FEHLING MICS IMA Intercostal Retractor

Retractor frame MQC-1I .....IMA retractor complete with two rotatable arms

Components

IMA blades

MQC-6I.....IMA blade 70 x 30 mm
MQC-7I.....IMA blade 90 x 30 mm
MQC-8I.....IMA blade 110 x 30 mm
MQC-9I.....IMA blade 130 x 30 mm
MQC-6R.....IMA blade 70 x 30 mm, rigid
MQC-7R.....IMA blade 90 x 30 mm, rigid
MQC-8R.....IMA blade 110 x 30 mm, rigid
MQC-9R.....IMA blade 130 x 30 mm, rigid
MQC-2I.....IMA blade 70 x 40 mm
MQC-3I.....IMA blade 90 x 40 mm
MQC-4I.....IMA blade 110 x 40 mm
MQC-5I.....IMA blade 130 x 40 mm
MQC-2R.....IMA blade 70 x 40 mm, rigid
MQC-3R.....IMA blade 90 x 40 mm, rigid
MQC-4R.....IMA blade 110 x 40 mm, rigid
MQC-5R.....IMA blade 130 x 40 mm, rigid
MQC-2L.....IMA blade 70 x 90 mm
MQC-3L.....IMA blade 90 x 90 mm
MQC-4L.....IMA blade 110 x 90 mm
MQC-5L.....IMA blade 130 x 90 mm
MQC-2M.....IMA blade 70 x 90 mm, rigid
MQC-3M.....IMA blade 90 x 90 mm, rigid
MQC-4M.....IMA blade 110 x 90 mm, rigid
MQC-5M.....IMA blade 130 x 90 mm, rigid

Xiphoid blades

MQE-3I ..... Xiphoid and distal IMA blade 40 x 30 x 20 mm
MQE-2I ..... Xiphoid and distal IMA blade 40 x 45 x 20 mm
MQE-1I ..... Xiphoid and distal IMA blade 40 x 60 x 20 mm
MQE-4I ..... Xiphoid and distal IMA blade 40 x 75 x 20 mm
MQE-5I ..... Xiphoid and distal IMA blade 40 x 90 x 20 mm
MQE-6I ..... Xiphoid and distal IMA blade 40 x 105 x 20 mm
MQE-3R..... Xiphoid and distal IMA blade 40 x 30 x 20 mm, rigid
MQE-2R..... Xiphoid and distal IMA blade 40 x 45 x 20 mm, rigid
MQE-1R..... Xiphoid and distal IMA blade 40 x 60 x 20 mm, rigid
MQE-4R..... Xiphoid and distal IMA blade 40 x 75 x 20 mm, rigid
MQE-5R..... Xiphoid and distal IMA blade 40 x 90 x 20 mm, rigid
MQE-6R..... Xiphoid and distal IMA blade 40 x 105 x 20 mm, rigid

Counter blades

MQF-0 .....IMA counter blade 30 x 35 x 60 mm
MQF-1 .....IMA counter blade 40 x 35 x 60 mm
MQF-2 .....IMA counter blade 50 x 35 x 60 mm

Fixations/guides

EEP-0 ..... Coupling rider
EEL-4F..... Blade guide, rotatable and swivelling 300 mm

Accessories

NVG-9 .....CERAMO® hex wrench for specula
NVG-9L .....CERAMO® hex wrench for specula, long version
LMT-4.....Cardan screwdriver
EEJ-1 .....Universal operating table mounting clamp 16 x 16 mm, angle-adjustable
EEJ-2 (a,b) .....Angled rod 16 x 16 x 600 x 600 mm
EEJ-2T .....T-screw for angled rod
EEJ-2C.....Spare screw for angled rod

The components listed here are also available with a CERAMO-coated surface. In this case, a “C” is added to the article number.

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

The MICS IMA intercostal retractor may only be used, reprocessed and disposed of by qualified medical personnel!

The MICS IMA intercostal retractor is intended for reuse.

1) Intended purpose

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

- in or at a specific position

- or to move them into or to a specific position

This excludes retractors (as specified in the TD for Classes I and IIa retractors), hooks, vessel and tissue clamps, forceps and needle holders.

Additional information regarding the intended purpose

Duration of application: Holding and guiding instruments are intended for short-term use.

Field of application: Holding and guiding instruments are used in all patients where products and tissue must be held or fixed in or to a specific position and/or moved to or in a specific position.

User profile: Holding and guiding instruments may only be used by medically trained personnel (e.g. specialist surgeons).

Application environment: Holding and guiding instruments are only to be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions

2) Indications

Treatment methods requiring the holding and guiding of products and tissue.

3) Contraindication

All applications that are inconsistent with the physical and/or mechanical properties of the specific holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding and guiding instruments.

Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.

