FEHLING retractor system for aortic valve reconstruction (AVR retractor)

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

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

Components

Fixations/guides

MRW-6..... AVR connector carriage
MRW-7..... AVR clamping carriage for holding blades

Retractor blades

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

Extension modules

Optional supplementary retractor systems

MBU-5 ..... Mercedes thoracic retractor (frame 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..... Hook guide for ball adapter Ø 8 mm, 120 mm

Accessories

MRW-0..... AVR sterilisation and storage container 530 x 250 x 100 mm

This instrument or medical device is non-sterile when delivered. It is to be reprocessed before use. The instrument must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing.

The retractor system for aortic valve reconstruction (AVR retractor) may only be used, reprocessed and disposed of by qualified medical personnel!

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

1) Intended purpose

The purpose of holding and guiding instruments is to hold or fix products and tissue (e.g. sizers, cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position

- or to move them into or to a specific position

This excludes retractors (as specified in the IFU, Classes I and IIa), hooks, vessel and tissue clamps, forceps and needle holders.

Additional information regarding the intended purpose

Duration of application: Holding and guiding instruments are intended for short-term use.

Field of application: Holding and guiding instruments are used in all patients where products and tissue must be held or fixed in or to a specific position and/or moved to or in a specific position.

User profile: Holding and guiding instruments may only be used by medically trained personnel (e.g. specialist physician).

Application environment: Holding and guiding instruments are only to be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions.

2) Indications

Treatment methods requiring the holding and guiding of products and tissue.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding 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 side effects

The following side effects are described in the medical literature and may also occur during the intended use of holding and guiding instruments:

- Bone fractures, such as spinous processes or vertebral bodies
- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischaemia 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) Before use

The retractor system for aortic valve reconstruction (AVR retractor) is supplied non-sterile and must be cleaned and sterilised by the user before first use and before each subsequent use (see section 6) Reprocessing).

⚠	Perform a safety check before each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section *6) Reprocessing* under *"Maintenance, Inspection and Testing"*).

⚠	Handle the retractor system for aortic valve reconstruction (AVR retractor) with care during storage, transport and cleaning! Avoid mechanical shock and point loading on the retractor system for aortic valve reconstruction (AVR retractor) to minimise causing any secondary damage! Do not overload functional parts.
⚠	Use only intact and sterilised products!

6) Reprocessing	
⚠	The medical device is to be reprocessed before use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before 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 mechanical shock and point loading on instruments to minimise causing any secondary damage! Do not overload functional parts.
⚠	Do not clean instruments with plastic components using oxidative processes (processes with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative ageing of the material, which may under certain circumstances not be detectable by visible discolouration or embrittlement.
Limitations on reprocessing	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure – also see "Maintenance, Inspection and Testing"). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.

General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilisation) were validated with the respective parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (detergent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of potable water quality and fully deionised water (deionised water, demineralised, microbiologically at least of potable water quality) are used for cleaning. Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result. There is also the option of cleaning our instruments with other tested and approved chemicals which have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's information on concentration, exposure time, temperature and renewal of the detergents and disinfectants. All of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-treatment at the place of use	Pre-cleaning: Ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper wipe immediately after completion of the procedure and that they undergo 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 before cleaning	Instruments should be reprocessed immediately after use because it is very difficult to remove dried residues from instrument parts that are difficult to access. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Instruments that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • Rinse instruments, if possible in disassembled condition, under running cold water of potable water quality (< 40 °C) until all visible contamination has been removed. Remove stubborn contamination with a soft brush (not a wire brush). • Cavities, crevices, slits and lumens must be rinsed intensively (> 10 seconds) with cold water (potable water quality, < 40 °C) using a water spray gun (or similar).

	• Place the products for 10 – 30 minutes in a solution with 0.5 – 2% Neodisher® MediClean forte with water (potable water quality, < 40 °C). • Use only an approved solution of a detergent that has no protein-fixing effect. Follow the instructions of the detergent and disinfectant manufacturer. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, the moving parts of the instrument may be moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush) during the exposure time. • Rinse the instruments for one minute in cold deionised water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, 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 sterilisation baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh. <u>Validated procedure:</u> Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the washer/disinfector. <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 deionised water (< 30 °C)

	• Emptying • Thermodisinfection for 5 minutes with deionised water (> 90 °C) • Dry for 30 minutes (90 °C) After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.
Cleaning: manually	<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 contamination is no longer 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). • Deionised water (< 40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant solution (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner.

