FEHLING retractor system for aortic valve reconstruction (AVR retractors)

Retractor body	MRW-1G	AVR retractor Ø 140 mm, body only

Table 1: Listing of components, accessories and extension modules for the aortic valve reconstruction (AVR) retractor system

Components

Fixations/guides

MRW-6	AVR coupling rider
MRW-7	AVR coupling rider for retractor blades

Retractor blades

MRW-2G	Retracting blade 70 mm
MRW-3G	Retracting blade 85 mm
MRW-4G	Retracting blade 100 mm
MRW-5G	Retracting blade 115 mm

Extension modules

Possible supplementary retractor systems

MBU-5	Mercedes thoracic retractor (body only)
MBU-0	Blades for Mercedes retractor 50 x 65 mm, fenestrated (pair)
MBU-1	Blades for Mercedes retractor 75 x 75 mm, fenestrated (pair)
MBU-8	Mercedes thoracic retractor blade holder with knurled nut
MBU-6	Blades for Mercedes retractor 50 x 65 mm, closed (pair) knurled
MBU-7	Blades for Mercedes retractor 75 x 75 mm, fenestrated (pair) knurled
MRF-1V	Ball adapter for round instruments Ø 8 mm
MRI-0	Blade guide for ball adapter Ø 8 mm, 120 mm

Accessories

MRW-0	AVR Sterilizing and storage container 530 x 250 x 100 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 retractor system for aortic valve reconstruction (AVR retractors) may only be used, reprocessed and disposed of by qualified medical personnel!

The retractor system for aortic valve reconstruction (AVR retractors) is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The retractor system for aortic valve reconstruction (AVR retractors) is intended for short-term application.

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

The medical literature describes the following side effects, which may also possibly occur during the intended use of the retractor system for aortic valve reconstruction (AVR retractors):

- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses
- Ischemia of other organs due to compression of blood vessels

⚠	Medical devices may, for example, contain chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use

The FEHLING INSTRUMENTS retractor system for aortic valve reconstruction (AVR retractors) is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before any further use (see 6) Reprocessing).

⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Handle the retractor system for aortic valve reconstruction (AVR retractors) with care during storage, transport and cleaning! Avoid striking and applying pressure to the retractor system for aortic valve reconstruction (AVR retractors), 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). 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)

	Procedure/Parameters: • Place instruments, if possible in disassembled condition, in cold water (potable water quality, <40 °C) for 10 minutes. • Move any movable parts, if present, back and forth over the entire range of movement. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). Ultrasonic cleaning: • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • After cleaning, place the products in an ultrasonic bath (35 kHz, <40 °C) with a suitable disinfectant solution (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See 9) Assembly

Maintenance, checking and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. Perform a safety check of the instruments prior to each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorized by the manufacturer. A verification form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments!
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer Autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products largely consist of steel or titanium. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness and potential adverse consequences.	
	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The MRW-1G retractor body, together with its components, forms the aortic valve reconstruction retractor system (AVR retractors). This is specifically intended for exposing the aortic root and AV pockets during AV reconstructions as well as interventions for further surgically invasive treatment of the heart.
Figure 1 illustrates a configuration example of the aortic valve reconstruction retractor system (AVR retractors) with a Mercedes thoracic retractor as a possible extension of the retractor system. Table 2 lists the corresponding components.

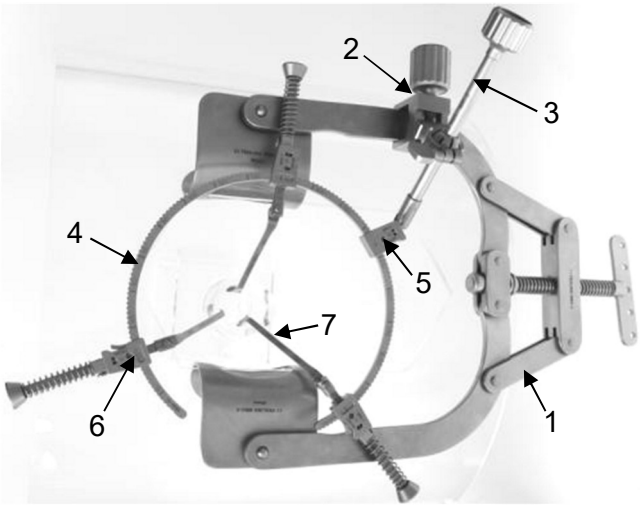

Fig. 1: Configuration example of the aortic valve reconstruction retractor system (AVR retractors) with a Mercedes thoracic retractor

