FEHLING MICS Intercostal Retractor

Retractor frame	MRP-1	MICS Intercostal Retractor, frame only
	MRP-1F	MICS Intercostal Retractor, short arm, frame only

Table 1: List of components, 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 ... Fenestrated and slotted retractor blades, 40 x 35 mm
MRP-3F ... Fenestrated and slotted retractor blades 50 x 35 mm
MRP-4F ... Fenestrated and slotted retractor blades, 60 x 35 mm
MRP-2V ... Fenestrated retractor blades, 40 x 35 mm
MRP-3V ... Fenestrated retractor blades, 50 x 35 mm
MRP-4V ... Fenestrated retractor blades, 60 x 35 mm
MRO-7V .. Fenestrated retractor blades, 70 x 35 mm
MRQ-7 ..... Fenestrated retractor blades, 80 x 35 mm
MRQ-8 ..... Fenestrated retractor blades, 90 x 35 mm
MRQ-9 ..... Fenestrated retractor blades, 100 x 35 mm
MRP-2K ... Fenestrated and single-slotted retractor blades, 40 x 35 mm
MRP-3K ... Fenestrated and single-slotted retractor blades, 50 x 35 mm
MRP-4K ... Fenestrated and single-slotted retractor blades, 60 x 35 mm
MRI-1M ... MILuTX retractor blade, longitudinally profiled 33 x 15 mm
MRI-2M ... MILuTX retractor blade, longitudinally profiled 43 x 15 mm
MRI-3M ... MILuTX retractor blade, longitudinally profiled 53 x 15 mm
MRI-4M ... MILuTX retractor blade, longitudinally profiled 63 x 15 mm
MRI-5M ... MILuTX retractor blade, longitudinally profiled 73 x 15 mm
MRI-6M ... MILuTX retractor blade, longitudinally profiled 83 x 15 mm
MRI-7M ... MILuTX retractor blade, longitudinally profiled 93 x 15 mm
MRE-4M .. MILuTX retractor blade, longitudinally profiled 23 x 24 mm
MRE-5M .. MILuTX retractor blade, longitudinally profiled 33 x 24 mm
MRE-6M .. MILuTX retractor blade, longitudinally profiled 43 x 24 mm
MRE-7M .. MILuTX retractor blade, longitudinally profiled 53 x 24 mm
MRE-8M .. MILuTX retractor blade, longitudinally profiled 63 x 24 mm
MRE-9M .. MILuTX retractor blade, longitudinally profiled 73 x 24 mm
MRI-8M ... MILuTX retractor blade, longitudinally profiled 83 x 24 mm

Other retaining elements

MRU-1K ..... Atrial loop 27 x 30 mm
MRX-2 ..... Atrial loop 30 x 30 mm
MRU-1 ..... Atrial loop 45 x 30 mm
MRU-2 ..... Atrial loop 60 x 30 mm
MRU-5 ..... Atrial loop, RA (tricuspid) 18x35mm
MRX-3 ..... Atrial loop 30 x 45 mm
MRU-3 ..... Atrial loop 45 x 45 mm
MRU-4 ..... Atrial loop 60 x 45 mm
MRO-2 ..... Atrial retractor, angle-adjustable, 30 mm
MRO-3 ..... Atrial retractor, angle-adjustable, 40 mm
MRO-4 ..... Atrial retractor, angle-adjustable, 50 mm
MRO-5 ..... Atrial retractor, angle-adjustable, 60 mm
MRO-6 ..... Atrial retractor, angle-adjustable, 70 mm
MSN-2 ..... Expandable atrial retractor, 35 x 25 mm
MSN-3 ..... Expandable atrial retractor, 55 x 30 mm
MRN-4 ..... Angle-adjustable atrial blade, 30 x 8 mm
MRN-5 ..... Angle-adjustable atrial blade, 40 x 8 mm
MRN-6 ..... Angle-adjustable atrial blade, 50 x 8 mm
MRU-6 ..... Retainer for septal fold and diaphragm
MRJ-5 ..... Atrial suction retainer 60 mm
MRJ-6 ..... Atrial suction retainer 70 mm
MRJ-7 ..... Atrial suction retainer 80 mm
MRR-3V ..... Myocardial stabiliser with ball connector (Ø 7 mm)
MRR-3S ..... Myocardial stabiliser 90° with ball connector (D7), narrow
MRR-3L ..... Myocardial stabiliser 90° with ball connector KV (D7)
MRJ-9 ..... Myocardial stabiliser 90° with ball connector (D7)
MRV-8 ..... CERAMO SUPERPLAST spatula 2 x 70 x 35 x 182 (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 malleable retractor for MV leaflet (Ø 4 mm), 250 mm
MRX-6 ..... SUPERPLAST eyelid hook (Ø 4 mm), 12x14x250 mm
MRK-5 ..... SUPERPLAST MICS sump suction device LL 270 mm

Ball-joint adapters

MRO-0 ..... Ball-joint adapter (Ø 4 mm) with eccentric cam and wing screw
MRO-0V** ... Ball-joint adapter (Ø 4 mm) with eccentric cam and hexagon screw
MRR-1** ..... Ball-joint adapter (Ø 8 mm) with eccentric cam and wing screw for MRR-2/MRR-2V/MRR-2L

MRI-9M ... MILuTX retractor blade, longitudinally profiled 93 x 24 mm
MRU-0 ..... MICS retractor blade for transseptal 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-joint adapter (Ø 4 mm), 120 mm
MRI-0L .... Blade guide for ball-joint adapter (Ø 4 mm), 200 mm
MZI-5 ..... MiLuTX joint connector, 30 mm spacing
MRD-8V .. FANTASMICS crossbar for retractor blades 35 mm
MRD-9V .. FANTASMICS crossbar for retractor blades 60 mm
MRR-5 ..... Ball-joint adapter D4 for MRP-1 left
MRR-6 ..... Ball-joint adapter D4 for MRP-1 right

Fastening elements

MZZ-1Q ... Fastening element for length- and height-adjustable ball-joint adapter, flat
MZZ-1N ... Fastening element for length- and height-adjustable ball joint adapter, small clamping range
MZZ-2 ..... Fastening element for length- and height-adjustable ball-joint adapter with crank handle
MRO-9 ..... Fixation device for MRN-3, angle-adjustable (Ø 4 mm) with wing screw
MRO-9V .. Fixation device for MRN-3, angle-adjustable (Ø 4 mm) with hexagon screw