	• After disinfection, rinse all products thoroughly with deionised water (< 40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. • Ensure that no residues remain on the products. • Dry with sterile, oil-free compressed air.
Drying	If drying is to be achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C. Then dry with suitable compressed air in accordance with Robert Koch Institute (RKI) recommendations. Pay particular attention to the drying of difficult-to-access areas.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilisable and steam-permeable is to be applied before sterilisation. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and compromise the effect of steam sterilisation. Perform a safety check of the instruments before each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components. Check instruments with movable parts for smooth operation (avoid excessive looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. In particular, inspect the critical points on moving parts and in the working area. Defective or damaged instruments, or those with illegible markings, must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or by workshops authorised by the manufacturer. A confirmation form for this process is available from the manufacturer. Instruments that can no longer be repaired must be disposed of as scrap metal in accordance with hospital practice. In the case of surgical instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments.
Packaging	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665 (Parts 1 and 2). 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 Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature 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. They are to be cleaned prior to disposal. They can be disposed of at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually performed using equipment, materials, and personnel in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy and potential adverse consequences.	
	Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability. Subject to change without notice.

7) Configuration and application

The MRW-1G retractor frame and the components form the retractor system for aortic valve reconstruction (AVR retractor). It is intended in particular for exposing the aortic root and aortic valve leaflets during aortic valve reconstruction and for procedures involving further invasive cardiac surgery.
Figure 1 shows a configuration example for the retractor system for aortic valve reconstruction (AVR retractor) with a Mercedes thoracic retractor as a possible extension of the retractor system. The corresponding components are listed in Table 2.

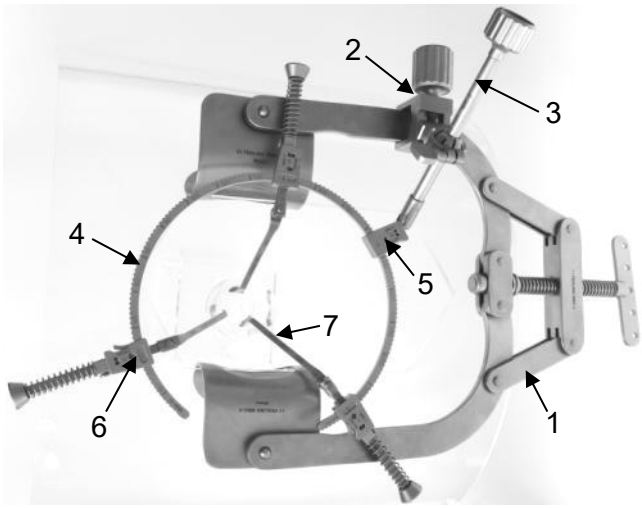

Fig. 1: Configuration example for the retractor system for aortic valve reconstruction (AVR retractor) with a Mercedes thoracic retractor.

Table 2: List of the corresponding components

	Item no.	Description
1	MBU-5 (for example: almost any other sternal retractor can be used instead)	Mercedes thoracic retractor (frame only)
2	MRF-1V	Ball adapter for round instruments Ø 8 mm
3	MRI-0	Hook guide for ball adapter Ø 8 mm, 120 mm
4	MRW-1G	AVR retractor Ø 140 mm Frame only
5	MRW-6	AVR connector carriage
6	MRW-7	AVR clamping carriage for holding blades
7	MRW-2G/3G/4G/5G	Holding blade available in lengths of 70/85/100/115 mm

⚠	Use only intact and sterilised products!
⚠	Before using the retractor system for aortic valve reconstruction (AVR retractor), ensure that the surgical field has been prepared accordingly beforehand.
⚠	Before using the retractor and the retractor components, ensure that their functionality is not impaired and that they are not damaged.
⚠	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of components depends on the anatomical and physiological conditions as well as the field of application. Care must be taken to ensure that the components used have the correct size and geometry, as well as sufficient stability.

7.1) Extension module

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

8) Required accessories

No accessories are required for using the retractor system for aortic valve reconstruction (AVR retractor).

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

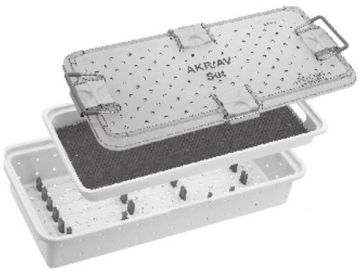

Fig. 2: AVR sterilisation and storage container MRW-0

9) Assembly

Please follow the assembly instructions below for assembling theretractor system for aortic valve reconstruction (AVR retractor).

