	Sternal blades 50 x 100 mm/fixed
	MQL-8/8F	Sternal blades 63 x 100 mm/fixed
	MQL-9/9F	Sternal blades 34 x 120 mm/fixed
	MQM-1/1F	Sternal blades 43 x 120 mm/fixed
	MQM-2/2F	Sternal blades 50 x 120 mm/fixed
	MQM-3/3F	Sternal 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
6		HOHE atrial retractor
	MRV-2H	Tricuspid 45/45/150 mm
	MRV-2L	Tricuspid 45/45/200 mm



4a **4b** **4c**

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

	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	IMA retracting blade

5a **5b** **5c**

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

⚠ An LMT-4 cardan screwdriver (see 8) Required accessories) is required for the use of the MRV-0F ball adapter (Fig. 5, 5a).

⚠	Use only sterilized products of sound quality!
⚠	Before employing the CEBOTARI universal sternal retractor, ensure that the surgical field is prepared accordingly.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.
During use	
⚠	Only use small sternotomy blades for **partial sternotomy**. Risk of injury! In **Z-sternotomy**, ensure that the retractor is not twisted. Risk of injury!

Insertion of the sternal blades

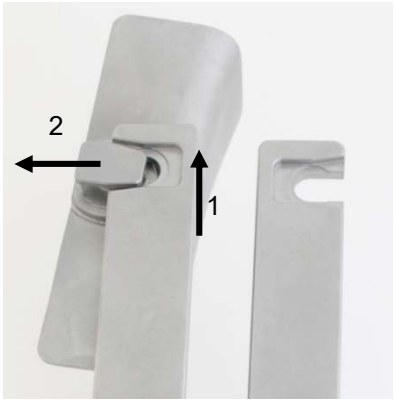


Fig. 6

Observe the direction of the clamping profile!
The blade suspension must be inserted with the narrow side first.
Slight engagement of the cylindrical cone on the bottom of the blade suspension signals the correct final position of the blade.
If the blade is suspended incorrectly, the angular rotation of the sternal blades is no longer given.
To disengage 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).

Observe correct orientation of the sternal and IMA blades! Risk of injury!

Depending on the surgical purpose and space available for assembly, the sternotomy blades can be connected to the retractor either before (A) or after (B) introduction to the sternal saw gap.

(A) The blades are first fastened to the receptacles of the retractor arms by inserting the cylindrical pins and then into the saw cut.

(B) The blades are first inserted into the saw cut. Then insert the two retractor arms into the space between the blade pins one after the other and slide the respective receptacles of the retractor arms over the blade pins. This can be performed with the retractor either closed or slightly open.

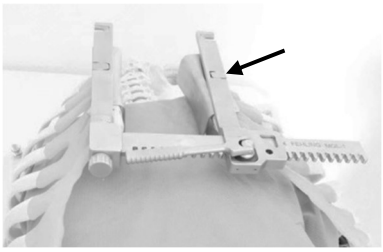


Fig. 7a

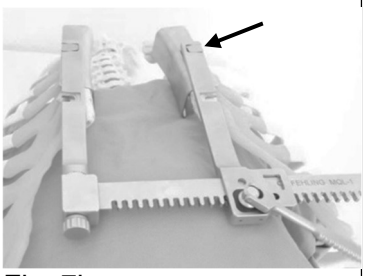


Fig. 7b

Depending on the requirements of the surgical field, the sternal blades can be positioned on either of the two slots on the retractor arms.
Figure 7a illustrates the slots of the sternal blades closer to the proximal end of the retractor arm and Figure 7b illustrates the slots of the sternal blades at the distal end of the retractor arm.

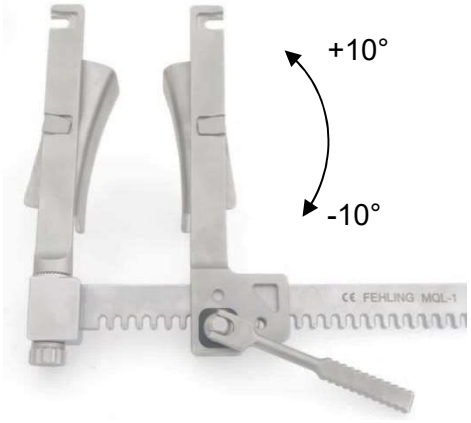


Fig. 8

Angular rotation of the sternal and IMA blades:
The design of the blade attachment allows an angle rotation of the blades of up to ±10° (Fig. 8). The sternal blade can thus lie against the edge of the sternum during retraction (better load distribution than with rigid suspension) and distend the sternum safely.

