FEHLING atrial blade MMZ-7
MMZ-7 ..... Atrial blade 50 x 45-53 mm
Accessories LMT--4 ..... Cardan screwdriver MRN-3 ..... Transthoracic atrial retractor – blade guide, 220 mm

⚠	This instrument resp. medical device is non-sterile when delivered. It is to be reprocessed prior to use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing. The atrial blade may only be used, reprocessed and disposed of by qualified medical personnel! The atrial blade is intended for re-use.

1) Intended purpose

Retractors and retractor components, which are used invasively and for short periods in surgery, serve to separate or hold back various tissue structures, such as skin, bone, muscles and organs.

Additional information regarding the intended purpose

Duration of application: The retractor or retractor components are only intended for short-term use.

Field of application: retractors and retractor components are used for all patients where tissue has to be retracted for a short period of time (max. 24 hours) to improve visibility of the underlying tissue for the surgeon.

User profile: retractors and retractor components may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: retractors and retractor components are only to be used in controlled environments (e.g. OR).

2) Indications

Surgical procedures that require the temporary spreading and holding of various tissue structures, such as skin, bones, muscles and organs, to reach the body structure requiring treatment. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the retractors or retractor blades used are of the correct size and have adequate stability.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no generally applicable contraindications for the use of retractors.
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 retractors: - Infections - Impaired wound healing - Lesions of structures (tissues, nerves, vessels) - Necroses - Ischemia	
⚠	Medical devices may, for example, contain chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
FEHLING INSTRUMENTS atrial blades 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").
⚠	Atrial blades must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to the atrial blade, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

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

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 cracking). Instruments which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 10) Disassembly
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (<40 °C) until all visible contamination

	has been removed. Remove stubborn contamination with a soft brush (not a wire brush!). • Cavities, crevices, slits and lumens must be rinsed intensively (>10 seconds) with cold water (potable water quality, <40 °C) using a water spray gun (or similar). • Place the products for 10 - 30 minutes in a solution with 0.5 - 2 % Neodisher® MediClean forte with water (potable water quality, <40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument are moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. <u>Procedure/Parameters:</u> • Pre-wash for 3 minutes with cold water (potable water quality, <40 °C) • Emptying • Clean for 10 minutes with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (potable water quality) at 55 °C

	• Emptying • Rinse for 2 minutes with water (potable water quality, <40 °C) • Emptying • Rinse for 1 minute with cold deionized water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized water (>90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: Manually	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <u>Ultrasonic cleaning:</u> • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH)

	Procedure/Parameters: • After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly
Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.

Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.

⚠	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The size-adjustable atrial blade MMZ-7 (Fig. 1a) consists of three elements of different sizes: basic element (1), primary element (2) and secondary element (3) (Fig. 1b). One element is composed of the cage module (4) and rib blades (5) (Fig. 1a).

Using the LMT-4 cardan screwdriver (see 8) Required Accessories), the rib blades are adjusted via the gear shaft located inside the cage module (4) and allow the desired spreading width to be set.

Using the MRN-3 blade guide (see 8) Required Accessories), the angle of the atrial blade is continuously adjustable and can be raised or lowered. To do this, the MRN-3 blade guide is screwed into the threaded joint (6).

In particular, the MMZ-7 atrial blade is used for mitral valve surgery to provide better access and an optimal view of the surgical field.