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

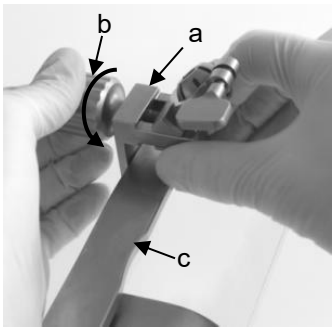

Fig. 3

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

Fig. 4a:

Figure 4b shows the individual parts of the MRI-0 hook guide. They are disassembled into three parts in the instrument tray: Outer sleeve (d), inner rod (e) and proximal locking nut (f).

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

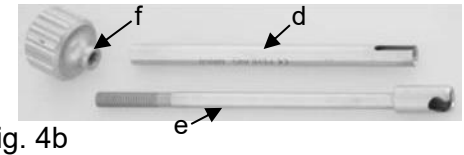

Fig. 4b

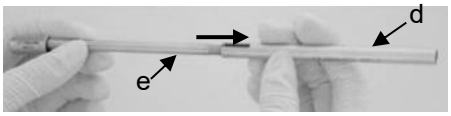

Fig. 4c:

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

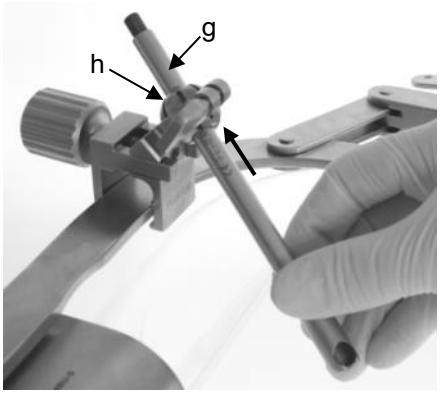

Fig. 5

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

To facilitate the subsequent assembly steps, the connection between the ball adapter and hook guide can be temporarily secured by tightening the wing screw (i) of the ball adapter clockwise (Fig. 6a).

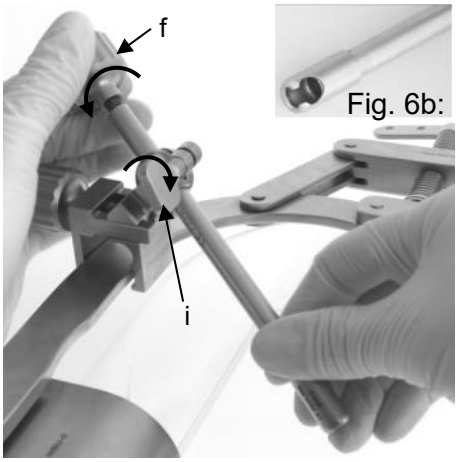

Fig. 6a:

Fig. 6b:

Figures 7 – 9 show the carriage, the retractor ring and their connection.

Figure 7a shows the MRW-6 connector carriage. It has a box-shaped fenestrated receptacle (j) for the MRW-1G retractor ring and a curved cylindrical bracket with a spherical end (k). The labelled side is the top from the surgeon's perspective.

Fig. 7a

Figure 7b shows an MRW-7 clamping carriage.
Its components: A box-shaped fenestrated receptacle (l) for the retractor ring, an axle (m) guided through this receptacle in the longitudinal direction and a coil spring (n). The labelled side of the receptacle is the top. At the proximal end of the ring receptacle, on the right side – viewed from above – there is a push button with locking and unlocking function. In Figure 7b, the axle of the carriage is unlocked.

Figure 7c shows the clamping carriage with the axle pushed distally and locked by the push button (o).

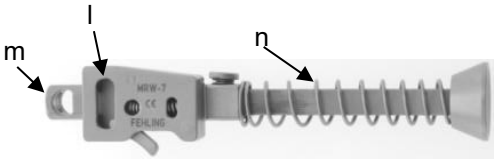

Fig. 7b:

Fig. 7c:

Figure 8 shows the MRW-1G retractor ring.
It is serrated on the outside and has an angle graduation with intervals of 15° on the top. The ring has an opening over an angle of approx. 60°. This open ring area usually faces the surgeon.

Fig. 8

Figures 9a – 9c show the connection of the retractor ring with the carriages. All carriages have a lever on their left side – viewed from above – which facilitates the insertion of the carriages onto the ring and the movement of the carriages over the ring by finger pressure.

Figure 9a shows in detail the insertion of the connector carriage (j) onto the retractor ring (p).