If the blade is suspended incorrectly, the angular rotation of the sternal blades and IMA blades is no longer given.

Sternal blades and the IMA blade with the additional letter "F" are fixed and therefore do not offer angular rotatation.

For exposure of the thorax, open the retractor as far as necessary using the gear control.

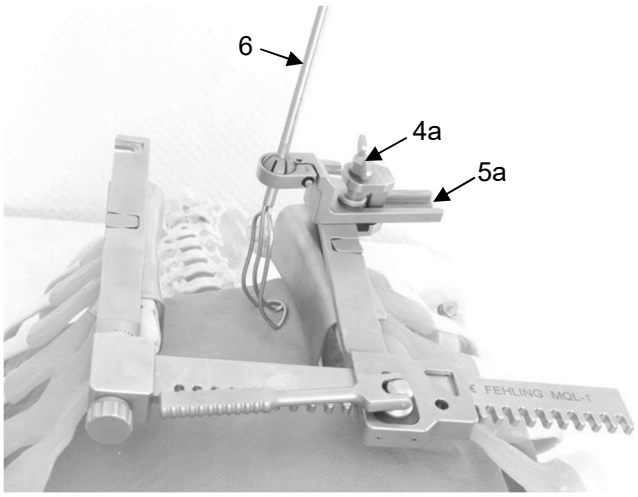


Fig. 9: Configuration example for the CEBOTARI universal sternal retractor with an atrial retractor

Atrial retractors (6) (see Table 2, Page 9) can be positioned anywhere on the retractor arms (Fig. 9) (including the area of the blades) using clamping element MZZ-1Q (4a) as well as a a suitable ball adapter (5a).
Assembly of the clamping element and the ball adapter is performed according to the G217 Instructions for Use.

Use in sternotomy for IMA exposure

When using the CEBOTARI universal sternal retractor in total sternotomy for exposure and preparation of the internal mammary arteries (IMA), the following configuration of the retractor system is to be applied:

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

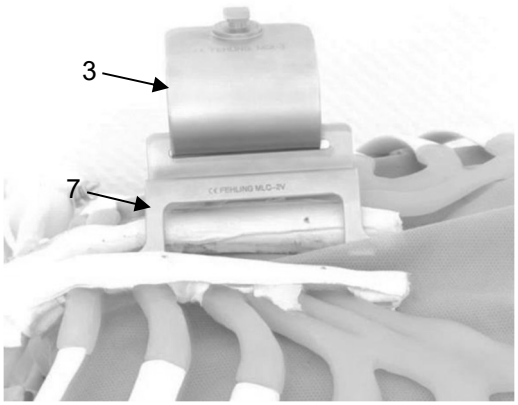


Fig. 10

1. Introduction of the IMA blade (3) in conjunction with the IMA retracting blade (7) into the sternal incision (Fig. 10).

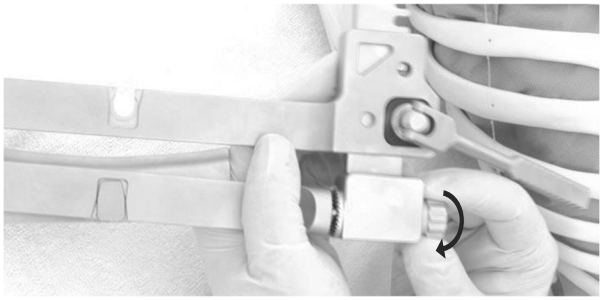


Fig. 11

2. Turn the rotary clamping arm by loosening the clamping screw until the gears no longer engage.
   Turn the rotating retractor arm anticlockwise up the stop (the gearing also allows less rotation).
   Tighten the clamping screw by hand (Fig. 11).

⚠ The profiles of the gears must be engaged securely and may not be canted (see 9) Assembly, Fig. 19e)! Risk of injury!

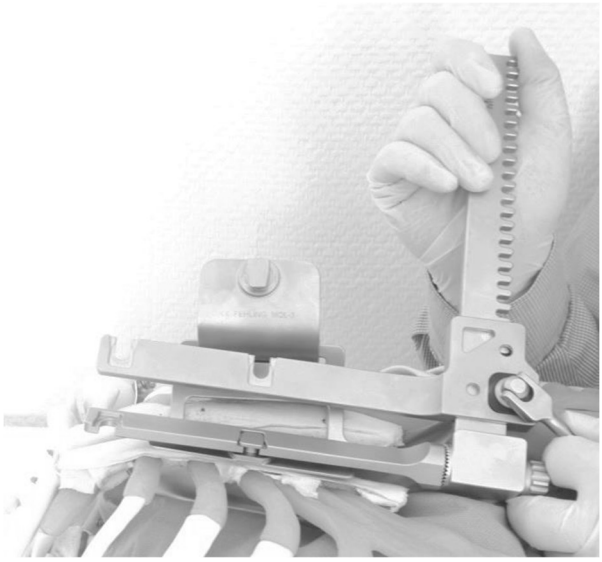


Fig. 12

3. Introduce the sternal retractor with the mounted sternal blade into the saw cleft and position at the desired retraction site (Fig. 12).

