FEHLING V-CUT Titanium Pediatric Sternotomy Spreader

MSX-1	for weight of 3 - 7 kg
MSX-2	for weight of >7 - 15 kg
MSX-3	for weight of >15 - 40 kg
MSX-5A	Blade guide
MSX-5B	Coupling rider
MSX-5C	Coupling rider with adjustable angle

Diaphragm hooks:

MSY-6	40x15 mm
MSY-7	50x15 mm
MSY-8	60x15 mm
MSY-9	70x15 mm
MSZ-6	40x24 mm
MSZ-7	50x24 mm
MSZ-8	60x24 mm
MSZ-9	70x24 mm

Lid hooks:

MSX-6	20x10 mm
MSX-7	30x10 mm
MSX-8	40x10 mm

HORKE Blade Swings:

MTH-0	HORKE blade swing with 25 mm pitch
MTH-1	HORKE blade swing with 35 mm pitch
MTH-2	HORKE blade swing with 20 mm pitch

Sternal blades:

MTH-3	15x15 mm
MTH-4	15x20 mm
MTH-5	21x15 mm
MTH-6	21x20 mm
MTH-7	26x15 mm
MTH-8	26x20 mm

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.

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

Intended use:

The V-CUT titanium pediatric sternotomy retractor serves for the exposition of the operation area for the partial sternotomy within the scope of – mainly – pediatric cardiac surgery, and for the complete sternotomy in operation areas near the diaphragm. Then the partial sternotomy can be executed as lower sternotomy from the xiphoid process to the angulus sterni or as upper partial sternotomy (manubrium and upper corpus part).

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).

The V-CUT titanium pedaitric sternotomy retractor is a U-shaped bar retractor with an additional center arm. The mobile frame bar as well as the center arm can move freely on the ratchet.

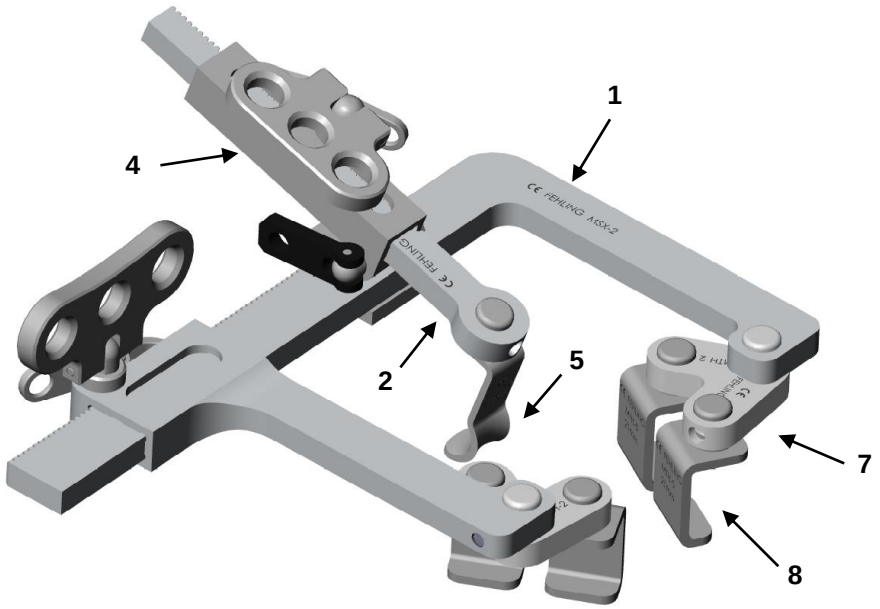
Retraction elements of different sizes, e.g. lid and diaphragm hooks as well as HORKE blade swings and sternal blades, can be inserted at the distal end of the two frame bars as well as of the center arm.

The mobile frame bar is displaced in lateral direction by means of a tooth drive. The coupling rider of the center arm can be placed on the ratchet at any position. The retaining element fixed inside can be displaced in cranial-caudal direction by means of a tooth drive.

The V-CUT titanium pediatric sternotomy retractor is made completely of titanium. Thus intraoperative control photographs can be taken with the arrester lying. The titanium elements are only shown as grey shadows but do not cause any artifacts.

