FEHLING MICS intercostal retractor

Retractor body	MRP-1	MICS intercostal retractor, body only
	MRP-1F	MICS intercostal retractor, short arm, body only

Table 1: List of the components, the extension modules and accessories for the MICS intercostal retractor

Components

Retractor blades

MRP-2	Retractor blades 40 x 35 mm
MRP-3	Retractor blades 50 x 35 mm
MRP-4	Retractor blades 60 x 35 mm
MRO-7	Retractor blades 70 x 35 mm
MRP-2F	Retractor blades, fenestrated, slit, 40 x 35 mm
MRP-3F	Retractor blades, fenestrated, slit, 50 x 35 mm
MRP-4F	Retractor blades, fenestrated, slit, 60 x 35 mm
MRP-2V	Retractor blades, fenestrated, 40 x 35 mm
MRP-3V	Retractor blades, fenestrated, 50 x 35 mm
MRP-4V	Retractor blades, fenestrated, 60 x 35 mm
MRO-7V	Retractor blades, fenestrated, 70 x 35 mm
MRQ-7	Retractor blades, fenestrated, 80 x 35 mm
MRQ-8	Retractor blades, fenestrated, 90 x 35 mm
MRQ-9	Retractor blades, fenestrated, 100 x 35 mm
MRP-2K	Retractor blades, fenestrated, single slit, 40 x 35 mm
MRP-3K	Retractor blades, fenestrated, single slit, 50 x 35 mm
MRP-4K	Retractor blades, fenestrated, single slit, 60 x 35 mm
MRI-1M	MILuTX retractor blade, profiled lengthwise 33 x 15 mm
MRI-2M	MILuTX retractor blade, profiled lengthwise 43 x 15 mm
MRI-3M	MILuTX retractor blade, profiled lengthwise 53 x 15 mm
MRI-4M	MILuTX retractor blade, profiled lengthwise 63 x 15 mm
MRI-5M	MILuTX retractor blade, profiled lengthwise 73 x 15 mm
MRI-6M	MILuTX retractor blade, profiled lengthwise 83 x 15 mm
MRI-7M	MILuTX retractor blade, profiled lengthwise 93 x 15 mm
MRE-4M	MILuTX retractor blade, profiled lengthwise 23 x 24 mm

Other retracting elements

MRU-1K	Atrial bracket 27 x 30 mm
MRX-2	Atrial bracket 30 x 30 mm
MRU-1	Atrial bracket 45 x 30 mm
MRU-2	Atrial bracket 60 x 30 mm
MRU-5	Atrial bracket 18 x 35 mm
MRX-3	Atrial bracket 30 x 45 mm
MRU-3	Atrial bracket 45 x 45 mm
MRU-4	Atrial bracket 60 x 45 mm
MRO-2	Atrial hook adjustable angle, 30 mm
MRO-3	Atrial hook adjustable angle, 40 mm
MRO-4	Atrial hook adjustable angle, 50 mm
MRO-5	Atrial hook adjustable angle, 60 mm
MRO-6	Atrial hook adjustable angle, 70 mm
MSN-2	Atrial hook expandable, 35 x 25 mm
MSN-3	Atrial hook expandable, 55 x 30 mm
MRN-4	Atrial blade adjustable angle, 30 x 8 mm
MRN-5	Atrial blade adjustable angle, 40 x 8 mm
MRN-6	Atrial blade adjustable angle, 50 x 8 mm
MRU-6	Downholder for septal fold and diaphragm
MRJ-5	Atrial downholder 60 mm
MRJ-6	Atrial downholder 70 mm
MRJ-7	Atrial downholder 80 mm
MRR-3V	Myocardial muscle stabilizer with ball connector (Ø 7 mm)
MRV-8V	CERAMO® SUPERPLAST spatula 1.25 x 70 x 35 x 182 (Ø 6.35 mm)
MRV-8	CERAMO® SUPERPLAST spatula 2 x 70 x 35 x 182 (Ø 6.35 mm)
MRV-7V	CERAMO® SUPERPLAST spatula 1.25 x 70 x 35 x 225 (Ø 6.35 mm)
MRV-7	CERAMO® SUPERPLAST spatula 2 x 70 x 35 x 225 (Ø 6.35 mm)
EOJ-7	CERAMO® SUPERPLAST spatula 24 x 250
MRX-1V	SUPERPLAST flexible retractor for mitral valve cusp (Ø 4 mm), 250 mm
MRK-5	SUPERPLAST MICS sump suction device LL 270 mm

MRE-5M	MILuTX retractor blade, profiled lengthwise 33 x 24 mm
MRE-6M	MILuTX retractor blade, profiled lengthwise 43 x 24 mm
MRE-7M	MILuTX retractor blade, profiled lengthwise 53 x 24 mm
MRE-8M	MILuTX retractor blade, profiled lengthwise 63 x 24 mm
MRE-9M	MILuTX retractor blade, profiled lengthwise 73 x 24 mm
MRI-8M	MILuTX retractor blade, profiled lengthwise 83 x 24 mm
MRI-9M	MILuTX retractor blade, profiled lengthwise 93 x 24 mm
MRU-0	MICS retractor blade for transsept. access, 40 x 58 mm
MRX-7	MIDCAB rib blade 50 x 53 mm
MRX-8	MIDCAB rib blade 60 x 53 mm

Fixations/guides

MRN-3	Blade guide transthoracic (Ø 4 mm), 220 mm
MRN-3A	Blade guide transthoracic (Ø 4 mm), 223 mm
MRN-3L	Blade guide transthoracic (Ø 4 mm), 265 mm
MRF-0	Blade guide with single-joint adapter (Ø 4 mm) MRF-1, 200 mm
MRF-0V	Blade guide (Ø 8 mm), 200 mm
MRI-0S	Blade guide for ball adapter (Ø 4 mm), 120 mm
MZI-5	MiLuTx joint connector, distance 30 mm
MRD-8V	FANTASMICS cross bracket for retractor blades 35 mm
MRD-9V	FANTASMICS cross bracket for retractor blades 60 mm

Ball adapters

MRO-0/0V	Ball joint adapter (Ø 4 mm) with excenter and wing screw/hexagon screw
MRR-1/1V	Ball adapter (Ø 8 mm) with excenter and wing screw/hexagon screw for MRR-2/MRR-2V/MRR-2L
MRR-2/2V	Ball joint adapter (Ø 4 mm) with spacing lever 70mm and wing screw/hexagon screw for blade guide MRN-3
MRR-2L	Ball joint adapter (Ø 4 mm) with spacing lever 90mm and hexagon screw for blade guide MRN-3
MRP-5/5V	Ball joint adapter (Ø 8 mm) with wing screw/hexagon screw, left
MRP-6/6V	Ball joint adapter (Ø 8 mm) with wing screw/hexagon screw, right
MRV-9F	Ball joint adapter straight (Ø 4 mm), adjustable length and height
MRV-1F	Ball joint adapter straight (Ø 6.35 mm), adjustable length and height
MRX-5	Ball joint adapter mini front load (Ø 4 mm), adjustable height
MRN-9	Ball adapter (Ø 8 mm) with excenter for MICS retractor system