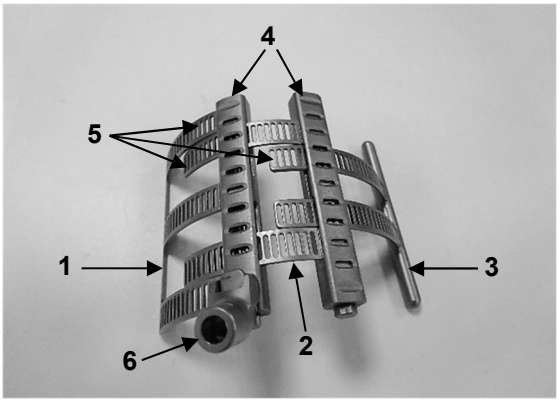
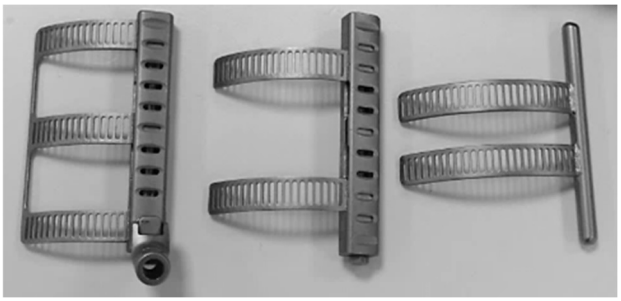


Fig. 1a: MMZ-7



Basic element (1) | Primary element (2) | Secondary element (3)

Fig. 1b: Individual elements of the MMZ-7

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the atrial blade, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Before using the atrial blade, ensure that its functionality is not impaired and that there is no damage!
⚠	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.

During use

Before the MMZ-7 atrial blade can be used, the surgical field must be prepared appropriately. This will not be discussed in detail in the following. The atrial blade must be inserted into the atrium in the fully retracted state.

⚠	When inserting the atrial blade, ensure that no tissue structures are unintentionally damaged (especially nerves and blood vessels)!
⚠	Too long and too high pressure on the tissue can cause necroses and other lesions!

⚠	Excessive load can cause plastic deformation or breakage of the atrial blade!
⚠	Observe the sequence of extending or advancing the primary and secondary elements!
⚠	When setting the desired spreading width of the atrial blade, ensure that the primary and secondary elements are not extended beyond the point at which the last oblong hole at the end of the respective rib blade is still fully visible. Do not extend the primary and secondary elements to the end of the cage module, as they could then fall out completely and possibly into the patient's body.

Extending the elements of the atrial blade

To set the desired spreading width of the elements, first extend the secondary element (3) using the LMT-4 cardan screwdriver (7).

To do this, turn the outer hexagon screw on the cage module of the primary element (4b) clockwise using the LMT-4 cardan screwdriver (7) (Fig. 2a) until the ends of the rib blades are positioned completely in the cage module of the basic element (4a), as illustrated in Figure 2b.

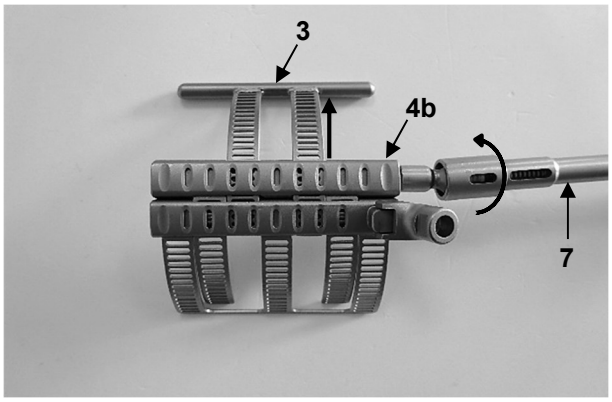


Fig. 2a

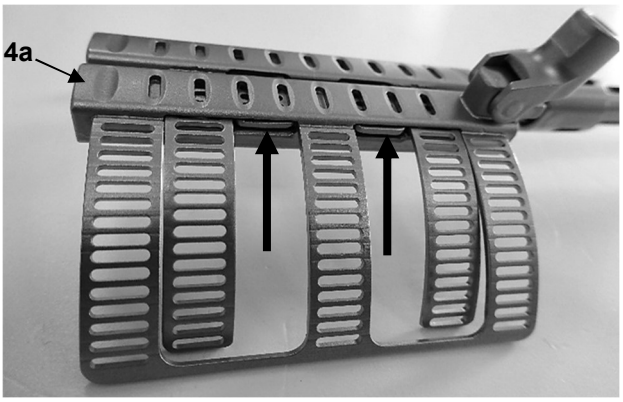


Fig. 2b

Then extend the primary element (2) using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the basic element (4a) clockwise using the LMT-4 cardan screwdriver (7) (Fig. 3a). Ensure that the primary element (2) is not extended beyond the point at which the last oblong hole at the end of the respective rib blade is still fully visible (Fig. 3b).

