FEHLING MICS IMA intercostal retractor

REF **MQC-1I**

consisting of:
MQC-1, toothed rack
MQC-1A, Arm rotatable lateral curved
MQC-1B, Arm rotatable for IMA

IMA blades:
MQC-2I ..... 70 x 40 mm
MQC-3I ..... 90 x 40 mm
MQC-4I ..... 110 x 40 mm
MQC-6I ..... 70 x 30mm
MQC-7I ..... 90 x 30 mm
MQC-8I ..... 110 x 30 mm
MQC-9I ..... 130 x 30 mm

Counter blades:
MQF-1..... 40 x 35 x 60 mm
MQF-2..... 50 x 35 x 60 mm

Xiphoid blades:
MQE-1I .....40 x 60 x 20 mm
MQE-2I .....40 x 45 x 20 mm
MQE-3I .....40 x 30 x 20 mm

Accessories:
NVG-9 .....CERAMO hexagonal wrench
LMT-4.....Kardan screwdriver
EEJ-1 .....Operating table adapting clamp 16x16mm, adjustable, universal
EEJ-2 (a,b,c) .....Angulated rod 16 x 16 x 1000 x, 600 mm
EEP-0.....Coupling rider
EEL-4F.....Blade guide turning and swinging 300 mm

Not sterile. Clean and sterilize prior to first use and before subsequent uses!

Do not use Orthovario or Oxivario procedures to clean CERAMO® instruments (those which have a black surface). Using these procedures will gradually destroy the CERAMO® coating that contains titanium due to their oxidative processes (corrosion of titanium by H_2O_2).

Only trained medical personnel may use, reprocess or dispose of retractor systems!
The FEHLING MICS IMA intercostal retractor is intended for temporary use only (< 60 minutes)!

Intended use:

The MICS IMA intercostal retractor is intended for the exposure of the internal mammary arteries (IMA) as preparation for MIDCAB operations.

Indications and contraindications:

Indications:

The use of the FEHLING MICS IMA intercostal retractor is generally indicated in the following cases:

Patients with severe concomitant diseases for which a regular bypass procedure with a sternotomy and the use of a cardiopulmonary bypass is contraindicated

- Patients for whom a sternotomy is also contraindicated
- Patients for whom cosmetic aspects are a priority

Contraindications:

- Recent rib fractures
- Thoracic anomalies with pleural involvement
- Disorders with pulmonary and/or pleural involvement, pleural adhesions
- Sternal abnormalities
- E.g. sternal dehiscence (separation of the sternum after a prior cardiac procedure)
- Prior cardiac procedure with severe adhesions
- Prior IMA resection on the affected side
- Severe obesity (e.g. BMI > 35 kg/m^2)

Possible adverse effects during resection of the IMA and MIDCAB procedures

In the medical literature, the following adverse effects have been described that can possibly occur when an intercostal approach is used despite the correct application of retraction with the FEHLING MICS IMA intercostal retractor for IMA resection or MIDCAB procedures (method-specific complications):

- Rib fractures,
- Separation of the ribs from the sternum

- Healing disorders of the sternum, possibly with subsequent instability of the sternum
- Stretching- and pressure-related skin lesions
- Pain in the affected body parts

Components:

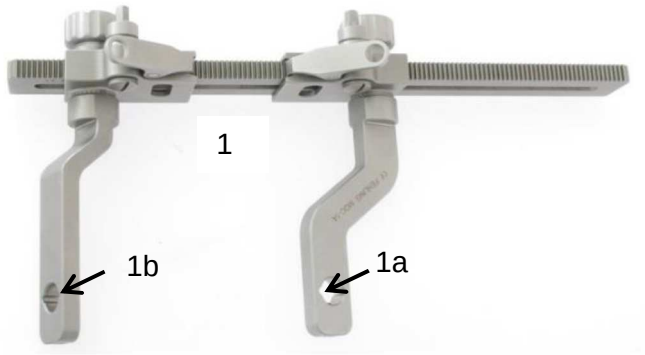
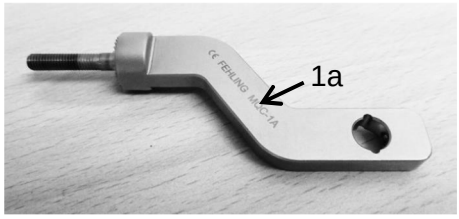
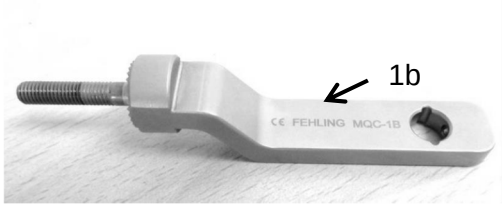


Fig. 1

	Article no.	Description
1	MQC-1I	MICS IMA retractor complete
1a	MQC-1a	Arm for retractor, lateral curved
1b	MQC-1b	Arm for retractor for IMA
2	MQC-2I..9I	IMA blades
3	MQF-1/2	Counter blades
4	MQE-1I..3I	Xiphoid blades



