MARJAN MGH Retractor system	REF MRY-1..MRY-9, MSC-8, MSC-9 MLM-2, MLM-4, MLM-6, MLC-2 MLM-3V, MLM-6V, MLC-2V

Not sterile, clean and sterilize prior to usage!

Intended use

The MARJAN MGH retractor system is intended for all usual sternotomy accesses, total and partial, IMA exposition inclusive.

Indications and contraindications

Surgical invasive treatment of the heart with sternotomy access.
All applications going against the physical and/or mechanical properties of the instrument are contraindicated.

Prior to usage:

Check functionality and surface condition of the instruments.

⚠ Use only perfect and sterilized products!

During usage:

After purpose-dependent sternotomy, application of the retractor MRY-6 with the following options:

1. Total sternotomy with blades MRY-3 or -4 with plane retraction area, alternatively MRY-7 oder MRY-8 or MRY-9 with retraction area that is convex towards the sternum (cf. fig. 1).


Fig. 1

2. Total sternotomy with IMA exposure using blades MRY-5 combined with BAYKUT claw MLM-6, MLM-2, MLC-2, MLM-4, MLM-3V, MLM-6V or MLC-2V (cf. fig. 2).

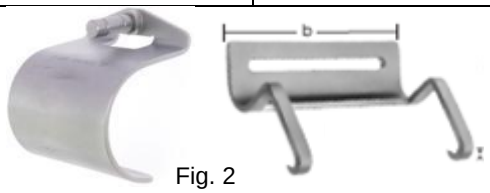


Fig. 2

3. Partial sternotomy by L-Cut in the cranial or caudal sternum area with blades MRY-1 (cf. fig. 3).

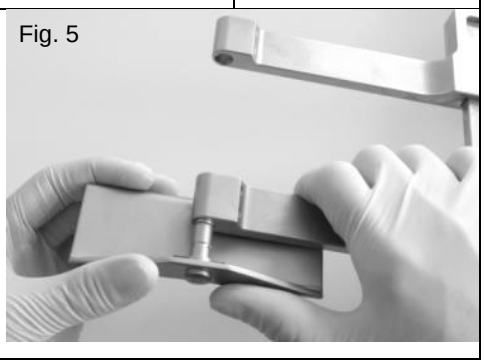

Fig. 3

4. Partial sternotomy by Z-cut using blades MRY-2 (cf. fig. 4).


Fig. 4

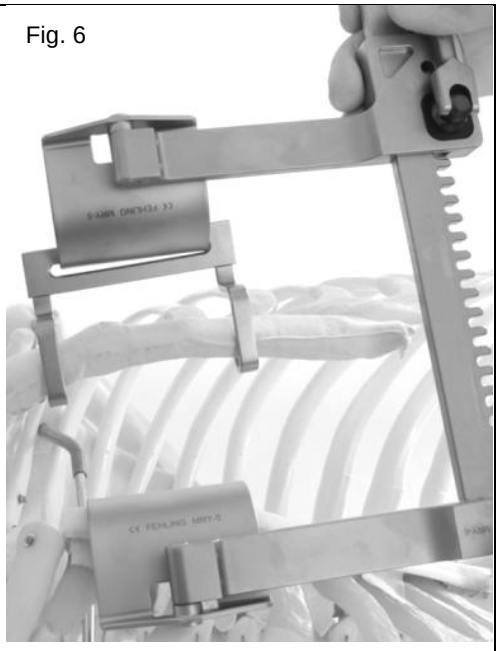
The blades are fixed to the retractor frame by inserting the cylindrical pins at the upper side of the blades into the holes provided at the distal end of the retractor arms. Important: Always insert the pins from the outside of the frame to the inside. (cf. fig. 5).

Fig. 5



For the sternotomy with IMA exposure using blades MRY-5, in accordance with the IMA to prepare the BAYKUT claw can be slipped over the blade MRY-5 on the relevant dissection side from the outside such that the claws reach under the sternum from median to lateral as far as possible (cf. fig. 6).

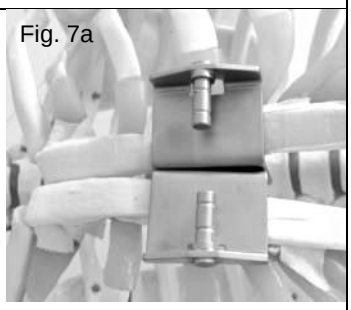
Fig. 6



In accordance with the purpose of the operation and the available assembly space, the blades can be connected to the retractor frame either before or after insertion into the sternotomy gap. The latter option is the rule for a sternotomy with Z-shaped incision in particular. Recommended procedure:

- Insert the two blades MRY-2, that have an extremely small 'lower lip', one after the other into the sternotomy gap (cf. fig. 7a).