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	Fastening element for length and height adjustable ball joint adapter with crank

Extension modules

Possible supplementary retractor systems

MTI-0	SUPERFLEX soft tissue retractor

Accessories

LMT-4	Cardan screwdriver
TXW-9X	Screwdriver Allen, 3 mm, sterilizable
MRK-6	Counter wrench for MRK-4/MRK-5
NGM-6	Forceps for changing blades (optional)
MRN-7	Guiding forceps for atrium and septum holders
MRU-9	Guiding clamp for atrium and septum holders

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 MICS intercostal retractor may only be used, reprocessed and disposed of by qualified medical personnel! The MICS intercostal retractor is intended for re-use.

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 MICS intercostal retractor is only intended for short-term use.

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

In medical literature, the following adverse effects are described that can possibly occur during the intended use of the MICS intercostal 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 MICS intercostal 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").
⚠	The MICS intercostal retractor must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to the MICS intercostal 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 CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time. In the same meaning, do not clean instruments containing plastic components with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.

⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilization should be used to activate the shape memory. The following should be observed here: • SUPERPLAST instruments must be stored in such a way that they are not prevented from regaining their original shape by environmental influences (e.g., other instruments or restricted space). • After disinfection/sterilization, allow the SUPERPLAST instruments to cool down to room temperature. The functionality of the instruments may be impaired if they are bent at temperatures in excess of approx. 40 °C.
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). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • 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!

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 MICS intercostal retractor is a U-shaped bar retractor with one fixed and one movable retractor arm. A gear control is used to move the flexible retractor arm along the toothed rack. Different retractor blades can be used at the distal end of the two retractor arms.

In particular, the MICS intercostal retractor is used for intercostal approaches and partial sternotomies in conjunction with the associated retractor blades and other relevant accessories.

The two models of the MICS intercostal retractor MRP-1 (Fig. 0a) and MRP-1F (Fig. 0b) differ in two respects. One is in the arm length and the other is the distal end of the retractor arms. Unlike the MRP-1F, the MRP-1 features an alternative attachment for retraction elements (e.g., inferior retraction of the atrial wall) at the distal end of the retractor arms.

Arm length: 90 mm

Fig. 0a: MRP-1

Arm length: 75 mm

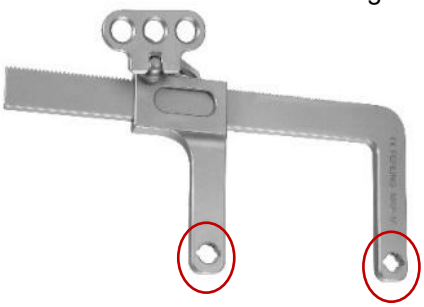


Fig. 0b: MRP-1F

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the MICS intercostal retractor, ensure that the surgical site has been prepared accordingly beforehand.
⚠	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.

Application with intercostal access
(e.g. minimally invasive exposure of the mitral valve)

Fig. 1 depicts a possible overall configuration. Deviations, e.g. in the blade variants, are possible (see Table 1, Pages 1-2).
To optimize access, the body is open facing the surgeon and the toothed rack is positioned medially. All accessory components can be selected and positioned according to their purpose. Table 2 lists the corresponding components.

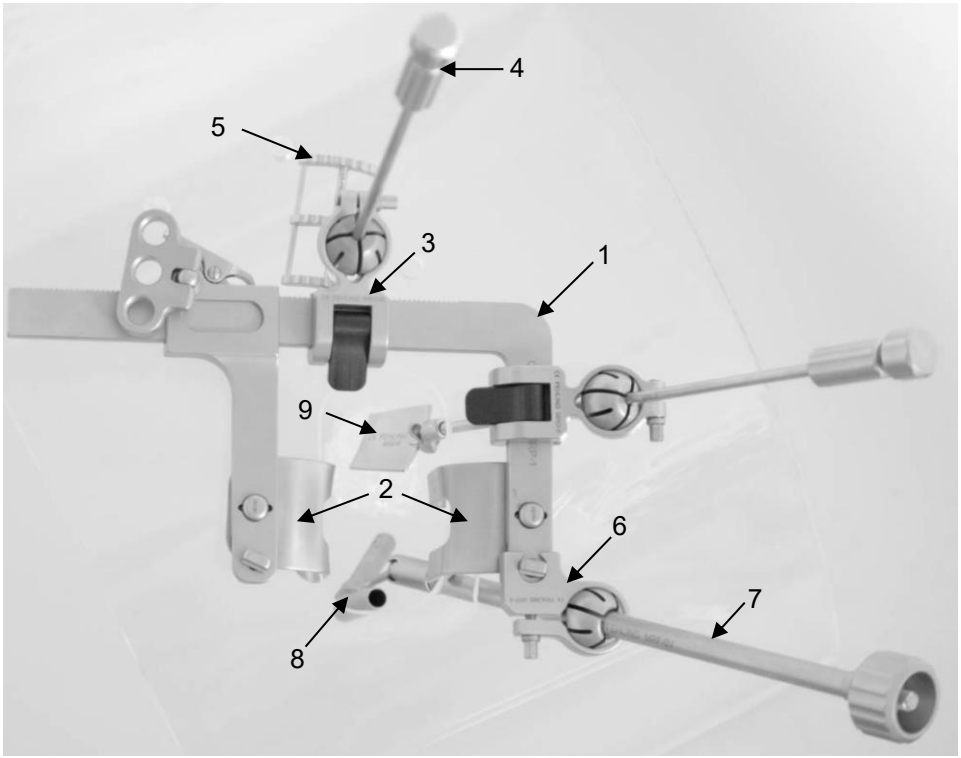


Fig. 1: Configuration example for the MICS intercostal retractor MRP-1 on the thorax model from the surgeon's perspective

Table 2: List of the corresponding components

	Article no.	Description
1	MRP-1	MICS Intercostal retractor with longer retractor arms, body only
2	MRP-2/3/4, MRO-7, MRP-2F/3F/4F, MRP-2V/3V/4V, MRO-7V, MRQ-7/8/9, MRP-2K/3K/4K	Retractor blades (see also Table1, Pages 1-2)
3	MRO-0	Ball adapter (Ø 4 mm) with excenter and wing screw
4	MRN-3	Blade guide transthoracic (Ø 4 mm), 220 mm
5	MRU-1/2/3/4	Atrial bracket
6	MRP-5	Ball adapter (Ø 8 mm) with wing screw, left
7	MRF-0V	Blade guide (Ø 8 mm)
8	MRJ-5/6/7	Suction downholder
9	MRU-6	Downholder for septal fold and diaphragm
Individual configurations of the MICS intercostal retractor with the individual retraction elements are possible in principle and are determined by the treating physician.		