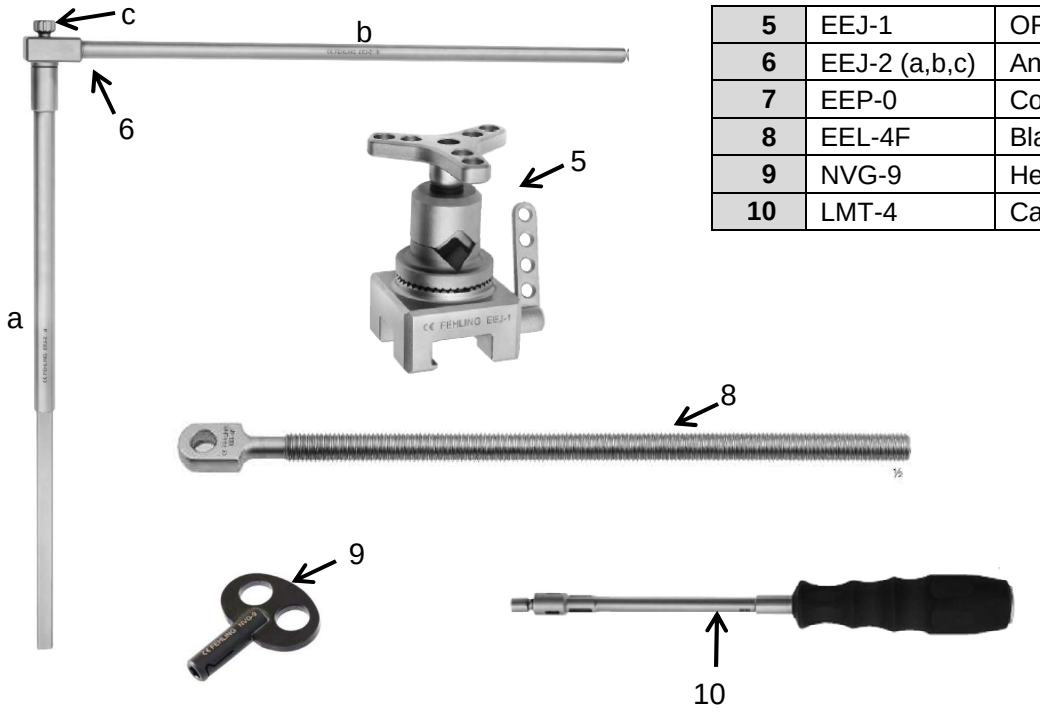


2 (example)

3 (example)

4 (example)

Accessories:



5	EEJ-1	OR-table mounting clamp
6	EEJ-2 (a,b,c)	Angulated rod
7	EEP-0	Coupling rider
8	EEL-4F	Blade guide
9	NVG-9	Hexagonal wrench
10	LMT-4	Cardan screwdriver

Figures are not to scale!

The MICS IMA intercostal retractor is a U-shaped bar retractor with Z-shaped retractor arms (Fig. 1).

The two retractor arms can be rotated 360° about their axis and can be moved freely along the toothed rack.

The movable retractor arms are moved along the toothed rack by means of a gear control using the NVG-9 hexagonal wrench or the LMT-4 cardan screwdriver.

For IMA exposure, retractors in the form of xiphoid blades, counter plates, and IMA blades are used. These are connected with the horizontal arm of the EEJ-2 angulated rod by means of the long, threaded blade guide. (Fig. 2)

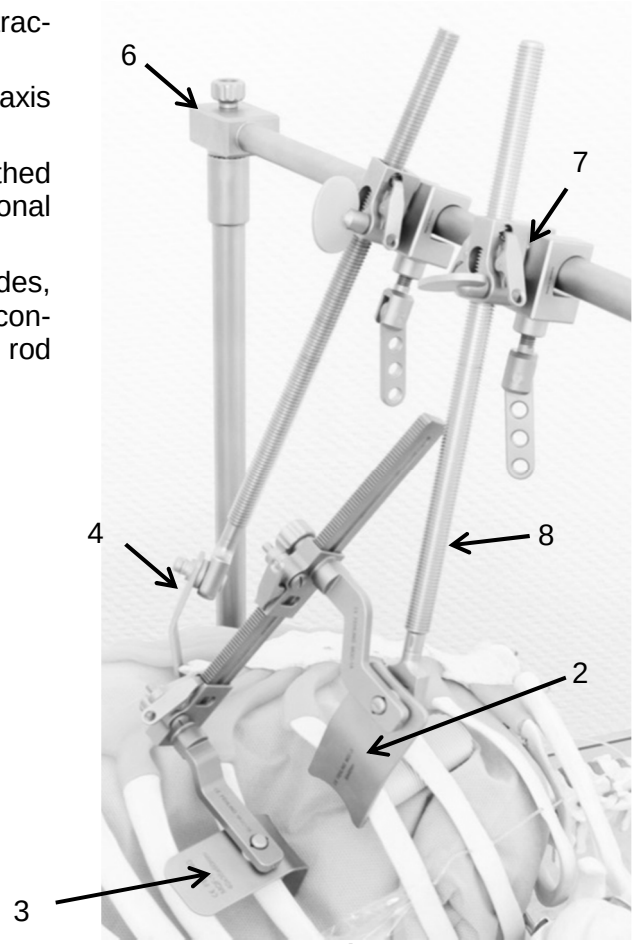


Fig. 2

Prior to use:	
⚠	FEHLING INSTRUMENTS retractor systems are non-sterile when delivered and must be cleaned and sterilized by the user before initial use and all subsequent uses (see Reprocessing).→ Risk of infection! Retractor components must be handled with care during storage, transportation and cleaning! Avoid striking the instrument or applying pressure to small areas of it! Perform a safety check prior to each use. When doing so, check for cracks, fractures and mechanical malfunctions (see Maintenance, Checking and Functional Testing) otherwise there is a risk of injury! **Use only sterilized products which are in perfect working order!**

Assembly:

To clean and reprocess the system (see Reprocessing instructions), the rotatable retractor arms must be detached and must be re-assembled prior to use.