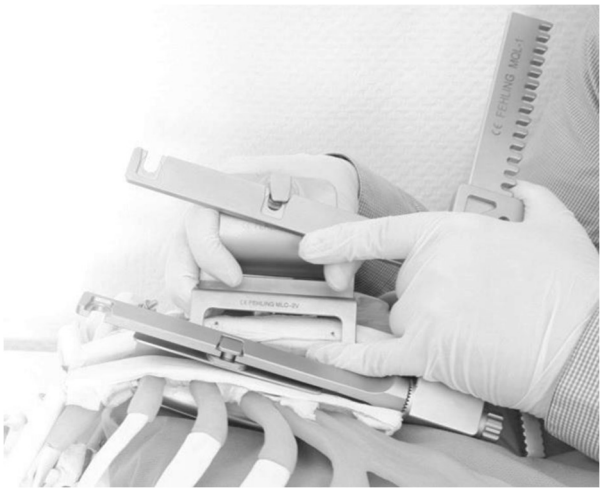


Fig. 13

4. Use the drive lever to open the moveable retractor arm until the IMA retracting blade can be attached (Fig. 13).

⚠ Ensure secure mounting of the blade! Risk of injury!

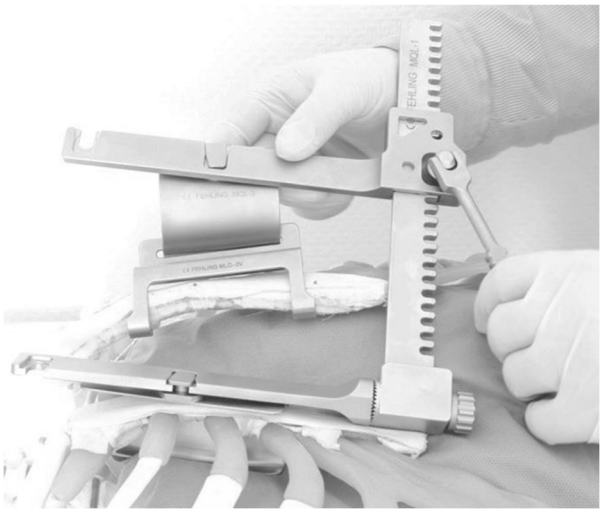


Fig. 14

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

Design for exposure and preparation of the LIMA:
The gear rack is located caudal (Fig. 15).

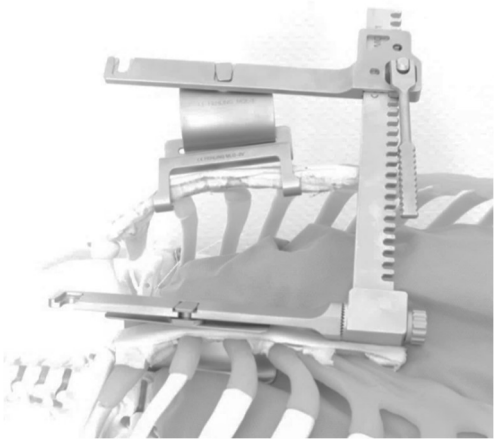


Fig. 15

Design for exposure and preparation of the RIMA:
The gear rack is located cranial (Fig. 16).

Fig. 16

⚠ Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

8) Required accessories

No accessories are necessary for using the CEBOTARI universal sternal retractor.
A cardan screw driver LMT-4 (Fig. 17) is required for application of the MRV-0F ball adapter.

Fig. 17: Cardan screw driver LMT-4

9) Assembly

For assembly of the CEBOTARI universal sternal retractor, please observe the following assembly instructions.

To assemble the sternal blades or IMA blades, please observe 7) Configuration and Application - during application.