Table 2: List of the corresponding components

	Article no.	Description
1	MBU-5 (exemplary: almost any other sternal retractor can also be used instead)	Mercedes thoracic retractor (body only)
2	MRF-1V	Ball adapter for round instruments Ø 8 mm
3	MRI-0	Blade guide for ball adapter Ø 8 mm, 120 mm
4	MRW-1G	AVR retractor Ø 140 mm, Body only
5	MRW-6	AVR coupling rider
6	MRW-7	AVR coupling rider for retractor blades
7	MRW-2G/3G/4G/5G	Retracting blade in lengths 70/85/100/115 mm

⚠	Use only sterilized products of sound quality!
⚠	Before employing the retractor system for aortic valve reconstruction (AVR retractors), ensure that the surgical field is prepared accordingly.
⚠	Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

7.1) Extension module

The retractor system for aortic valve reconstruction (AVR retractors) can be extended with other retractor systems (see Table 1, Page 1).

8) Required accessories

No accessories are necessary for the retractor system for aortic valve reconstruction (AVR retractors).

An AVR sterilization and storage container (Fig. 2) can be used for sterilization or storage.

Fig. 2: AVR Sterilizing and storage container MRW-0

9) Assembly

For assembly of the retractor system for aortic valve reconstruction (AVR retractors) please observe the following assembly instructions.

Place the MRF-1V ball adapter (a) on the left arm (assistant side) of the in situ sternal retractor in the lower part of the two jaws and fixate on the retractor arm (c) by turning the compression screw (b) clockwise (Fig. 3).

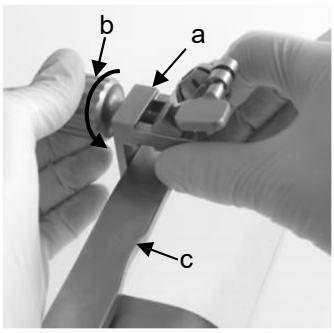

Fig. 3

Figure 4a illustrates the MRI-0 blade guide, which is inserted into the MRF-1V ball adapter in the next step. This consists of three components as shown in Figure 4b.

Fig. 4a

Figure 4b illustrates the individual parts of the MRI-0 blade guide. These are located disassembled in three parts in the instrument tray: outer sleeve (d), inner rod (e) and proximal fixing nut (f).

Figure 4c illustrates insertion of the inner rod (e) through the tubular sleeve (d) of MRI-0. Ensure that the distal end of the inner rod (e) slides into the two distal longitudinal slots of the sleeve (d).

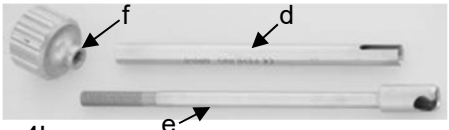

Fig. 4b

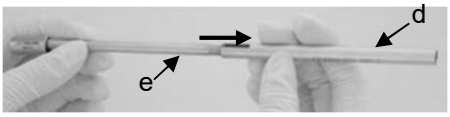

Fig. 4c

The two assembled elements (g) are then pushed through the ball (h) of the MRF-1V ball adapter from below (Fig. 5).