These include, for example,

- Recent rib fractures
- Chest wall anomalies involving the pleura
- Diseases involving the lungs or pleura, pleural adhesions
- Sternal dehiscence (separation of the sternum after previous cardiac surgery)
- Previous cardiac surgery with severe adhesions
- Previous IMA harvesting on the affected side
- Severe obesity (e.g. BMI >35 kg/m2)

4) Possible side effects
The medical literature describes the following side effects that may occur during or after IMA dissection or MIDCAB surgery despite the intended use of the MICS IMA intercostal retractor (method-specific complications): - Impaired sternal healing, potentially causing sternal instability - Stretch- or pressure-induced skin lesions - Bone fractures, e.g. ribs, sternum, spinous processes, vertebral bodies - Infections - Wound healing disorders - Injury to structures (tissues, organs, nerves, vessels) - Necrosis - Ischaemia - Haematoma

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

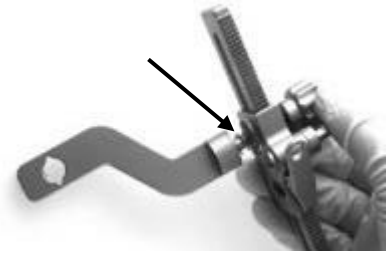
5) Before use	
The MICS IMA intercostal retractor is supplied non-sterile and must be cleaned and sterilised by the user before initial use and before each subsequent use (see Section 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section *6) Reprocessing* under *"Maintenance, Inspection and Testing"*).
⚠	Handle the MICS IMA intercostal retractor with care during storage, transport and cleaning! Avoid impacts and point loading on the MICS IMA intercostal retractor to prevent any possible secondary damage! Do not overload functional parts!
⚠	Use only intact and sterilised products!

6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing are to be complied with.
⚠	The applicable national regulations must be followed for the reprocessing of instruments used in patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	The instruments must be handled with care during storage, transportation and cleaning. Avoid mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts!

⚠	Do not clean CERAMO® instruments (recognisable by their black-brown surface) with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these processes leads to the destruction of the titanium-containing CERAMO® coating after some time, due to the leaching of titanium.
Limitations on reprocessing	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible labels, functional failure - also see *"Maintenance, Inspection and Testing"*). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilisation) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionised water (deionised water, demineralised, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-treatment at the place of use	Pre-cleaning: Ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo automated cleaning immediately. After completion of initial treatment of the instruments, visual inspections must be performed to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing such that neither the user, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	Instruments should be reprocessed immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert)

	Procedure/Parameters: • 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 may be moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush) during the exposure time. • Rinse the instruments for one minute in cold deionised water (see *"General Information on Reprocessing"*) and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, for preference use a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilisation baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. Validated procedure: Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) Preparation: • Instruments with joints are to be placed in the device so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the washer/disinfector. Procedure/Parameters: • 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 deionised water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionised water (> 90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Place instruments, if possible in disassembled condition, in cold water (potable water quality, < 40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until contamination is no longer visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at < 40 °C with 0.5 – 2% cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, < 40 °C). • Deionised water (< 40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant solution (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionised water (< 40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.

Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), apply a biocompatible, steam sterilisable, steam-permeable paraffin-/white oil-based instrument oil (according to the valid European or United States Pharmacopoeias) before sterilisation. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and impair the effectiveness of steam sterilisation. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorised by the manufacturer. A confirmation form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical 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 assemble instruments comprising multiple components loosely before packaging and sterilisation; do not tighten the components securely. This applies to the rotatable retractor arm of the MICS IMA intercostal retractor (Fig. 1).  Fig. 1: MICS IMA intercostal retractor with a retractor arm not tightened
Packaging	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation using a fractionated vacuum process in a steriliser complying with DIN EN 285 and DIN EN ISO 17665. To prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer autoclave Type B 3870 EHS / Lautenschläger ZentraCert

	Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature 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. They must be cleaned prior to disposal. They can be disposed of at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy and potential adverse consequences.	
	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability. Subject to change without notice.

7) Configuration and application

The MICS IMA intercostal retractor is a U-shaped bar retractor with Z-shaped-retractor arms (Fig. 2). The two retractor arms can be rotated 360° about their axes and are freely movable along the toothed rack. The movable retractor arms are adjusted via a gear drive using the NVG-9 hex wrench or the LMT-4 Cardan screwdriver (see 8) Required accessories). The corresponding components are listed in Table 1.

The MICS IMA intercostal retractor is intended for the following procedures in particular:

- Patients with severe comorbidities for whom conventional bypass surgery with sternotomy and cardiopulmonary bypass is not intended
- Patients in whom sternotomy is also contraindicated
- Patients in whom cosmetic aspects are also a priority.

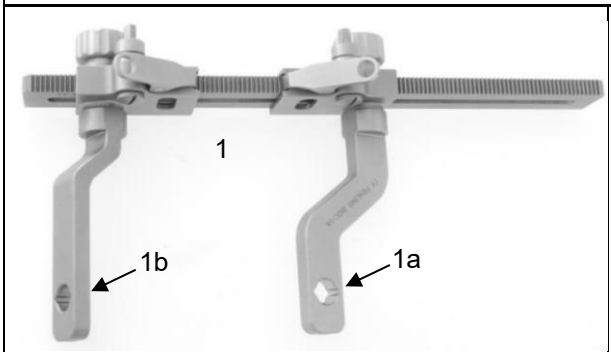
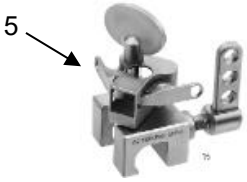


Fig. 2: MICS IMA intercostal retractor complete – MQC-1I

Table 1: List of the corresponding components

	Item no.	Description
1	MQC-1I	IMA retractor complete
1a		Retractor arm, rotatable, laterally angled
1b		Retractor arm, rotatable
2	MQC-2I/2R..9I/9R	IMA blades
3	MQF-0|1/2	Counter blades
4	MQE-1I/1R..6I/6R	Xiphoid blades
5	EEP-0	Coupling rider
6	EEL-4F	Blade guide
7	EEJ-2 (a,b)	Angled rod



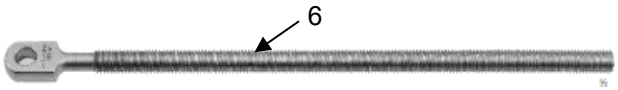


Figure 3 shows an example configuration of a MICS IMA intercostal retractor for exposure of the IMA.