Fig. 7a



- Insert the distal ends of both arms one after the other into the space between the free ends of the two blade pins, and slide the respective hole of the arms over the blade pin. You can choose to do so with the retractor frame firmly closed or opened by app. 100 mm. The second option might be a little more comfortable, as the rigid arm can be pushed easily over the left pin as seen from the operator, then the moving arm is moved completely to the fixed arm and can be guided into the pin space by slightly tilting the left blade and pushed over the right pin – by opening the frame accordingly (cf. fig. 7b and 7c).

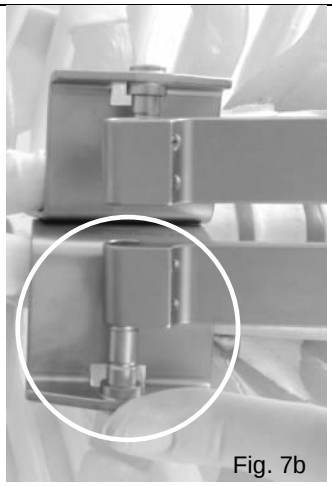
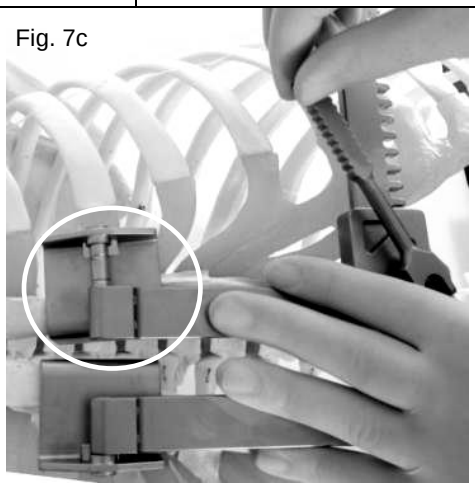


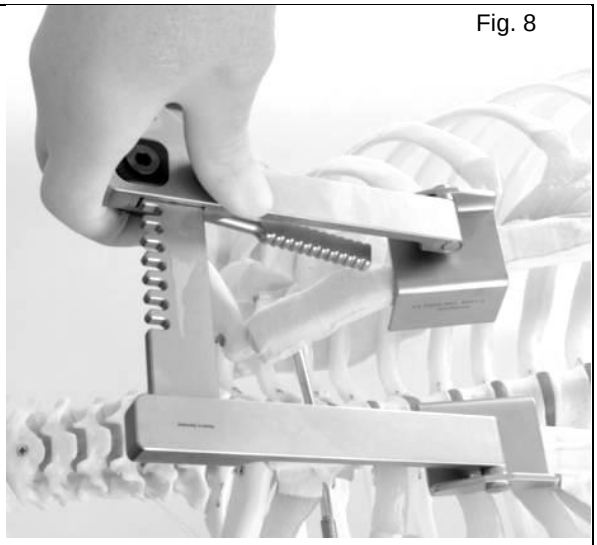
Fig. 7b

Fig. 7c



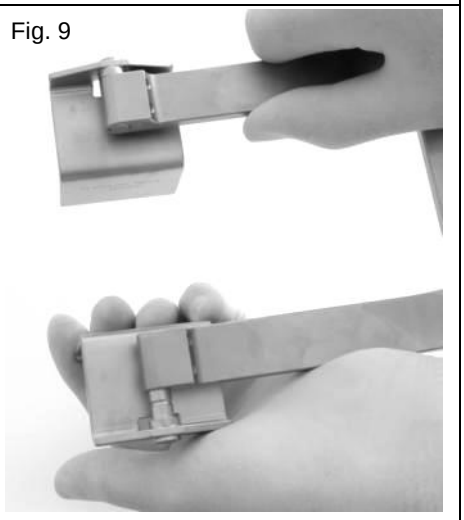
For a small exposure in particular, as is the rule with the sternotomy by Z-cut, the surgical field is extremely small, which is an above-average challenge for the operator in the cannulation but also in subsequent steps of surgery. The MARJAN MGH retractor solves this problem through the possibility of flipping the entire frame around the axis of the blades to the cranial side. Result: an exposure that is totally freely accessible (cf. fig. 8).

Fig. 8



The connection of the blades with the retractor frame is secured against accidental disengagement of the blades by two ball snap locks. When the blades are removed this locking can be easily overcome with little force (cf. fig. 9).

Fig. 9



After use - Reprocessing of sterilizable instruments

Restriction for reprocessing:

Frequent reprocessing has only minor effects on these instruments. Usually the end of the product service life is determined by wear and damage from use.

INSTRUCTIONS:

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage:	Store instruments in dry room to avoid condensation. It is recommended to start reprocessing the instruments directly after use, as dried residues located in areas with limited access are quite difficult to remove.