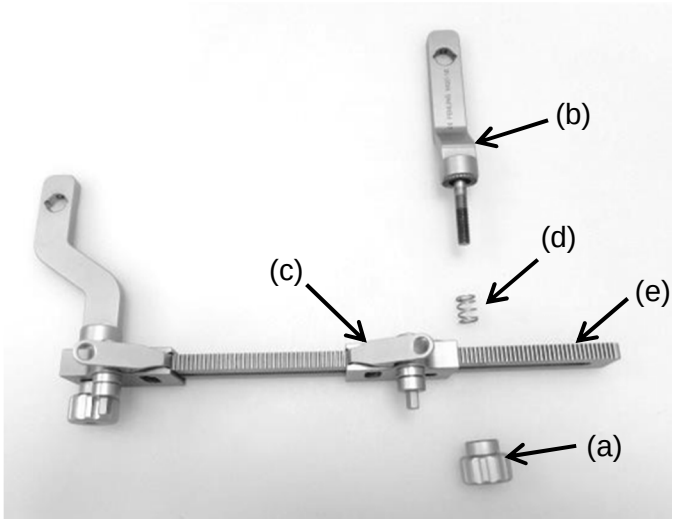


Fig. 3

(a) Milled nut
(b) Retractor arm
(c) Coupling rider body
(d) Spring
(e) Toothed rack

To assemble the retractor arms prior to use, push the coupling rider bodies (c) onto the toothed rack (e). When doing so, the latches must point towards each other and towards the centre of the toothed rack.

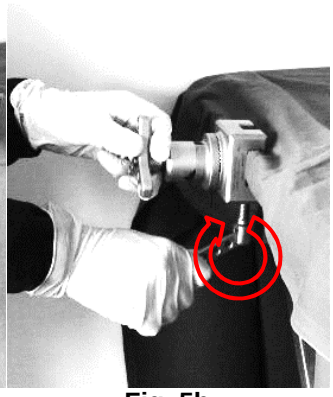
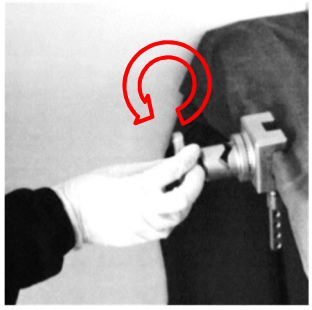
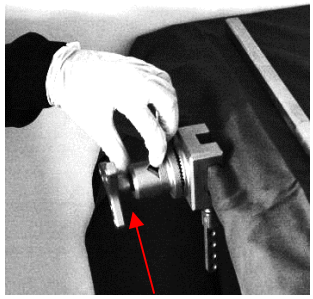
Push the spring (d) onto the threaded bolt of the retractor arm (b) (Fig. 4a).

Place the threaded bolt of the retractor arm through the hole in the toothed rim of the rider body (c) and thus simultaneously through the slit of the toothed rack (Figure 4b).

The retractor arm is locked in place by attaching the milled nut (a).

Fig. 4a

Fig. 4b

Use:			
⚠ **Warning!** When placing connections, ensure that sliding is not possible. → Risk of injury!			
1.	Assembly and mounting of angulated rod (EEJ-2). Attach the EEJ-1 operating table mounting clamp to the track of the operating table either below (Fig. 5a) or above (Fig. 5b) the sterile drape at the level of the patient's right shoulder.	 **Fig. 5a**	 **Fig. 5b**
2.	Attach the vertical holding rod (square; EEJ-2a) of angulated rod EEJ-2 to the table mounting clamp and tighten.		
	 **Fig. 6a:** Loosen the retaining screw handle	 **Abb. 6b** Align the clamping jaws so that a square opening for receiving the vertical holding rod is created	 **Fig. 6c:** Insert the vertical holding rod and tighten the retaining screw

3. Attach the EEJ-2b horizontal arm onto the vertical post using its associated EEJ-2c screw, pointing about 20° cranially.

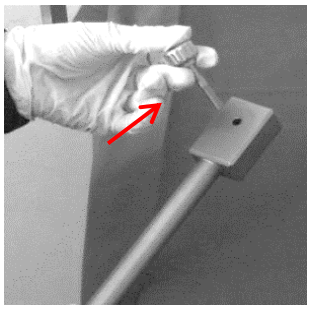


Fig. 7a

Fig. 7b

⚠ **Warning!** Take care that the horizontal arm is mounted so that the two facing, toothed areas engage fully, otherwise there is a risk of screw breakage and consequent patient injury!

