FEHLING MARJAN MGH Retractor System		
Retractor frame	MRY-6	MARJAN MGH retractor, frame only

Components

Retractor blades for partial sternotomy
MRY-1 MARJAN MGH retractor blade for partial sternotomy, 35 x 50 mm
MRY-2 MARJAN MGH retractor blade for Z sternotomy, 35 x 50 mm

Retractor blades for total sternotomy
MRY-3K MARJAN MGH retractor blade for total sternotomy, 35 x 70 mm
MRY-3 MARJAN MGH retractor blade for total sternotomy, 35 x 100 mm
MRY-4 MARJAN MGH retractor blade for total sternotomy, 45 x 100 mm
MRY-7 MARJAN MGH retractor blade for total sternotomy, convex, 34 x 100 mm
MRY-8 MARJAN MGH retractor blade for total sternotomy, convex, 43 x 100 mm
MRY-9 MARJAN MGH retractor blade for total sternotomy, convex, 50 x 100 mm
MSD-0 MARJAN MGH retractor blade for total sternotomy, convex, 34 x 120 mm

IMA blades
MLM-6V Baykut IMA blade, 15 x 50 mm
MLC-2V Baykut IMA blade, 15 x 90 mm
MLM-3V Baykut IMA blade, 15 x 120 mm
MSC-8 MARJAN MGH retractor blade for IMA exposure with Baykut blade, 30 x 65 mm
MSC-9 MARJAN MGH retractor blade for IMA exposure with Baykut blade, 40 x 65 mm
MRY-5 MARJAN MGH retractor blade for IMA exposure with Baykut blade, 50 x 65 mm

The components listed here are also available with a CERAMO-coated surface. In this case, a “C” is added to the article number.

This instrument or 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 MARJAN MGH retractor system may only be used, reprocessed and disposed of by qualified medical personnel!

The MARJAN MGH retractor system 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 TD for Classes I and IIa retractors), 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 surgeons).

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 are inconsistent with the physical and/or mechanical properties of the specific holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding and guiding instruments.
Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.

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, e.g. ribs, sternum, spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Injury to structures (tissues, organs, nerves, vessels)
- Necrosis
- Ischaemia
- Haematoma
- Impaired sternal healing, potentially causing sternal instability

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

5) Before use	
The MARJAN MGH retractor system is supplied non-sterile and must be cleaned and sterilised by the user before initial use and before each subsequent use (see Section 6) Reprocessing).	
⚠	Perform a safety check prior to 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 MARJAN MGH retractor system with care during storage, transport and cleaning! Avoid impacts and point loading on the MARJAN MGH retractor system to prevent any possible secondary damage! Do not overload functional parts!
⚠	Use only intact and sterilised products!

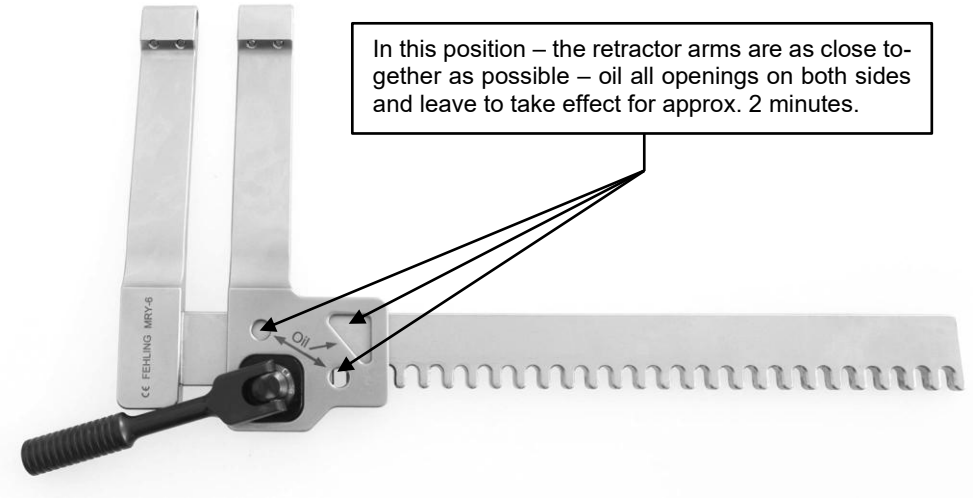
6) Reprocessing	
⚠	The medical device is to be reprocessed prior to use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) prior to reprocessing.
⚠	The national legal regulations, national and international standards and guidelines as well as 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 mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts!
Reprocessing limitations	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 labels or 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 automated 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	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, for preference use a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
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), apply a biocompatible, steam sterilisable, steam-permeable paraffin-/white oil-based instrument oil (according to the valid European or United States Pharmacopoeias) 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 impair the effectiveness of steam sterilisation. 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 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 instru-

