FEHLING Fastening elements and ball joint adapters

Fastening element for ball joint adapter

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

Ball joint adapter for retractor system

MRR-5	Ball joint adapter for MRP-1 (Ø 4 mm), left
MRP-5	Ball joint adapter for MRP-1 (Ø 8 mm), left
MRP-5V	Ball joint adapter for MRP-1 (Ø 8 mm), left
MRR-6	Ball joint adapter for MRP-1 (Ø 4 mm), right
MRP-6	Ball joint adapter for MRP-1 (Ø 8 mm), right
MRP-6V	Ball joint adapter for MRP-1 (Ø 8 mm), right
MRO-0	Ball joint adapter with excenter, fixation for MRP-1 (Ø 4 mm)
MRO-0V	Ball joint adapter with excenter, fixation for MRP-1 (Ø 4 mm)
HTA-1	Ball joint adapter with excenter, fixation for MRP-1 (Ø 6.35 mm)
MRN-9	Ball joint adapter with excenter for MICS retractor system (Ø 8 mm)
MRR-1	Ball joint adapter for MRR-2/2V/2L/ MRP-1 (Ø 8 mm)
MRR-1V	Ball joint adapter for MRR-2/2V/2L/ MRP-1 (Ø 8 mm)
MRR-2	Ball joint adapter with spacing lever for blade guide MRN-3 (Ø 4 mm)
MRR-2V	Ball joint adapter with spacing lever for blade guide MRN-3 (Ø 4 mm), 70 mm
MRR-2L	Ball joint adapter with spacing lever for blade guide MRN-3 (Ø 4 mm), 90 mm
MRR-4	Ball joint adapter with spacing lever (Ø 8 mm)
MRV-1F	Ball joint adapter straight (Ø 6.35 mm), adjustable length and height
MRV-9F	Ball joint adapter straight (Ø 8 mm), adjustable length and height
MRU-8F	Ball joint adapter bayonet (Ø 4 mm), adjustable length and height
MRV-0F	Ball joint adapter bayonet (Ø 6.35 mm), adjustable length and height
MRV-0J	Ball joint adapter bayonet with joint, (Ø 6.35 mm), adjustable length and height
MRV-0R	Ball joint adapter bayonet with joint, (Ø 6.35 mm), adjustable length and height
MSZ-2	Ball joint adapter mini (Ø 3.175 mm), front load, adjustable height
MRX-5	Ball joint adapter mini (Ø 4 mm), front load, adjustable height
MRV-5	Ball joint adapter 60° angled ball (Ø 8 mm)
MRF-1V	Ball joint adapter for round instruments (Ø 8 mm)

Ball joint adapter for long shafts

MTI-3	Holder for long shafts

Ball joint adapter for puncture incision

MRO-1	Fixation device for MRN-3 atrial retractor
MRO-9	Fixation device for MRN-3 atrial retractor, with adjustable angle
MRO-9V	Fixation device for MRN-3 atrial retractor, with adjustable angle

Accessories

LMT-4	Cardan screwdriver
TXW-9X	Screwdriver Allen, 3 mm, sterilizable
MRJ-3	Wrench for cloverleaf screws
Slotted screwdriver	

⚠	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. Fastening elements and ball joint adapters may only be used, reprocessed and disposed of by qualified medical personnel! Fastening elements and ball joint adapters are 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: fastening elements and ball joint adapters are intended for temporary 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 a fastening element and a ball joint adapter:

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses

⚠	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	
FEHLING INSTRUMENTS fastening elements and ball joint adapters are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (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 fastening elements and ball joint adapters must be handled with care during storage, transportation and cleaning! Avoid striking the fastening elements and ball joint adapters or applying pressure to their parts so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!
⚠	**Never compress the ball of the ball joint adapter without using an instrument that has been inserted into the drill hole with a wing or Allen screw: this could cause the ball to be permanently misshapen and compromise its usability.**

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 instruments containing plastic components with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.