MRR-1V ..... Ball-joint adapter (Ø 8 mm) with eccentric cam and hexagon screw for MRR-2/MRR-2V/ MRR-2L
MRR-2/2V ... Ball-joint adapter (Ø 4 mm) with distance lever 70 mm and wing screw/hexagon screw for blade guide MRN-3
MRR-2L ..... Ball-joint adapter (Ø 4 mm) with distance lever 90 mm and hexagon screw for blade guide MRN-3
MRP-5 ..... Ball-joint adapter (Ø 8 mm) with wing screw, left
MRP-5V ..... Ball-joint adapter (Ø 8 mm) with hexagon screw, left
MRP-6 ..... Ball-joint adapter (Ø 8 mm) with wing screw, right
MRP-6V ..... Ball-joint adapter (Ø 8 mm) with hexagon screw, right
MRV-9F ..... Ball-joint adapter straight (Ø 4 mm), variable length and height
MRV-1F ..... Ball-joint adapter straight (Ø 6.35 mm), variable length and height
MRX-5 ..... Ball-joint adapter mini front load (Ø 4 mm), variable height
MRN-9N ..... Ball-joint adapter (Ø 8 mm) with eccentric cam for MICS retractor system
MRU-8F ..... Ball-joint adapter bayonet-shaped D4mm, variable length and height
MRV-0F ..... Ball-joint adapter bayonet-shaped D6.35 mm, variable length and height
MRV-0J ..... Ball-joint adapter bayo. with joint D6.35mm, variable length and height
MRV-0R ..... Ball-joint adapter bayo. with joint D6.35mm, variable length and height

Extension modules
Optional supplementary retractor systems

MTI-0 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 25 x 200 mm, 0.13 mm
MTK-1 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 25 x 200 mm, 0.25 mm
MTK-2 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 25 x 200 mm, 0.34 mm
MTK-3 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 25 x 200 mm, 0.45 mm
MTK-4 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 30 x 300 mm, 0.17 mm
MTK-5 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 30 x 300 mm, 0.22 mm
MTK-6 ..... SUPERFLEX Soft-tissue Retractor, spatulated, 30 x 300 mm, 0.34 mm

Accessories

LMT-4 ..... Cardan screwdriver
TXW-9X ..... Allen screwdriver, 3 mm, sterilisable
MRK-6 ..... Counter spanner for MRK-4/MRK-5
NGM-6 ..... Forceps for blade change (optional)
MRN-7 ..... Guiding forceps for atrial retractors and retainers
MRU-9 ..... Guiding clamp for atrial retractors and retainers
MRJ-4 ..... Insertion forceps for MRJ-5 - 7 suction retainer

⚠	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 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

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.

4) Possible side effects	
The following adverse effects are described in the medical literature and may also occur during the intended use of the MICS Intercostal Retractor: - 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 contain, for example, chromium and/or nickel. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.

5) Before use	
The MICS 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"*).
⚠	The MICS Intercostal Retractor must be handled with care during storage, transportation and cleaning! Avoid impacts and point loading on the MICS 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 striking the instruments or applying pressure to their parts so as not to cause any consequential 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.
⚠	**SUPERPLAST instruments:** Thermal disinfection and steam sterilisation are recommended to activate the shape memory. The following must be observed: • SUPERPLAST instruments must be stored in such a way that the recovery of their straight shape is not hindered by external influences (e.g. other instruments or limited space). • After disinfection/sterilisation, allow the SUPERPLAST instruments to cool to room temperature. Bending the instruments at temperatures above approx. 40°C may impair their function.
Reprocessing limitations	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 marking, 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) <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 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, preference should be given to 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. <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) 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	Validated procedure: Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) Procedure/Parameters: • 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). Ultrasonic cleaning: • 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.
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 <u>Procedure/Parameters:</u> 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 loss of 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 Intercostal Retractor is a U-shaped bar retractor with one fixed and one movable retractor arm. The movable retractor arm is moved along the toothed rack by means of a gear drive. Various retractor blades can be inserted at the distal end of the two retractor arms.

The MICS Intercostal Retractor is specifically intended for use in intercostal approaches and partial sternotomies in conjunction with the corresponding 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 arm length and in the shape of the distal ends of the retractor arms. In contrast to MRP-1F, MRP-1 has an alternative attachment for retraction elements at the distal end of the retractor arms (e.g. for caudal retraction of the atrial wall).

Arm length:
90 mm

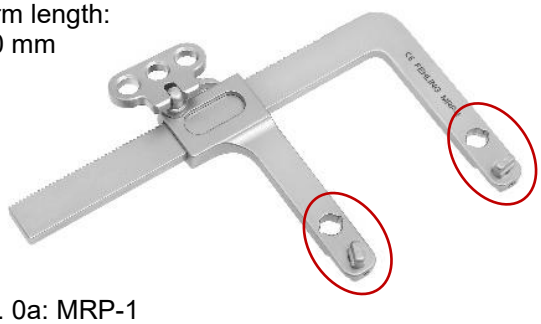


Fig. 0a: MRP-1

Arm length:
75 mm

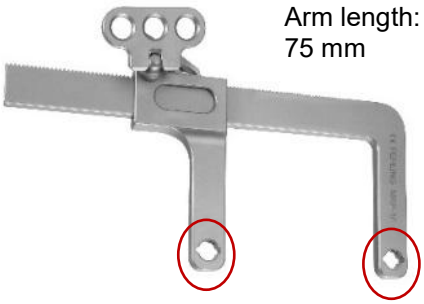


Fig. 0b: MRP-1F

⚠	Use only intact and sterilised products!
⚠	Before inserting the retractors and the retractor components, ensure that the surgical- field has been prepared accordingly beforehand.
⚠	Before using the retractors and the retractor components, ensure that they are fully functional and not damaged!
⚠	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. Care must be taken to ensure that the components used have the correct size and geometry, as well as sufficient stability.

Application with an intercostal approach
(e.g. for minimally invasive exposure of the mitral valve)

Figure 1 shows a possible overall configuration. Alternative configurations, e.g. different blade variants, are possible (see Table 1, pages 1-2).

To optimise access, the open side of the frame faces the surgeon, and the toothed rack is arranged medially. All accessory components can be selected and positioned as required.

The corresponding components are listed in Table 2.