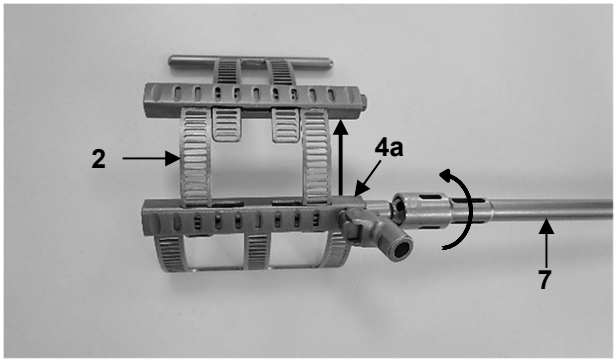


Fig. 3a

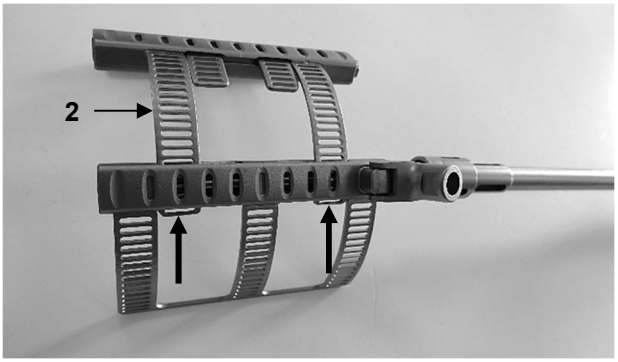


Fig. 3b

If the spreading width is not sufficient, the secondary element (3) can still be extended (Fig. 4a) to the point at which the last oblong hole at the end of the respective rib blade is still fully visible (Fig. 4b).
Figure 4b also illustrates the maximum possible spreading width of the atrial blade.

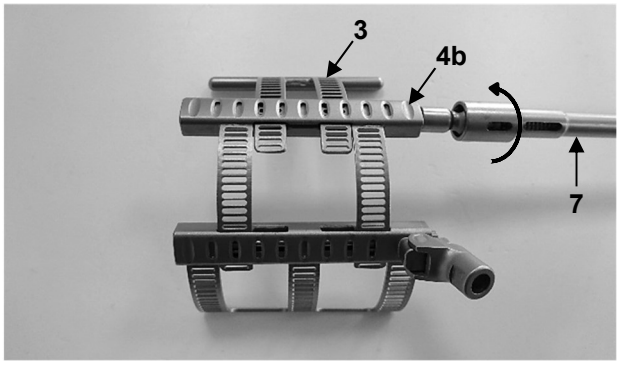


Fig. 4a

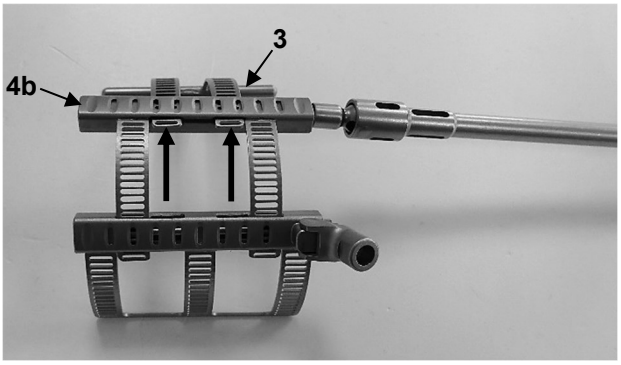


Fig. 4b

Advancing the elements of the atrial blade

⚠ Before removing the atrial blade from the surgical field, always first slowly retract the primary element (2) fully, followed by the secondary element (3).