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)

	Procedure/Parameters: • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument 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. Validated procedure: Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) Preparation: • Instruments with joints are to be placed in the device 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

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the fastening elements and ball joint adapters, ensure that the surgical field 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 component depends on the anatomical and physiological conditions as well as the field of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

Fastening elements

The fastening element is intended for connection with ball joint adapters, which can be attached variably to the retractor bodies both in height and length.
There are three different variants of fastening elements. Figures 1 - 3 illustrate the respective fastening elements and their distinguishing features.

Fig. 1: MZZ-1N – Fastening element with wing screw and extended screw thread

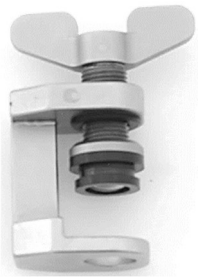


Fig. 2: MZZ-1Q – Fastening element with wing screw

Fig. 3: MZZ-2 – Fastening element with crank

Table 1 lists the fastening elements with the corresponding bar height of the retractor body and the matching ball joint adapters. The listed ball joint adapters are compatible with all three fastening elements and are described in detail in the section "Ball joint adapter for retractor systems - 1) Ball joint adapter with rail (page 10)". The fastening elements can be used for all retractor bodies with a bar height of 3.0 mm or 4.5 mm up to 13.0 mm.

Table 1: Listing of the fastening elements with the corresponding bar height of the retractor body and the matching ball joint adapters

Article no.	Bar height	Ball joint adapter
MZZ-1N	3.0 mm – 13.0 mm	MRU-8F MRV-0F MRV-0J MRV-0R MRV-1F MRV-9F
MZZ-1Q	4.5 mm – 13.0 mm	
MZZ-2	4.5 mm – 13.0 mm	

Ball joint adapter

The ball joint adapters, which are available in a wide range of variants, are used to accommodate blade guides with round shanks. The ball joint adapters can be positioned anywhere on the toothed rack, or if appropriate, on the retractor arms next to the blades. Depending on patient's anatomy and the position of the incision, the ball on the toothed rack can be aligned medially or laterally.

Each ball joint adapter features a usually U-shaped mount (a) and a fixation device (b) (Fig. 4). This is connected to a clamp (c) with a freely rotating compression ball (d). The round shaft instruments are inserted through the bore of the slotted ball (d) and fixed in place with an adjusting screw (e) which compresses the clamp (c).
The exception being ball joint adapters with a rail, as these require a fastening element to be attached to the retractor body (see section "Fastening elements", Page 9).

Fig. 4: Design of an exemplary ball joint adapter

There are numerous variants of the ball joint adapters, which differ in terms of their design features. On the one hand, these are special ball joint adapters which form part of a specific system, and on the other hand, there are those which can be used variably, regardless of the retractor system. These distinguishing features are described in the following.

⚠ **Never compress the ball of the ball joint adapter without using an instrument that has been inserted into the drill hole with a wing screw: this could cause the ball to be permanently misshapen and compromise its usability.**

⚠ **Observe the diameter of the instrument shaft! Ball joint adapters may only be used with the intended shaft diameter given on the label.**

⚠ 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.

Ball joint adapters for retractor systems

1) Ball joint adapter with rail

⚠ For the ball joint adapters with a rail, an additional fastening element is required, as this variant of ball joint adapters would not attach to the retractor body by itself. The combinations are listed in Table 1, Page 9.

Fig. 5: MRV-1F

Ball joint adapter straight for accommodating instruments with cylindrical shafts.

Article no.	Ø in mm	Fixation of the movable ball
MRV-9F	4	Cardan screwdriver
MRV-1F	6.35	Cardan screwdriver

Fig. 6: MRU-8F

Ball joint adapter in bayonet form for accommodating instruments with cylindrical shafts.

Article no.	Ø in mm	Fixation of the movable ball
MRU-8F	4	Cardan screwdriver
MRV-0F	6.35	Cardan screwdriver

Fig. 7: MRV-0J

Fig. 8: MRV-0R

Ball joint adapter in bayonet form for accommodating instruments with cylindrical shafts with additional adjustment of the retracting angle.