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

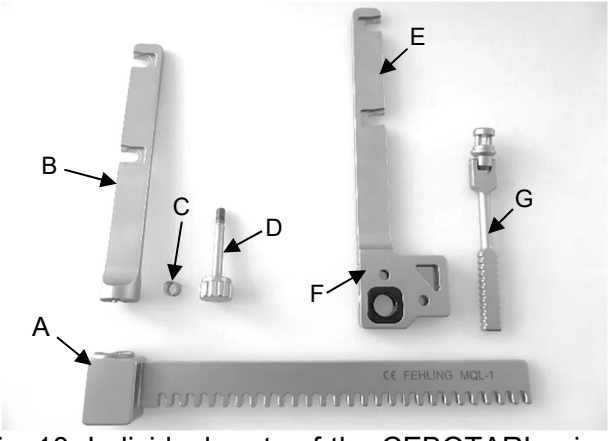


Fig. 18: Individual parts of the CEBOTARI universal sternal retractor

Table 3: Designation of the individual parts

	Designation of the individual parts
A	Toothed rack
B	Rotating retractor arm
C	Spring
D	Clamping screw
E	Movable retractor arm
F	Cage with recess of the movable retractor arm
G	Drive lever

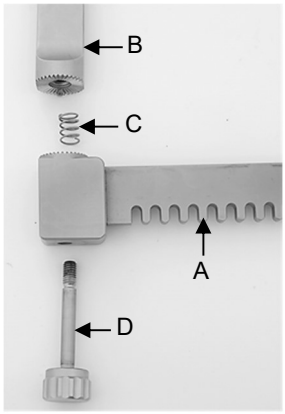


Fig. 19a

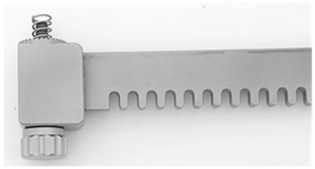


Fig. 19b

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

To fasten the rotating retractor arm B to the toothed rack A, first push the clamping screw D through the hole of the toothed rack A. Slide spring C over the protruding thread of the clamping screw D (Fig. 19b).

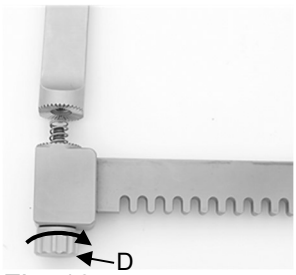


Fig. 19c

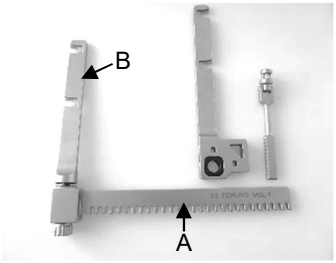


Fig. 19d

Then mate the rotating retractor arm B and the clamping screw D and screw them together (Fig. 19c). To do this, rotate the clamping screw D clockwise.

Figure 19d depicts the assembled rotating retractor arm B on the toothed rack A.

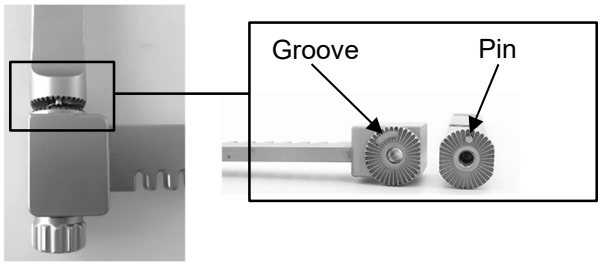


Fig. 19e

⚠ When assembling the rotating retractor arm, make sure that the pin located on the front side of the rotating retractor arm B engages in the groove on the toothed rack A (Fig. 19e).
This pin limits the rotation ability of the rotating retractor arm B.

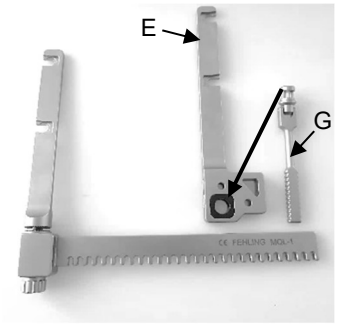


Fig. 20a

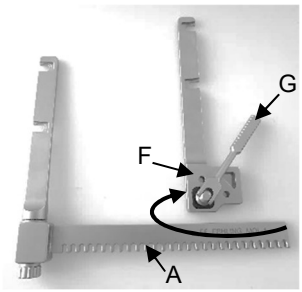


Fig. 20b

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

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

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

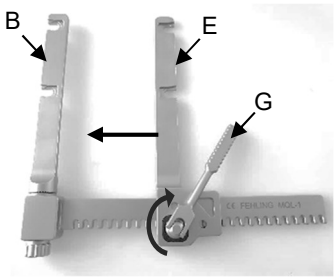


Fig. 20c

By rotating the drive lever G clockwise, transport the movable retractor arm E on the toothed rack A inwards towards the rotating retractor arm B (Fig. 20c).