Fig. 2: The blades are connected to a retractor arm in a fixed-angle fashion using a ball snap mechanism. Four depths are available (40, 50, 60, 70 mm). The blades are convex toward the ribs to avoid applying pressure to certain parts only and to reduce the risk of fracture. The blade area close to the body is beveled to improve access.	 Fig. 2
Fig. 2a: The blades are connected to a retractor arm in a fixed-angle fashion using a ball snap mechanism. Seven depths are available (40, 50, 60, 70, 80, 90, 100 mm). The blades are convex toward the ribs to avoid applying pressure to certain parts only and to reduce the risk of fracture. This blade variant is fenestrated.	 Fig. 2a
Fig. 2b: The blades are connected to a retractor arm in a fixed-angle fashion using a ball snap mechanism. Three depths are available (40, 50, 60 mm). The blades are convex toward the ribs to avoid applying pressure to certain parts only and to reduce the risk of fracture. This blade variant is fenestrated and features a slot at the top and bottom for inserting a spatula.	 Fig. 2b
Fig. 2c: The blades are connected to a retractor arm in a fixed-angle fashion using a ball snap mechanism. Three depths are available (40, 50, 60 mm). The blades are convex toward the ribs to avoid applying pressure to certain parts only and to reduce the risk of fracture. This blade variant is fenestrated and features a slot at the top for inserting a spatula. The slot on the bottom has been removed to give the spatula an additional degree of freedom when positioning.	 Fig. 2c
Fig. 2d: The flexible spatula is inserted downwards from the top through the two slots, or when using blades according to Fig. 2c through the single slot, into the retractor blade. The proximal part of the spatula is bent outwards over the retractor arm without restricting the view of or access to the surgical site. The distal end of the spatula can be adapted as needed to the anatomical circumstances within the surgical site.	 Fig. 2d
⚠ SUPERPLAST instruments such as the EOJ-7 spatula are intended to be shaped to fit the respective anatomical requirements during surgery. The permissible minimum bending radius is approx. 10 mm.	

⚠ After application, bring the two retractor arms as close together as possible to allow the two blades and the mounted spatulas to be removed from the incision easily.	
To detach the spatula, bend the distal end back until the spatula can be carefully pulled through the single or two slits resp. in the blade. During reprocessing, the activation of the shape memory will straighten out any remaining bending.	
⚠ The spatula must always be removed from the surgical site at the same time as the blade and be removed from the blade once it is no longer in the surgical site. Do not pull the EOJ-7 spatula through the slit in the blade when it is bent. Avoid bending the spatula too far.	
⚠ The spatulas are made of martensitic NiTi material with shape memory. They are pliable at room temperature and regain their initial shape during reprocessing due to the heat applied there. Do not bend when shaping the instrument during use, but leave a minimum permissible radius of approx. 10 mm.	
Fig. 3 depicts the MRO-0 ball adapter. This can be positioned anywhere on the toothed rack, or if appropriate, also medially on the retractor arms next to the blades and fixated with the excenter bracket. Depending on patient's anatomy and the position of the incision, the ball on the toothed rack can be aligned medially or laterally. To position the adapter, the excenter lever must point upwards. To lock, the excenter lever is pushed to an approx. 45° position (see Fig. 3a).	 Fig. 3  Fig. 3a
Fig. 3b illustrates the alternative option in case the intercostal incision has been placed more postero-laterally and the desired position for the transthoracic atrial retractor can thus no longer be achieved with the MRO-0 ball joint adapter. The alternative is to combine the MRR-1 ball joint adapter with the MRR-2 ball joint adapter with spacing lever. In this way, the position of the transthoracic atrial retractor can be continuously shifted medially by 20 to 25 mm.	 Fig. 3b
 Fig. 4: MRN-3 – Blade guide for transthoracic atrial retractor	

Fig. 5 illustrates insertion of the MRN-3 blade guide through the MRO-0 ball joint adapter and the thoracic wall. The analog insertion of the MRN-3 blade guide through the MRR-2 ball joint adapter is not illustrated.

Fig. 5a: The hexagon screw of the ball joint adapter is tightened with the LMT-4 cardan screwdriver (see 8) Required accessories).

Fig. 5

Fig. 6:
Atrial hooks
MRO-2,3,4,5,6
(30, 40, 50, 60, 70 mm)

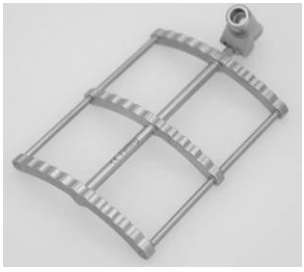


Fig. 7:
Atrial bracket
MRU-1,2,3,4
(45 x 30, 60 x 30, 45 x 45, 60 x 45 mm)

Fig. 7a
Atrial blades
MRN-4,5,6
(30, 40, 50 mm)

Fig. 7b
Atrial hook
Expandable
MSN-2/3

Fig. 8: Guiding forceps MRN-7 are an auxiliary instrument for inserting the atrial hooks or alternatively the atrial brackets or atrial blades into the surgical site (cf. Figs. 6 and 7).

Fig. 8

Fig. 9

Fig. 9 illustrates the insertion of an atrial hook or (not shown) an atrial bracket or atrial blade into the MRN-7 guiding forceps.

The MRN-7 guiding forceps consist of a sleeve with distal half ring and proximal handle and a rod which passes through the sleeve, and is moved via a thread in the sleeve at its proximal end.

⚠ To accommodate the atrial hooks, the rod must be positioned such that it does not protrude from the distal end of the guiding sleeve.