Article no.	Ø in mm	Fixation of the movable ball
MRV-0J	6.35	Cardan screwdriver
MRV-0R	6.35	Wing screw

Configuration example for ball joint adapter with rail and fastening element

Figure 9 illustrates an example for the configuration of the ball joint adapter MRV-9F (a) mounted on the retractor body MRP-1 (b) with the fastening element MZZ-1Q (c) (see also section "During use", Page 12) and fitted with a holding device for the septal fold and diaphragm MRU-6 (d) with a cylindrical shaft.

⚠ The rail of the ball joint adapter and the fastening element are pushed loosely onto each other. When handling, care must be taken to hold both parts to avoid unintentional slipping and dropping of a part.

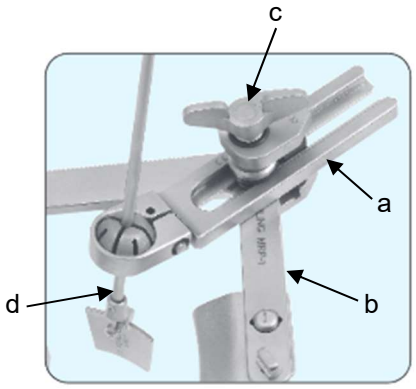


Fig. 9: Configuration example for MRV-9F

During use

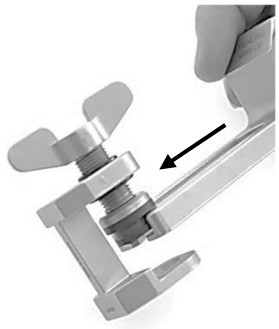


Fig. 10a

Lateral view:
Inserting the fastening element into the ball joint adapter rail

Fig. 10b

Connection with retractor arm at 45° viewing angle

Fig. 10c

Fixation by rotating the wing screw of the fastening element clockwise

⚠ The rail of the ball joint adapter and the fastening element are pushed loosely onto each other. When handling, care must be taken to hold both parts to avoid unintentional slipping and dropping of a part.

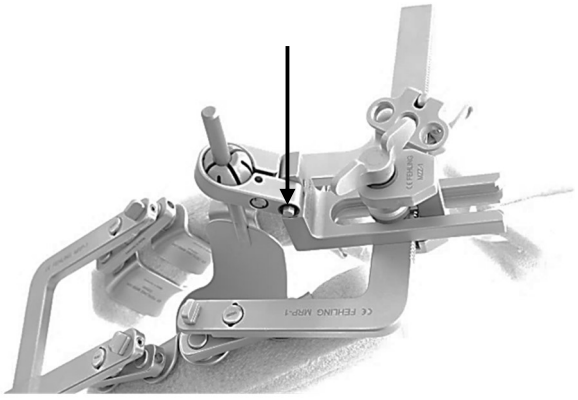


Fig. 11a: Operation of the ball joint adapters with a hexagon head screw

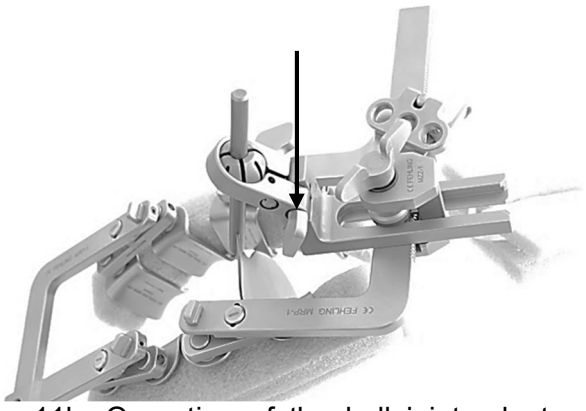


Fig. 11b: Operation of the ball joint adapters with wing screws

⚠ An cardan screwdriver (see 8) Required accessories) is required for the use of ball joint adapters (Fig. 11a).
An cardan screwdriver is not required for the use of ball joint adapters with wing screws (Fig. 11b).

2) Ball joint adapter with adjustable fixation

Fig. 12: MRF-1V

Ball joint adapter for accommodating instruments with cylindrical shafts with additional adjustment of the retracting angle. The ball joint adapter consists of a U-shaped profile which can be attached to rectangular retractor bodies of different heights. The ball joint adapter is attached via a compression screw.