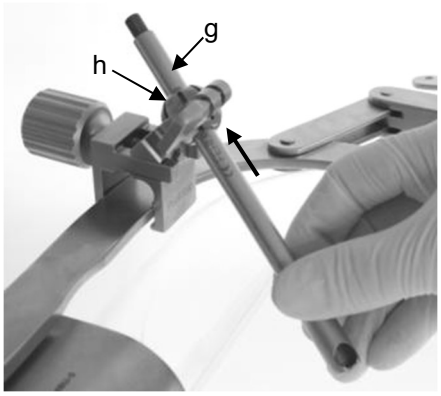

Fig. 5

Figure 6a:
Then screw on the fixing nut (f) by turning it clockwise, but only so far that the distal mounting is still freely accessible for the ball of the MRW-6 coupling rider (Fig. 6b).

To facilitate the following assembly steps, the connection between the ball adapter and the blade guide can be fixed provisionally by tightening the thumbscrew (i) of the ball adapter clockwise (Fig. 6a).

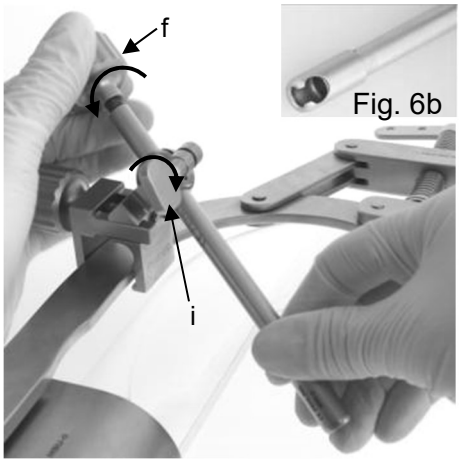

Fig. 6a

Figures 7 - 9 illustrate the rider, the retractor ring and their connection.

Figure 7a illustrates the MRW-6 coupling rider, which has a box-shaped fenestrated mounting (j) for the MRW-1G retractor ring as well as a curved cylindrical bracket with a spherical end (k). The imprinted side is the top side as seen by the surgeon.

Fig. 7a

Figure 7b illustrates a MRW-7 coupling rider.
Its components: A box-shaped fenestrated mounting (l) for the retractor ring, an axle (m) guided through this mounting in longitudinal direction, and a spiral spring (n). The imprinted side of the mounting is the top side. At the proximal end of the ring mounting - as viewed from above - there is a push button on the right side with a locking and unlocking function. In Figure 7b, the axis of the rider is unlocked.

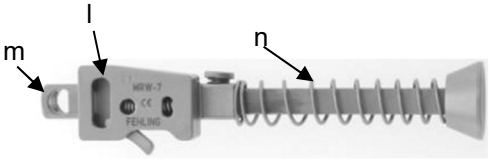

Fig. 7b

Figure 7c illustrates the coupling rider with the axis shifted to distal and locked by the push button (o).

Fig. 7c

Figure 8 illustrates the MRW-1G retractor ring.
It is toothed on the outside and bears angular graduations on the top interspaced at 15°. The ring is open at an angular range of approx. 60°. This open ring area usually faces the surgeon.

Fig. 8

Figures 9a - 9c illustrate the connection of the retractor ring to the riders. Viewed from the top, all riders feature a lever on their left side, which facilitates insertion of the riders onto the ring and the movement of the riders over the ring by applying finger pressure.

Figure 9a illustrates insertion of the coupling rider (j) onto the retractor ring (p) in detail.

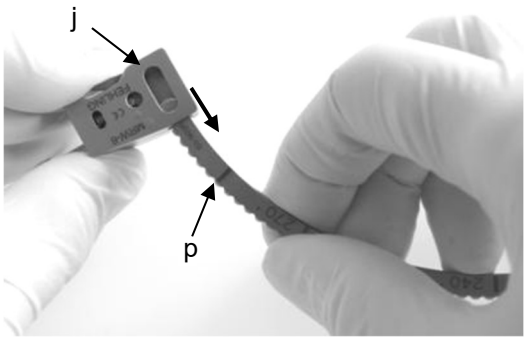

Fig. 9a

Figure 9b illustrates the connecting rider in a position at approx. 165° on the retractor ring.