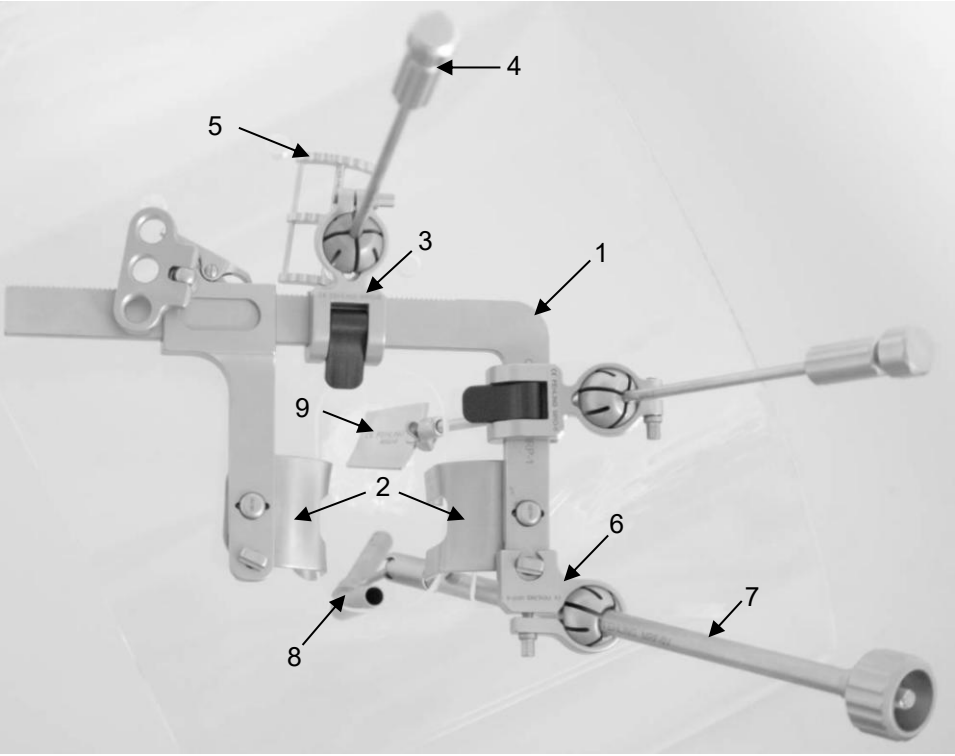


Fig. 1: Configuration example of the MRP-1 MICS Intercostal Retractor on the thoracic model, viewed from the surgeon's perspective

Table 2: List of the corresponding components

	Item no.	Description
1	MRP-1	MICS Intercostal Retractor, frame 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 Table 1, pages 1-2)
3	MRO-0V	Ball-joint adapter (Ø 4 mm) with eccentric cam and hexagon screw
4	MRN-3	Blade guide, transthoracic (Ø 4 mm) in 220 mm
5	MRU-1/2/3/4	Atrial loop (see also Table 1, pages 1-2)
6	MRP-5V	Ball-joint adapter (Ø 8 mm) with hexagon screw, left
7	MRF-0V	Blade guide for ball-joint adapter Ø 8 mm, 220 mm
8	MRJ-5/6/7	Atrial suction retainer
9	MRU-6	Retainer for septal fold and diaphragm
Individual configurations of the MICS Intercostal Retractor with the individual retraction elements are generally possible and are determined by the attending surgeon.		

Fig. 2: The blades are connected to a retractor arm with a ball snap mechanism that retains them at the selected angle. Four blade depths are available (40, 50, 60, 70 mm). The blades are convex towards the ribs to reduce point loading and the risk of fractures. The section of the blade adjacent to the frame is bevelled to improve access.	 Fig. 2
Fig. 2a: The blades are connected to a retractor arm with a ball snap mechanism that retains them at the selected angle. Seven blade depths are available (40, 50, 60, 70, 80, 90, 100 mm). The blades are convex towards the ribs to reduce point loading and the risk of fractures. This blade variant is fenestrated.	 Fig. 2a
Fig. 2b: The blades are connected to a retractor arm with a ball snap mechanism that retains them at the selected angle. Three blade depths are available (40, 50, 60 mm). The blades are convex towards the ribs to reduce point loading and the risk of fractures. This blade variant is fenestrated and has a slot at the top and bottom for insertion of a spatula.	 Fig. 2b
Fig. 2c: The blades are connected to a retractor arm with a ball snap mechanism that retains them at the selected angle. Three blade depths are available (40, 50, 60 mm). The blades are convex towards the ribs to reduce point loading and the risk of fractures. This blade variant is fenestrated and has a slot at the top for insertion of a spatula. The slot at the bottom has been removed to provide greater freedom of movement when positioning the spatula.	 Fig. 2c
Fig. 2d: The flexible spatula is inserted into the retractor blade from top to bottom through the two slots or, when using blades as shown in Fig. 2c, through the single slot. The proximal part of the spatula is bent outwards over the retractor arm so that the view of and access to the surgical site are not restricted. The distal end of the spatula can be adjusted within the surgical site to suit the anatomical conditions.	 Fig. 2d:

⚠ SUPERPLAST instruments, such as the EOJ-7 spatula, are designed to be shaped intraoperatively to suit the specific anatomical requirements. The minimum permissible bending radius is approximately 10 mm.
⚠ After use, bring the two retractor arms as close together as possible so that the blades, together with the attached spatula, can be easily removed through the incision.
To detach the spatula, bend the distal end back until the spatula can be carefully withdrawn through the slot or two slots in the blade. Any residual bend is eliminated by activation of the shape memory during reprocessing.
⚠ The spatula must always be removed from the surgical site together with the blade and then detached. Do not pull the EOJ-7 spatula through the slots in the blade while it is bent. Avoid excessive bending back!
⚠ The spatulas are made of martensitic NiTi alloy and have shape-memory. They are pliable at room temperature and return to their original shape when heated during reprocessing. Do not kink the spatulas when shaping them during use, and observe the minimum permissible bending radius of approximately 10 mm.

Figure 3 shows the MRO-0 ball-joint adapter. It can be attached at any point on the rack or, if appropriate, to the retractor arms immediately medial to the blades and secured using the eccentric cam. Depending on patient anatomy and incision position, the ball can be aligned medially or laterally on the toothed rack. To attach the adapter, the eccentric lever must point upwards. To lock the adapter, press the eccentric lever down to an angle of approximately 45° (see Fig. 3a).

Fig. 3

Fig. 3a

Figure 3b shows the alternative configuration for cases in which the intercostal incision is positioned more posterolaterally, and the required position of the transthoracic atrial retractor can therefore no longer be reached with the MRO-0 ball-joint adapter. This alternative configuration combines the MRR-1 ball-joint adapter with the MRR-2 distance lever. This allows the transthoracic atrial retractor to be continuously repositioned 20–25 mm medially.

Fig. 3b

Fig. 4: MRN-3 – Blade guide for transthoracic atrial retractor

Figure 5 shows insertion of the MRN-3 blade guide through the MRO-0 ball-joint adapter and the chest wall. The MRN-3 blade guide is inserted through the MRR-2 ball-joint adapter in the same manner; this is not shown.

