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INSTRUCTIONS FOR USE - IFU -



FEHLING MICS Retractor System For Minimally Invasive Cardiac Surgery	MRP-2/2V/3/3V/4/4V, MRO-7/7V: Retracting blades for MRP-1	
MRP-1 Intercostal retractor MRO-0/0V Ball-joint adapter with eccentric (Ø 4) MRR-1/1V/2/2L/2V. Ball-joint adapter with distance lever MRP-5/5V/6/6V Ball-joint adapter (Ø 8) MRV-9/9V Ball-joint adapter with sliding ball (Ø 4)	MRU-1/2/3/4 Atrial blade MRO-2/3/4/5/6 Atrial hooks MRN-4/5/6 Atrial blade MRU-6 Stabilizer for septal fold and dia- phragm MRJ-5/6/7 Atrial retractor/suction device	
MRN-3/3L Blade guide for transthoracic atrial retractor MRF-0/0V Blade guide MRI-0/0S Blade guide for ball-joint adapter Ø 4, 120 mm	MRR-3/3V Myocardial muscle stabilizer with ball connector (Ø 7) LMT-4 Cardan screwdriver	

Warning: Prior to processing a risk assessment on the instrument must be performed.

Retractor systems may only be used, processed and disposed of by competent medical personal!

Intended use:

The intercostal retractor MRP-1 is used for the exposition of the heart with minimum invasive, intercostal access.

Before use:

FEHLING INSTRUMENTS retractor systems are delivered non-sterile and have to be cleaned and sterilized by the user before their first and any further use (see reprocessing).

Handle retractors with care on storage, transport and cleaning! Avoid impacts and selective loads! Perform a safety check before each use. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing).

Minimally invasive exposition of the mitral value

Example configuration on the thorax model as seen by the operator

- 1 Intercostal retractor
- 2 Retracting blades for MRP-1
- 3 Ball-joint adapter with eccentric
- 4 Blade guide for transthoracic atrial retractor
- 5 Atrial blade
- 6 Ball joint adapter
- 7 Blade guide
- 8 Atrial retractor/suction device
- 9 Stabilizer for septal fold and diaphragm
- 10 Cardan screwdriver

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Fig. 3

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Fig. 1 shows the possible general configuration.

To optimize the access the frame is open towards the operator and the ratchet is located in median position. All accessory components can be chosen and positioned according to their suitability.

Fig. 2: The blades are connected to a frame in a fixed angle by means of a ball snap mechanism. There is a choice of 4 depths (40, 50, 60, 70 mm). The blades are convex towards the ribs to avoid point loads and the risk of fractures.

In order to enhance the access the blade section near the frame is slanted.

Fig. 3 shows the ball-joint adapter MRO-0. It can be placed in any position on the frame ratchet, but also on the frame bar median next to the blades, if suitable, and fixed with the eccentric bow. Depending on the patient's anatomy and the position of the incision the ball can be oriented on the ratchet in median or lateral direction. To place the adapter the eccentric lever must point upwards. To lock it, the eccentric lever is pushed in an app. 45° position (see fig. 3 a).

Fig. 3b shows the alternative option in case the intracostal incision was placed more posterolaterally and thus the desired position for the transthoracic atrial retractor with the ball-joint adapter MRO-0 can no longer be reached. The alternative is the combination of the ball-joint adapter MRR-1 with the ball adapter with distance lever MRR-2. Thus the position of the transthoracic atrial retractor can be displaced continuously in median direction by 20 to 25 mm.



Fig. 3b

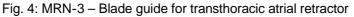
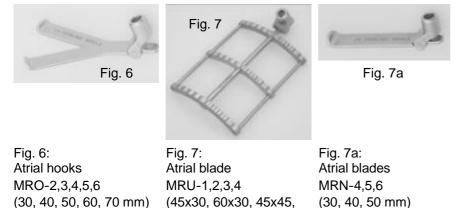
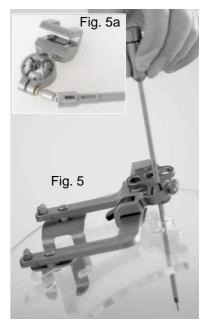


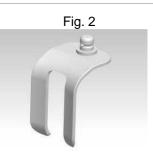
Fig. 5 shows how the blade guide MRN-3 is inserted through the ball-joint adapter MRO-0 and the thoracic wall. It is not shown how the blade guide MRN-3 is inserted through the blade guide MRR-2.

Fig. 5a The hex head screw of the ball-joint adapter is tightened using the Cardan screwdriver LMT-4.



