MILuTX **Retractor System**	**REF** MRP-1 ..... MICS intercostal retractor, body only MRD-8V/MRD-9V . FANTASMICS cross bracket for blades MRI-1S…MRI-7S,. FANTASMICS retracting blades MRE-4S…MRE-9S MRV-1F ..... Ball-joint adapter, straight, ø 6.35 mm, length and height variable MZZ-1..... Clamping element f. ball joint adapter movable MRV-7/MRV-8, ... SUPERPLAST lung/diaphragm spatula MRV-7V/MRV-8V

⚠ Non-sterile, clean and sterilize before first and each further use.
Prior to processing a risk assessment on the instrument must be performed.
Retractor systems may only be used, processed and disposed of by competent medical personnel!

Intended use:

The MILuTX retractor system is used to provide intercostal accesses to the thorax, especially the access for a minimally invasive lung transplantation.

Before use:

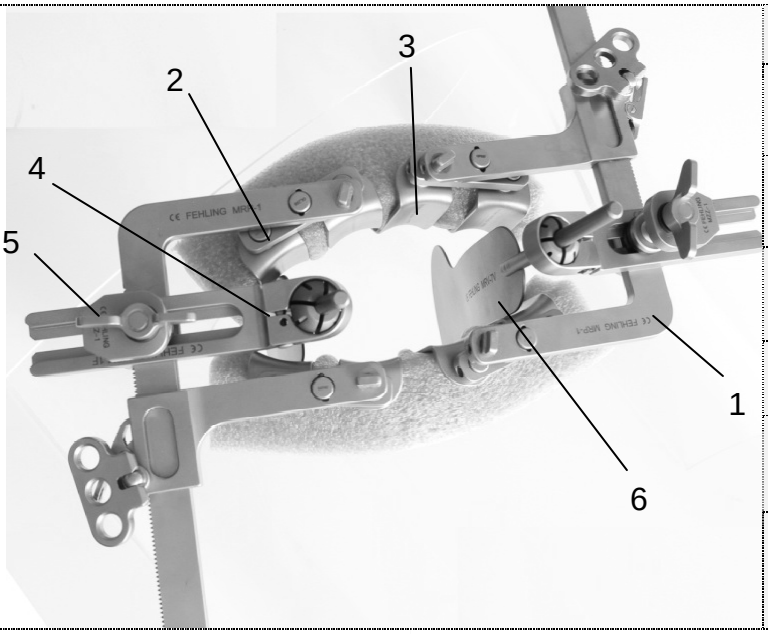
FEHLING INSTRUMENTS retractor systems are delivered non-sterile and have to be cleaned and sterilized by the user before their first and any further use (see reprocessing).

⚠ Handle retractors with care on storage, transport and cleaning! Avoid impacts and selective loads!
Use only flawless and sterilized products!

Perform a safety check before each use. Check for cracks, fractures and mechanical malfunctions. (see Maintenance, control and functional testing)

Components:

Fig. 1: Configuration example on the thorax model



	Art. no.	Designation
1	MRP-1	MICS intercostal retractor body
2	MRD-8V / MRD-9V	FANTASMICS cross bracket for blades
3	MRI-1S..-7S MRE-4S..-9S	FANTASMICS retracting blades
4	MRV-1F	Ball-joint adapter
5	MZZ-1	Clamping element f. ball joint adapter movable
6	MRV-7V/-8V MRV-7/-8	SUPERPLAST lung/diaphragm spatula

Assembly:

To assemble the retractor, first connect the retracting blades to the cross brackets. Depending on the anatomical requirements, the cross brackets can be selected in two different sizes (35 and 60 mm), and the retracting blades in different widths (15 and 24 mm) and depths (25 - 90 mm).

Figure 2a shows how the pin of the retracting blade is completely inserted into the blade socket in the cross bracket. There the blade is fixed by means of a ball snap mechanism but remains rotatable.

The cross bracket is equipped with two blades at a time (s. figure 2b).