For IMA exposure, retraction elements in the form of xiphoid, counter and IMA blades are used, which are connected to the EEJ-2 angled rod via the blade guide (Fig. 3).

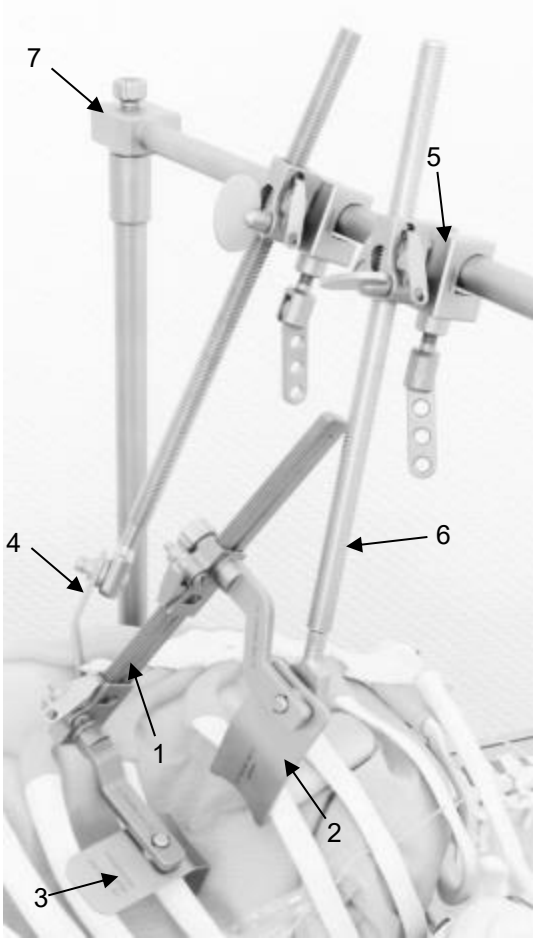
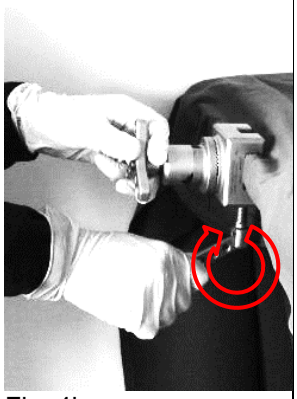
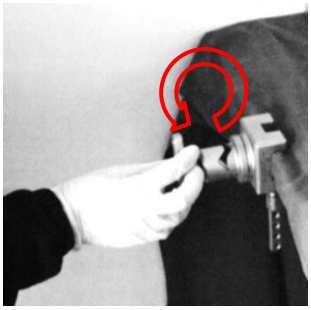
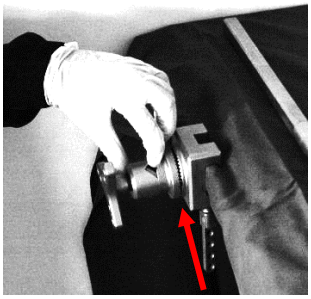
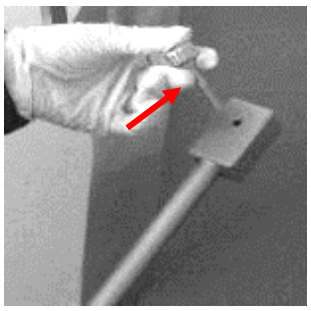
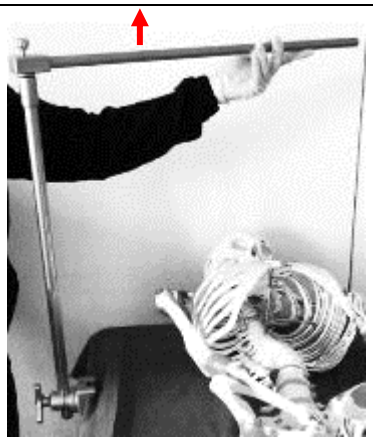
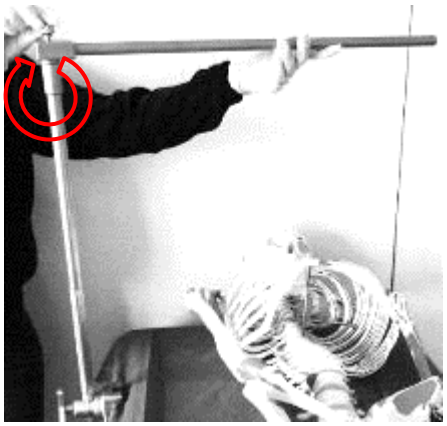
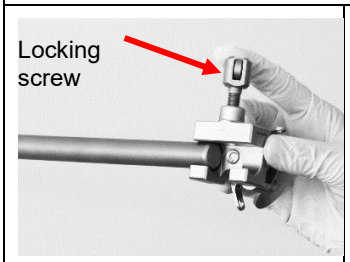
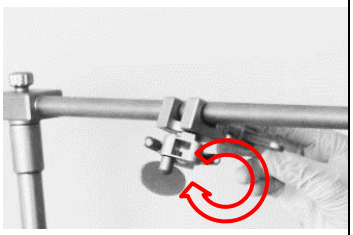
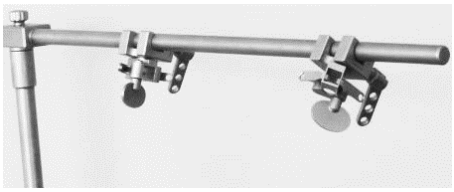
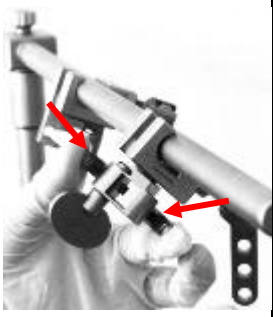
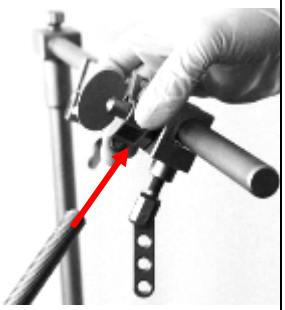
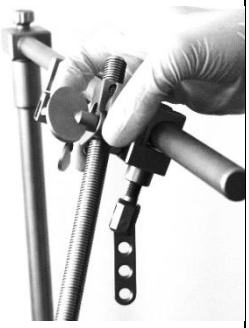
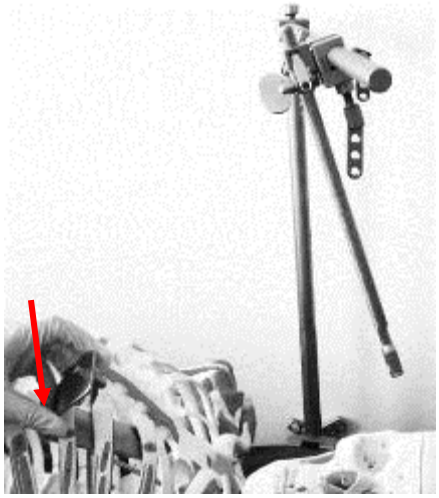
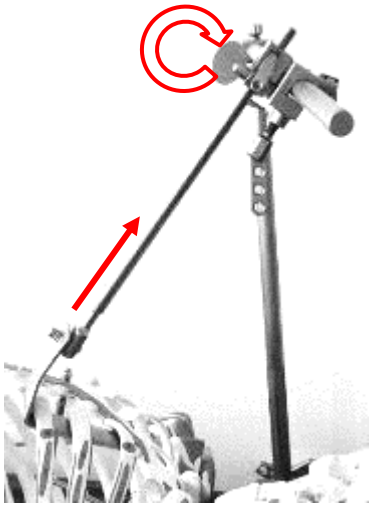