60x45 mm)







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Fig. 8: Guiding forceps MRN-7 is an auxiliary instrument to help insert the atrial hooks or, alternativley, the atrial blades into the situs (cf. fig. 6 and 7).

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Fig. 8	



Fig. 9 shows how an atrial hook or an atrial bow or atrial blade (not shown) is inserted into the guiding forceps MRN-7.

The guiding forceps MRN-7 consists of a sleeve with distal semi-ring and proximal handle and a rod running through the sleeve, which is moved at its proximal end by means of a thread inside the sleeve.

Attention: To receive the atrial hooks the rod has to be positioned such that it does not project out of the distal end of the guiding sleeve.

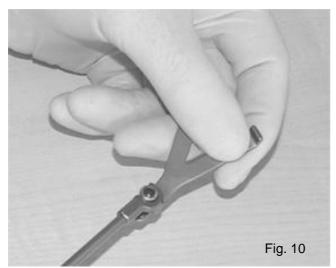


Fig. 10: The atrial hooks are inserted axially to the blade guide in their distal socket up to the lateral stop.

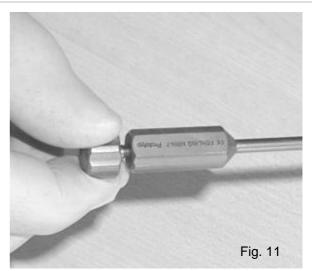


Fig. 11: By turning the small proximal handle the guiding rod is pushed onto the atrial hooks resulting in a secure connection between the elements.

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Fig. 12: The atrial hook is inserted into the situs through the intracostal incision. The blade guide is screwed into the socket of the atrial hook up to the stop.

Attention: The ball of the ball-joint adapter MRO-0 must be released when the blade guide is screwed in.



Fig. 13: By unscrewing the small proximal handle of the guiding forceps the connection between the guiding forceps and the atrial blade is loosened. The guiding forceps is removed from the atrial blade and withdrawn from the situs.

Now the atrial hook is placed in the desired position within the atrium. In this position the ball joint of the adapter MRO-0 is fixed by turning the thumb screw clockwise.

Fig. 14: In order to optimize the exposition of the mitral valve, the angle of the atrial hook is adjusted by turning the small proximal handle of the blade guide.

Fig. 14a shows the introducer forceps MRU-9 that can be used alternatively to introduce the atrial hook. Advantage: The atrial hook can be fastened by simply pressing the shanks together. Disadvantage: Opening the shanks inside the situs which is necessary to release the atrial hook, requires more space.











The elements shown in figs. 15, 16 and 17 a/b provide a simple and space-saving possibility to hold the indicated atrium laterally open and to suction it permanently at the same time (cf. fig. 1).

The adapters MRP-5/6 are available as right or left version. Thus there are different possibilities of use according to the surgical requirements and individual preferences.

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Fig. 18 shows how the inner rod is inserted through the tubular sleeve of MRF-0V. In doing so, attention has to be paid that the transverse lock at the distal end of the inner rod slips into both distal longitudinal slots of the sleeve.

Fig. 19 shows how the previously assembled components of the blade guide are pushed through the ball. The third component of the blade guide, the terminal nut, was not yet screwed on.

Fig. 20 shows how the terminal nut is screwed on. Only screw on the tightening nut so far that the distal socket for the atrial aspirator/stabilizer is still freely accessible for the ball of the atrial aspirator/stabilizer.

Fig. 21 shows how the ball-joint adapter MRP-5 is attached to the lateral end of the retractor frame. In order to optimize the access it is recommended to attach it to the right (caudal) - as seen from the operator - retractor arm. The adapter is placed on the end of the retractor arm by means of the slot provided for this purpose. It has to be ensured that the lock provided on the retractor arm is aligned in parallel with the retractor arm. As soon as the adapter is in position the lock is turned by 90°, and thus secures the connection with the retractor. The hook adapter is fixed in the chosen position by means of the thumb screw of the ball-joint adapter.

Fig. 22 shows how the atrial aspirator/stabilizer is attached to the blade guide. Before this, a suction tube with a lumen of 8 mm is connected to the proximal end of the atrial aspirator/stabilizer. The other end of the suction tube is connected to the suction inlet of the heart-lung machine.

The ball of the atrial aspirator/stabilizer is inserted in the socket provided for that purpose at the distal end of the blade guide. To facilitate the introduction of the atrial aspirator/stabilizer in the operation area on narrow accesses, the guiding forceps MRJ-4 can be used as an option as shown here.

The tightening nut of the blade guide is turned down until the ball in the socket is maintained in the angle position required for the operative application.