	ments 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.
⚠	Instrument oil must be applied to the MARJAN MGH retractor system at the appropriately marked points. The relevant points are indicated by the arrows on the movable retractor arm (Fig. 1). When lubricating the MARJAN MGH retractor system, position the retractor arms as shown in Figure 1. Oil all openings on both sides and leave to take effect for approx. 2 minutes.
	 Fig. 1: MARJAN MGH retractor system with the appropriately marked points
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 using a fractionated vacuum process in a steriliser complying with DIN EN 285 and DIN EN ISO 17665. 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 must 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 MARJAN MGH retractor system is a U-shaped bar retractor with one fixed and one movable retractor arm. The movable retractor arm is driven along the toothed rack by means of the drive lever and pinion. The blades are attached to the distal end of the retractor arms.

Figures 2 – 4 show various configuration examples for a retractor system comprising the MARJAN MGH retractor frame (1), and Table 1 lists the corresponding retractor blades (2-5).

- The MARJAN MGH retractor system is intended for exposure of the thorax during total and partial sternotomy approaches, to facilitate invasive surgical treatment of the heart, including exposure of the IMA.

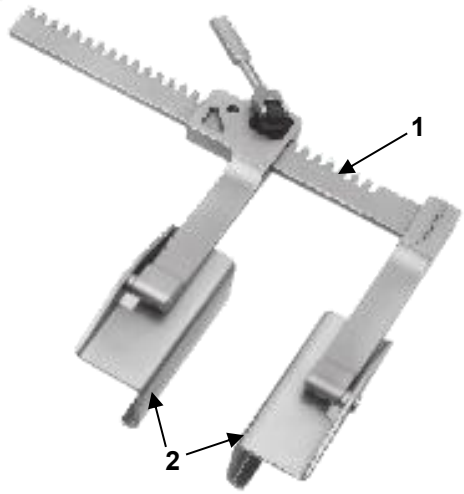


Fig. 2: Example of a total sternotomy

Table 1: List of the corresponding components

	Item no.	Description
1	MRY-6	MARJAN MGH retractor, frame only
2	MRY-3	MARJAN MGH retractor blade for total sternotomy, 35 x 100 mm
3	MRY-1	MARJAN MGH retractor blade for partial sternotomy, 35 x 50 mm
4	MRY-5	MARJAN MGH retractor blade for IMA exposure with Baykut blade, 50 x 65 mm
5	MLC-2V	Baykut IMA blade, 15 x 90 mm