Components:

Figure 1



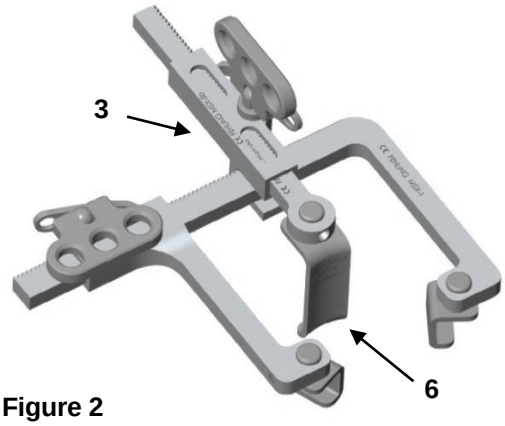


Figure 2

	Article no.	Designation
1	MSX-1,2,3	Retractor body, complete
2	MSX-5a	Blade guide
3	MSX-5b	Coupling rider
4	MSX-5c	Coupling rider, adjustable angle
5	MSX-6,7,8	Lid hook, width 10 mm
6	MSY-6,7,8,9 MSZ-6,7,8,9	Diaphragm hook, width 15 mm Diaphragm hook, width 24 mm
7	MTH-0,1,2	HORKE Blade swing
8	MTH-3,5,7 MTH-4,6,8	Sternal blade, width 15 mm Sternal blade, width 20 mm

Assembly:

Select an appropriate retractor body (1) for the patient on the basis of his specific anatomy and according to his weight/size.

If MSX-1 is used, usually no HORKE blade swings are required, place two appropriate sternal blades (8) in each of the sockets at the distal end of the retractor arms (see figure 2).

If MSX-2 or MSX-3 are used, place one HORKE blade swing (7) in each socket at the distal end of the retractor arms. Then insert the surgically suitable sternal blades (8) into each of the two sockets of the HORKE blade swing (see figure 1).

Caution: The HORKE blade swings can be placed from below or from above. If the less deep sternal blades are used, they should be inserted from below, to be able to make use of the entire depth of the sternal blades (see figure 1).

To install the center arm the blade guide (2) must be inserted into the fixed (3) or the coupling rider with variable angle (4). The blade guide should project out of the coupling rider as far as possible. Now determine the optimum lid (5) or diaphragm hook (6) for the patient-specific application and insert it into the blade guide.

Figure. 3a

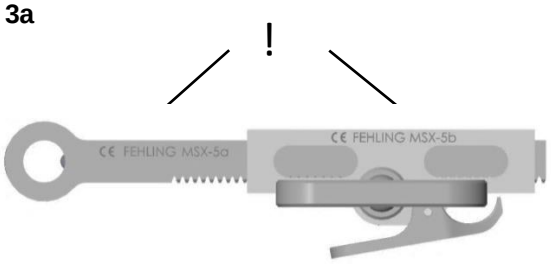
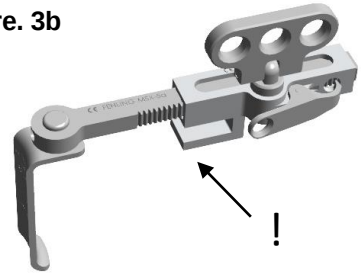


Figure. 3b



Important: The marks on the blade guide and the rider must be on top (fig. 3a).
The coupling rider must be oriented such that its U-profile is open to the situs (fig. 3b).

Application:

Bring the two frame bars so close together that the sternal blades can be inserted in the sternal cleft with ease. Then open the two frame bars so far that the sternal blades are just anchored in the tissue. This creates

- a situs in form of an upside down V for partial sternotomy from caudal,
- a situs in form of a V for partial sternotomy from cranial.

As the sternum broken up in V form pushes the sternal blades towards the V opening due to the inclination, now place the blade guide MSX-5A with the fixed coupling rider MSX-5B or the oupling rider MSX-5C with adjustable angle on the toothed crossbar of the retractor as a counterforce. Another purpose this blade serves, is to retract the soft tissue entering the situs from the caudal or cranial side.

Introduce the lid or diaphragm hook into the incision. Then pull the entire center bar along with the soft tissue in cranial-caudal direction, and lead the U-profile of the rider over the ratchet.

If the rider MSX-5C with adjustable angle is used, the angle of the blade guide passing through the rider is adjusted and fixed in a surgically suitable way. The angle is fixed using an eccentric lever installed on the coupling rider.