Fig. 3: Example configuration of a MICS IMA intercostal retractor

⚠	Use only intact and sterilised products!
⚠	Before inserting the MICS IMA intercostal retractor, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of components depends on the anatomical and physiological conditions as well as the field of application. Ensure that the components used have the correct size and geometry, as well as sufficient stability.

During application			
⚠	Ensure that all connections are secured in such a way as to prevent slipping. → Risk of injury!		
1.	Attach the EEJ-1 mounting clamp to the rail of the operating table – either below (Fig. 4a) or above (Fig. 4b) the sterile drape – at the level of the patient's right shoulder.	 Fig. 4a	 Fig. 4b
2.	Attach the vertical-square-section holding rod (EEJ-2a) of the EEJ-2 angled rod to the mounting clamp.		
	 Fig. 5a: Loosen the retaining screw.	 Fig. 5b: Align the clamping jaws so that a square opening is created to accommodate the vertical holding rod.	 Fig. 5c: Insert the vertical holding rod and tighten the retaining screw.
3.	Secure the EEJ-2b crossbar to the vertical holding rod using the corresponding EEJ-2c screw horizontally and angled about 20° cranially.		
	 Fig. 6a	 Fig. 6b	

⚠	Ensure that the crossbar is raised so that the two toothed rings are flush with each other. Risk of screw breakage → Risk of injury!
	 Fig. 6c  Fig. 6d
4.	If both the LIMA and RIMA are to be dissected, attach two EEP-0 coupling riders to the crossbar. If only the LIMA is to be dissected, one coupling rider is sufficient.
	 Fig. 7a To place the coupling riders, loosen the locking screw completely.  Fig. 7b The coupling riders should be secured in a suitable position by tightening the locking screw to prevent unintended slipping.  Fig. 7c
5.	Insert the EEL blade guide-4F.
	 Fig. 8a Grasp the coupling rider by the two locking pawls.  Fig. 8b Press the locking pawls together.  Fig. 8c Insert blade guide.  Fig. 8d

6.	Insert the IMA blade (e.g. MQC-3I) into the fourth intercostal space (below the nipple in men, in the inframammary fold in women).	 Fig. 9
7.	Connect the IMA blade to the blade guide and lift.	 Fig. 10
⚠	During this procedure, the crossbar bends slightly downwards. This movement is subsequently compensated for by use of the IMA retractor (MQC-1I). To avoid rib fractures, ensure that the IMA blade has the greatest possible contact with every rib and is not lifted excessively.	
8.	Advance the caudal arm (see Table 1, 1b) of the IMA retractor to the end of the toothed rack (Fig. 11a), and position the cranial arm (see Table 1, 1a) near the caudal arm (Fig. 11b and 11c).	