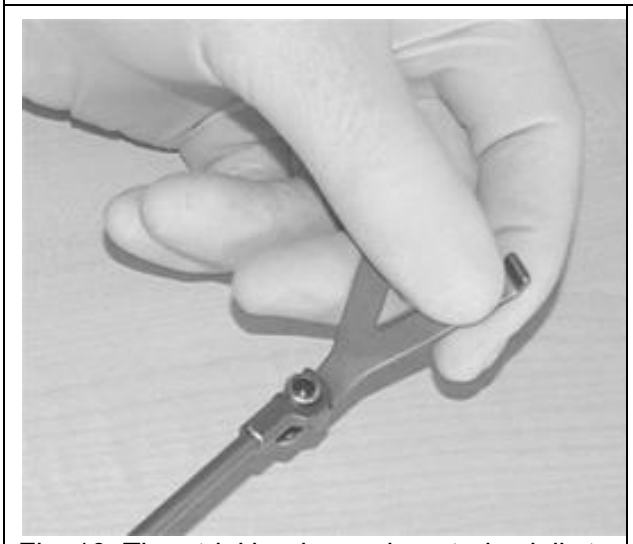


Fig. 10: The atrial hooks are inserted axially to the blade guide in its distal mount up to the lateral stop.

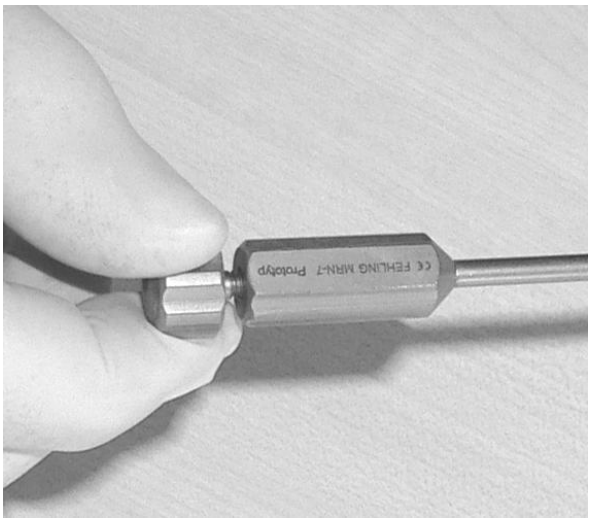


Fig. 11: By rotating the proximal small handle, the guiding rod is pushed onto the atrial hooks, resulting in a secure connection between the elements.

Fig. 12

Fig. 12: The atrial hook is inserted into the surgical site through the intracostal incision. The blade guide is screwed into the mount of the atrial hook as far as the stop.

⚠ The ball of the MRO-0 ball adapter must be in a relaxed condition during the screwing process.

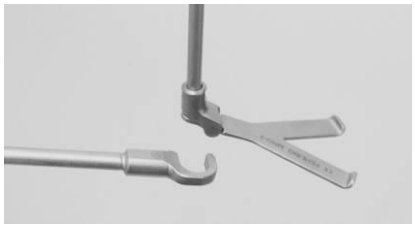


Fig. 13

Fig. 13: Untwisting the small proximal handle of the guiding forceps loosens the connection between guiding forceps and atrial blade. The guiding forceps are released from the atrial blade and retracted from the surgical site. The atrial hook is now placed in the desired position within the atrium. Once this position is reached, the ball joint of the MRO-0 adapter is fixated by rotating the wing screw clockwise.

Fig. 14a: To optimize mitral valve exposure, adjust the angle of the atrial hook by rotating the small proximal handle of the blade guide.

Fig. 14b depicts the MRU-9 insertion forceps, which can be used as an alternative to the MRN-7 guiding forceps (Fig. 8) for inserting the atrial hook.

The advantage: the atrial hook can be fixated by simply squeezing the jaws together.

The disadvantage: opening the jaws in the surgical site, which is required to release the atrial hook, takes up more space.

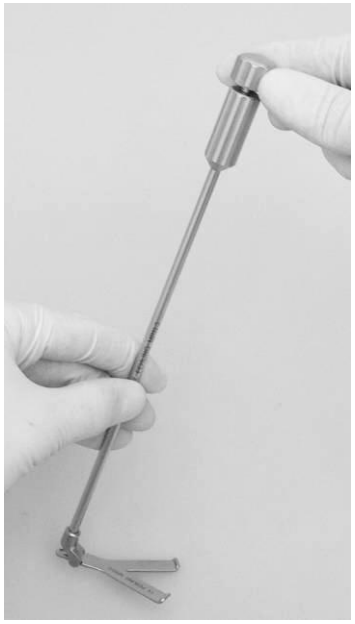


Fig. 14a

Fig. 14b

Fig. 15

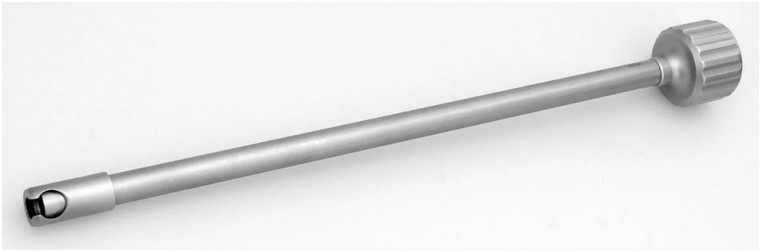


Fig. 16

Fig. 17a

Fig. 17b

The elements depicted in Figs. 15, 16 and 17a/b offer the option of permanently keeping the indicated atrium laterally open in a simple and space-saving manner, while at the same time keeping it permanently free through suction (cf. Fig. 1). The MRP-5/6 adapters are available in right-hand and left-hand versions. This enables flexible application options according to surgical requirements and personal preferences.

Fig. 18 illustrates insertion of the inner rod through the tubular sleeve of MRI-0V. Here it should be ensured that the crossbar at the distal end of the inner rod slides into the two distal oblong slots of the sleeve.