At last, adapt the position of the diaphragm or lid hook to the respective surgical requirements. Turn the rocker arm of the rider clockwise until the desired exposition of the operation area is reached.

Useful note: The tilting wing of the transport mechanism at the movable arm and rider can be tilted to either side, which enhances the visibility and the access.

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 due to utilization.

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.
Storage: acc. to § 4 MPBetreibV (regulation on the operation of medical devices)	Store instruments in dry rooms to avoid condensation. It is recommended to start reprocessing the instruments directly after use as residues beginning to dry located at hardly accessible spots are quite difficult to remove.

Preparation of cleaning: Mechanical processing acc. to RKI directives. 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 operation and that they are immediately forwarded to mechanical cleaning. To do so, clean these instruments with soft brushes under running water until there are no more residues visible. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use a released 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 instrument screens and washing trays – use appropriate instrument carriers only. Be particularly careful that the points do not get stuck in the mesh when placing and removing the instruments into/from the screen baskets. Disassemble dismountable instruments according to the appropriate assembly instructions.
Cleaning/Disinfection acc. to DIN EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfecting are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.
Cleaning: Mechanically acc. to DIN EN ISO 15883-1:2009	Validated procedure: Equipment: Cleaning and disinfection automaton G 7836 CD (Miele) Process: 2-component process alkaline/enzymatic Detergent: deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland) Preparation: • Make sure that all cavities are completely flushed on the inside as well. • Make sure that no flushing shadows arise. Parameters: • First rinse with cold water for 3 minutes • Empty • Wash 10 minutes with tap water and 0.3 % TWIN PH10 at 35 °C, and 0.2 % TWINZYME at 40 °C • Empty • Flush with demineralized water at min. 30 °C for 2 minutes • Empty • Flush with demineralized cold water for 1 minute • Empty • Thermal disinfection at 93 °C for at least 5 minutes • After the mechanical cleaning check cavities, blind holes, etc. in particular 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 on the surface from the instrument. 2. Apply detergent solution on all surfaces using a soft cloth/sponge. Make sure that articulated instruments are cleaned in open as well as in 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 demineralized 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). (Thermal disinfector, see indications of the device manufacturer.) Demineralized water has to be used for the final flushing. Make sure that no residues remain on the products.
Drying:	If the drying is achieved as part of the cleaning/disinfection cycle 120 °C should not be exceeded.
Maintenance:	Assemble the instruments according to the assembly instructions. Apply a small amount of high-grade, water-soluble instrument spray on the hinges.
Control and functional testing:	Check instruments for easy operation (avoid too much play). Check locking mechanisms. Using a magnifying lamp visually inspect for damage and wear. Pay special attention to the critical points on movable parts and in the working area. Sort out defective instruments and return them to the manufacturer for repair. Clean and disinfect instruments before sending them to be repaired. A confirmation form for this procedure is available at the manufacturer.
Packaging:	Individually: acc. to standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments in trays provided for that purpose or place them on universal sterilization trays. Use an appropriate procedure to pack the trays.
Sterilization:	Vapor sterilization using the fractional vacuum process at 134 °C (retention time min. 5 minutes) in an equipment acc. to DIN EN 285, validated sterilization processes! To avoid formation of stains and corrosion the vapor must be free of components. The recommended limit values of the components for feed-water and vapor condensate are defined in DIN EN 285. <u>Validated procedure:</u> Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Retention time: 5 minutes 4. Drying time: min. 10 minutes
Storage:	Acc. to § 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.
Additional information:	Do not exceed the maximum charge of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).

Contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: 06188-957440 Fax: 06188-957445 e-mail: info@fehling-instruments.de

Storage / Symbols

					
Protect from excessive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Observe instructions for use	Article number	Attention	

Each modification to the product or deviation from these instructions of use results in exclusion of liability!
Subject to change without notice.

Manufacturer:	**FEHLING INSTRUMENTS GmbH & Co. KG** Hanauer Landstr. 7A 63791 Karlstein/Germany www.fehling-instruments.de

The instructions mentioned above have been validated as being appropriate by the manufacturer of the medical devices for the preparation of a medical device for reuse. The processor is responsible for that the actual processing using the equipment, material and personnel in the processing facility attains the desired results. Generally, this requires the validation and routine monitoring of the process. In the same way each deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.