First fully retract the primary element (2) using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the basic element (4a) counter-clockwise using the LMT-4 cardan screwdriver (7) (Fig. 5).

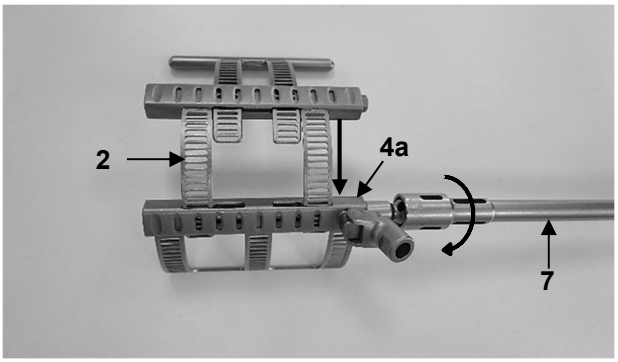


Fig. 5

Then retract the secondary element (3) using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the primary element (4b) counter-clockwise using the LMT-4 cardan screwdriver (7) (Fig. 6).

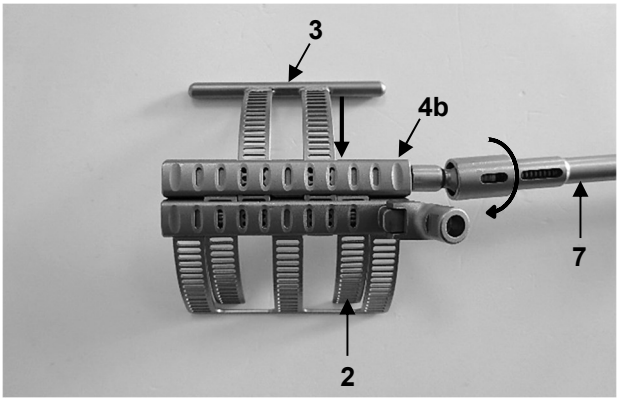


Fig. 6

If the sequence is not observed, the ends of the rib blades of the secondary element may be pushed over the cage module of the basic element (4a) (Fig. 7, **B**) instead of into the cage module (Fig. 7, **A**).

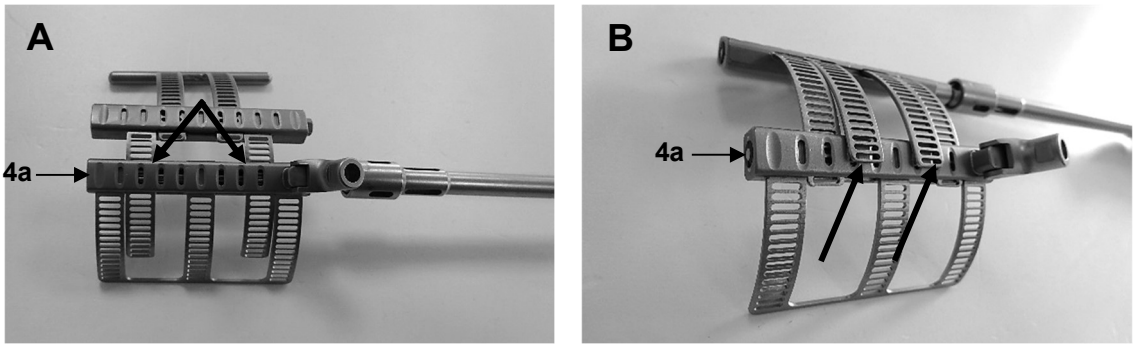


Fig. 7: Exemplary illustration for following the sequence (**A**) and for disregarding the sequence (**B**)

Using the transthoracic atrial retractor - blade guide MRN-3

To raise or lower the atrial blade, first screw the MRN-3 blade guide (8) clockwise into the thread of the joint (6) (Fig. 8).