Article no.	Ø in mm	Fixation of the movable ball
MRF-1V	8	Wing screw

Configuration example for ball joint adapter with adjustable fixation

Figure 13 illustrates the MRF-1V ball joint adapter (a) in conjunction with the MRF-0V blade guide (b) on an MNS-1 sternal retractor (c).

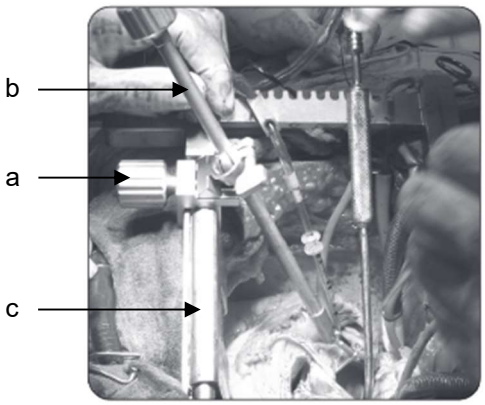


Fig. 13: Configuration example for MRF-1V

3) Ball joint adapter mini

Fig. 14: MRX-5

Ball joint adapter (mini) for frontal accommodating of instruments with cylindrical shafts. The ball joint adapter consists of a U-shaped profile which can be attached to retractor bodies of different heights. The ball joint adapter is fastened via a pressure screw which is tightened with a hexagonal Allen key (accessories: TXW-9X screwdriver Allen key see 8) Required accessories).

Article no.	Ø in mm	Fixation of the movable ball
MSZ-2	3.175	Wing screw
MRX-5	4	Wing screw

Configuration example for ball joint adapter mini

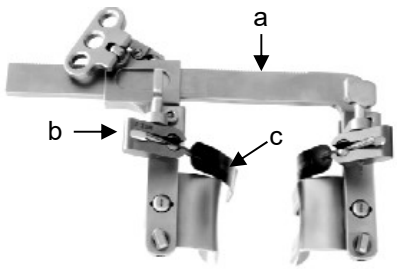


Fig. 15a: Configuration example for MSZ-2 from an anterior view

Figures 15a and 15b depict the MSZ-2 ball joint adapter (b) mounted on both arms of a MICS MRP-1 intercostal retractor (a) from two different angles. These are each fitted with a spatula with a cylindrical shaft (c), such as the EOL-1/2/3/4/5 or the EOM-1/2/3/4/5.

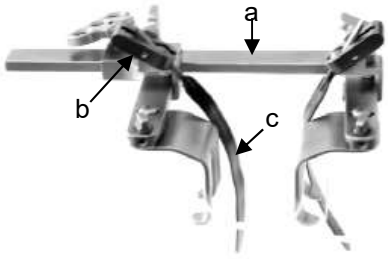


Fig. 15b: Configuration example for MSZ-2 from a lateral view

Figure 16 depicts the MRX-5 ball joint adapter (b), also mounted on a MICS MRP-1 intercostal retractor (a), fitted with a SUPERPLAST retractor (Ø 4 mm) MRX-1V (c) for retraction of the anterior MV cusp.

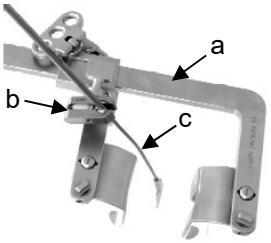


Fig. 16: Configuration example for MRX-5

4) Ball joint adapter for sliding onto the retractor arm

Fig. 17: MRP-5V

Fig. 18: MRP-6V

Ball joint adapter for accommodating instruments with cylindrical shafts. For fastening to the FEHLING MICS intercostal retractor MRP-1. Fixation of the ball joint adapter via the latch attached to the retractor arm. For this purpose, it must be aligned parallel to the retractor arm. The ball joint adapter is pushed onto the end of the retractor arm using the slot provided for this purpose, and the latch is turned by 90° to ensure that the connection is securely fixed.