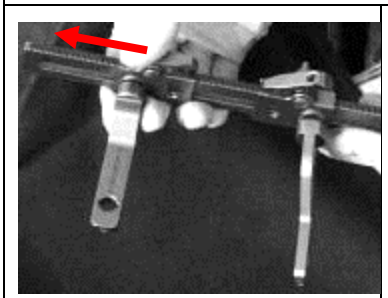


Fig. 11a

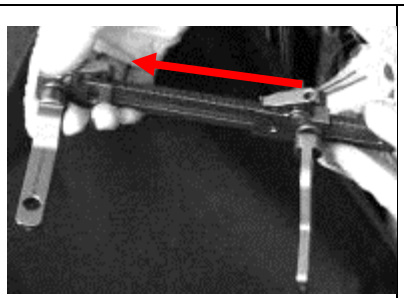


Fig. 11b

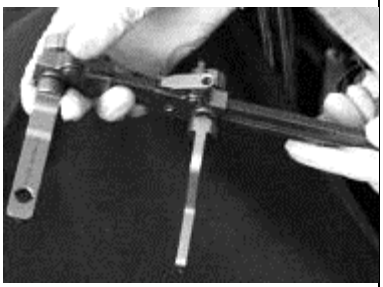


Fig. 11c

9.	Start by detaching both nuts (Fig. 12a). Then connect the caudal arm of the IMA retractor to the IMA counter blade (e.g., MQF-1) (Fig. 12b and 12c). Then connect the cranial arm (see Table 1, 1a) to the IMA-blade (Fig. 12d).

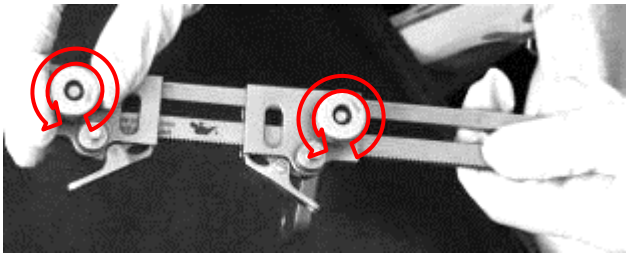


Fig. 12a

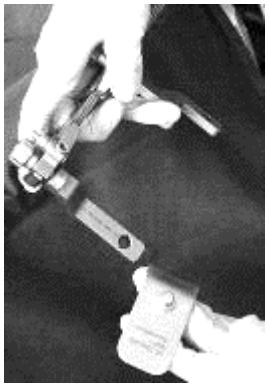


Fig. 12b

Fig. 12c

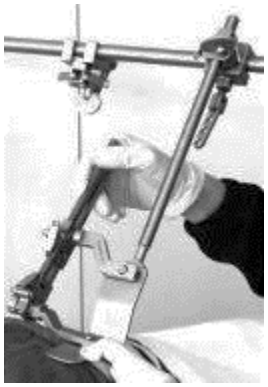


Fig. 12d

10.	Attach both nuts to the cranial and caudal arms of the IMA retractor in a suitable position (Fig. 13).

Options:

a) The toothed rack of the IMA retractor, when positioned vertically, presses the lower rib inwards towards the body.
b) The toothed rack of the IMA retractor, when positioned horizontally, distracts the lower rib.
c) An oblique position of the toothed rack produces both distraction and depression.