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

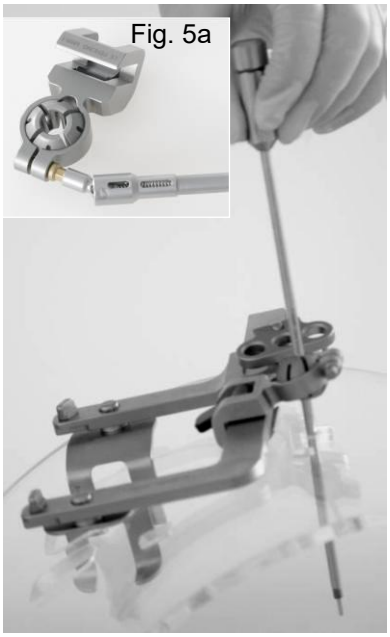


Fig. 5

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

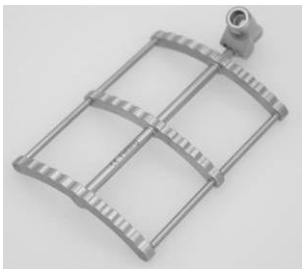


Fig. 7:
Atrial loop
MRU-1,2,3,4
(45 x 30, 60 x 30, 45 x 45, 60 x 45 mm)

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

Fig. 7b:
Atrial retractor, expandable
MSN-2/3

Fig. 8: The MRN-7 guiding forceps are used as an auxiliary instrument for inserting the atrial retractors or, alternatively, the atrial loops or atrial blades into the surgical site (see Figs. 6 and 7).

Fig. 8

Fig. 9

Fig. 9 shows the insertion of an atrial retractor or (not shown) an atrial loop or atrial blade into the MRN-7 guiding forceps.

The MRN-7 guiding forceps consist of a sleeve with a distal retaining ring and a proximal handle, and a rod running through the sleeve that is moved at its proximal end by a thread in the sleeve.

⚠ To accommodate the atrial retractors, position the rod so that it does not protrude from the distal end of the guide sleeve.

Fig. 10: Insert the atrial retractors axially into the distal receptacle of the blade guide as far as the lateral stop.

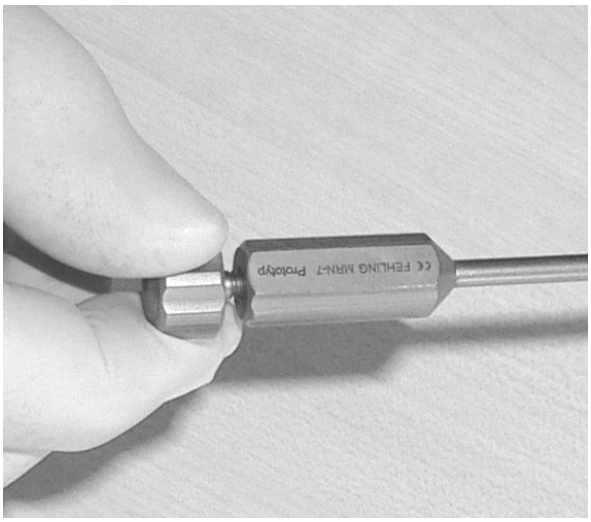


Fig. 11: Turn the small proximal handle to press the guide rod onto the atrial retractors, thereby securely connecting the components.

Fig. 12

Fig. 12: Insert the atrial retractors into the surgical site through the intercostal incision. Screw the blade guide into the receptacle of the atrial retractor as far as it will go.

⚠ When screwing in, the ball joint of the MRO-0 adapter must remain unclamped.

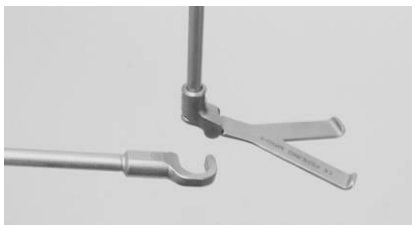


Fig. 13

Fig. 13: Unscrewing the small proximal handle of the guiding forceps loosens the connection between the guiding forceps and the atrial blade. Detach the guiding forceps from the atrial blade and withdraw them from the surgical site. The atrial retractor is now brought into the desired position within the atrium. Once the required position has been reached, lock the ball joint of the MRO-0 adapter by turning the wing screw clockwise.

Fig. 14a: To optimise mitral valve exposure, adjust the angle of the atrial retractor by turning the small proximal handle of the blade guide.

Figure 14b shows the MRU-9 insertion forceps, which may be used as an alternative to the MRN-7 guiding forceps (Fig. 8) to insert the atrial retractor.

The advantage: The atrial retractor can be secured simply by closing the jaws.

The disadvantage: The jaws must be opened within the surgical site to release the atrial retractor, which requires additional space.

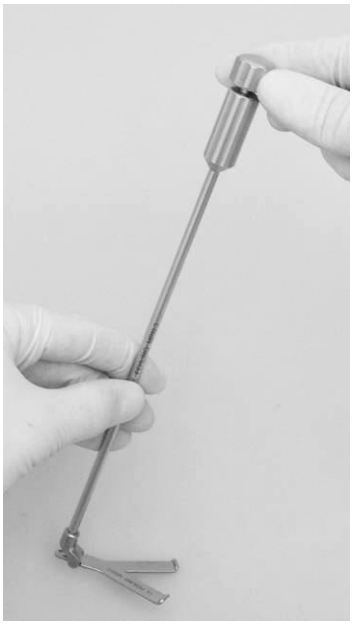


Fig. 14a

Fig. 14b

Fig. 15

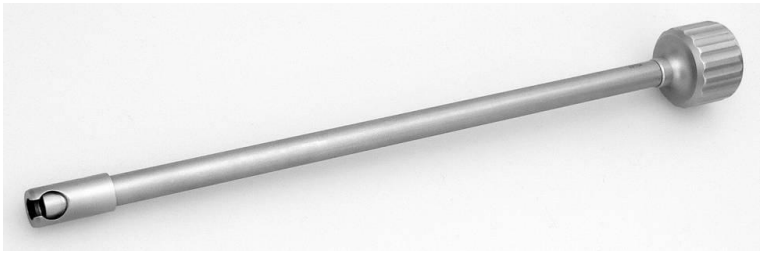


Fig. 16

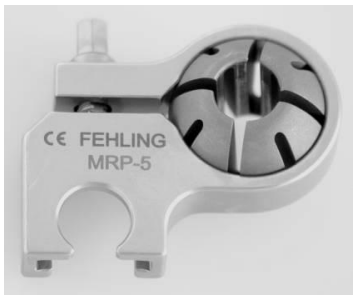


Fig. 17a

Fig. 17b

The components shown in Figures 15, 16 and 17a/b allow the relevant atrium to be held open laterally in a simple, space-saving manner while being continuously kept clear by suction (see Fig. 1). The MRP-5/6 adapters are available in right and left versions. This provides a wide range of configuration options to suit the surgical requirements and the surgeon's own preferences.

Figure 18 shows insertion of the inner rod through the tubular sleeve of MRF-0V. Ensure that the crossbar at the distal end of the inner rod slides into the two distal longitudinal slots in the sleeve.