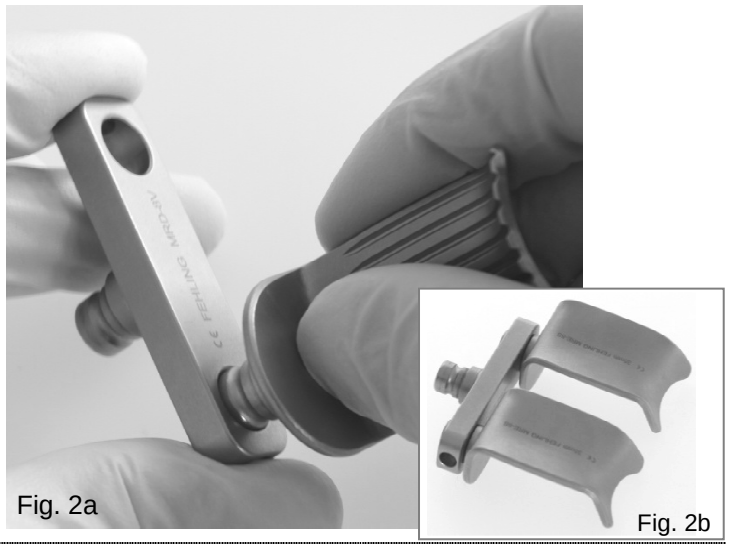


Fig. 2a

Fig. 2b

Now the cross bracket equipped with two retracting blades is connected to the retractor body.

Figure 3a shows how the pin of the cross bracket is completely inserted into the blade socket in the retractor bar. There the cross bracket is fixed by means of a ball snap mechanism but remains rotatable.

Figure 3b shows the complete retractor body equipped with two cross brackets.

Fig. 3a

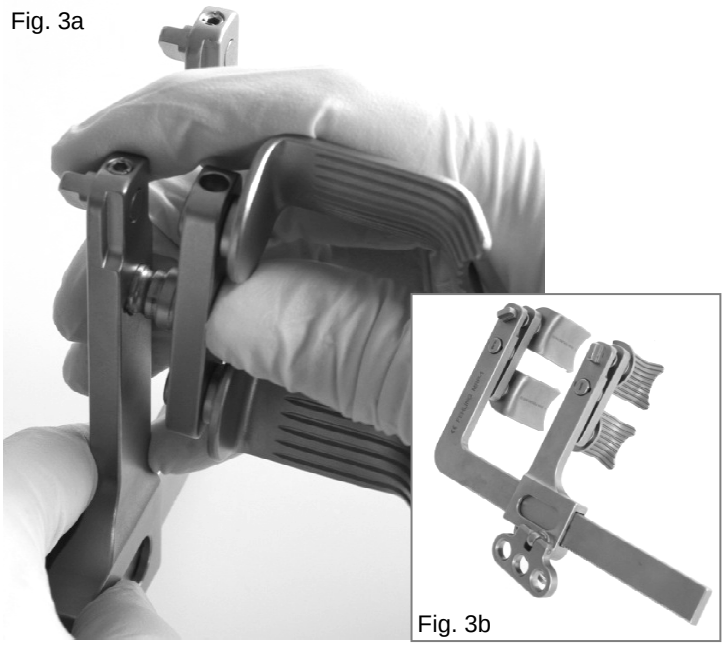


Fig. 3b

Figure 4 shows the retractor in situ.

Fig. 4

Now a second body is configured as described above and placed into the situs. Figure 5 shows clearly how the retractor perfectly adapts itself to the curved situs due to the pivoting retractors and cross brackets.

Fig. 5

Figure 6 shows the adaptable ball-joint adapter that is used to fasten the lung/diaphragm spatulas. The adapter consists of the elements MRV-1F and MZZ-1. Before installing the adapter on the retractor, the spatula should be connected to the adapter and the two parts of the adapter should be assembled.

Fig. 6

Figure 7 shows how the flexible spatula that has a shape memory is inserted into the ball of the adapter from below.

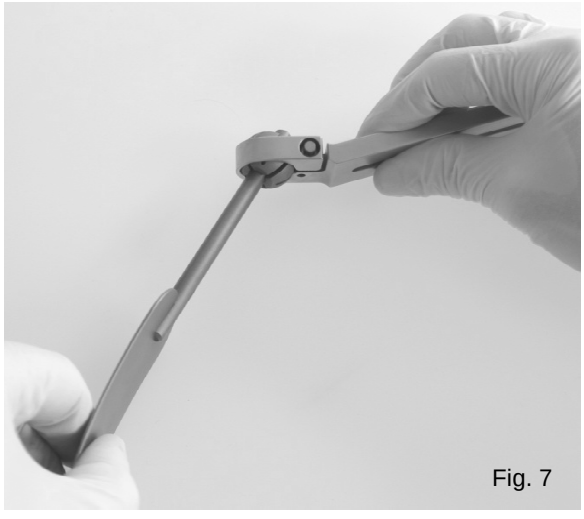


Fig. 7

Figures 8a and b show how the clamping element MZZ-1 is connected to the element MRV-1F. Make sure to assemble the two elements correctly. Please follow the instructions for use G 071 for this.