Fig. 18

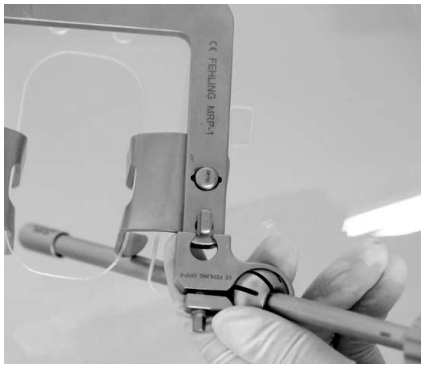
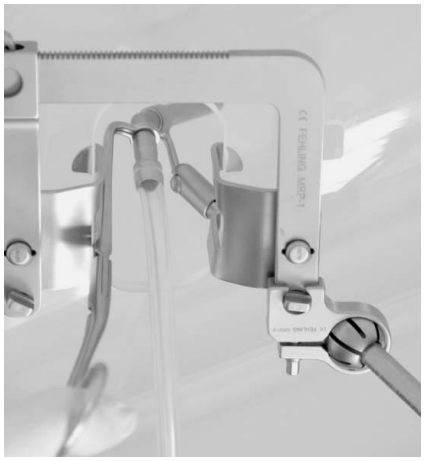
Fig. 19 illustrates how the previously assembled components of the blade guide are pushed through the ball. The third component of the blade guide, the clamping nut, is not yet screwed on.	 Fig. 19
Fig. 20 shows how to screw on the clamping nut. Only screw on the clamping nut so far that the distal mount for the suction downholder is still freely accessible for the ball of the suction downholder.	 Fig. 20
Fig. 21 illustrates the connection of the MRP-5 ball joint adapter to the lateral end of the retractor body. To optimize access, it is recommended to connect to the right (inferior) retractor arm as perceived by the surgeon. The adapter is placed on the end of the retractor arm using the slot provided for this purpose. Make sure that the latch attached to the retractor arm is aligned parallel to the retractor arm in this process. As soon as the adapter is in position, the latch is rotated 90°, thus securing the connection to the retractor. The wing screw of the ball adapter is used to fasten the blade adapter in the selected position.	 Fig. 21
Fig. 22 illustrates the connection of the suction downholder to the blade guide. Beforehand, a suction tube with a lumen of 8 mm is placed on the proximal end of the suction downholder. The other end of the suction tube is connected to the suction inlet of the heart-lung machine. The ball of the suction downholder is inserted into the mount provided for this purpose at the distal end of the blade guide. To facilitate insertion of the suction downholder into the surgical site in case of narrow accesses, the MRJ-4 guiding forceps can be used as an option - as illustrated here. The clamping nut of the blade guide is tightened to such an extent that the ball is held at a stable angle in the mount in the position intended for operational use. ⚠ The margin of movement of the suction downholder is maximized by aligning the lateral opening of the mount with the distal end of the suction downholder (Fig. 22). The bar between the ball and tube of the suction downholder can then - if required - utilize the space of the lateral opening.	 Fig. 22

Fig. 23 illustrates the downholder for the septal fold and diaphragm (cf. 10 in Fig. 1). The MRO-0 (Fig. 3) and MRN-3 (Fig. 4) elements, which are to be attached to the inferior retractor arm, are required for assembly. The procedure is the same as that for the application of the transthoracic atrial retractor. However, here the MRN-3 blade guide is inserted through the ICR located inferior to the main incision. In all other respects, the procedure is the same as that for placement of the transthoracic atrial retractor (3, 4, and 5). Ensure that the downholder for the septum fold is positioned with its convex side on the side of the septum: one must be able to see the marking placed on the concave side.	 Fig. 23
Fig. 24 depicts the ball adapter mini front load (Ø 4 mm) MRX-5 in conjunction with the flexible retaining element for the mitral valve cusp (Ø 4 mm) MRX-1V. This setup can be used for chordae (tendinous cords) replacement.	 Fig. 24
Fig. 24a illustrates an alternative in the form of the MTI-0 for the MRX-5 shown in Fig. 24 in conjunction with the MRX-1V. To insert the MTI-0 mesh retractor, this is rolled up by hand and inserted into the mitral valve annulus using a MICS needle holder. **Please observe the Instructions for Use G096!**	 Fig. 24a

⚠	Ensure that the various retaining elements are fastened securely! Risk of injury!
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

Application with intercostal access
(e.g. use in MIDCAB)

Fig. 25 depicts a possible overall configuration. The toothed rack of the retractor body is positioned medially here. Alternatively, lateral positioning would also be possible. All accessory components can be positioned according to their purpose.
Table 3 lists the corresponding components.

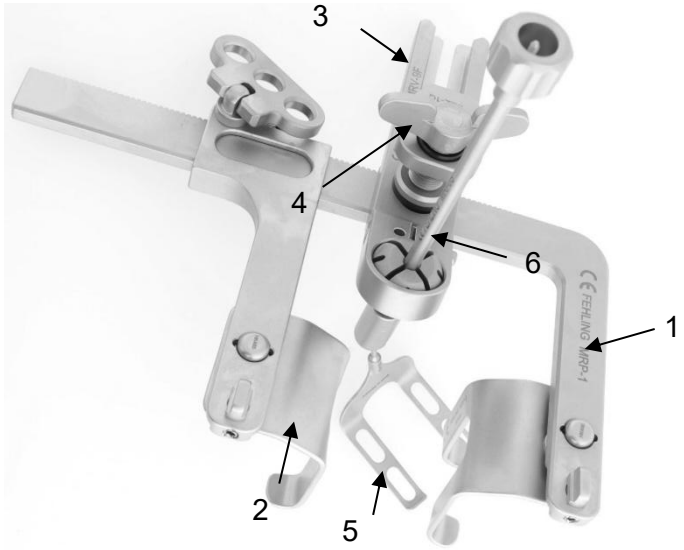


Fig. 25: Configuration example for the MICS intercostal retractor MRP-1 with a myocardial muscle stabilizer on a blade guide attached to a ball adapter and a fastening element as a middle arm

Table 3: List of the corresponding components

	Article no.	Description
1	MRP-1	MICS Intercostal retractor with longer retractor arms, body only
2	MRP-2/3/4, MRO-7, MRP-2F/3F/4F, MRP-2V/3V/4V, MRO-7V, MRQ-7/8/9, MRP-2K/3K/4K	Retractor blades for MRP-1 (see also Table1, Pages 1-2)
3	MRV-9F	Ball joint adapter straight (Ø 4 mm), adjustable length and height
4	MZZ-1Q	Clamping element for length and height adjustable ball adapter
5	MRR-3V	Myocardial muscle stabilizer with ball connector (Ø 7 mm)
6	MRI-0S	Blade guide for ball adapter (Ø 4 mm), 120 mm
Individual configurations of the MICS intercostal retractor with the individual retraction elements are possible in principle and are determined by the treating physician.		

Fig. 26 depicts the MRV-9F ball adapter, which can be mounted either on the toothed rack or the retractor arms of the MRP-1 retractor body.