Fig. 18

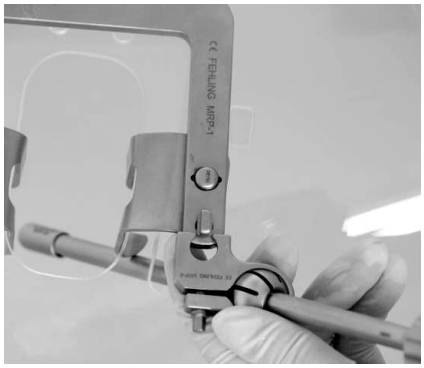
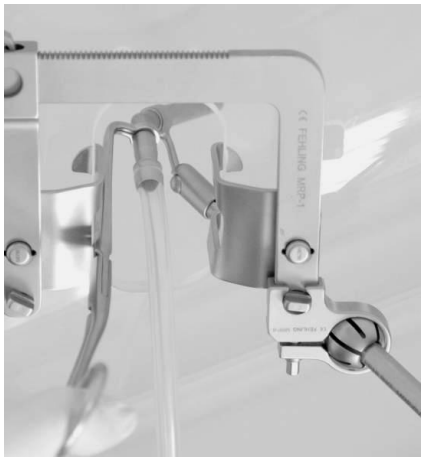
Figure 19 shows how the previously assembled components of the blade guide are pushed through the ball. The third component of the blade guide, the clamping nut, has not yet been screwed on.	 Fig. 19
Figure 20 shows the clamping nut being screwed on. Screw the clamping nut on only far enough to ensure that the ball of the suction retainer can still be freely inserted into the distal receptacle.	 Fig. 20
Figure 21 shows the MRP-5 ball-joint adapter connected to the lateral end of the retractor frame. Connection to the right (caudal) retractor arm, from the surgeon's perspective, is recommended to optimise access. Fit the adapter onto the end of the retractor arm using the slot provided for this purpose. Ensure that the latch on the retractor arm is aligned parallel to the retractor arm. Once the adapter is in position, rotate the latch through 90° to secure the connection to the retractor. Secure the hook adapter in the selected position using the wing screw of the ball-joint adapter.	 Fig. 21
Figure 22 shows the suction retainer connected to the blade guide. First, attach a suction tube with an 8 mm lumen to the proximal end of the suction retainer. Connect the other end of the suction tube to the suction inlet of the heart–lung machine. Insert the ball of the suction retainer into the receptacle provided for this purpose at the distal end of the blade guide. If access is restricted, the optional MRJ-4 guiding forceps may be used to facilitate insertion of the suction retainer into the surgical field, as shown here. Tighten the clamping nut of the blade guide until the ball is held securely in the receptacle in the position required for use and is stable at the selected angle. ⚠ The suction retainer's range of movement is maximised by orienting the lateral opening of the receptacle towards the distal end of the suction retainer (Fig. 22). The connecting stem between the ball and the tube of the suction retainer can then move into the lateral opening as required.	 Fig. 22

Figure 23 shows the retainer for the septal fold and diaphragm (see label 10 in Fig. 1).
The components required for assembly are MRO-0 (Fig. 3) and MRN-3 (Fig. 4), which must be attached to the caudal retractor arm. The procedure is the same as for positioning the transthoracic atrial retractor. However, in this case, the MRN-3 blade guide is inserted through the intercostal space caudal to the main incision. The remainder of the procedure is the same as for positioning the transthoracic atrial retractor (steps 3, 4 and 5). Ensure that the septal fold retainer is positioned with its convex side against the septal side: The marking on the concave side must be visible.

Fig. 23

Figure 24 shows the MRX-5 mini front-load ball-joint adapter (Ø 4 mm) connected to the MRX-1V malleable retaining element for the mitral valve leaflet (Ø 4 mm).
This assembly method can be used for chordal replacement.


Fig. 24

Figure 24a shows the MTI-0 as an alternative to the MRX-5 in the configuration with the MRX-1V shown in Figure 24.
To insert the MTI-0 SUPERFLEX Soft-tissue Retractor, roll it up by hand and insert it into the mitral annulus using the MICS needle holder.

⚠ Please refer to the Instructions for Use G 096 when using the MTI-0 SUPERFLEX Soft-tissue Retractor

Do not use a holding instrument with surgical serrations of any kind to hold the MTI-0.


Fig. 24a

⚠ Ensure that the various retaining elements are securely attached!
Risk of injury!

⚠ Before removing the retractor from the surgical field, ensure that the retractor arms are slowly moved back together.

Application with an intercostal approach
(e.g. for MIDCAB procedures)

Figure 25 shows a possible overall configuration. In this configuration, the toothed rack of the retractor frame is positioned medially. Alternatively, it may be positioned laterally. All accessory components can be positioned as required.
The corresponding components are listed in Table 3.

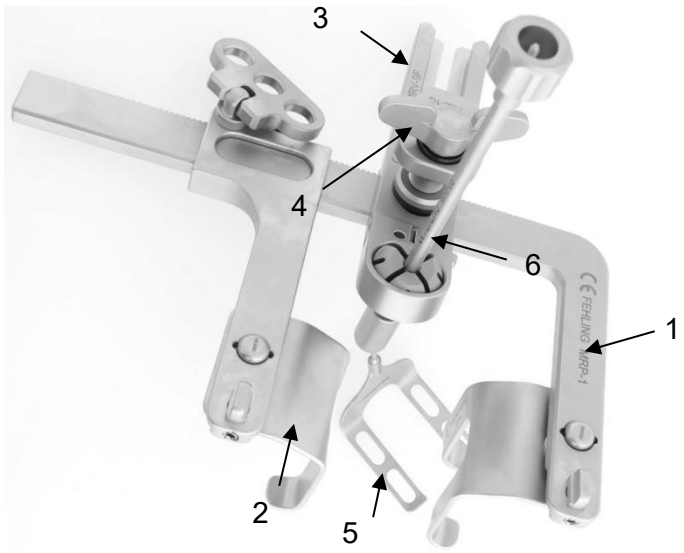


Fig. 25: Example configuration of the MRP-1 MICS Intercostal Retractor with a myocardial stabiliser mounted on a blade guide, which is secured as a central arm using a ball-joint adapter and a fastening element

Table 3: List of the corresponding components

	Item no.	Description
1	MRP-1	MICS Intercostal Retractor, frame 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 Table 1, pages 1-2)
3	MRV-9F	Ball-joint adapter straight (Ø 4 mm), variable length and height
4	MZZ-1Q	Fastening element for length- and height-adjustable ball-joint adapter, flat
5	MRR-3V	Myocardial stabiliser with ball connector (Ø 7 mm)
6	MRI-0S	Blade guide for ball-joint adapter (Ø 4 mm), 120 mm
Individual configurations of the MICS Intercostal Retractor with the individual retraction elements are generally possible and are determined by the attending surgeon.		

Figure 26 shows the MRV-9F ball-joint adapter, which can be mounted either on the toothed rack or the retractor arms of the MRP-1 retractor frame.