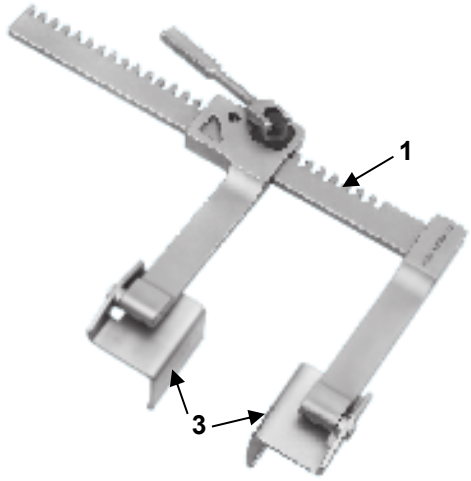


Fig. 3: Example of a partial sternotomy

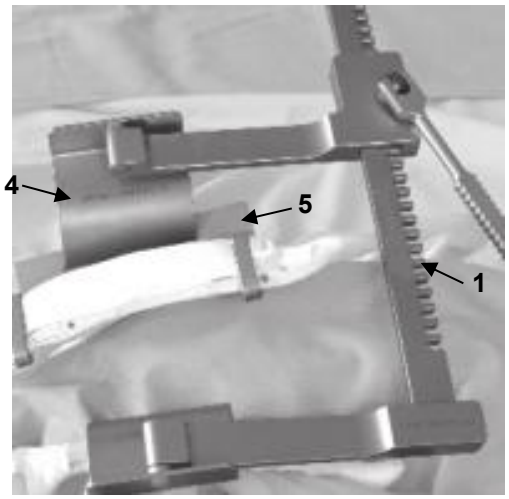


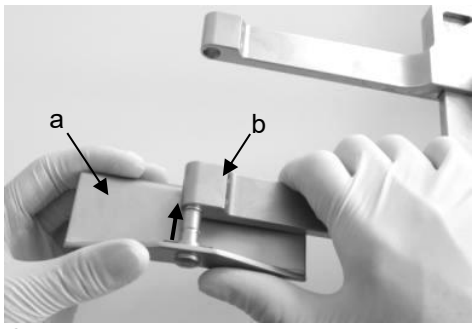
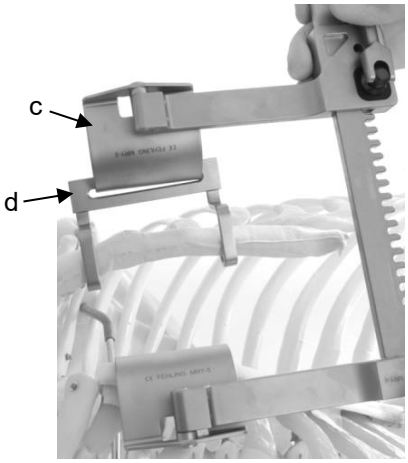
Fig. 4: Example of IMA exposure

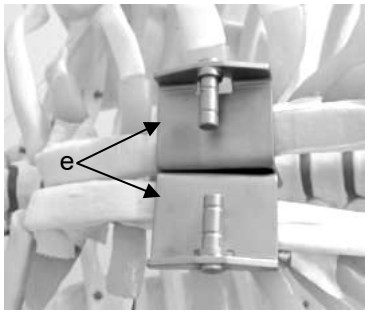
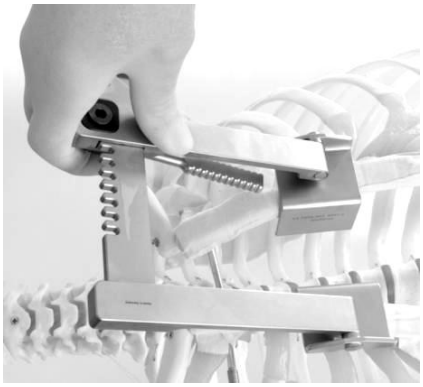
⚠	Use only intact and sterilised products!
⚠	Before inserting the MARJAN MGH retractor system, ensure that the surgical site has been prepared accordingly beforehand.
⚠	Before using the MARJAN MGH retractor system, ensure that it is fully functional and not damaged!
⚠	Medical devices made of ferromagnetic 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.