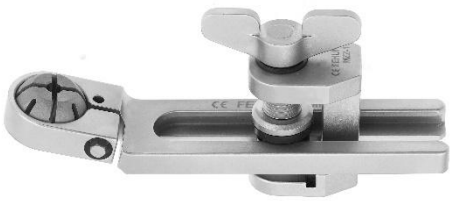


Fig. 26

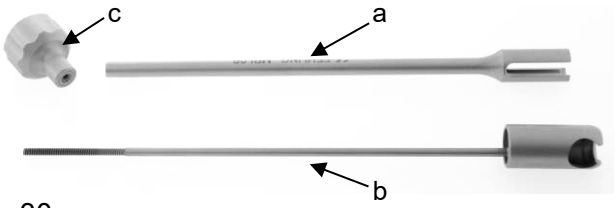
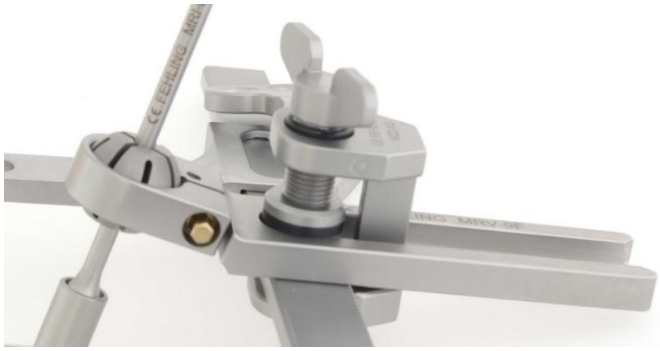
Fig. 27: The hexagon screw of the ball joint adapter MRV-9F is tightened with the LMT-4 cardan screwdriver (see 8) Required accessories).	 Fig. 27
Fig. 28 depicts the MRI-0S blade guide.	 Fig. 28
Fig. 29 depicts the myocardial muscle stabilizer MRR-3V with ball connector (Ø 7 mm).	 Fig. 29
Fig. 30 depicts the MRI-0S blade guide. This is located disassembled in three parts in the instrument tray: outer sleeve (a), inner rod (b) and proximal fixing nut (c).	 Fig. 30
Fig. 31 illustrates insertion of the inner rod (b) through the tubular sleeve (a) of MRI-0S. Here it should be ensured that the crossbar at the distal end of the inner rod (b) slides into the two distal oblong slots of the sleeve (a).	 Fig. 31
Fig. 32 illustrates the insertion of MRI-0S through the ball of MRV-9F. The third component of the blade guide, the clamping nut, is not yet screwed on.	 Fig. 32

Fig. 33 shows how to mount the clamping nut. Only screw on the clamping nut so far that the distal mount for the myocardial muscle stabilizer MRR-3V is still freely accessible for the ball connector of the myocardial muscle stabilizer (see Fig. 33a).	 Fig. 33  Fig. 33a
Fig. 34 illustrates the insertion of the myocardial muscle stabilizer MRR-3V into the mount of the blade guide MRI-0S.	 Fig. 34
Fig. 35 illustrates how the MRV-9F adapter is mounted on the MRP-1 retractor body.	 Fig. 35

⚠	Ensure that the various retaining elements are fastened securely! Risk of injury!
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

Application with large intercostal access
(e.g. MILuTX use = lung transplant)

Fig. 36 depicts a possible overall configuration. A joint connector is used to connect two MICS intercostal retractors. Rotatable crossbars which can each accommodate 2 retractor blades, are used for better adaptation of the retractor blades to the operating site. All accessory components can be positioned according to their purpose.
Table 4 lists the corresponding components.

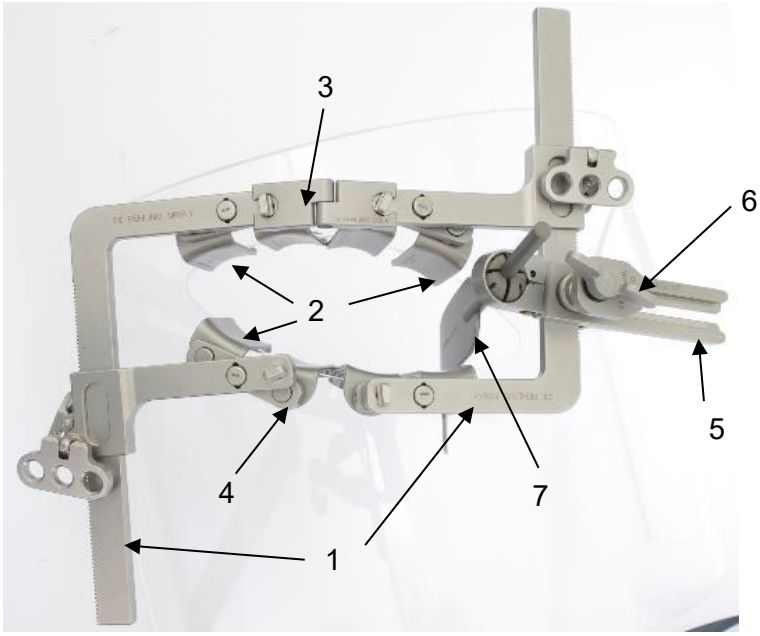


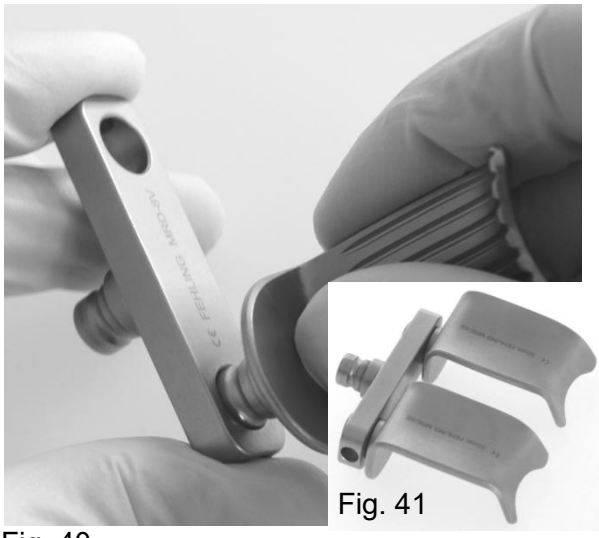
Fig. 36: Configuration example for two MICS intercostal retractors connected by means of a joint connector

Table 4: List of the corresponding components

	Article no.	Description
1	MRP-1	MICS Intercostal retractor with longer retractor arms, body only
2	MRI-1M/2M/3M/4M/5M/6M/7M/8M/9M MRE-4M/5M/6M/7M/8M/9M	Retractor blades for MRP-1 (see also Table1, Pages 1-2)
3	MZI-5	MiLuTx joint connector, distance 30 mm
4	MRD-8V/9V	FANTASMICS cross bracket for retractor blades
5	MRV-1F	Ball joint adapter straight (Ø 6.35 mm), adjustable length and height
6	MZZ-1Q	Clamping element for length and height adjustable ball adapter
7	MRV-7/7V/8/8V	SUPERPLAST spatula
Individual configurations of the MICS intercostal retractor with the individual retraction elements are possible in principle and are determined by the treating physician.		