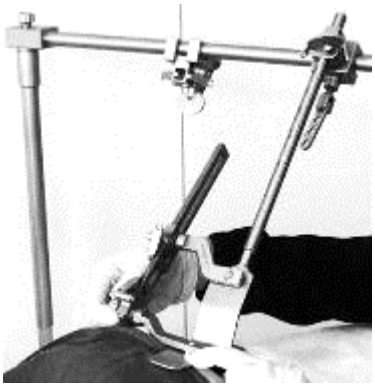
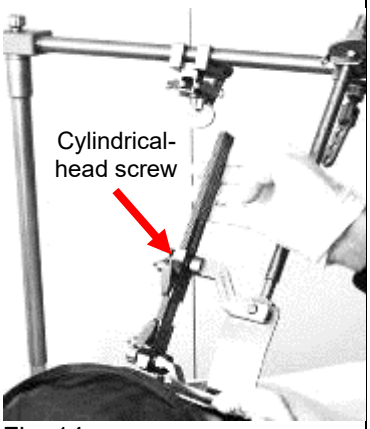
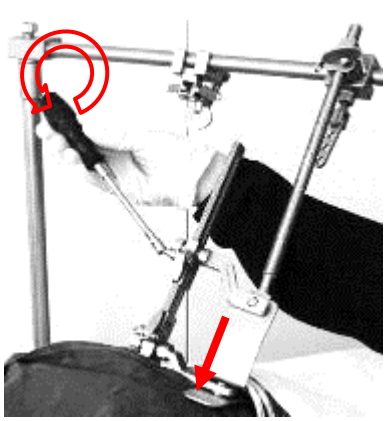
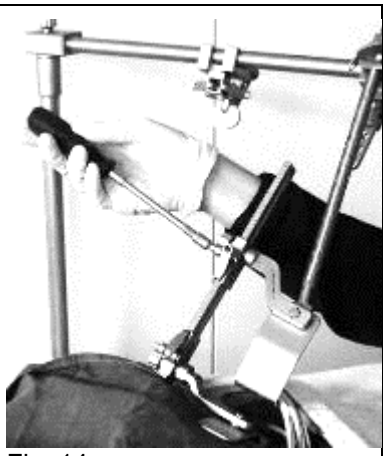
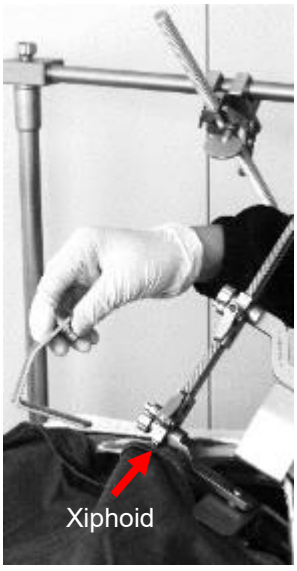
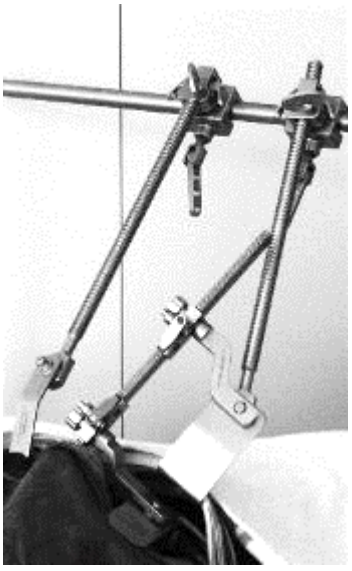


Fig. 13:

⚠ When using the retractor, ensure that the rider is positioned on the toothed rack in such a way that inadvertent loosening of the locking pawls is avoided. → Risk of injury!
Do not unscrew the knurled nut completely, otherwise individual parts (e.g. spring) may fall into the surgical field. → Risk of injury!
Before spreading the retractor, ensure that the two toothed discs are correctly and fully engaged and that the knurled nut is firmly tightened. → Instrument failure may result in injury!

⚠ To avoid rib fractures, ensure that the IMA counter blade lies as flat as possible against all ribs and is not excessively distracted. → Risk of injury!

To spread the retractor, fit the screwdriver (LMT-4) onto the external hex drive of the cylindrical-head screw (Fig. 14a) on the cranial retractor arm and turn it anticlockwise (Fig. 14b and 14c).

	 Fig. 14a	 Fig. 14b	 Fig. 14c
11.	Dissection of the proximal LIMA		
⚠	To prevent tearing of the LIMA and depending on the anatomy, it may be necessary to expose the LIMA a few centimetres in the region of the incision before spreading the IMA retractor!		
12.	If only the LIMA is dissected, skip this step and continue with point 13. To avoid having to re-assemble the system, the proximal part of the RIMA should now be dissected. To do this, elevate the xiphoid using a xiphoid blade (e.g., MQE-2I), attached to the second (medial) coupling rider via the blade guide:		
	 Fig. 15a Insert the xiphoid blade.	 Fig. 15b Position the medial blade guide.	 Fig. 15c Xiphoid blade attached to crossbar by means of the blade guide and rider.
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.		
⚠	Before releasing the locking pawl, ensure that the pinion (Fig. 16a and 16b) or the cylindrical head screw with external hex drive (Fig. 16c and 16d) is held securely with the fingers or the screwdriver, respectively, to avoid sudden release. → Risk of injury!		