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

10) Disassembly

The CEBOTARI sternal retractor must be disassembled as follows for reprocessing.

To disassemble the sternum blades or IMA blades, please observe 7) Configuration and Application - during application.

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

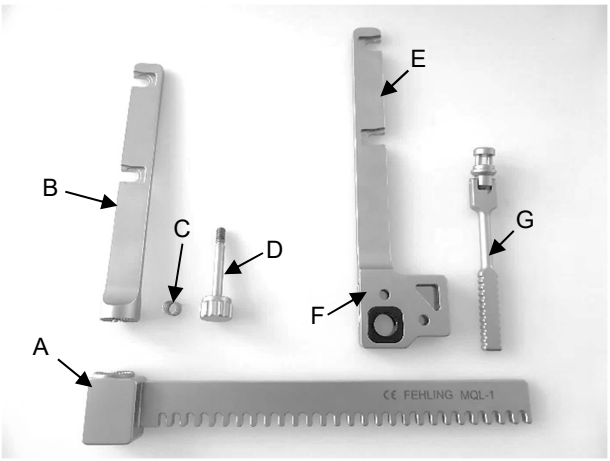


Fig. 21: Individual parts of the CEBOTARI universal sternal retractor

Table 4: Designation of the individual parts

	Designation of the individual parts
A	Toothed rack
B	Rotating retractor arm
C	Spring
D	Clamping screw
E	Movable retractor arm
F	Cage with recess of the movable retractor arm
G	Drive lever

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

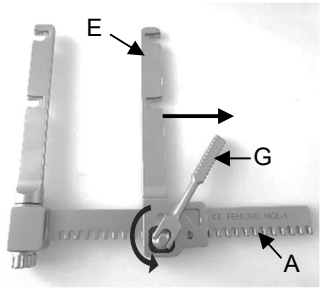


Fig. 22a

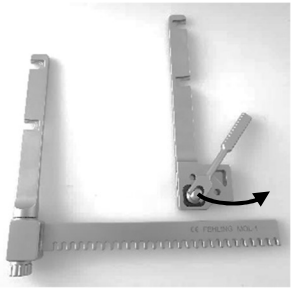


Fig. 22b

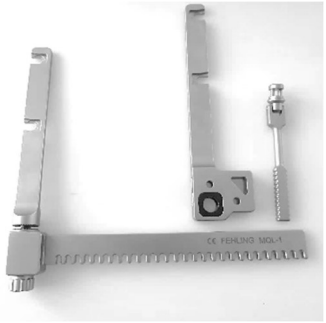


Fig. 22c

The clamping screw D must be unscrewed completely from the toothed rack A (Figs. 23a and 23b). To do this, rotate the clamping screw D anticlockwise. The rotating retractor arm B and the spring C are thus released (Fig. 23c).

Fig. 23a

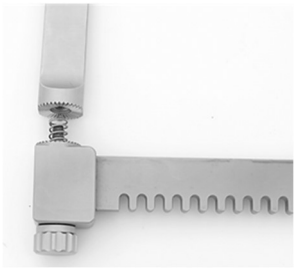


Fig. 23b

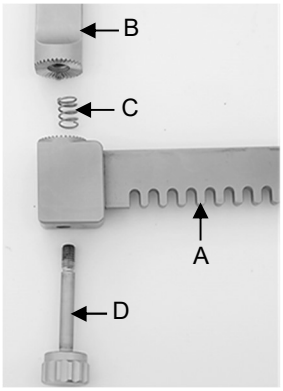


Fig. 23c

The instrument is now disassembled and can be reprocessed.

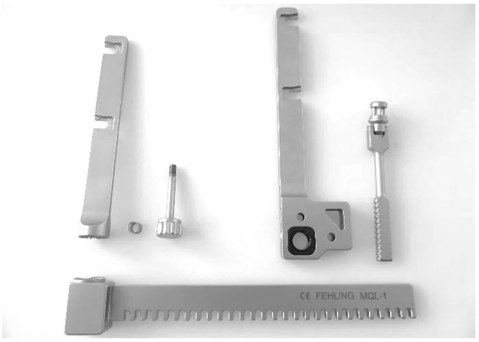


Fig. 24

⚠ Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning 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 by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:		
 Manufacturer	 Instructions for Use are to be observed	 Warning
 Article number	 Batch code	 Serial number
 CE labeling	 0297 CE labeling	 Oil can for points to be lubricated

To contact the manufacturer:		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de