Fig. 9b

Figure 9c illustrates the retractor ring after complete assembly with the connecting rider and the 3 coupling riders. The coupling riders are arranged here at the 'ideal' angular distance of 120°. The correct patient-specific position is in the center between the commissures of each pocket.

Fig. 9c

Figures 10a - 10c: Loading the coupling riders with the retractor blades

The system includes 3 retractor blades each in 4 different lengths. The decision on the length to be selected is based on the patient's anatomy in each case.

Figure 10a illustrates the insertion of a retractor blade (q) into the bore at the distal end of a coupling rider axis (m) in detail.

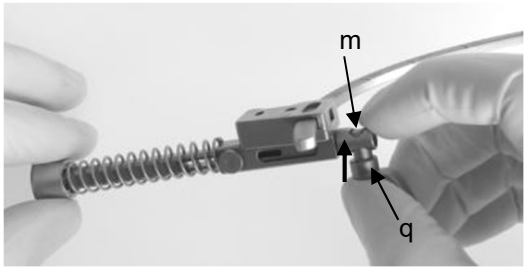

Fig. 10a

Figure 10b illustrates the retractor ring with all riders and retractor blades. The axes of the coupling riders are unlocked.

Fig. 10b

Figure 10c depicts the same assembly as in Figure 10b, but with locked coupling rider axes: the distal vanes of the retractor blades are therefore in a position where they can be comfortably inserted into the patient's aortic root.

Fig. 10c

Figure 11 illustrates the connection of the AVR retractor to the sternal retractor.

Grasp the connection ball (k) of the MRW-6 connector rider with the distal mounting of the MRI-0 blade guide (r). Temporarily fixate the connection ball (k) in the desired position by rotating the fixing nut (f) clockwise.

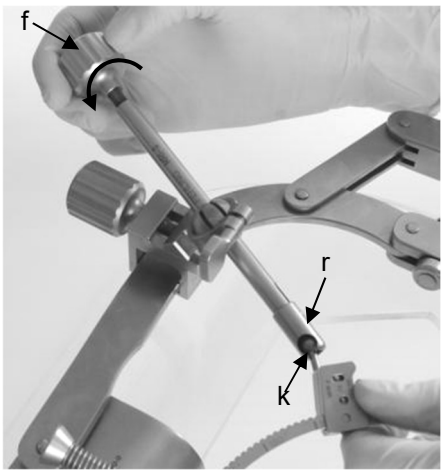

Fig. 11

Figure 12a illustrates the insertion of the retractor and its retracting arms into the aortic root.

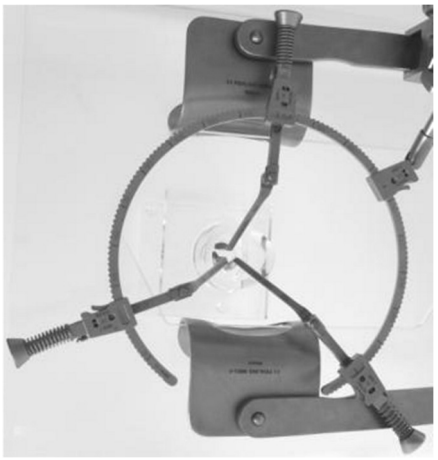

Fig. 12a

Figure 12b illustrates the retractor after unlocking the axes.

Fig. 12b

Once the optimal retractor position has been reached, it is fixated in two steps:

- The connection between the blade guide MRI-0 and the ball of the connector rider MRW-6 (k) is made by rotating the fixing nut (f) of the blade guide clockwise (see Fig. 11),
- the position of the blade guide MRI-0 in the ball of the ball adapter MRF-1V by rotating the thumb screw (i) of the ball adapter clockwise (see Fig. 6a).

⚠ Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

10) Disassembly	
For reprocessing, the retractor system for aortic valve reconstruction (AVR retractors) must be disassembled. Therefore, please observe the corresponding assembly instructions (see 9) Assembly).	
⚠	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 represent 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