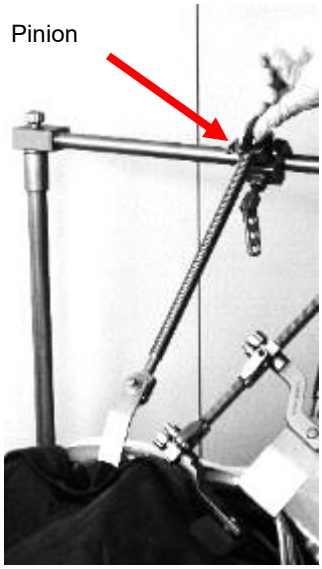
<table>
<tr><td></td><td> 

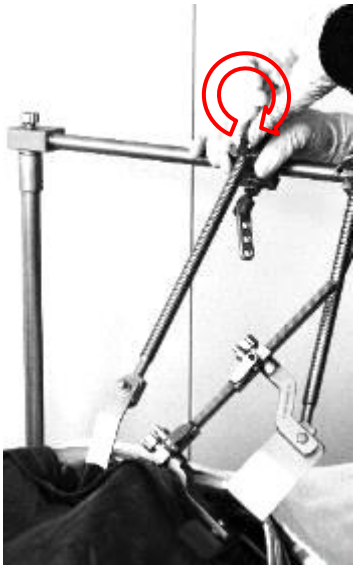
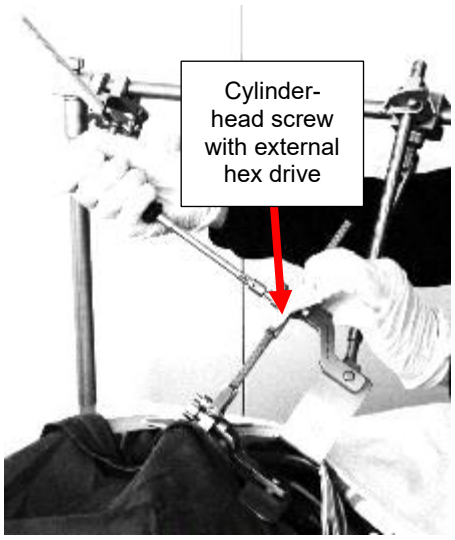
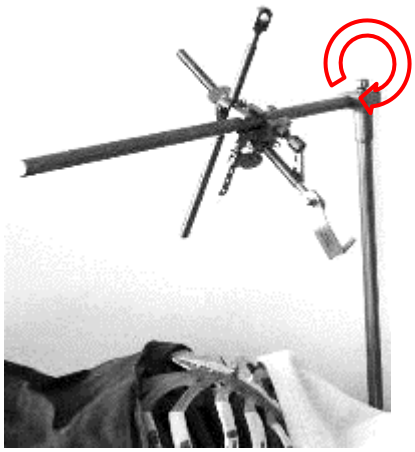
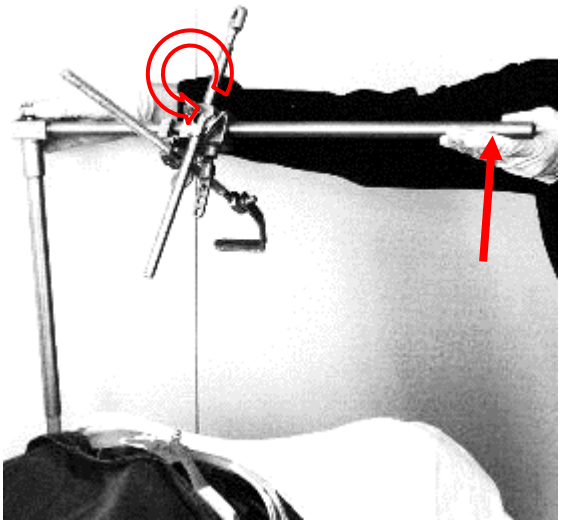
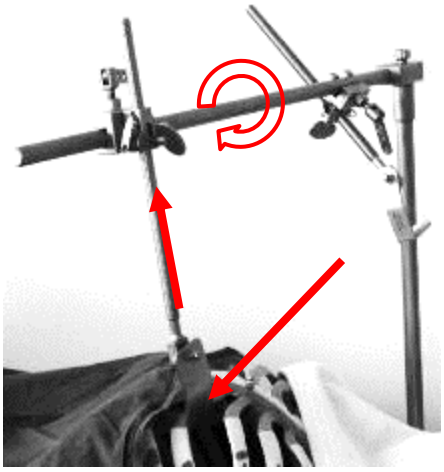
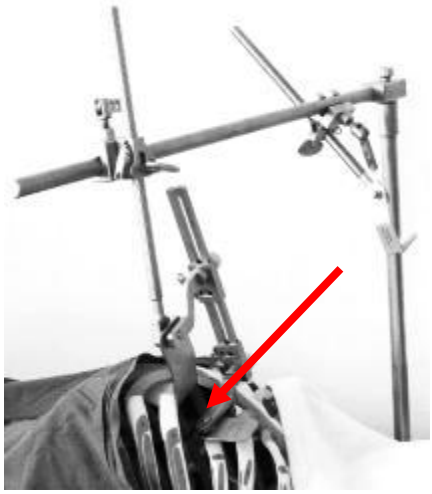
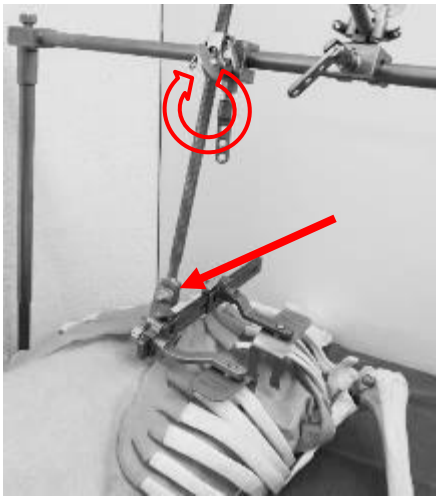
Fig. 16a</td><td> 
Fig. 16b</td></tr>
<tr><td></td><td> 
Fig. 16c</td><td> 

Fig. 16d</td></tr>
<tr><td>14.</td><td colspan="2">Loosen the screw of the crossbar and rotate the crossbar caudally (Fig. 17a).
The crossbar should then be locked at an angle of about 20° caudally.</td></tr>
<tr><td>⚠</td><td colspan="2">Lift the crossbar when releasing and locking (Fig. 17b).</td></tr>
</table>

	 Fig. 17a	 Fig. 17b
15.	Place a short IMA or xiphoid blade beneath the caudal ribs and raise them.	 Fig. 18
16.	As described in step 9, attach the IMA retractor to the blade and press the cranial rib downward as described in step 10. The toothed rack of the IMA retractor may be positioned either laterally or medially.	 Fig. 19

17.	Dissect the distal LIMA. In most cases, this requires raising the xiphoid as described in step 12.	 Fig. 20
18.	In most cases, raising the caudal ribs is not required to expose the distal RIMA. Should this be necessary, however, raise the IMA blade as described in 15.	
19.	Dissect the distal RIMA.	
20.	Perform MIDCAB as usual.	
⚠	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.	