Article no.	Ø in mm	Fixation of the movable ball
MRR-5 (left)	4	Cardan screwdriver
MRR-6 (right)	4	Cardan screwdriver
MRP-5V (left)	8	Cardan screwdriver
MRP-6V (right)	8	Cardan screwdriver
MRP-5 (left)	8	Wing screw
MRP-6 (right)	8	Wing screw

Configuration example for ball joint adapter for sliding onto the retractor arm

Figure 19 illustrates keeping the incised atrium open. For this purpose, the MRP-6V ball joint adapter (a) was connected to the FEHLING MICS MRP-1 intercostal retractor (b) and fitted with an MRF-0V blade guide with a cylindrical shaft (c).

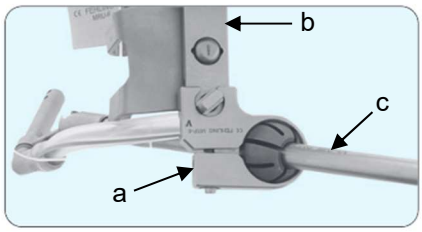


Fig. 19: Configuration example for MRP-6V

5) Ball joint adapter with excenter lever

Fig. 20: MRO-0V

Ball joint adapter for fastening to the FEHLING MICS intercostal retractors MRP-1 and MRP-1F. This can be placed on the toothed rack of the MRP-1/1F at any position. The ball can be aligned medially or laterally. The excenter lever (black lever) can be used to fasten or detach the ball joint adapter to or from the toothed rack. For accommodating instruments with cylindrical shafts.

Article no.	Ø in mm	Fixation of the movable ball
MRO-0	4	Wing screw
MRO-0V	4	Cardan screwdriver
HTA-1	6.35	Cardan screwdriver

Fig. 21: MRR-1V

Ball joint adapter for accommodating the ball joint adapter with spacing lever (MRR-2, MRR-2V, MRR-2L, see 6) ball joint adapter with spacing lever, Page 15) for fastening to the FEHLING MICS intercostal retractors MRP-1 and MRP-1F. This can be placed on the toothed rack of the MRP-1/1F at any position. The excenter lever (black lever) can be used to fasten or detach the ball joint adapter to or from the toothed rack.

Article no.	Ø in mm	Fixation of the movable ball
MRR-1	8	Wing screw
MRR-1V	8	Cardan screwdriver

Configuration example for ball joint adapter with excenter lever

Figure 22 depicts the MRO-0V ball joint adapter (a) as a configuration for retraction of the atrial roof. For this purpose, the MRO-0V ball joint adapter (a) was connected to the FEHLING MICS MRP-1 intercostal retractor (b) and fitted with an MRN-3 blade guide with a cylindrical shaft (c).

A configuration example for the MRR-1V ball joint adapter in combination with a ball joint adapter with spacing lever can be seen in Fig. 24 on Page 16.

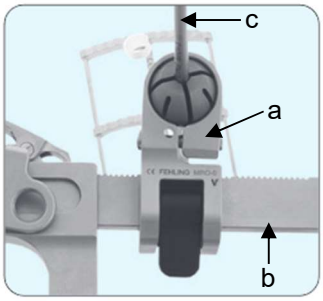


Fig. 22: Configuration example for MRO-0V

6) Ball joint adapter with spacing lever

Fig. 23: MRR-2V, MRR-2L

Ball joint adapter serves as an extension if the desired position for the transthoracic atrial retractor cannot be achieved with other ball joint adapters (e.g. MRO-0). Stepless extension is possible by 20 to 25 mm. Serves for accommodating instruments with cylindrical shafts. Fixation of the ball joint adapter is possible by combination with MRR-1/MRR-1V.

Article no.	Ø in mm	Fixation of the movable ball
MRR-2V spacing lever 70 mm	4	Cardan screwdriver
MRR-2L spacing lever 90 mm	4	Cardan screwdriver
MRR-2 spacing lever 70 mm	4	Wing screw
MRR-4 spacing lever 70 mm	8	Wing screw

Configuration example for ball joint adapter with spacing lever

Figure 24 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 or MRR-1V ball joint adapter (a) with the MRR-2 ball joint adapter with spacing lever (b). For this purpose, the MRR-1V ball joint adapter (a) was connected to the MICS MRP-1 intercostal retractor (b). The ball joint adapter with spacing lever MRR-2 (b) was fastened with the aid of the ball joint adapter MRR-1V (a) and fitted with a blade guide MRN-3 with cylindrical shaft (d). In this way, the position of the transthoracic atrial retractor can be continuously shifted medially by 20 to 25 mm.