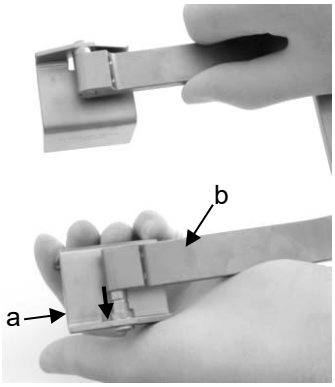
During application

Following sternotomy as appropriate for the intended procedure, apply the MARJAN MGH retractor system using one of the following options:

1	Total sternotomy using blades MRY-3 or MRY-4 with a flat retraction surface, or alternatively MRY-7, MRY-8 or MRY-9 with a retraction surface convex towards the sternum (see Fig. 5).	 Fig. 5
2	Total sternotomy with IMA exposure using blades MRY-5 in combination with a BAYKUT claw MLM-3V, MLM-6V or MLC-2V (see Fig. 6).	 Fig. 6

3	Partial sternotomy via an L-incision in the cranial or caudal sternal region using MRY-1 blades (see Fig. 7).	 Fig. 7
4	Partial sternotomy via a Z-incision using MRY-2 blades (see Fig. 8).	 Fig. 8
5	The blades (a) are attached to the retractor frame (b) by inserting the cylindrical pins on the upper side of the blade into the holes at the distal end of the retractor arms. Important: Always insert the pins from the outside to the inside of the frame (see Fig. 9).	 Fig. 9
6	For sternotomy with IMA exposure using MRY-5 blades (c), the BAYKUT claw (d) may be slipped over the MRY-5 blade from the outside on the respective dissection side, depending on which IMA is being dissected, so that its hooks engage as far as possible beneath the sternum from medial to lateral (see Fig. 10).	 Fig. 10

7	Depending on the purpose of the operation and the available assembly space, the blades may be connected to the retractor frame either before or after insertion into the sternotomy gap. The latter is the usual option, especially for a Z-shaped sternotomy. Recommended procedure: Insert the two MRY-2 blades (e), which have an extremely small “lower lip”, one after the other into the sternotomy gap (see Fig. 11a).	 Fig. 11a
8	Insert the distal ends of the two retractor arms one after the other into the space between the free ends of the two blade pins and slide the hole in each retractor arm over the corresponding blade pin. This may be accomplished either with the retractor frame firmly closed or open to a width of approx. 100 mm. The second option may be somewhat more convenient, as the fixed retractor arm can be easily slid over the left pin, from the surgeon's view. The movable retractor arm is then moved completely toward the fixed retractor arm and, while slightly tilting the left blade, guided into the space between the pins and slid over the right pin by opening the retractor frame accordingly (see Fig. 11b and 11c).	
	 Fig. 11b	 Fig. 11c
9	Especially in a small surgical field, as is usually the case with a Z-shaped sternotomy, the dissection space is extremely small, making cannulation and subsequent dissection steps, for example, most demanding for the surgeon. The MARJAN MGH retractor solves this problem by allowing the entire retractor frame to be flipped cranially around the axis of the blades. The result is a fully accessible surgical field (see Fig. 12).	 Fig. 12

10	Each connection between a blade (a) and the retractor frame (b) is secured against unintentional disengagement of the blades by two ball-snap locks. When removing the blades, this locking mechanism can be disengaged with minimal force (see Fig. 13).	 Fig. 13
⚠	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.	

8) Required accessories

No accessories are required for using the MARJAN MGH retractor system.

9) Assembly

Please follow the instructions below to assemble the MARJAN MGH retractor system.

Figure 14 shows the MARJAN MGH retractor, a U-shaped bar retractor with a pinion. The bar retractor consists of a fixed retractor arm (1), a toothed rack (2) and a movable retractor arm (4).

The proximal end of the movable retractor arm is the box (5) which houses the drive lever (3).