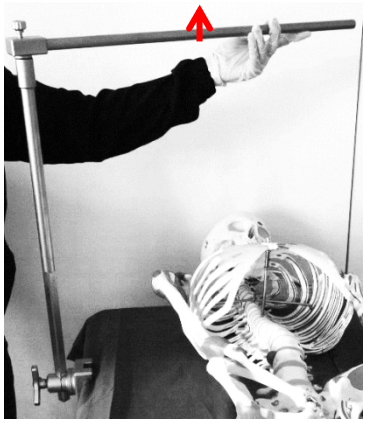


Fig. 7c

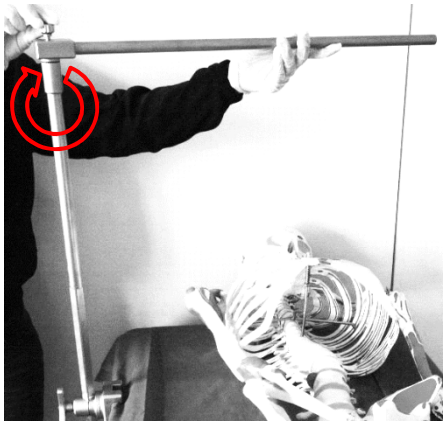


Fig. 7d

4. Attach the EEP-0 coupling rider to the horizontal arm. (NB Attach two if both RIMA and LIMA are to be dissected).

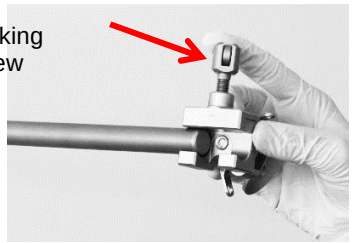


Fig. 8a
To place the coupling riders, the locking screw must be completely unscrewed

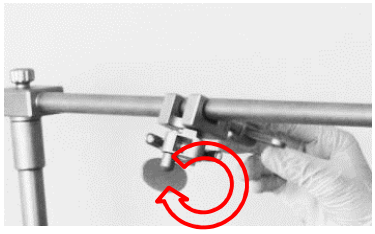


Fig. 8b
At the proper position, the coupling riders should be locked in place by tightening the locking screw in order to prevent slippage

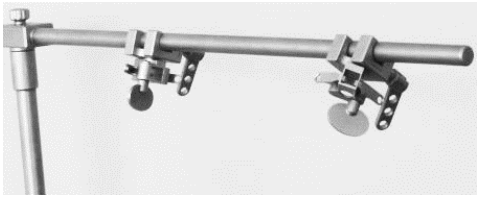


Fig. 8c

5. Insertion of the blade guide EEL-4F

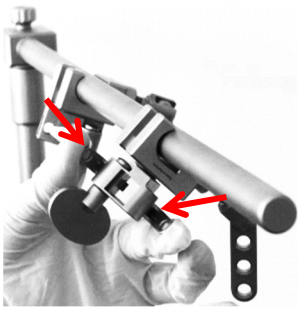


Fig. 9a
Grasp the pawl of the coupling rider

Fig. 9b
Press the pawl together

Fig. 9c
Insert the blade guide

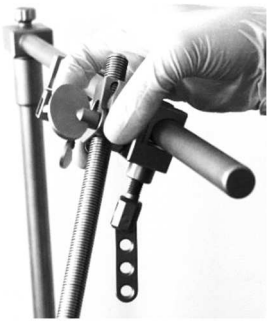


Fig. 9d

6. Position the IMA blade (e.g. MQC-3l) in the fourth intercostal space (for men, below the nipple, for women, in the mammary fold).

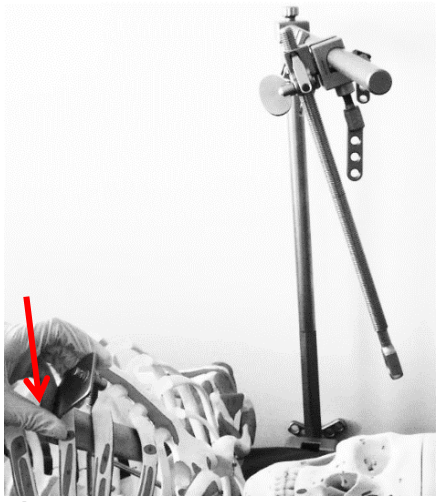


Fig. 10

7. Connect the blade guide to the IMA blade and turn the key on the coupling rider to elevate the ribs.

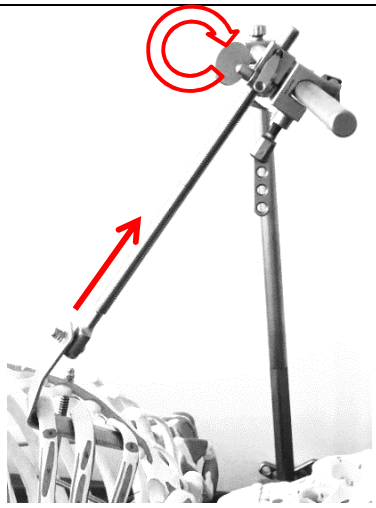


Fig. 11

⚠ **Warning!** During this procedure, the horizontal arm bends slightly downward. This movement is cancelled out later by using the IMA retractor (MQC-1).

Warning! To prevent rib fractures, ensure that the IMA blade has the greatest possible contact internally to several ribs and is not raised excessively.

8. Advance the caudal arm (MQC-1B) of the IMA retractor to the end of the toothed rack (see Fig. 12a) and position the cranial arm (MQC-1A) close to the caudal arm (see Fig. 12b and 12c).