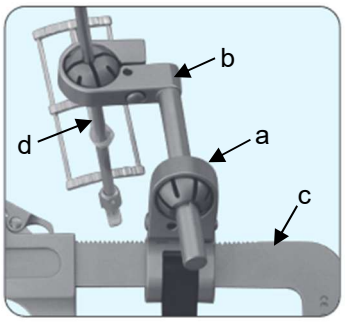


Fig. 24: Configuration example for MRR-2

7) Ball joint adapter with cloverleaf screw

Fig. 25: MRV-5

Ball joint adapter, angled at.60°, for accommodating instruments with cylindrical shafts. The ball joint adapter consists of a U-shaped profile which can be attached to rectangular retractor bodies of different heights. The ball joint adapter is fastened via the attached cloverleaf screw. The MRJ-3 wrench (see 8) Required accessories) is required for this cloverleaf screw.

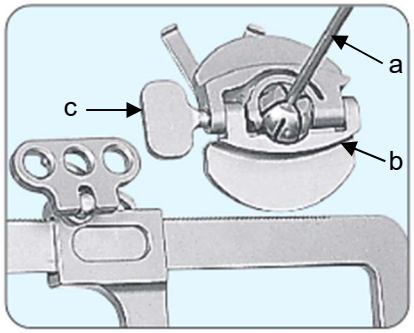
Article no.	Ø in mm	Fixation of the movable ball
MRV-5	8	Cardan screwdriver

Ball joint adapter for puncture incisions

Fig. 26: MRO-9

Ball joint adapter for separate puncture incision for placing and accommodating instruments with a cylindrical shaft.

Article no.	Ø in mm	Fixation of the movable ball
MRO-1	4	Excenter
MRO-9	4	Wing screw
MRO-9V	4	Cardan screwdriver

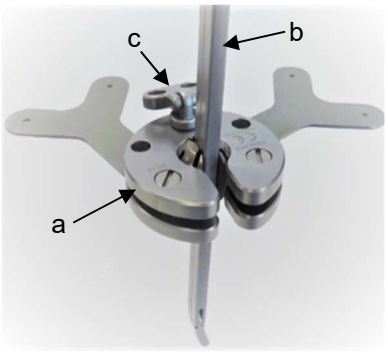
Configuration example for ball joint adapter for puncture incision	
Figure 27 depicts the MRN-3 blade guide (a) which was inserted into the MRO-9 ball joint adapter. Once the blade guide has reached the desired position, it is fixated by rotating the wing screw of the ball joint adapter clockwise (c).	 Fig. 27: Configuration example for MRO-9

Ball joint adapter for long shafts

Fig. 28: MTI-3

Ball joint adapter round for frontal accommodating of instruments with rectangular shafts. This can be attached via the two Y-shaped fasteners.

Article no.	Ø in mm	Fixation of the movable ball
MTI-3	5	Wing screw

Configuration example for clamp for long shafts	
Figure 29 depicts the instrument used in the ball joint adapter (a) for minimally invasive surgery with a rectangular shaft (b). Once the instrument has reached the desired position, it is fixated by rotating the wing screw of the ball joint adapter (c) clockwise.	 Fig. 29: Configuration example for MTI-3

8) Required accessories

A LMT-4 cardan screwdriver (Fig. 30) is required to use the HTA-1, MRO-0V, MRO-9V, MRR-1V, MRR-2L, MRR-2V, MRR-5, MRP-5V, MRR-6, MRP-6V, MRU-8F, MRV-0F, MRV-0J, MRV-1F, MRV-5 and MRV-9F ball joint adapters.
For the application of the MRX-5 and MSZ-2 ball joint adapters, a TXW-9X Allen screwdriver (Fig. 31) is required to tighten or loosen the pressure screw.
For the application of the ball joint adapter MRV-5, a wrench for cloverleaf screws MRJ-3 (Fig. 32) is required.
An appropriate slotted screwdriver is required for assembly and disassembly of the fastening element.