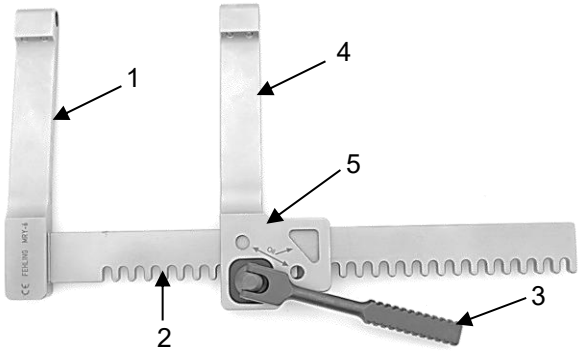


Fig. 14

First insert the drive lever (3) into the recess provided in the box (5) (Fig. 15).

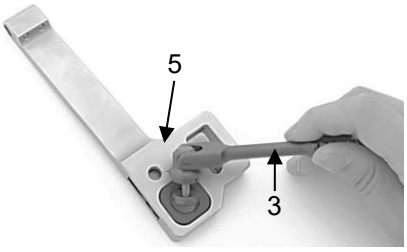


Fig. 15

Insert the toothed rack (2) into the recess in the box (5) until the pinion of the drive lever (3) engages in the toothed rack (2) (Fig. 16).

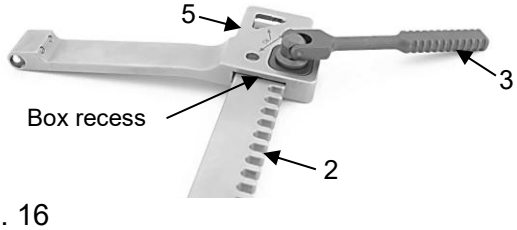
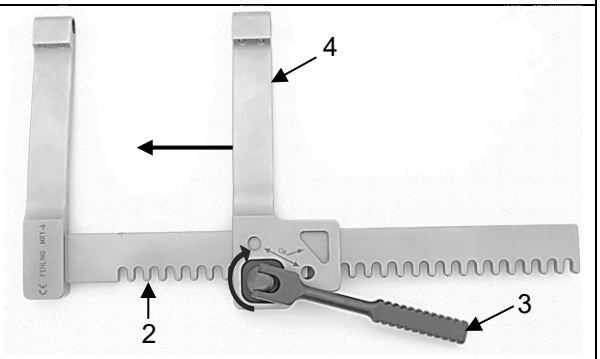
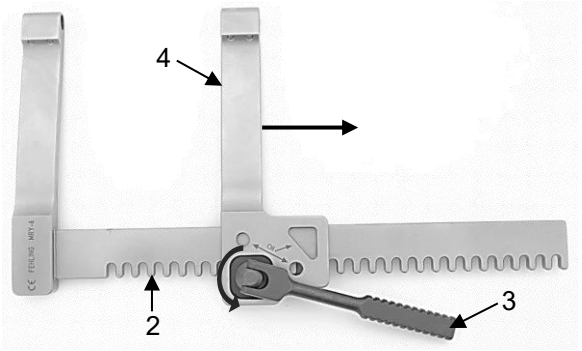


Fig. 16

⚠	Ensure that both retractor arms point in the same direction, as shown in Figure 17.
Rotate the drive lever (3) clockwise to move the movable retractor arm (4) inwards on the toothed rack (2) towards the fixed retractor arm (1) (Fig. 17). After a functional test, the assembled instrument is ready for use again.	 Fig. 17

10) Disassembly	
1. For reprocessing, the MARJAN MGH retractor system must be disassembled as follows.	
To disassemble the retractor blades or IMA blades, please refer to 7) Configuration and Application – During Application.	
Rotate the drive lever (3) anticlockwise to move the movable retractor arm (4) outwards on the toothed rack (2) until it can be removed (Fig. 18).	 Fig. 18
In a second step, remove the drive lever (3). Disassembled into its three individual components (Fig. 19), the instrument can now be reprocessed.	 Fig. 19
⚠	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 at https://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