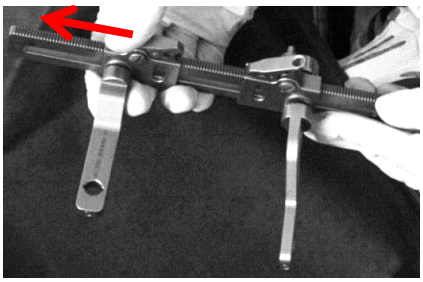


Fig. 12a

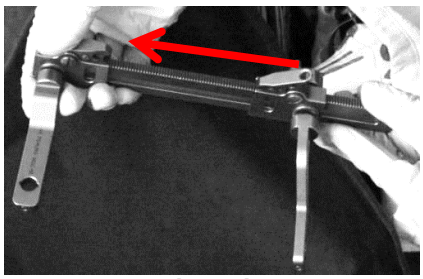


Fig. 12b

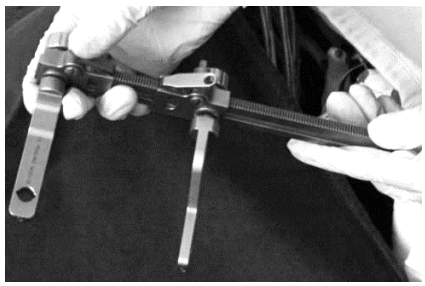


Fig. 12c

9. Start by detaching both milled nuts (Fig. 13a).
Then attach the IMA counter blade (e.g. MQF-1) to the caudal arm of the IMA retractor (see Fig. 13b and 13c). Connect the IMA blade (MQC-1A) to the cranial arm (see Fig. 13d).

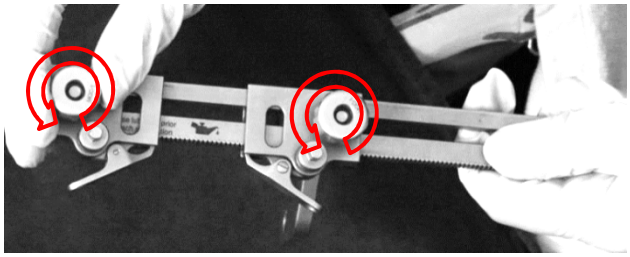


Fig. 13a

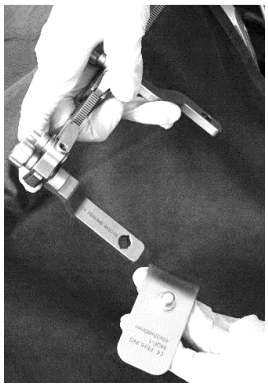


Fig. 13b

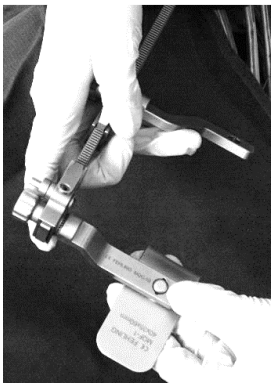


Fig. 13c

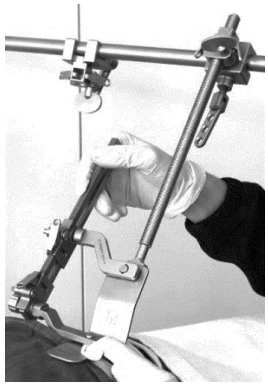


Fig. 13d

10. Attach both nuts to the cranial and caudal arm of the IMA retractor in a suitable position (see Fig. 14a).

Options:

a) The toothed rack of the IMA retractor in the vertical position presses the lower rib inwards towards the body.
b) The toothed rack of the IMA retractor in the horizontal position distracts the lower rib.
c) The toothed rack in an oblique position causes simultaneous distraction and downward pressure.

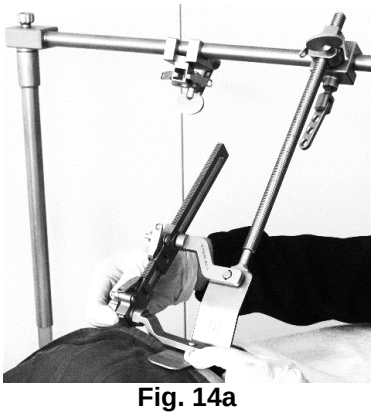


Fig. 14a

Warning!
When using the retractor, care must be taken to ensure that the coupling rider lies on the toothed rack in a manner preventing the pawls from becoming inadvertently released → Risk of injury!
Do not completely unscrew the milled nut; otherwise individual parts (e.g. spring) may drop into the surgical field. → Risk of injury!
Prior to retraction, ensure that the two lock washers interlock properly and completely and the milled nut is tightened. → Possible risk of injury due to loss of function!

Warning! To prevent rib fractures, ensure that the IMA counter blade has the greatest possible contact to several ribs and is not raised excessively. → Risk of injury!

The screwdriver (LMT-4) is now placed on hexagon head of the cranial retractor arm and is turned counter clockwise (see Fig. 15a and 15b).

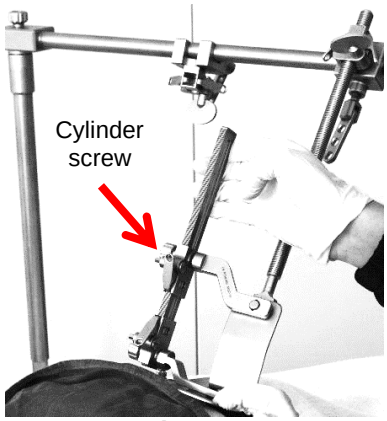


Fig. 15a

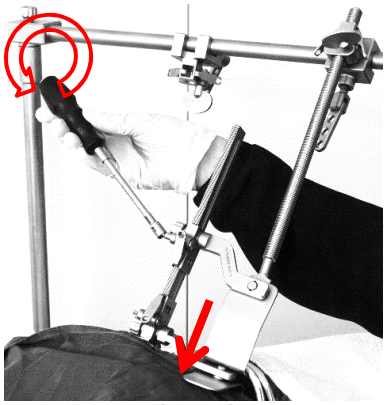


Fig. 15b

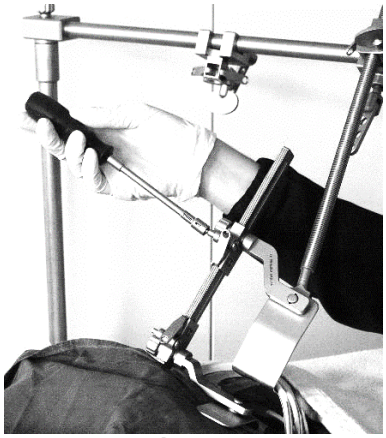


Fig. 15c

11. Dissection of the proximal LIMA:

Warning!
Depending on the anatomy, to prevent ruptures of the LIMA, it may be necessary to expose the LIMA for several centimeters in the area of the incision prior to spreading the IMA retractor!