Preparation of cleaning: Mechanical processing should be preferred over manual processing.	Make sure that traces of blood, tissue and medication are removed from the instruments directly after termination of the surgery and that they are immediately forwarded to mechanical cleaning. Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use an approved solution of a combined cleaning and disinfecting agent without protein fixing effect (observe the recommendation of the chemicals producer when mixing the solution). Avoid overfilling of instrument sets and washing trays – use appropriate instrument carriers only. Be particularly careful that the mouths/points do not get stuck in the mesh when placing and removing the instruments into/from the set baskets. Always open and/or disassemble joint instruments for processing. Release the springs if necessary.
Cleaning/Disinfection according to EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfection are available on the market and approved for the respective application, and that the recommended concentrations, time of exposure and temperatures are observed.
Cleaning/disinfection: mechanically acc. to standard EN ISO 15883-1:2009	<u>Validated Procedure:</u> Equipment: Washer/disinfector Miele G7836 CD Process: 2-component alkaline/enzymatic Cleaning Agents: deconex TWIN PH 10 and deconex TWIN ZYME (Borer, Switzerland) <u>Preparation:</u> • Joint instruments are to be placed in the device such that the hinge is open and that water can flow off cavities and blind holes. • Make sure that all cavities are completely flushed on the inside as well. • Make sure that no flushing shadows arise. <u>Parameter:</u> • 3 min pre-cleaning with tap water • Drain • 10 min cleaning with tap water 0,3 % dosing TWIN PH10 at 35 °C (95°F) and 0,2 % dosing TWINZYME at 40 °C (104°F) • Drain • 2 min rinsing with deionized water > 30 °C (86°F) • Drain • 1 min rinsing with deionized cold water • Drain • 5 min thermal disinfection at 93 °'C (200°F) • After mechanical cleaning, check cavities, blind holes, etc. for visible dirt. Repeat cycle or clean manually if required.

Cleaning/disinfection: manually Manual cleaning should be avoided as it cannot be validated.	Equipment: Detergent (active and non protein-fixing cleaner, with or without antimicrobial effect and/or enzymes), compressed-air cleaning gun, soft cloths/sponges, running water. 1. Thoroughly rinse dirt from the surface of the instrument. 2. Apply detergent solution on all surfaces using a soft cloth or sponge. Make sure that joint instruments are cleaned in open as well as closed position. 3. Thoroughly rinse all cavities and blind holes with a sufficient amount of detergent solution (min. 200 ml) using a syringe. Take special care that enough solution flows to the distal end. 4. Hold the instrument under running water. The running water must flow through the cavities, and blind holes must be filled and emptied several times. Use deionized water for the final rinsing. For manual cleaning the detergent solution should not be warmer than room temperature. <u>Disinfection</u> Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (min. 5 minutes at 93 °C – 200°F). (Thermal disinfector, see instructions of the device manufacturer.) Demineralized water must be used for the final flushing. Make sure that no residues remain on the products.
Drying:	If drying is achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C (248°F).
Maintenance:	Apply a small amount of high-grade, water-soluble instrument spray on the ratchet mechanism according to instruction R09. Sort damaged instruments (check for cracks or damage). Verify usability.
Control and function test:	Check joint instruments for easy operation (avoid too much play). Check locking mechanisms. All instruments: Using a magnifying lamp visually inspect for damage and wear. Edges should not show nicks and should be even. Sort out defective instruments and return them to the manufacturer for repair. Cleaning, disinfection and sterilization must be performed prior to returning the instruments. A confirmation form sheet can be obtained from the manufacturer.
Packaging:	Separate: according to standards of the series EN 868 and EN ISO 11607. Sets: Sort instruments in provided trays or place them on universal sterilization trays. The edges must be protected. Use an appropriate procedure to pack the trays.
Sterilization:	Steam-sterilize using the fractional vacuum process at 134 °C (273°F) (min. 5 minutes holding time) with equipment acc. to EN 285, validated sterilization processes! To avoid formation of stains and corrosion, the steam must be free of components. The recommended limit values of the components for feed-water and steam condensation are defined in EN 285. <u>Validated process:</u> Equipment: Selectomat HP (MMM) 1. Three times pre-vacuum 2. Sterilization temperature: 134 °C (273° F) 3. Holding time: 5 min 4. Drying time 10 min
Storage:	according to EN 868 and EN ISO 11607
Additional information:	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).

The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.
Additional national standards like AAMI TIR-12-2004 may be applicable.

Used symbols:					
 Protect from excessive heat!	 Keep dry! Do not store below +5 °C and above +40 °C for longer periods!	 Observe instructions for use	 Item number	 Warning	CE

	Any changes to the product or failure to observe these operating instructions lead to exclusion of liability

Changes may occur without notice.

Manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG, Hanauer Landstr. 7A, 63791 Karlstein/Germany, Tel.: +49 (0) 6188-957440 Fax: +49 (0) 6188-957445 www.fehling-instruments.de