FEHLING CALAFIORE sternal retainer		
Sternal blades, implant-quality stainless steel	**PEEK nut**	**Accessories**
⚠ Reusable	Single-use product	⚠ Reusable
Newborn: MPC-1R 7 x 30 mm right-hand thread MPC-1L 7 x 30 mm left-hand thread	MPA-5 Ø 8 mm, spreading width 25-35 mm	MPB-1 Fork wrench (2 units), wrench width 7 mm MPC-0P Storage tray, pediatric
Pediatric MPB-7R 10 x 18 mm right-hand thread MPB-7L 10 x 18 mm left-hand thread MPA-2R 10 x 50 mm right-hand thread MPA-2L 10 x 50 mm left-hand thread	MPA-6 Ø 12 mm, spreading width 45-65 mm	MPB-2 Fork wrench (2 units), wrench width 10 mm MPC-0P Storage tray, pediatric
Adult MPA-3R 15 x 70 mm right-hand thread MPA-3L 15 x 70 mm left-hand thread	MPA-9 Ø 16 mm, spreading width 45-65 mm (adult) MPA-7 Ø 16 mm, spreading width 70-90 mm MPA-8 Ø 16 mm, spreading width 95-115 mm	MPB-3 Fork wrench (2 units), wrench width 14 mm MPC-0A Storage tray, adult
Obese MPA-4R 20 x 100 mm right-hand thread MPA-4L 20 x 100 mm left-hand thread		
Osteoporosis MPB-5R 15 x 30 mm right-hand thread MPB-5L 15 x 30 mm left-hand thread MPB-6R 20 x 30 mm right-hand thread MPB-6L 20 x 30 mm left-hand thread		MPB-3 Fork wrench (2 units), wrench width 14 mm MPC-0C Storage tray, curved

⚠	This instrument resp. 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. Sternal retainers may only be used, reprocessed and disposed of by qualified medical personnel! Sternal retainers and accessories are intended for re-use.
Single-use product	The PEEK nut is intended for single use and must not be reprocessed or reused after use!

1) Intended purpose

The sternal retainer is used to hold open the sternum after surgery. The system is used in particular with the delayed sternal closure technique following cardiovascular surgical procedures. The sternal retainer may be used for a maximum of 30 days.

Additional information regarding the intended purpose

Duration of application: the sternal retainer is only intended for short-term use.

Field of application: sternal retainers are used in all patients in whom the sternum must be kept open after cardiac surgery.

User profile: sternal retainers may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: sternal retainers are only to be used in controlled environments (e.g. OR).

2) Indications

Holding open the sternum after cardiovascular surgical procedures

- Delayed sternal closure technique
- Open chest technique

Can be used in patients ranging from newborns to obese patients

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual sternal retainer model are contraindicated. There are no generally applicable contraindications for the use of sternal retainers.
Nevertheless, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects

In medical literature, the following adverse effects are described that can possibly occur during the intended use of sternal retainers:

- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Bone fractures due to overdistraction
- Necroses

⚠	The PEEK nut consists of PEEK. The sternal blades consist of steel and contain chrome and nickel. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use

⚠	Sternal blades are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see 6) Reprocessing).

⚠	The PEEK nut is non-sterile when delivered and must be cleaned and sterilized by the user before initial use and every time before it is used thereafter (see 6) Reprocessing).
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Sternal blades and PEEK nuts must be handled with care during storage, transportation and cleaning! Avoid striking the probe or applying pressure to the sternal blades and PEEK nuts so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!

6) Reprocessing	
⚠ ⊘	The PEEK nut is intended for single use and must not be reprocessed or reused after use! It must be disposed of properly.
⚠	After they have been cleaned and disinfected, sternal blades and PEEK nuts may be sorted into the storage trays and sterilized together. The storage trays are not intended for use in the washer/disinfector.
⚠	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 striking and applying pressure to instruments, so as not to cause any consequential damage! Do not overstrain functional parts!
Limitations on reprocessing	Frequent reprocessing has little impact on these instruments. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible marking, functional failure - also see "Maintenance, Checking and Testing"). While the PEEK nut may used on patients only once, it may be reprocessed and sterilized more than once (for example, if it is prepared but not used and was not contaminated). According to the material manufacturer, the PEEK used for the nut can be sterilized up to 500 times without compromising its static properties.