12. To dissect the RIMA (If only the LIMA is to be dissected, skip to step 13)
To avoid having to re-assemble the system, the proximal part of the RIMA should now be dissected.
To do this, a xiphoid blade (e.g. MQE-2l), attached to the second (more medial) coupling rider, is used to lift the xiphoid:

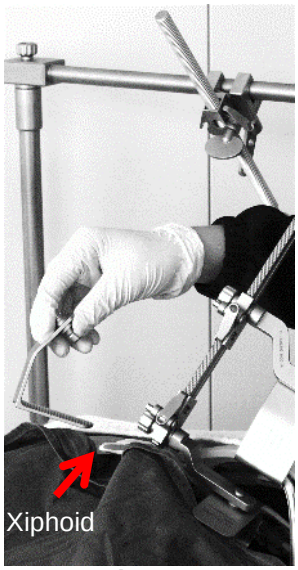


Fig. 16a

Insert xiphoid blade

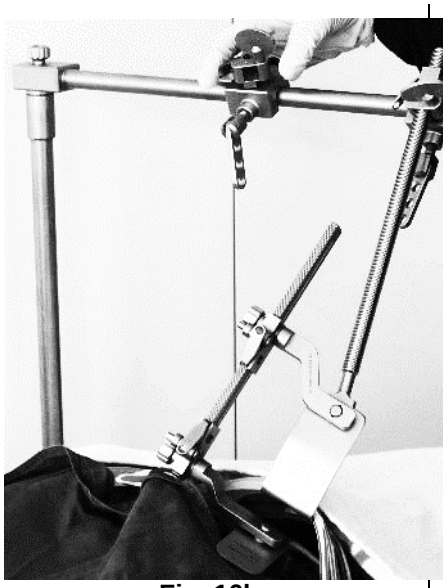


Fig. 16b

Position medial blade guide

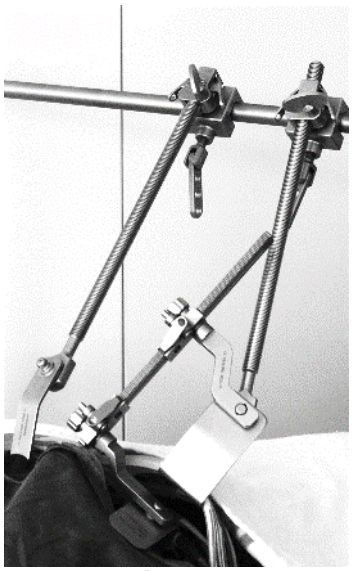


Fig. 16c

Xiphoid blade attached to the horizontal arm by means of the blade guide and riders

13. To prepare the distal area of the LIMA/RIMA, re-assemble the retractor:
To do this, remove the xiphoid blade, IMA retractor and IMA blade.

⚠ **Warning!**
Before releasing the pawl, ensure that the sprocket (see Fig. 17a and 17b) and the cylinder screw with the external hex (see Fig. 17c and 17d) are grasped firmly either with the fingers or the screwdriver in order to prevent sudden loosening. → **Risk of injury!**