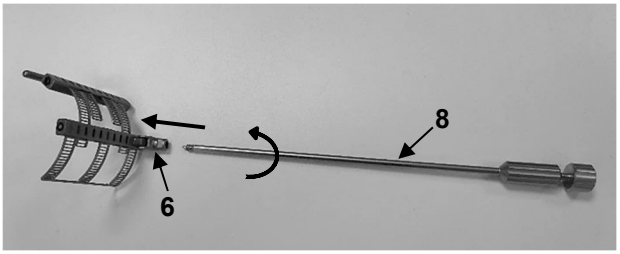


Fig. 8

The atrial blade can be raised or lowered via the blade guide (8) by turning the fixing nut (9) clockwise or counter-clockwise (Fig. 9).

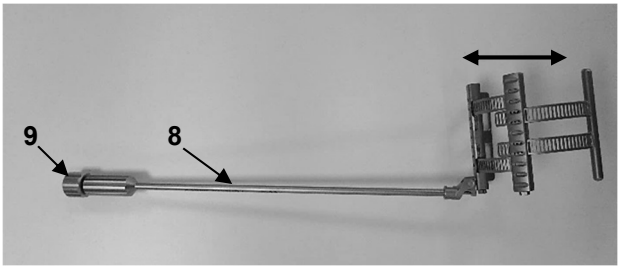


Fig. 9

To remove the MRN-3 blade guide (8), it must be completely unscrewed counter-clockwise from the thread of the joint (6) (Fig. 10).

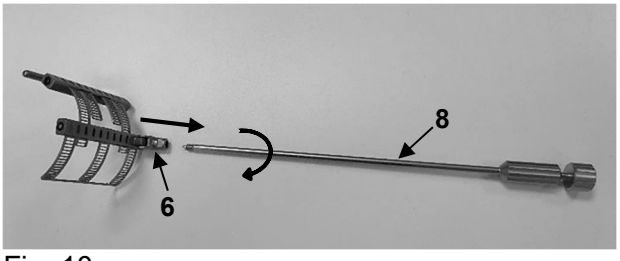


Fig. 10

8) Required accessories

The LMT-4 cardan screwdriver (Fig. 11) and the MRN-3 transthoracic atrial retractor - blade guide (Fig. 12) are required for applying the atrial blade.

Fig. 11: Cardan screwdriver LMT-4

Fig. 12: Transthoracic atrial retractor – blade guide MRN-3

9) Assembly

To assemble and disassemble the transthoracic atrial retractor - blade guide please follow the assembly instructions M36.

For assembly of the atrial blade please observe the following assembly instructions.

Figure 13a illustrates the atrial blade, which is composed of three elements of different sizes. It consists of a basic element (1), a primary element (2) and a secondary element (3) (Fig. 13b).

The LMT-4 cardan screwdriver is required for assembly/disassembly (see 8) Required Accessories). Using the LMT-4 cardan screwdriver, the rib blades (5) are adjusted via the gear shaft located inside the cage module (4).

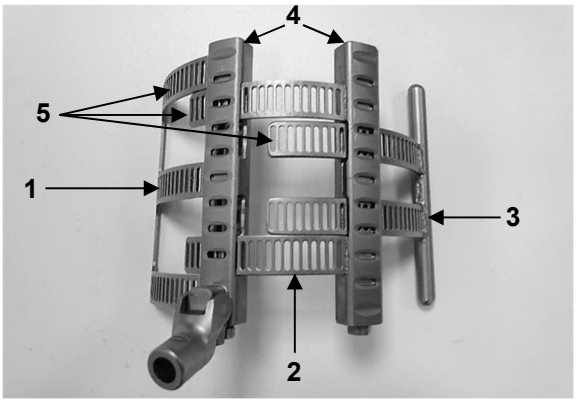
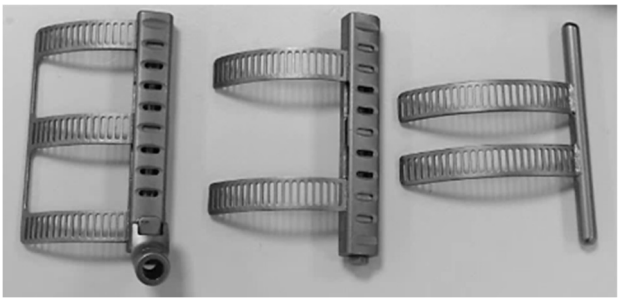


Fig. 13a: MMZ-7



Basic element (1) | Primary element (2) | Secondary element (3)

Fig. 13b: Individual elements of the MMZ-7

1. Insert the primary element (2) into the basic element (1) and retract using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the basic element (4a) counter-clockwise using the LMT-4 cardan screwdriver (7) (Fig. 14).