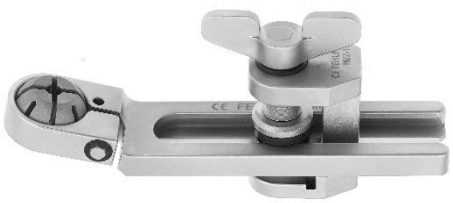


Fig. 26

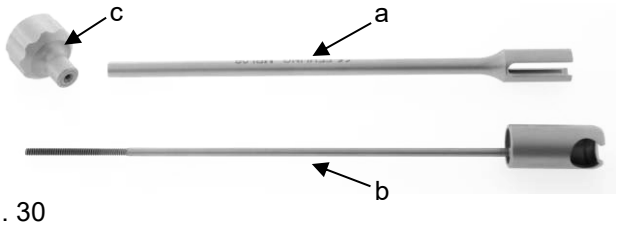
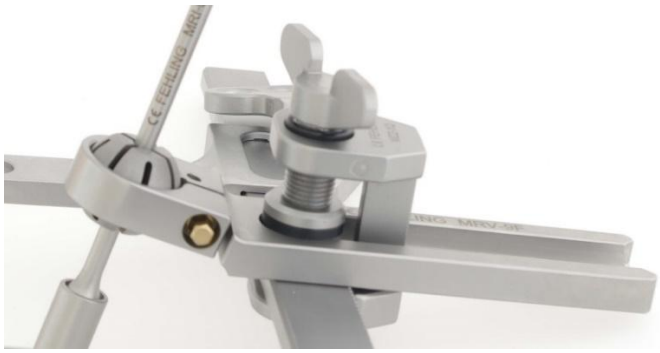
Fig. 27: The hexagon screw of the MRV-9F ball-joint adapter is tightened using the LMT-4 cardan screwdriver (see Section 8) Required accessories and instructions for use G217).	 Fig. 27
Figure 28 shows the MRI-0S blade guide.	 Fig. 28
Figure 29 shows the MRR-3V myocardial stabiliser with ball connector (Ø 7 mm).	 Fig. 29
Figure 30 shows the MRI-0S blade guide. It is provided in the instrument tray, disassembled into three parts: Outer sleeve (a), inner rod (b) and proximal locking nut (c).	 Fig. 30
Figure 31 shows insertion of the inner rod (b) through the tubular sleeve (a) of MRI-0S. Ensure that the crossbar at the distal end of the inner rod (b) slides into the two distal longitudinal slots in the sleeve (a). *For details on handling/assembly, see Assembly Instructions M36.*	 Fig. 31
Figure 32 shows insertion of MRI-0S through the ball of MRV-9F. The third component of the blade guide, the clamping nut, has not yet been screwed on.	 Fig. 32

Figure 33 shows the clamping nut being fitted. Screw on the clamping nut only far enough to ensure that the ball connector of the MRR-3V myocardial stabiliser can still be freely inserted into the distal receptacle (see Fig. 33a).	 Fig. 33  Fig. 33a
Figure 34 shows the insertion of the MRR-3V myocardial stabiliser into the receptacle of the MRI-0S blade guide.	 Fig. 34
Figure 35 shows how the MRV-9F adapter is fitted onto the MRP-1 retractor frame.	 Fig. 35
⚠	Ensure that the various retaining elements are securely attached! Risk of injury!
⚠	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.

Use with a large intercostal approach
(e.g. use of MiLuTX for lung transplantation)

Figure 36 shows a possible overall configuration. A joint connector is used to connect two MICS Intercostal Retractors. Rotatable crossbars, each capable of accommodating two retractor blades, are used to improve adaptation of the retractor blades to the surgical field. All accessory components can be positioned as required.
The corresponding components are listed in Table 4.

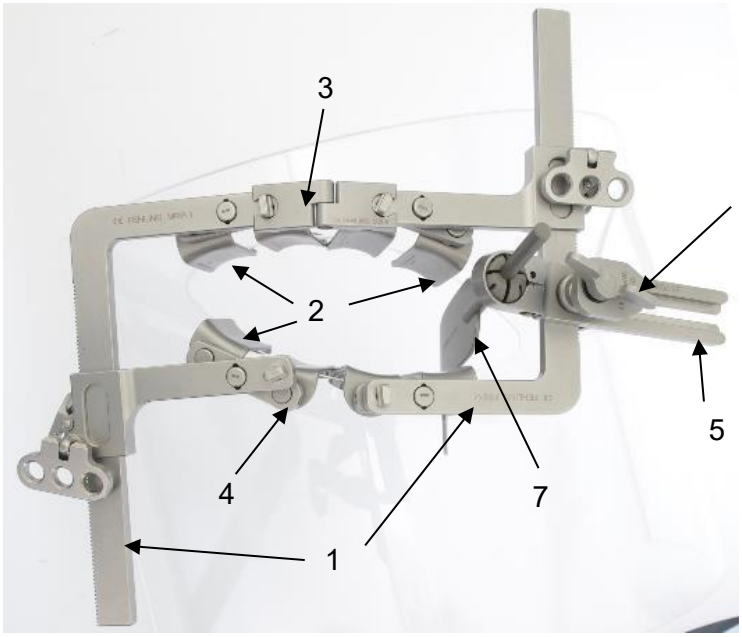


Fig. 36: Example configuration of two MICS Intercostal Retractors connected by means of a joint connector

Table 4: List of the corresponding components

	Item no.	Description
1	MRP-1	MICS Intercostal Retractor, frame only
2	MRI-1M/2M/3M/4M/5M/6M/7M/8M/9M MRE-4M/5M/6M/7M/8M/9M	Retractor blades (see also Table 1, pages 1-2)
3	MZI-5	MILuTX joint connector, 30 mm spacing
4	MRD-8V/9V	FANTASMICS crossbar for retractor blades
5	MRV-1F	Ball-joint adapter straight (Ø 6.35 mm), variable length and height
6	MZZ-1Q	Fastening element for length- and height-adjustable ball-joint adapter, flat
7	MRV-7/8	SUPERPLAST spatula (see also Table 1, pages 1-2)

Individual configurations of the MICS Intercostal Retractor with the individual retraction elements are generally possible and are determined by the attending surgeon.

To connect two MICS Intercostal Retractors, fit a joint connector (Fig. 37).
Before fitting the joint connector, align the rotatable mounting pins of both retractors with their respective retractor arms. The joint connector can then be slid onto the respective retractor arms. To secure the connection, rotate the mounting pins back through 90°, as shown in the Figure.

Fig. 37

⚠ Ensure that the joint connector is securely attached! Risk of injury!

Like the retractor blades, the crossbar (Fig. 38) is equipped with a mounting pin and can be inserted into the respective retractor arm in the same manner. The crossbar is securely retained by a pressure piece integrated into the retractor and can be removed by applying slight counterpressure. The retractor blades can be inserted into the crossbar in the same manner.