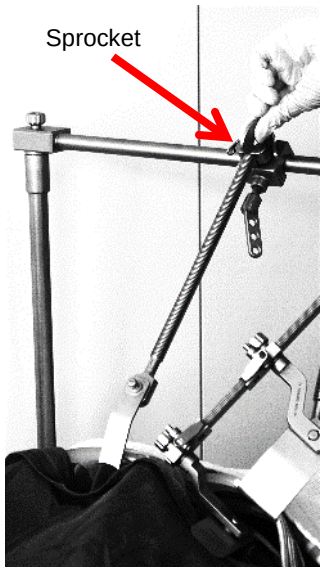


Fig. 17a

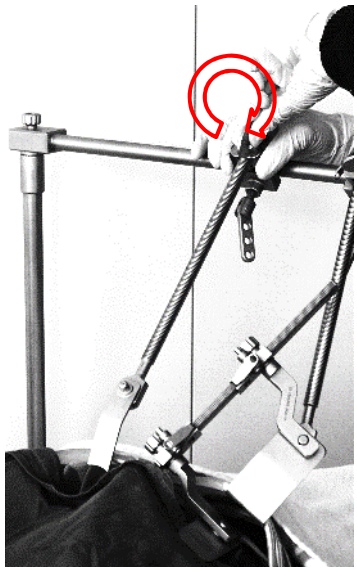


Fig. 17b

Fig. 17c

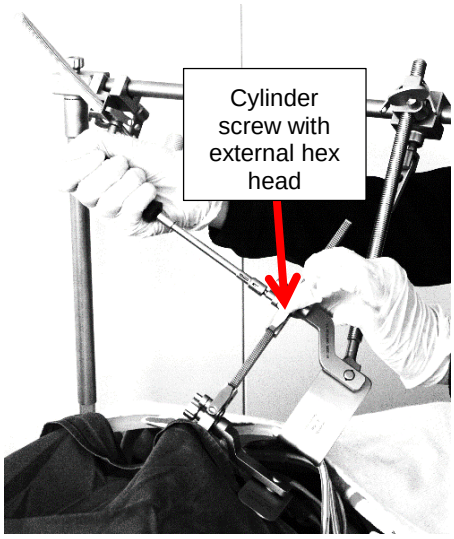


Fig. 17d

14. Loosen the screw of the horizontal arm and turn the horizontal arm in a caudal direction (Fig. 18a). The horizontal arm should then be locked in place pointing around 20° in a caudal direction.

⚠ **Warning!**
Lift the horizontal arm when loosening it and locking it in place (Fig. 18b).

Fig. 18a

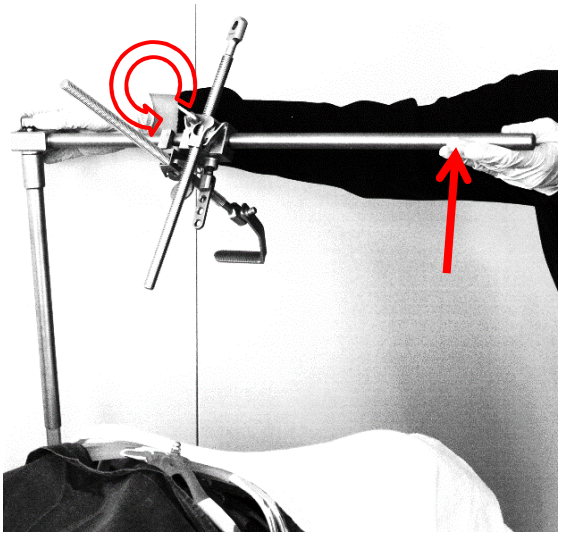
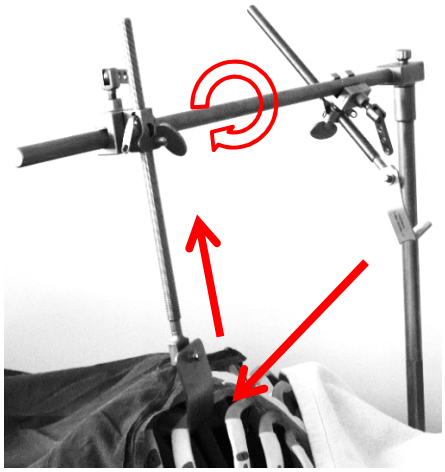
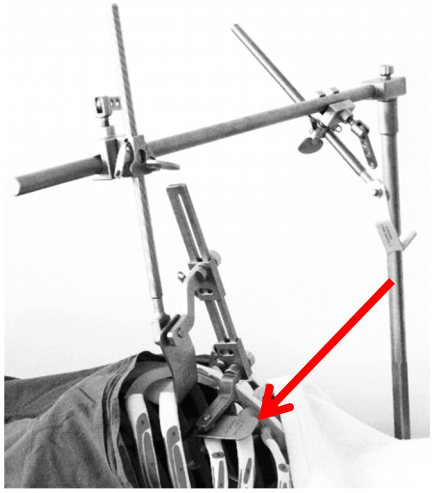
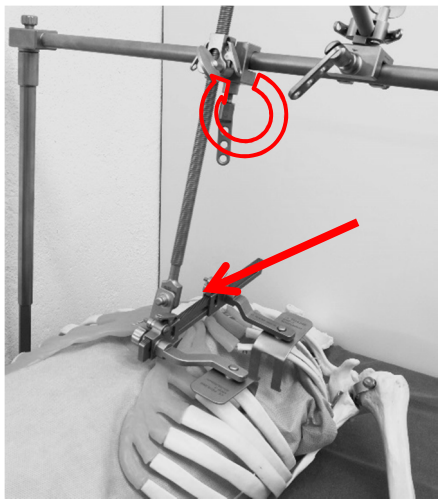
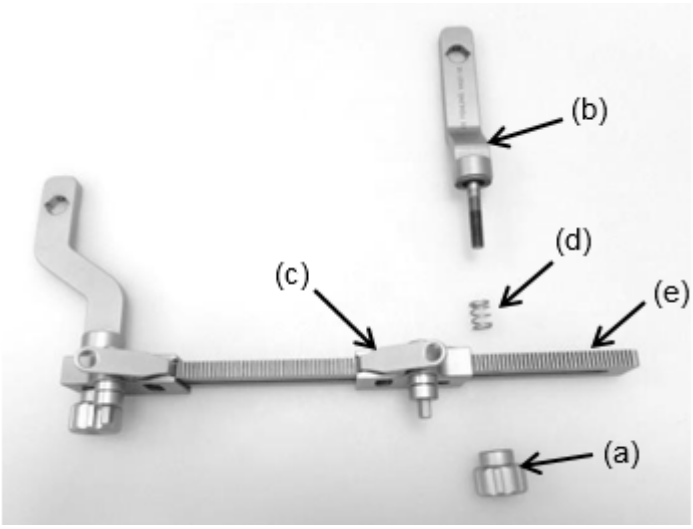