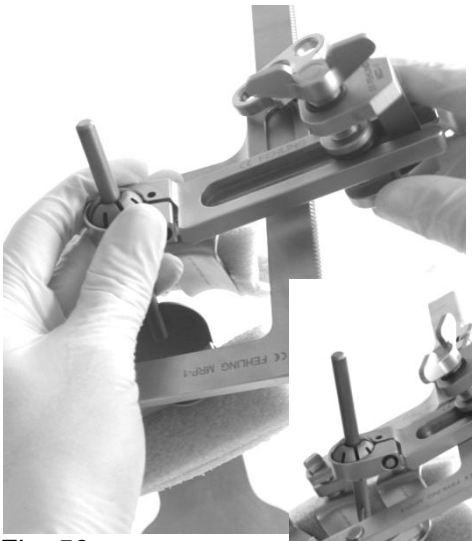
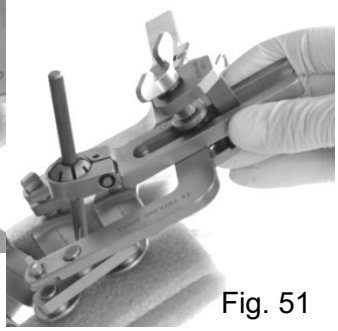
A joint connector is attached to combine two MICS intercostal retractors (Fig. 37).
To attach the joint connector, the rotating locating pins of both retractors must first be aligned with the retractor arm. The joint connector can then be slid onto the respective retractor arms. To secure the connection, the rotatable locating pins are again rotated by 90° as illustrated.

Fig. 37

⚠	Ensure that the joint connector is fastened securely! Risk of injury!
The cross bracket (Fig. 38) is fitted with a locating pin same as the retractor blades and can be inserted in exactly the same manner into the respective retractor arm. The cross bracket is retained permanently by means of a pressure element incorporated in the retractor and can be removed again by applying slight counterpressure. The retractor blades can be inserted into the cross bracket in the same manner.	 Fig. 38
Special retractor blades are used for this application (Fig. 39). These retractor blades are connected to the cross bracket in a fixed-angle fashion using a ball snap mechanism. Eight depths are available (23, 33, 43, 53, 63, 73, 83, 93 mm). To be able to attach these retractor blades in pairs to the cross bracket, they are narrower (15, 24 mm) than the other retractor blades. The retractor blades are shaped convex and longitudinal toward the ribs to avoid applying pressure to certain parts only and to reduce the risk of fracture.	 Fig. 39
⚠	Ensure that the retractor blades and the cross bracket are fastened securely! Risk of injury!
To assemble the retractor, first connect the retractor blades to the cross brackets. Depending on the anatomical requirements, cross brackets in two different sizes (35 and 60 mm) and retractor blades in different widths (15 and 24 mm) and depths (25 - 95 mm) can be selected. Fig. 40 illustrates how the retractor blade with its pin is inserted into the blade mount on the cross bracket up to the stop. The retractor blade is fixated there by means of a ball snap mechanism, yet remains rotatable. The cross bracket is fitted with two retractor blades each (see Fig. 41).	 Fig. 41 Fig. 40

The cross bracket fitted with two retractor blades is now connected to the retractor body. Fig. 42 illustrates how the pin of the cross bracket is inserted into the blade mount of the retractor arm up to the stop. The cross bracket is fixated there by means of a ball snap mechanism, yet remains rotatable. Fig. 43 illustrates the retractor body fully fitted with two cross brackets.	 Fig. 42  Fig. 43
Fig. 44 depicts the retractor in situ.	 Fig. 44
A second body, as described before, is now configured and inserted into the surgical site. Fig. 45 clearly demonstrates how the retractors adapt optimally to the curved surgical site due to the rotatable retractor blades and cross brackets.	 Fig. 45

As an option, the MICS intercostal retractors can be connected with MILuTX joint connectors MZI-5 to form a fixed body system (Fig. 46).	 Fig. 46
Fig. 47 illustrates the adjustable ball adapter used to attach the diaphragm/lung spatula. The adapter consists of the elements MRV-1F and MZZ-1Q. Before attaching the adapter to the MICS intercostal retractor, the spatula should be connected to the adapter and the two components of the adapter should be joined together.	 Fig. 47
Figs. 48 and 49 illustrate how the MZZ-1Q retaining element is connected to the MRV-1F element. Attention should be paid to the correct assembly of the two elements. Please also observe the Instructions for Use G217 for this purpose.	 Fig. 48  Fig. 49

Figs. 50 and 51 illustrate how the lung spatula connected to the adapter is inserted into the surgical site and how the adapter is placed on the retractor body.	 Fig. 50  Fig. 51
Once the adapter is placed on the retractor, the position of the lung spatula can be adjusted as desired. Once the desired position has been achieved, the adapter and spatula are fixated. Fig. 52 illustrates how to fixate the lung spatula in the adapter ball using the LMT-4 cardan screwdriver (see 8) Required accessories). Fig. 53 illustrates how to fixate the adapter on the retractor body by rotating the wing screw.	 Fig. 52  Fig. 53
⚠	Ensure that the various retaining elements are fastened securely! Risk of injury!
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

Application in partial sternotomy

Fig. 54 depicts a possible overall configuration. With regard to the use of the MICS intercostal retractor in partial sternotomy, a special wide MICS retractor blade is used on the movable retractor arm. All accessory components can be positioned according to their purpose.
Table 5 lists the corresponding components.

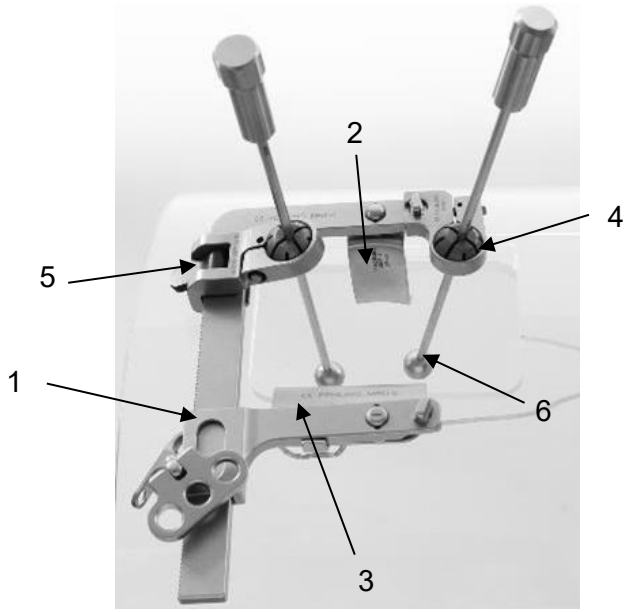


Fig. 54: Configuration example for the MICS intercostal retractor in a partial sternotomy

Table 5: List of the corresponding components

	Article no.	Description
1	MRP-1	MICS Intercostal retractor with longer retractor arms, body only
2	MRP/MRO/MRQ/MRI/MRE	Retractor blades for MRP-1 (see also Table1, Pages 1-2)
3	MRU-0	MICS retractor blade for MRP-1
4	MRR-5/6	Ball joint adapter (Ø 4 mm)
5	MRO-0/0V	Ball joint adapter (Ø 4 mm)
6	MRN-3	Blade guide (Ø 4 mm)

Individual configurations of the MICS intercostal retractor with the individual retraction elements are possible in principle and are determined by the treating physician.