8) Required accessories

The accessories listed in Table 2 are required for use of the MICS IMA intercostal retractor.

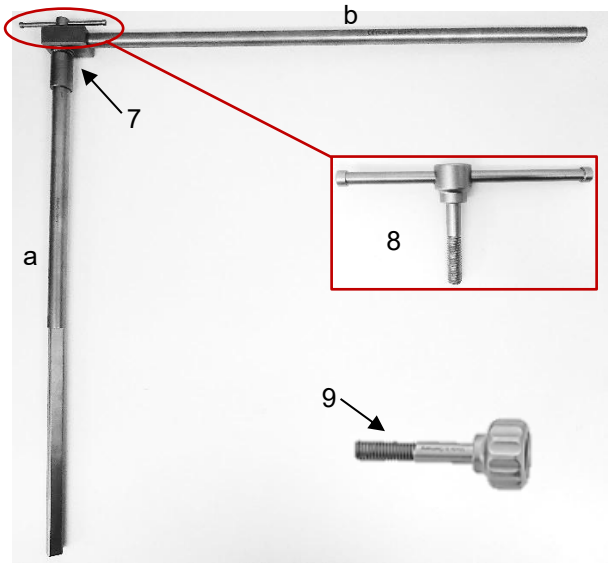
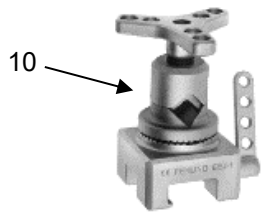


Table 2: List of required accessories

	Item no.	Description
7	EEJ-2 (a,b)	Angled rod
8	EEJ-2T	T-screw for angled rod
9	EEJ-2C	Spare screw for angled rod
10	EEJ-1	Operating table mounting clamp
11	NVG-9	CERAMO® hex wrench for specula
12	LMT-4	Cardan screwdriver



9) Assembly

For assembly and disassembly of the operating table mounting clamp (EEJ-1), please refer to the assembly instructions M33.

Please follow the instructions below to assemble the MICS IMA intercostal retractor.

The rotatable retractor arms must be disassembled for reprocessing (see 10) Disassembly). It is therefore necessary to assemble the retractor before use.

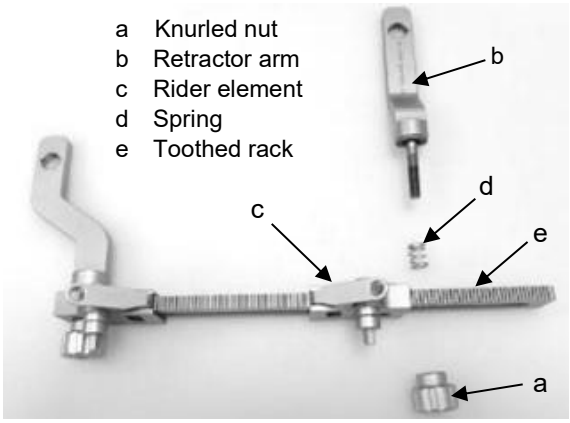


Fig. 21: MICS IMA intercostal retractor with one retractor arm removed

To assemble the retractor arms before use, slide the rider elements (c) onto the toothed rack (e). The locking levers must point towards the centre of the toothed rack. Slide the spring (d) onto the threaded bolt of the retractor arm (b) (Fig. 22a). Insert the threaded bolt of the retractor arm through the hole in the toothed ring of the rider element (c) and thus simultaneously through the slot in the toothed rack (Fig. 22b). The retractor arm is secured by screwing on the knurled nut (a).

Fig. 22a

Fig. 22b

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

10) Disassembly

For reprocessing, the MICS IMA intercostal retractor must be disassembled as follows.

The rotatable retractor arms must be disassembled for cleaning and reprocessing of the system.

To do so, unscrew the knurled nut (a) completely and pull the arm with integrated threaded bolt (b) out of the rider element (c). The spring (d) mounted between the two toothed rings is also removed. The rider element (c) can now be slid completely from the toothed rack (e).

Figure 23 shows the retractor with one retractor arm disassembled.

The other side is disassembled in the same way.

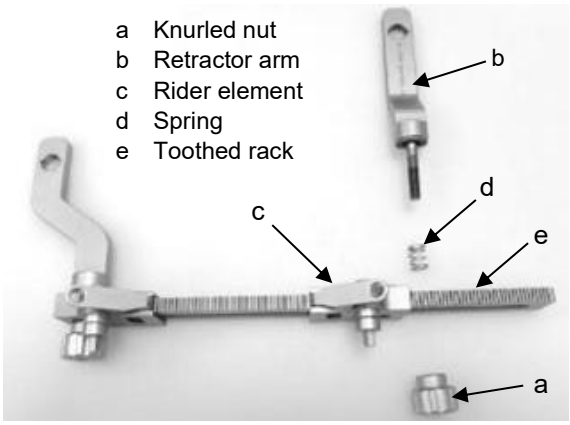


Fig. 23: MICS IMA intercostal retractor with one retractor arm removed

⚠	Place small parts in suitable containers (e.g., needle box) for storage and reprocessing!

11) Obligation to report serious incidents
The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use.	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE marking	

Manufacturer's contact information		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de	CE