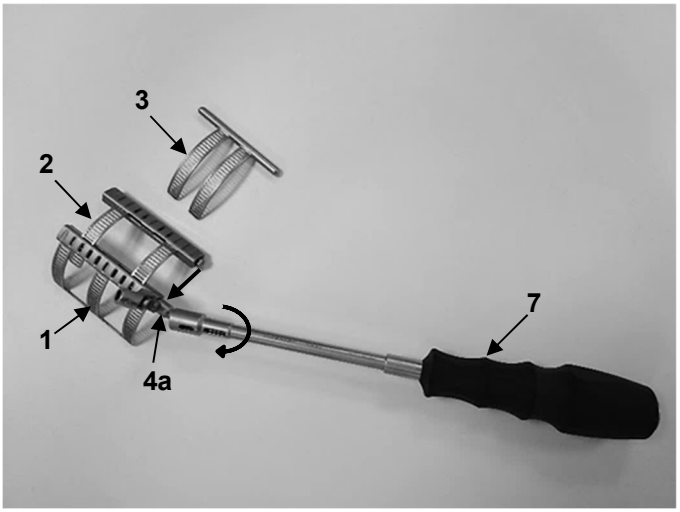
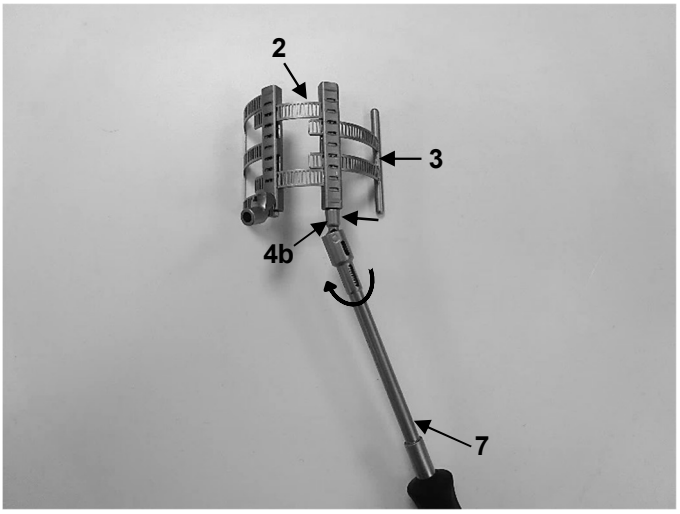
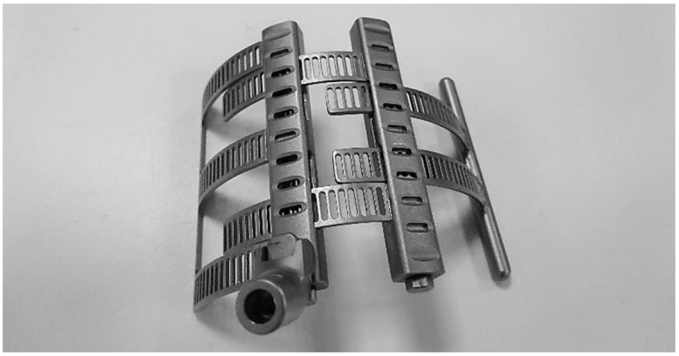
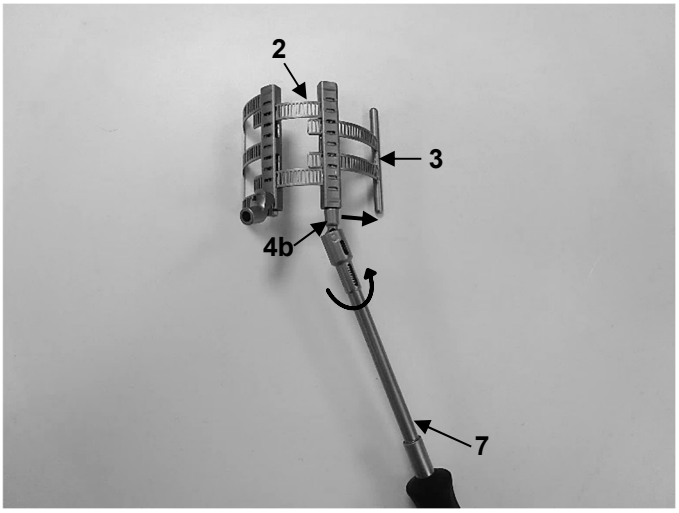