Fig. 38

Special retractor blades are used for this application (Fig. 39). These retractor blades are connected securely to the crossbar by a ball snap mechanism, ensuring that the angle remains fixed. Eight blade depths are available (23, 33, 43, 53, 63, 73, 83 and 93 mm). To allow these retractor blades to be attached to the crossbar in pairs, they are narrower (15 or 24 mm) than the other retractor blades. The retractor blades are convex towards the ribs and have a longitudinal profile to reduce point loading and the risk of fractures.

Fig. 39

⚠ Ensure that the retractor blades and crossbar are securely attached!
Risk of injury!

To assemble the retractor, first connect the retractor blades to the crossbars. Depending on the anatomical requirements, crossbars in two different sizes (35 and 60 mm) and retractor blades of different widths (15 and 24 mm) and depths (23–93 mm) can be selected.
Figure 40 shows the retractor blade being inserted by its mounting pin into the blade receptacle in the crossbar as far as it will go. The retractor blade is secured in the receptacle by a ball snap mechanism but remains rotatable.
Each crossbar is fitted with two retractor blades (see Fig. 41).

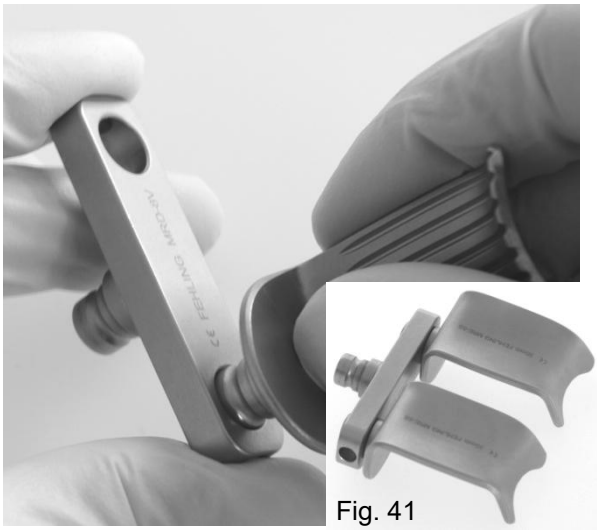


Fig. 40

Fig. 41

The crossbar fitted with two retractor blades is then connected to the retractor frame.
Figure 42 shows the pin on the crossbar being inserted into the blade receptacle in the retractor arm as far as it will go. The crossbar is secured in the receptacle by a ball snap mechanism but remains rotatable.
Figure 43 shows the retractor frame fully fitted with two crossbars.

Fig. 42

Fig. 43

Figure 44 shows the retractor in situ.

Fig. 44

As described above, a second frame is then configured and inserted into the surgical site. Figure 45 clearly shows how the rotatable retractor blades and crossbars allow the retractors to adapt optimally to the curved anatomy of the surgical site.	 Fig. 45
Optionally, the MICS Intercostal Retractors can be connected using MiLuTX MZI-5 joint connectors to form a rigid frame system (Fig. 46).	 Fig. 46
Figure 47 shows the adjustable ball-joint adapter used to attach the diaphragm/lung spatulas. The adapter consists of the MRV-1F and MZZ-1Q components. Before mounting the adapter on the MICS Intercostal Retractor, connect the spatula to the adapter and assemble the two components of the adapter.	 Fig. 47

Figures 48 and 49 show how the MZZ-1Q retaining element is connected to the MRV-1F component. Ensure that the two components are assembled correctly.

Fig. 48

Fig. 49

⚠ Please also refer to the Instructions for Use G 217.

Figures 50 and 51 show how the lung spatula attached to the adapter is inserted into the surgical site and the adapter is mounted on the retractor frame.

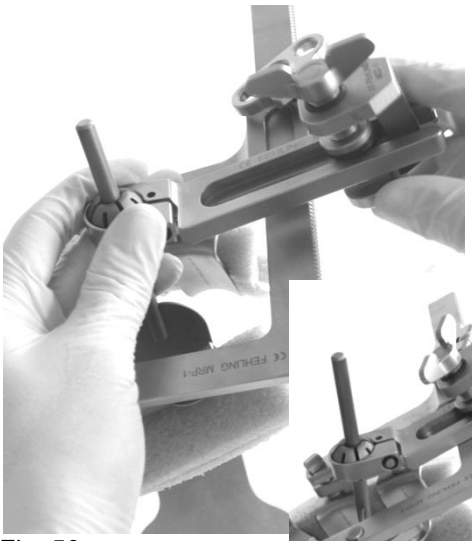


Fig. 50

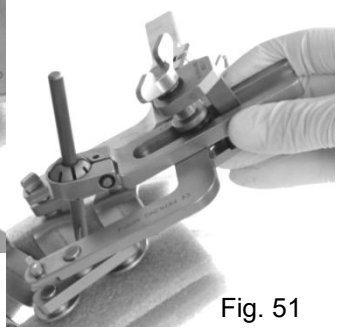


Fig. 51

After mounting the adapter on the retractor, adjust the position of the lung spatula as required. When the required position has been reached, secure the adapter and spatula.
Figure 52 shows how the lung spatula is secured in the ball of the adapter using the LMT-4 cardan screwdriver (see Section 8), Required Accessories).
Figure 53 shows how the adapter is secured to the retractor frame by turning the wing screw.

Fig. 52

Fig. 53

⚠ Ensure that the various retaining elements are securely attached!
Risk of injury!

⚠	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.

Use in partial sternotomy

Figure 54 shows a possible overall configuration. When the MICS Intercostal Retractor is used for partial sternotomy, a special wide MICS retractor blade is fitted to the movable retractor arm. All accessory components can be positioned as required.
The corresponding components are listed in Table 5.

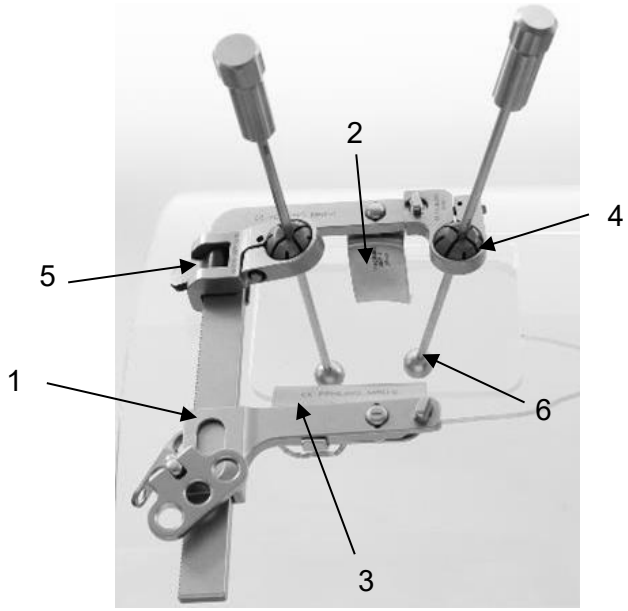


Fig. 54: Configuration example for the MICS Intercostal Retractor for partial sternotomy

Table 5: List of the corresponding components

	Item no.	Description
1	MRP-1	MICS Intercostal Retractor, frame only
2	MRP/MRO/MRQ/MRI/MRE	Retractor blades (see also Table 1, pages 1-2)
3	MRU-0	MICS retractor blade for transseptal access, 40 x 58 mm
4	MRR-5	Ball-joint adapter (Ø 4 mm) left
5	MRO-0V	Ball-joint adapter (Ø 4 mm) with eccentric cam and hexagon screw
6	MRN-3	Blade guide, transthoracic (Ø 4 mm) in 220 mm
Individual configurations of the MICS Intercostal Retractor with the individual retraction elements are generally possible and are determined by the attending surgeon.		