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 sterilization) 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 deionized water (deionized water, demineralized, 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 instructions for use of the chemical manufacturer must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature aging.
Initial 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 mechanical 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).
	⚠ Dispose of the PEEK nuts in accordance with the hospital's own regulations for infectious waste!
Preparation prior to cleaning	It is recommended to reprocess the instruments 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 which were connected to each other during use must be disassembled back into their original condition before cleaning.
Disassembly	See 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. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • Rinse the instruments for one minute in cold deionized water (see "General Information on Reprocessing").
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.
Cleaning: Automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilization 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> • Ensure that the inside of all cavities is also completely rinsed. • Ensure that no areas are left unwashed. <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 deionized water (<30 °C) • Emptying • Thermodisinfection for 5 minutes with deionized 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. • Use a soft brush (not a wire brush) to clean the instruments until no more contamination is 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). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer 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. • After disinfection, rinse all products thoroughly with deionized water (<40 °C) for at least 1 minute to remove the disinfectant. • 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 9) Assembly

Maintenance, checking and testing	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. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. In particular, inspect the critical points 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 authorized by the manufacturer. A verification 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 instruments 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!
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure. One flat wrench each should be separately packaged, sterilized and kept on hand on the premises of the intensive care unit.
Sterilization	Steam sterilization in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665. In order 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 Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 min. Drying time: 20 min. When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, 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). Instruments must be transported to their place of use in a closed, puncture-proof sterile container.

Disposal	The sternal blades consist of steel. These are to be cleaned prior to disposal. Disposal can be performed at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.
	⚠ Dispose of the PEEK nuts in accordance with the hospital's own regulations for infectious waste!

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 results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the provided instructions on the part of the reprocessor should be properly evaluated for effectiveness 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 sternal retainer (Fig. 1) is a retractor with two sternal blades and a retractor component between the two blades. The retractor components are single-use nuts made of (M-grade) PEEK suitable for use for up to 30 days. The sternal blades of the sternal retainer are manufactured completely from implant-quality stainless steel.

Due to the variety of anatomical and physiological conditions, the sternal retainer differs in its specific characteristics, such as the length and height of the sternal blades or the length and diameter of the PEEK nuts.

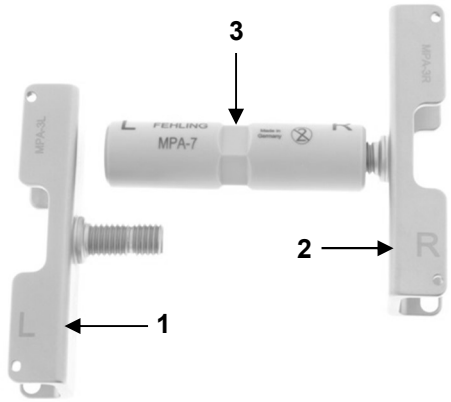

Fig. 1: Sternal retainer for adults (exemplary)

Table: List of the corresponding components

	Article no.	Description
1	MPA-2,3,4 L MPB-5,6,7 L MPC-1 L	Sternal blade with left-hand thread
2	MPA-2,3,4 R MPB-5,6,7 R MPC-1 R	Sternal blade with right-hand thread
3	MPA-5,6,7,8,9	PEEK nut

⚠ Use only sterilized products of sound quality!

⚠ Prior to inserting the sternal retainer, ensure that the surgical field has been prepared accordingly beforehand.

⚠ Medical devices made of ferromagnetic materials must not be exposed to either a magnetic field or external electromagnetic influences.

⚠ Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.

⚠	The choice of sternal blades and PEEK nuts depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the sternal blades and the PEEK nuts used are of the correct size and have adequate stability.

Choosing the suitable model

Based on the specific patient's anatomy, weight and height, select a retractor system appropriate for the patient, consisting of a PEEK nut (3) and two sternal blades (1/2).

Five different sizes have been defined for the following patient groups:

- Newborn
- Pediatric: Standard and double bracket
- Adult
- Obese patients
- Patients with osteoporosis and/or curved sternum

The sternal blades and PEEK nuts for adults, obese patients and patients with osteoporosis are compatible.

Use in patients with osteoporosis

In patients with a strongly curved sternum or patients with osteoporosis, the set specially designed for this patient group should be used.

⚠ In contrast to the other patient groups, **two** sternal retainers each consisting of a PEEK nut (3) and two sternal blades (1 and 2) (MPB-5 R/L, MPB-6 R/L) must be inserted parallel to each other (Fig. 2).