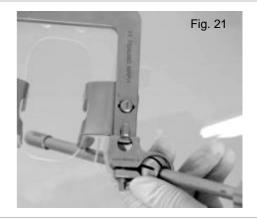
Attention: The free motion play of the atrial aspirator/stabilizer is maximized by aligning the lateral opening of the socket with the distal end of the atrial retractor/suction device (see fig. 22). Then the web between the ball and tube of the atrial retractor/suction device can use the space of the lateral opening, if required.

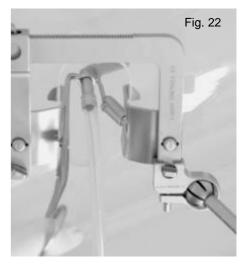




Fig. 20







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Fig. 23 shows the stabilizer for septal fold and diaphragm (cf. 10 in fig. 1)

The elements MRO-0 (fig. 3) and MRN-3 (fig. 4) are required for assembly and have to attached to the caudal spreader arm. The procedure corresponds to that of the application of the transthoracic atrial retractor. However, here the blade guide MRN-3 is inserted through the intercostal space which is caudally to the main incision. As for the rest, the procedure corresponds to that of the placement of the transthoracic atrial retractor (3, 4 and 5). Care has to be taken to that the convex side of the septal fold stabilizer lies on the septum side: The mark on the concave side must be visible.



Use of MIDCAB

Fig. 24 shows a possible general configuration. Here, the ratchet of the retractor frame is placed median. Alternatively, a lateral placement would also be possible. All accessory components can be positioned according to their suitability.

	Article no.	Designation
А	MRP-1	Intercostal retractor
В	MRP-2/3/4, MRO-7	Retracting blades for MRP-1
С	MRV-9V	Ball-joint adapter with sliding ball (Ø 4)
D	MRR-3V	Myocardial stabilizer with ball connector (Ø 7)
E	MRI-0S	Blade guide for ball-joint adapter Ø 4, 120 mm
F	LMT-4	Cardan screwdriver

Fig. 25 shows the ball-joint adapter MRV-9V that can be optionally mounted on the ratchet or the arms of the retractor frame MPR-1.

Fig. 26: The hex head screw of the ball-joint adapter MRV-9V

is tightened using the Cardan screwdriver LMT-4.

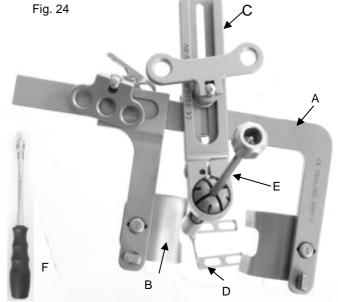








Fig. 27 shows the blade guide MRI-0S.

Fig. 26

Fig. 27

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Fig. 28

Fig. 29



Fig. 28 shows the myocardial stabilizer MRR-3V with ball connector (Ø 7).

Fig. 29 shows the blade guide MRI-0S. It is disassembled into three parts in the instrument tray: outer sleeve, inner rod and proximal fixing screw.

Fig. 30 shows how the inner rod is inserted through the tubular sleeve of MRI-0S. In doing so, attention has to be paid that the transverse lock at the distal end of the inner rod Fig slips into both distal longitudinal slots of the sleeve.

Fig. 31 shows how MRI-0S is inserted through the ball of MRV-9V. The third component of the blade guide, the terminal nut, was not yet screwed on.

Fig. 32 shows how the tightening nut is installed. Only screw on the tightening nut so far that the distal socket for the myocardial stabilizer MRR-3V is still freely accessible for the ball connector of the myocardial stabilizer (see fig. 32a).

Fig. 33 shows how the myocardial stabilizer MRR-3V is inserted into the socket of the blade guide MRI-0S.











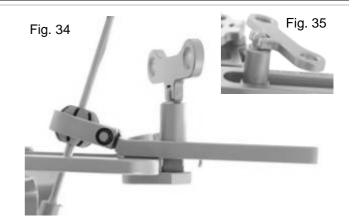
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Fig. 34 shows how the adapter MRV-9V is installed on the retractor frame MRP-1. To fix it, the nut must be in upright position. After fixing, the nut should be folded down (see fig. 35).



Reprocessing:

Restriction for reprocessing:

Frequent reprocessing has only minor effects on these instruments.

Usually the end of the product service life is determined by wear and damage due to utilization.