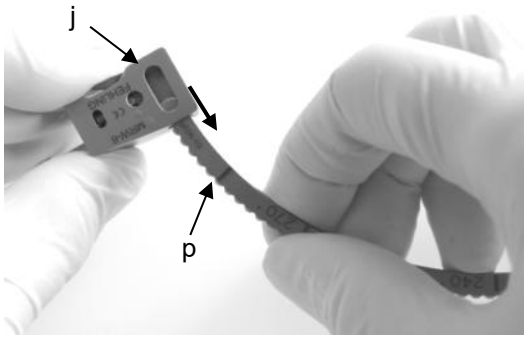

Fig. 9a:

Figure 9b shows the connector carriage in a position at approx. 165° on the retractor ring.

Fig. 9b

Figure 9c shows the retractor ring after complete assembly with the connector carriage and the 3 clamping carriages. The clamping carriages are arranged here at the 'ideal' angle interval of 120°. The correct patient-specific position is always in the middle between the commissures of each leaflet.

Fig. 9c

Figures 10a – 10c: Equipping the clamping carriages with the holding blades

The system contains 3 holding blades in 4 different lengths. The choice of length depends on the patient's anatomy.

Figure 10a shows in detail the insertion of a holding blade (q) into the hole at the distal end of a clamping carriage axle (m).

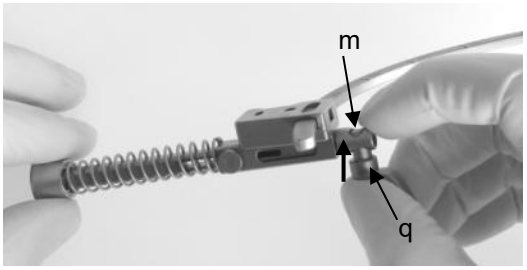

Fig. 10a

Figure 10b shows the retractor ring with all carriages and holding blades. The axles of the clamping carriages are unlocked.

Fig. 10b:

Figure 10c shows the same assembly as Figure 10b, but with locked clamping carriage axles: The distal portions of the holding blades are thus in a position in which they can be easily inserted into the patient's aortic root.

Fig. 10c

Figure 11 shows the connection of the AVR retractor with the sternal retractor.

Use the distal receptacle of the MRI-0 hook guide (r) to grasp the connection ball (k) of the MRW-6 connector carriage. Provisionally secure the connection ball (k) in the desired position by turning the locking nut (f) clockwise.

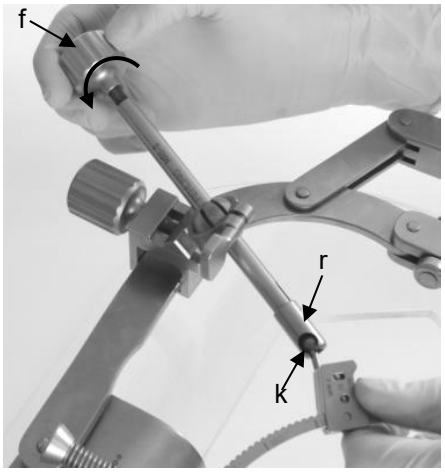

Fig. 11

Figure 12a shows the insertion of the retractor and its holding arms into the aortic root.

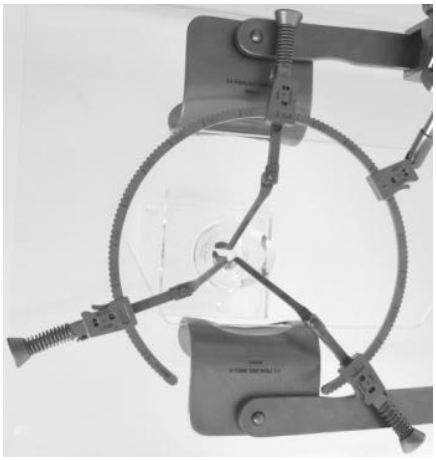

Fig. 12a

Figure 12b shows the retractor after unlocking the axles.

Fig. 12b

Once the optimal retractor position has been achieved, it is secured in two steps:

- The connection between the MRI-0 hook guide and the ball of the MRW-6 connector carriage (k) is established by turning the locking nut (f) of the hook guide clockwise (cf. Fig. 11),
- The MRI-0 hook guide is positioned in the ball of the MRF-1V ball adapter and secured by turning the wing screw (i) of the ball adapter clockwise (cf. Fig. 6a).

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

10) Disassembly

Please follow the assembly instructions for disassembling the retractor system for aortic valve reconstruction (AVR retractor) (see section 9) Assembly).

⚠	Place small parts in suitable containers (e.g., needle box) for storage and reprocessing.

11) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form athttps://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer's contact information		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 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