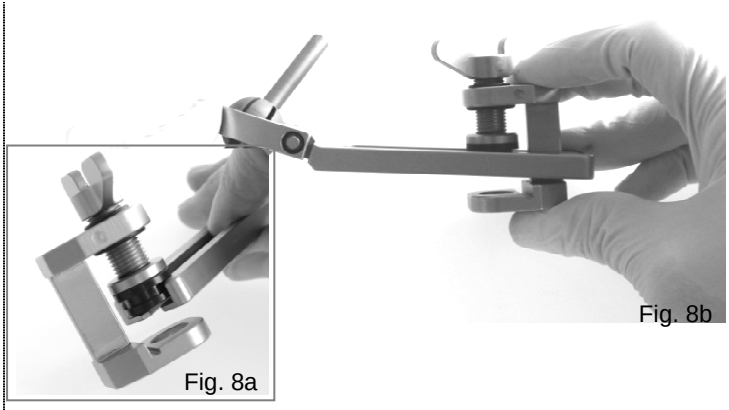
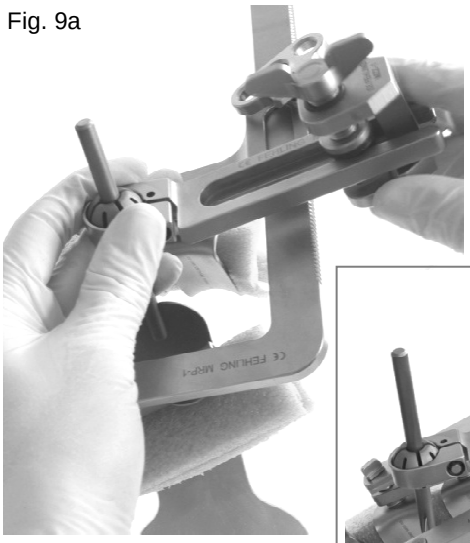


Fig. 8b

Fig. 8a

The figures 9a and b show how the lung spatula connected to the adapter is inserted into the situs and how the adapter is placed on the retractor body.

Fig. 9a



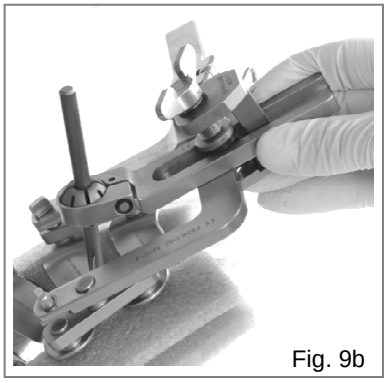


Fig. 9b

As soon as the adapter was placed on the retractor, the position of the lung spatula can be adjusted at will. When the desired position is reached, the adapter and the spatula are fixed.

Figure 10a shows how the lung spatula is fixed in the adapter ball using the Cardan screw driver LMT-4.

Figure 10b shows how the adapter is fixed on the retractor body by turning the thumb nut.

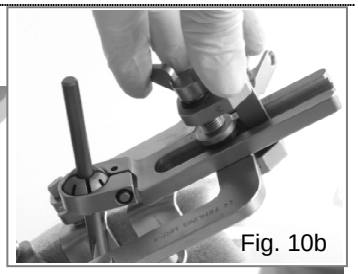


Fig. 10b

Fig. 10a

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. To activate the shape memory of the SUPERPLAST lung/diaphragm spatula, thermal disinfection or steam sterilization is recommended. Please note: • Place SUPERPLAST instruments in a manner that the activation of the shape memory is not inhibited by ambient conditions (e. g. other instruments or insufficient place) • Following sterilization, allow SUPERPLAST instruments to cool to room temperature. Bending probes at temperatures above about 40 ˚C (104°F) may impair their ability to function.
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	Validated Procedure: Equipment: Washer/disinfector Miele G7836 CD Process: 2-component alkaline/enzymatic Cleaning Agents: deconex TWIN PH 10 and deconex TWIN ZYME (Borer, Switzerland) Preparation: • 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. Parameter: • 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 anti-microbial 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. Disinfection 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 hinges. Sort out blunt or 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
Phone: 06188-957440 ● Fax: 06188-957445
E-Mail: info@fehling-instruments.de