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.		
Storage: acc. to § 4 MPBetreibV (regulation on the operation of medical devices)	Store instruments in dry rooms to avoid condensation. It is recommended to start reprocessing the instruments directly after use, as dried resi- dues located in areas with limited access are quite difficult to remove.		
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	 Make sure that traces of blood, tissue and medication are removed from the instruments directly after termination of the surgery and that they are immediately forwarded to mechanical cleaning. To do so, clean these instruments with soft brushes under running water until all visible contamination is removed. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use an approved solution of a combined cleaning and disinfecting agent without protein fixing effect (observe the recommendation of the chemicals producer when mixing the solution). Avoid overfilling instrument sets and washing trays – use appropriate instrument carriers only. Be particularly careful that the points do not get stuck in the mesh when placing and removing the instruments into/from the set baskets. Disassemble dismountable instruments according to the appropriate assembly instructions. 		
Cleaning/Disinfection acc. to DIN EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfecting are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.		
Cleaning: Mechanically acc. to DIN EN ISO 15883-1:2009	Validated procedure:Equipment:Washer/disinfector G 7836 CD (Miele)Process:2-component process alkaline/enzymaticDetergent:deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland)Preparation:•Make sure that all cavities are completely flushed on the inside as well.•Make sure that no flushing shadows arise.		

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	 Parameters: 3 min pre-cleaning with tap water Drain 10 min cleaning with tap water and 0.3 % TWIN PH10 at 35 ℃, and 0.2 % TWINZYME at 40 ℃ Drain 2 min rinsing with deionized water > 30 ℃ Drain 1 min rinsing with deionized cold water Drain 5 min thermal disinfection at 93 ℃ After mechanical cleaning check cavities, blind holes, etc. in particular for visible dirt. Repeat cycle or clean manually, if required. 		
Cleaning/Disinfection: Manually Manual cleaning should be avoided as it cannot be validated.	 <u>Equipment:</u> Detergent (active and non protein-fixing cleaner, with or without antimicrobial effect and/or enzymes), compressed-air cleaning gun, soft cloths/sponges, running water. 1. Thoroughly rinse dirt from the surface of the instrument. 2. Apply detergent solution on all surfaces using a soft cloth/sponge. Make sure that joint instruments are cleaned in open as well as in closed position. 3. Thoroughly rinse all cavities and blind holes with a sufficient amount of detergent solution (min. 200 ml) using a syringe. Take special care that enough solution flows to the distal end. 4. Hold the instrument under running water. The running water must flow through the cavities, and blind holes must be filled and emptied several times. Use demineralized water for the final rinsing. For manual cleaning the detergent solution should not be warmer than room temperature. Disinfection: Disinfection solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (min. 5 minutes at 93 °C). (Th ermal disinfector, see indications of the residues for the final rinsing. 		
Drying:	If the drying is achieved as part of the cleaning/disinfection cycle 120 $\ensuremath{\mathbb{C}}$ should not be exceeded.		
Maintenance:	Assemble the instruments according to the assembly instructions. Apply a small amou of high-grade, water-soluble instrument spray on the hinges.		
Control and function test:	Check instruments for easy operation (avoid too much play). Check locking mechanisms. Using a magnifying lamp visually inspect for damage and wear. Pay special attention to the critical points on movable parts and in the working area. Sort out defective instruments and return them to the manufacturer for repair. Clean and disinfect instruments before sending them to be repaired. A confirmation form for this procedure can be obtained from the manufacturer.		
Packaging:	Separate: acc. to standards of the DIN EN 868, DIN EN ISO 11607 and DIN 5895 series. Sets: Sort instruments in trays provided for that purpose or place them on universa sterilization trays. Use an appropriate procedure to pack the trays.		



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Sterilization:	 Steam-sterilize using the fractional vacuum process at 134 °C (min. 5 minutes holding time) with equipment acc. to DIN EN 285, validated sterilization processes! To avoid formation of stains and corrosion, the steam must be free of components. The recommended limit values of the components for feed-water and steam condensation are defined in DIN EN 285. <u>Validated process:</u> Equipment: Selectomat HP (MMM) 1. Three times pre-vacuum 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: min. 10 minutes 	
Storage:	Acc. to § 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.	
Additional information:	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).	
Contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: +49 (0) 6188-957440 Fax: +49 (0) 6188-957445 E-mail: info@fehling-instruments.de	

Storage / Symbols

茶	Ť	i	REF	CE
Protect from exces- sive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Observe instructions for use	Article number	

! Each modification to the product or deviation from these instructions of use results in exclusion of liability! Subject to change without notice.

Manufacturer:

FEHLING INSTRUMENTS GmbH & Co. KG, Hanauer Landstr. 7A, 63791 Karlstein/Germany, www.fehling-instruments.de

The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.