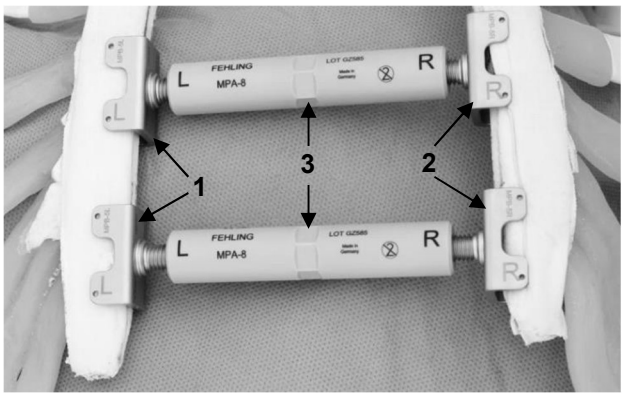

Fig. 2: Configuration example for use in osteoporosis

During use

The sternal retainer can be placed after the sternal retractor and the other surgical instruments used during the procedure have been removed.

Once the sternal retainer has been assembled, it is inserted such that the entire depth of the upper and lower lip of the bracket-shaped blades is hooked around the edges of the sternum (Fig. 3).

The upper lip of the blade must be pushed between the external soft tissue and the sternum.

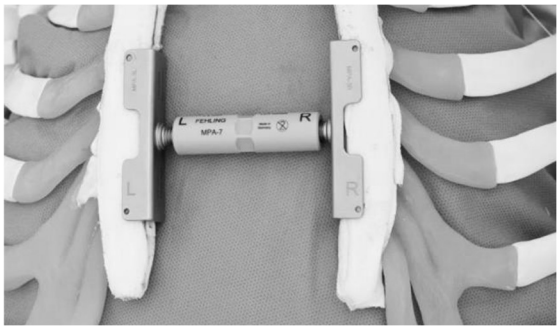

Fig. 3: Configuration example for a sternal retainer

⚠	Be sure that the sternal blades sit properly. The sternal blades must be as flush as possible around the sternum. Then use a suturing technique to secure the blades to prevent the sternum blades from becoming dislocated during transportation and/or repositioning of the patient.

Securing the position:
All sternal blades have round bore holes on top and elongated holes at the bottom (Fig. 4). A braided suture of appropriate strength should be punched through these holes, as well as through the sternum located between them.

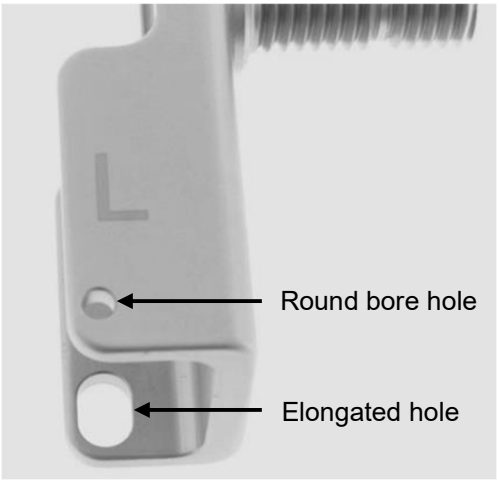

Fig. 4

Ideally, the position of the sternal retainer should be secured as follows:
Punch a braided suture with an appropriate strength on one side through the bore hole on the top part of the sternal retainer and through the sternum (Fig. 5). At the exit site (through the elongated hole) guide it down through the retainer. To prevent dislocation, reinsert the suture from the top into the second bore hole on the opposite end of the same blade. The suture then exits through the elongated hole on the lower part of the blade (Fig. 6).