A special wider retractor blade is used for partial sternotomy (Fig. 55). The special feature of the blade is the larger width, the off-center arranged mounting bolt as well as the additional stop to prevent twisting under load. This blade is attached to the movable retractor arm as a matter of principle. A standard blade adapted to the surgical site can be attached to the opposite fixed retractor arm.
This special retractor blade, like all other retractor blades, is also fitted with a locating pin. This pin can be inserted into the corresponding hole of the MICS intercostal retractor. The retractor blade is retained permanently by means of a pressure element incorporated in the retractor and can be removed again by applying slight counterpressure.

Fig. 55

Fig. 56

⚠	Ensure that the retractor blades are fastened securely! Risk of injury!
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.
Other holding elements used in this application of the MICS intercostal retractor have already been taken into account as part of the previously mentioned applications.	

7.1) Extension module

The MICS intercostal retractor can be expanded with other retractor systems (see Table 1 under "Expansion modules", page 1-2).

8) Required accessories

No accessories are required for using the MICS intercostal retractor. However, the NGM-6 blade ejector can be used as an option for removing or changing blades (Fig. 57).

Two 8 mm open-end wrenches (e.g. counter wrench MRK-6 (Fig. 58)) are required to remove the LL connection when using the SUPERPLAST MICS sump suction device MRK-5.

The TXW-9X Allen screwdriver (Fig. 59) is required for application of the MRX-5 ball adapter.
A cardan screwdriver (Fig. 60) is required for application of the MRV-0F ball adapter.

Both the MRN-7 guiding forceps (Fig. 61a) as well as the MRU-9 guiding clamp (Fig. 61b) are required for the application of the atrial retainers and downholders.

Fig. 57

Fig. 60

Fig. 58

Fig. 61a

Fig. 59

Fig. 61b

9) Assembly

For assembly and disassembly of the blade guides (for ball adapters) and guiding tongs, please observe the assembly instructions M36.

For assembly of the MICS intercostal retractor please observe the following assembly instructions.

Fig. 62 depicts the MICS intercostal retractor which is a U-shaped bar retractor. The bar retractor consists of one fixed retractor arm (1), a toothed rack (2) and one movable retractor arm (3).
The proximal end of the movable retractor arm is the cage (4) where the wing screw (5) with the gear as well as the lock (6) are located.

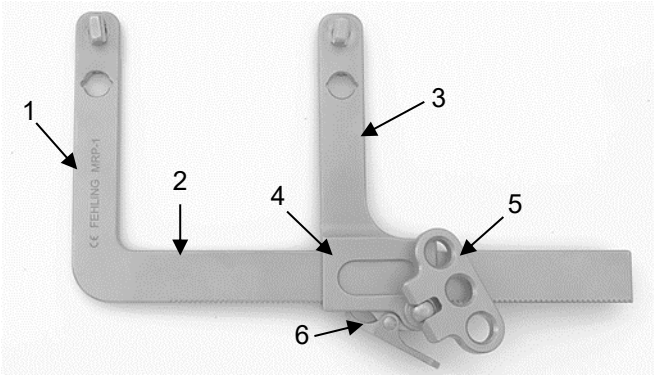


Fig. 62

Insert the toothed rack (2) into the recess of the cage (4). During this process, release the lock (6) by pressing in direction of the toothed rack (2) (Fig. 63).

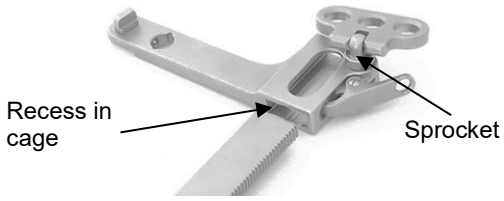


Fig. 63

⚠ Ensure that both retractor arms point in the same direction and the sprocket of the flexile retractor arm points outwards.

Advance the movable retractor arm (3) on the toothed rack (2) inwards towards the fixed retractor arm (1) (Fig. 64).

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

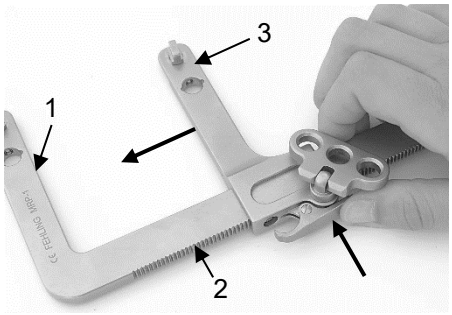


Fig. 64

10) Disassembly

The MICS intercostal retractor must be disassembled as follows for reprocessing.

Fig. 65 depicts the MICS intercostal retractor to demonstrate disassembly.
Advance the movable retractor arm (3) outwards along the toothed rack (2) until it can be removed. At the same time, release the lock (6) by pressing in the direction of the toothed rack (2).

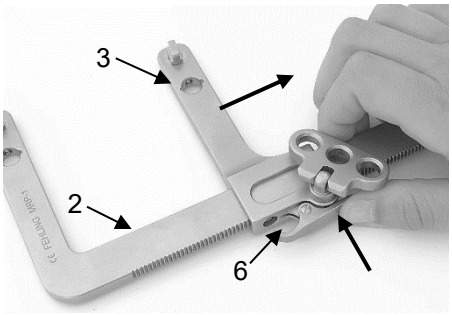
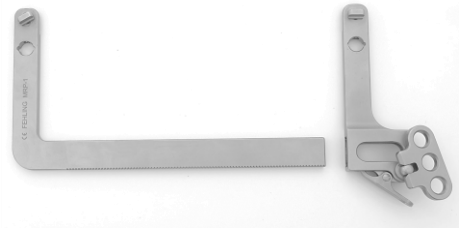


Fig. 65

The instrument is now disassembled into its separate parts (Fig. 66) and can be reprocessed.	 Fig. 66
⚠	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 have the following meaning:

Manufacturer	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

To contact the manufacturer:	
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