Fig. 14

⚠	Always assemble the primary element (2) first.
2. Then insert the secondary element (3) into the primary element (2) and retract using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the primary element (4b) counter-clockwise using the LMT-4 cardan screwdriver (7) (Fig. 15).	 Fig. 15
3. Following a functional test, the assembled instrument (Fig. 16) is now ready for use again.	 Fig. 16

10) Disassembly

The atrial blade must be disassembled as follows for reprocessing.

1. First remove the secondary element (3) from the primary element (2) using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the primary element (4b) clockwise using the LMT-4 cardan screwdriver (7) until it can be removed (Fig. 17).	 Fig. 17

⚠	Always extend the secondary element (3) first.

2. Then remove the primary element (2) from the basic element (1) using the LMT-4 cardan screwdriver (7). To do this, turn the outer hexagon screw on the cage module of the basic element (4a) clockwise using the LMT-4 cardan screwdriver (7) until it can be removed (Fig. 18).

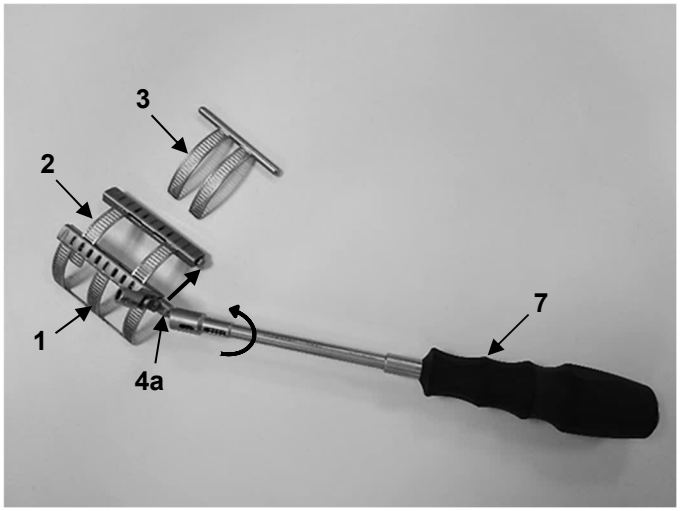


Fig. 18

3. The instrument is now disassembled into its separate parts (Fig. 19) and can be reprocessed.

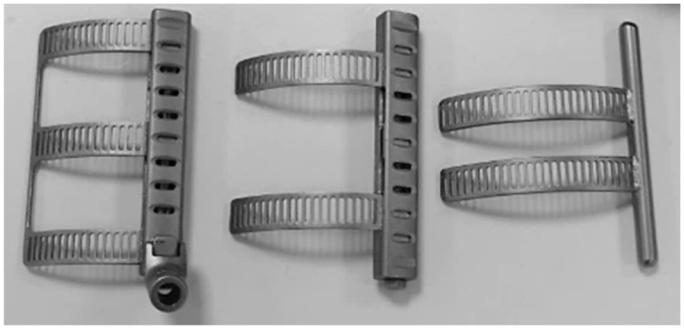


Fig. 19

⚠	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 0297