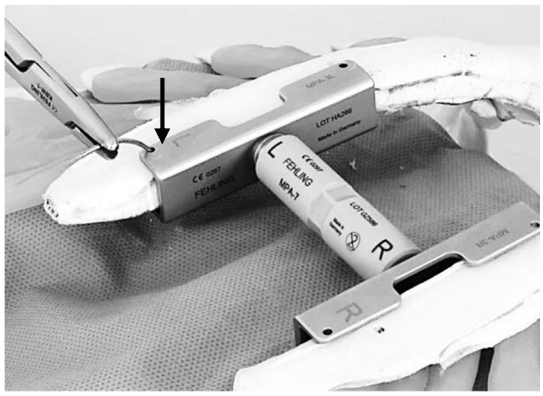
Fig. 5

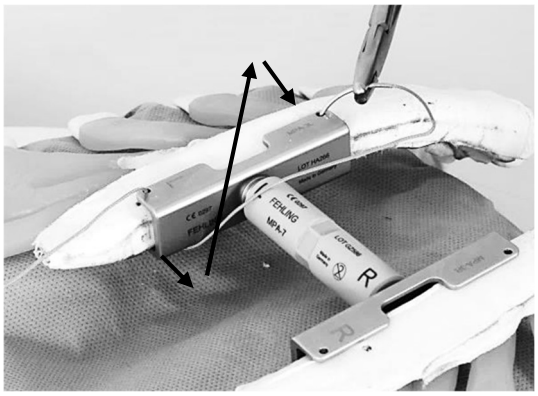
Fig. 6

Once the suture has been guided back up, use a firm and secure knot to tie the two ends of the suture on the top of the sternal blades. Care should be taken to ensure that the sutures on the lower part do not get caught on the facing edges (Fig. 7).

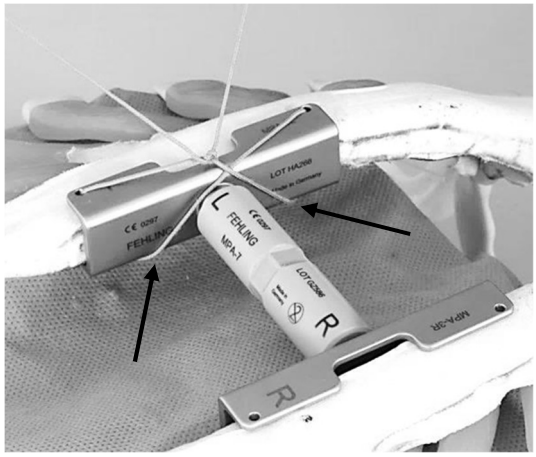
Fig. 7

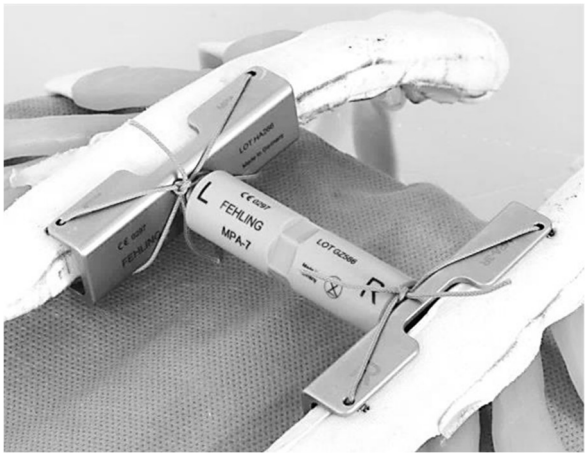
Fig. 8

	Securing the suture in this way provides additional protection against the risk of the sternal blades becoming dislocated in the event that the patient is improperly repositioned (Fig. 8).

The width of the sternal opening must be adapted to the surgical requirements. The distance between the sternal blades can be varied (Fig. 9) by rotating the PEEK nut (3) with the fork wrench (4) (see 8) Required accessories).

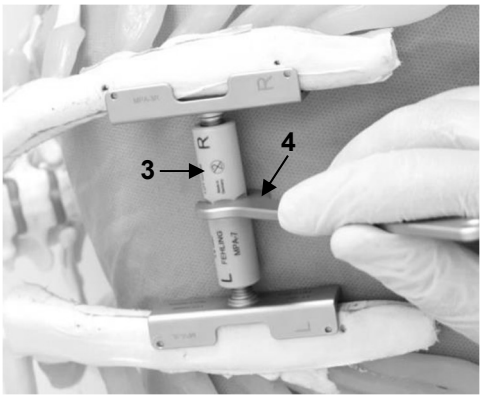

Fig. 9

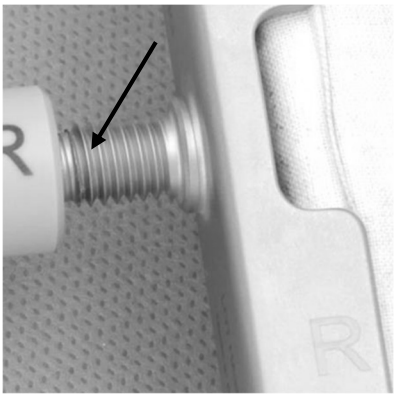

Fig. 10

The maximum opening width is then reached if the surrounding notch is just visible in the thread of the sternal blades (area without external thread) - see arrow in Figure 10.