Fig. 18b

15.	Place a short IMA or xiphoid blade below the caudal ribs and lift.	 **Fig. 19**
16.	In accordance with step 9, attach the IMA retractor to the blade guide and, as described in step 10, press the cranial rib downward. The toothed rack of the IMA retractor can be positioned either laterally or medially.	 **Fig. 20**
17.	Prepare distal LIMA To do this, in most cases it is necessary to lift the xiphoid, as described in step 12.	 **Fig. 21**
18.	In most cases, it is not necessary to lift the caudal ribs in order to expose the distal RIMA. If it should be necessary, the IMA blade should be positioned and raised as described in step 15.	
19.	Resect distal RIMA	

20.	Perform MIDCAB as usual.

Reprocessing instructions	
Frequent reprocessing has only minor effects on these instruments. Usually the end of the product service life is determined by wear and damage from use (see “Control and Function Test” for details).	
Place of application:	Pre-cleaning: Ensure that traces of blood, tissue and drug residues are removed from the instruments immediately after completion of the procedure and that they undergo mechanical cleaning immediately.
Storage:	Store instruments in a dry place to avoid condensation. 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.
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	Disassemble the instruments prior to processing. **Disassembly:** For cleaning and processing of the retracting system, the rotable retractor arms have to be disassembled. Screw off the milled nut (a) completly. Pull out the arm with integrated threated bolt (b) off the rider body (c). The spring (d), which is mounted between the two toothed areas, is also removed. Now, the rider body (c) can be completly pushed off the toothed rack (e). Die Abbildung unten zeigt den Spreizer mit einseitig demontiertem Spreizerarm. Die Demontage der anderen Seite erfolgt analog. The picture below shows the spreader with one spreader arm disassembled. The disassembly of the other side is analogous.  (a) Milled nut (b) Arm for retractor (c) Rider body (d) Spring (e) Toothed rack ⚠ **Warning:** **Place small parts for storage, cleaning and reprocessing in suitable containers (i.e. perforated baskets).**

	Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not immerse in normal saline (NaCl) solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemicals manufacturer's recommendation for the mixture). Avoid overfilling instrument trays and washing trays – use only suitable instrument holders. When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck anywhere. Always open and/or disassemble joint instruments for processing.
Cleaning/Disinfection according to DIN EN ISO 15883-1:2009	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with. If available, the use of a washer/disinfector unit which uses thermal disinfection is recommended.
Cleaning/disinfection: mechanically acc. to standard EN ISO 15883-1:2009	**Validated procedure** Pre-cleaning Equipment: Basin, soft brush Detergents: Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner (Steris®) Mixing proportion: 0,5 – 2 % Prolystica® in tap water Temperature: 40 °C Application time: 10 – 30 minutes Process: Remove all visible contamination with a suitable soft brush during application time and move the instruments in the basin. Rinse the instruments for one minute with cold deionized water by moving the instruments. Mechanically cleaning: Equipment: Miele PG 8536 Detergents: neodisher® MediClean forte (Dr. Weigert) Process: 1. 2 min. prewash with cold tap water (< 45 °C) 2. 10 min. cleaning with a solution of 0.5 – 2 % neodisher® in tap water at 55 °C 3. 2 min. rinsing with cold tap water (< 45 °C) 4. 5 min. rinsing with deionized water (90 °C) 5. 25 min. drying (> 50 °C)
Cleaning manually	Validated procedure Equipment: Bandelin Sonorex RK 1028 H Detergents: Cidezyme/Enzol (ASP) or Mucadont Zymaktiv (Merz Hygiene GmbH) Pre-cleaning • Place instruments in cold water for 10 minutes. • Move any movable parts back and forth. • Use a soft brush to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds with a water spray gun. Ultrasonic cleaning • Clean for 10 minutes at 45 °C with 0.8% cleaning solution at 35 kHz.

	After ultrasonic cleaning, rinse the instruments with a water spray gun for at least 20 seconds. Rinse the instruments with tap water. Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Desinfection: Manuell	Disinfection: Consult the instructions on the label when selecting a disinfectant (see information on chemical manufacturers). Deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Drying:	If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Montage:	*(Please refer to the picture shown in 'Disassembly')* To assemble the retractor arms prior to sterilization, push the coupling rider bodies (c) onto the toothed rack (e). When doing so, the latches must point towards each other and towards the center of the toothed rack. Push the spring (d) onto the threaded bolt of the retractor arm (b) (Fig. 4a). Place the threaded bolt of the retractor arm through the hole in the toothed rim of the rider body (c) and thus simultaneously through the slit of the toothed rack (Figure 4b). The retractor arm is locked in place by attaching the milled nut (a).
Maintenance:	Apply a small amount of high-grade, water-soluble instrument spray on the threaded bolt and the tooth-wheel drive.
Control and function test:	Check joint instruments for easy operation (avoid too much play). Check locking mechanisms. All Instruments: Use a magnifying lamp to visually inspect the components for damage and wear and tear. Edges should not show nicks and should be even. Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.
Packaging:	Single: in accordance with the standard series EN 868 and EN ISO . Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately.
Sterilization:	Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes! 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. Validated procedure: Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: at least 10 minutes 5. Other locally validated methods, including those described in HTM2010, may be used.

Storage:	In accordance with EN 868 and EN ISO 11607.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.
Additional national standards like AAMI TIR-12-2004 may be applicable.

Any modification to the device or deviation from these instructions for use will result in exclusion of liability.
Subject to change without notice.

Storage / Symbols

							
Store in a dry place	Protect from excessive heat!	Follow the instructions for use	Article number	Lot-number	Manufacturer	CE marking	Warning

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