A special wider retractor blade is used for partial sternotomy (Fig. 55). The distinguishing features of the blade are its greater width, the off-centre position of the mounting bolt and the additional stop to prevent rotation under load. This blade is generally fitted to the movable retractor arm. A standard blade suited to the surgical field can be attached to the opposite fixed retractor arm.

Fig. 55

Like all the other retractor blades, this special retractor blade is also equipped with a mounting pin. This pin can be inserted into the corresponding hole in the MICS Intercostal Retractor. The retractor blade is held in place by a pressure piece integrated into the retractor and can be removed by applying slight counterpressure.	 Fig. 56

⚠	Ensure that the retractor blades are securely attached! Risk of injury!
⚠	When inserting the retractor blades, care must be taken not to injure any tissue structures unintentionally (in particular nerves and blood vessels)!
⚠	Excessive and prolonged pressure on the tissue can cause necrosis, ruptures, fractures and other lesions!
⚠	Overloading can cause plastic deformation or fracture of the retractors and retractor components!
⚠	Before removing the retractor and retractor components from the surgical field, ensure that the retractor arms are slowly brought back together.

Other retaining elements used with the MICS Intercostal Retractor in this application have already been covered in the applications described above.

7.1) Extension module

The MICS Intercostal Retractor can be extended with other retractor systems (see Table 1 under "Extension modules", pages 1-2).

8) Required accessories

No accessories are required for use of the MICS Intercostal Retractor. However, the optional NGM-6 blade-changing forceps (Fig. 57) may be used to remove or change blades.

Two 8 mm open-ended spanners, e.g. the MRK-6 counter spanner (Fig. 58), are required to detach the LL connector when using the MRK-5 SUPERPLAST MICS sump suction device.

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

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

Fig. 57

Fig. 60

Fig. 58

Fig. 61a

Fig. 59

Fig. 61b

9) Assembly

Please refer to the Assembly Instructions M 36 for assembly and disassembly of the blade guides (for ball-joint adapters) and guiding forceps.

Please follow the assembly instructions below to assemble the MICS Intercostal Retractor.

Figure 62 shows the MICS Intercostal Retractor, which is a U-shaped bar retractor. The bar retractor consists of a fixed retractor arm (1), a toothed rack (2) and a movable retractor arm (3).

At the proximal end of the movable retractor arm is the housing (4), which accommodates the wing screw (5), together with the gear wheel and lock (6).

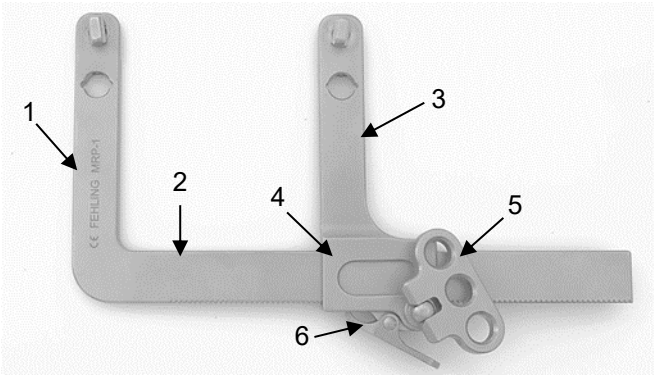


Fig. 62

Insert the toothed rack (2) into the recess in the housing (4). At the same time, release the lock (6) by pressing it in the direction of the toothed rack (2) (Fig. 63).

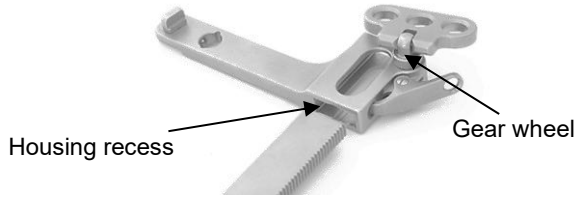
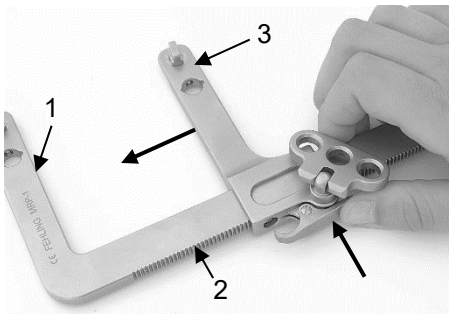


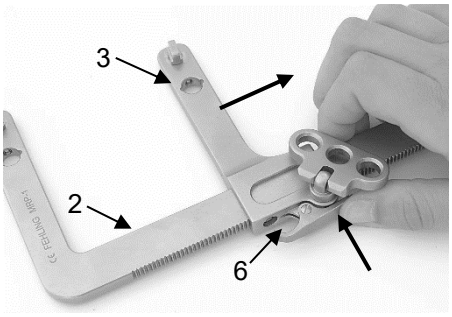
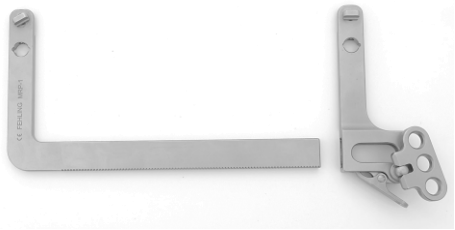
Fig. 63

⚠ Ensure that both retractor arms point in the same direction and that the gear wheel on the movable retractor arm faces outwards.

Slide the movable retractor arm (3) inwards along the toothed rack (2) towards the fixed retractor arm (1) (Fig. 64). After a functional test, the assembled instrument is ready for use again.	 Fig. 64

10) Disassembly

For reprocessing, the MICS Intercostal Retractor must be disassembled as follows.

Figure 65 shows the MICS Intercostal Retractor to illustrate disassembly. Slide 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 it in the direction of the toothed rack (2).	 Fig. 65
The instrument, now disassembled into its individual components (Fig. 66), can be reprocessed.	 Fig. 66

⚠ 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		
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