Fig. 30: Cardan screwdriver LMT-4

Fig. 31: TXW-9X screwdriver Allen, 3 mm, sterilizable

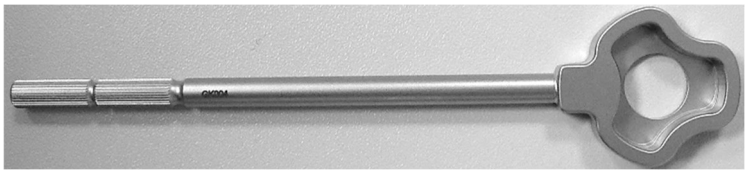


Fig. 32: Wrench for cloverleaf screws MRJ-3

9) Assembly

To assemble the ball joint adapter, please observe 7) Configuration and Application.

For assembly of the fastening element, please observe the following assembly instructions.

The fastening element is assembled in four steps:

1. First screw the wing screw (1) into the U-shaped mount (2) as shown in Figure 33
2. Place pressure disk (steel) (3) on the thread with the chamfer first
3. Slide the guide washer (PEEK) (4) onto the pressure disk with the large diameter facing upwards (Fig. 33)
4. Mount the fastening screw (5) with a slotted screwdriver

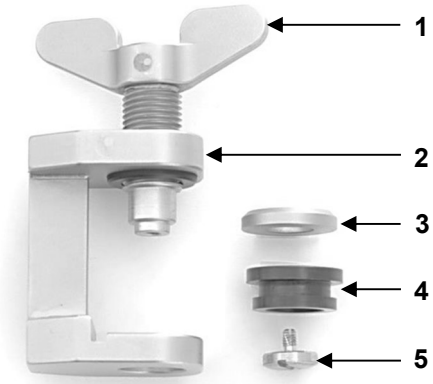


Fig. 33: Individual components of the exemplary fastening element

⚠ The pressure disk and guide washer must not be mounted incorrectly, otherwise the function of the fastening element is no longer given (Fig. 34).

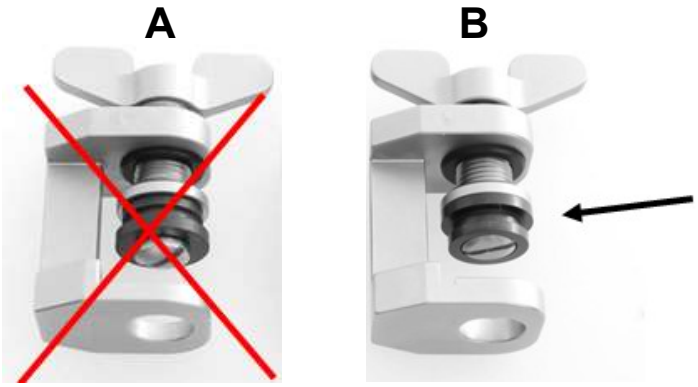


Fig. 34: Illustration of incorrect (A) and correct (B) assembly of the fastening element

10) Disassembly

To disassemble the ball joint adapter, please observe 7) Configuration and Application.

The fastening element must be disassembled as follows for reprocessing.

The fastening element is disassembled using a suitable slotted screwdriver to loosen the fastening screw (5) (Fig. 35). After the fastening screw (5) has been loosened and dismantled, the guide washer (PEEK) (4) and the pressure disk (steel) (3) can be removed from the wing screw (1) manually.

The wing screw (1) must be unscrewed completely for reprocessing.

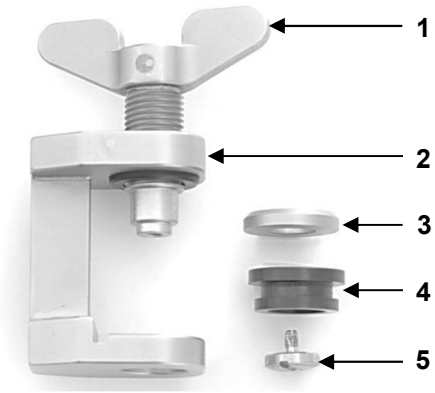


Fig. 35: Individual components of the exemplary fastening element

⚠ 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		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de	CE