FEHLING MICS intercostal retractor:

MRP-1F	MICS Intercostal retractor
MRP-2F	Blades, fenestrated with slit, 40 x 35 mm
MRP-3F	Blades, fenestrated with slit, 50 x 35 mm
MRP-4F	Blades, fenestrated with slit, 60 x 35 mm
EOJ-7	CERAMO® SUPERPLAST brain spatula 24x250

Accessories:

MRX-1V	SUPERPLAST Retractor for mitral valve cusp
MRX-5	Ball joint adapter D4, mini, front load, changeable height

Warning: Do not clean CERAMO® instruments (identifiable by the brownish black surface) and titanium instruments using the Orthovario and Oxivario process: Using the two processes will result in the destruction of titanium instruments or the titanic CERAMO® coating after some time due to oxidative processes (titanium is dissolved out by H_2O_2).

Prior to processing a risk assessment on the instrument must be performed..

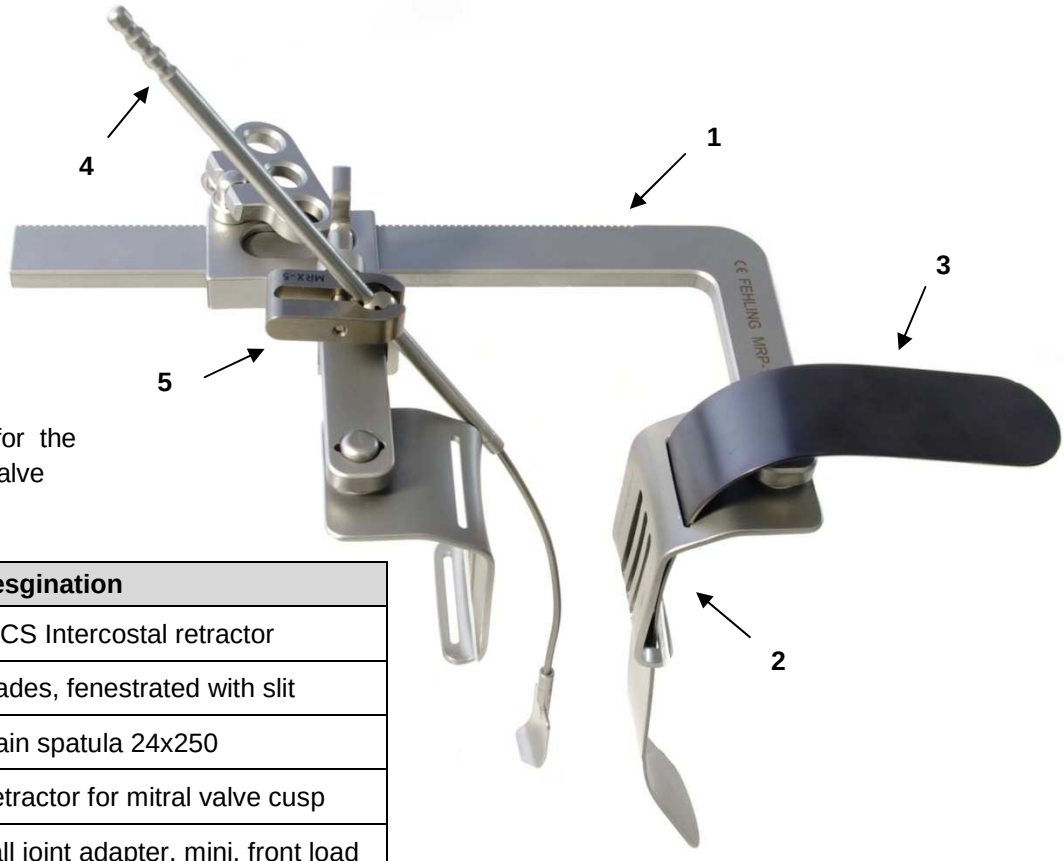
Retracting systems may only be used, processed and disposed of by competent medical personal!

Intended use:

The **MICS MRP-1F intercostal retractor** is intended for exposure of the surgical field for minimally invasive intercostal access for exposing the mitral valve.

Components:

Fig. 1



Sample configuration for the exposure of the mitral valve

	Article no.	Desgination
1	MRP-1F	MICS Intercostal retractor
2	MRP-2F/3F/4F	Blades, fenestrated with slit
3	EOJ-7	brain spatula 24x250
4	MRX-1V	Retractor for mitral valve cusp
5	MRX-5	Ball joint adapter, mini, front load

The MICS intercostal retractor is a U-shaped bar retractor with one rigid body bar and one body bar that is freely movable on the toothed rack. At the distal end of the two body bars, retractor blades of various sizes can be inserted. (compare with Fig. 1)

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!

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

During use:

The blades are connected to a body in a fixed-angle fashion using a ball snap mechanism. Three blade depths are available (40, 50, 60 mm). The blades are convex toward the ribs in order to avoid applying pressure to only certain parts and to prevent the risk of fracture. In addition, the blades are fenestrated and have a slit on the upper and lower edge.

Bring the two body bars as close together as possible to allow the two blades to be inserted into the incision easily. Then spread the two body bars far enough apart for the retractor blades to become anchored in the tissue.

Fig. 2

The flexible spatula is inserted into the retractor blade from top to bottom through the two slits (blue arrows).

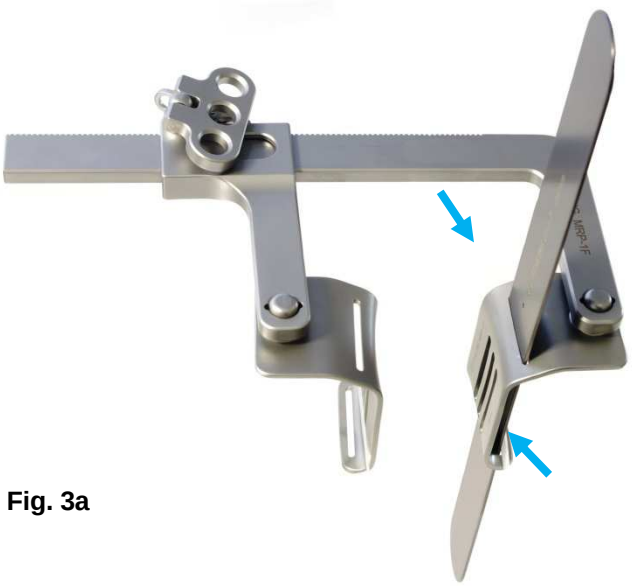


Fig. 3a

The proximal part of the spatula is bent outwards over the retractor body without restricting the view of or access to the surgical site.

The distal end of the spatula can be adapted as needed to the anatomical circumstances within the surgical site.

SUPERPLAST instruments such as the EOJ-7 brain spatula are intended to be shaped to fit the respective anatomical requirements during surgery. The permissible minimum bending radius is approx. 10 mm. Please consult IFU G014 for further information.

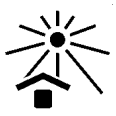
After use:
Bring the two body bars as close together as possible to allow the two blades and the mounted spatulas to be removed from the incision easily. To detach the spatula, bend the distal end back until the spatula can be carefully pulled through the two slits in the blade. During reprocessing, the activation of the shape memory will straighten out any remaining bending.
The spatula must always be removed from the surgical site at the same time as the blade and be removed from the blade once it is no longer in the site. Do not pull the EOJ-7 brain spatula through the slit in the blade when it is bent. Avoid bending the spatula too far. Please consult IFU G014 for further information on handling SUPERPLAST instruments.
Reprocessing:
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)

	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 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. Validated process: 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).

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	

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 www.fehling-instruments.de

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.