⚠	Only open the sternal retainer up to the notch in the thread of the sternal blades. Failure to comply with the minimum screw-in depth of the sternal blades in the PEEK nuts means that sufficient stability of the sternal retainer is no longer guaranteed!

Close the wound with a suitable wound dressing such as a sterile occlusive wound compress.
During use, it is possible to gradually reduce the spreading width of the sternal retainer used (progressive stent downsizing). Remove the sternal retainer as soon as the patient's medical condition permits. In order to be able to remove the entire system, the width of the opening should be reduced to a minimum.
During application of the sternal retainer, care should be taken to avoid inadvertent movement by the patient; if necessary, sedation of the patient is required to ensure that the sternal retainer does not come loose or slip.

⚠	We recommend keeping an extra fork wrench on hand for each set and to store it sterilely, separate from the set, in the intensive care area in order to enable revisions to be performed there.

The sternal blades are unscrewed from the PEEK nut and can then be reprocessed.
The PEEK nut is intended for single use and must be disposed of by properly trained personnel.

⚠	Do not exceed the maximum use period of 30 days!

8) Required accessories

A suitable fork wrench MPB-1, MPB-2 or MPB-3 (Fig. 11) is required for the application of the sternal retainer.

A suitable storage container MPC-0A (Fig. 12), MPC-0C or MPC-0P can be used for sterilization and storage.

Fig. 11: Fork wrench MPB-3 (2 pcs. each) (exemplary)

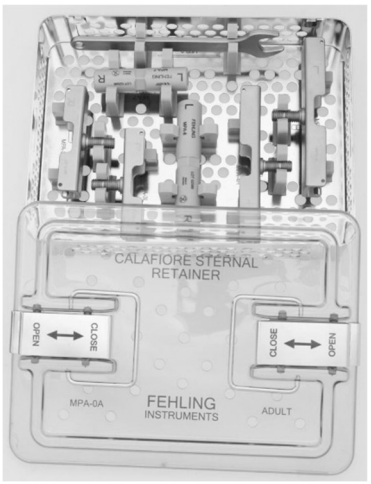

Fig. 12: Storage container adult MPA-0A (exemplary)

9) Assembly

For assembly of the sternal retainer please observe the following assembly instructions.

Take one suitable sternal blade with a left-hand thread (1) and one with a right-hand thread (2) and screw into the PEEK nut (3) as far as they will go (Fig. 13, curved arrow). Arrange the system so it is symmetrical.

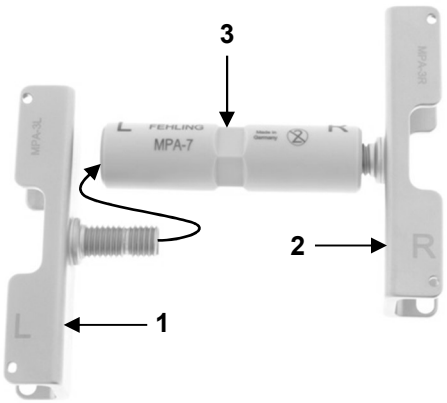

Fig. 13: Sternal retainer with sternal blade mounted on one side

The designations "L" and "R" on the PEEK nut and at the end of the article number indicate the direction of the thread (Fig. 14).

Example:

MPA-3L = Sternal blade with left-hand thread

MPA-3R = Sternal blade with right-hand thread

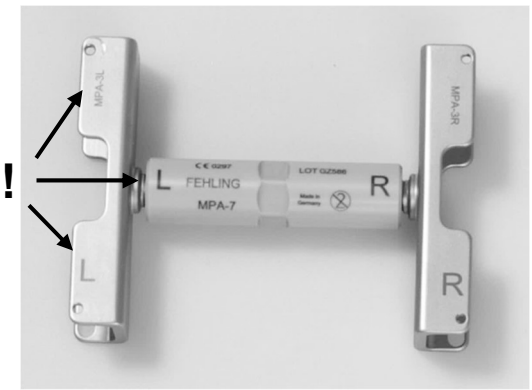

Fig. 14: Sternal retainer with both sternal blades mounted

⚠	When screwing in the blades, be sure to correctly match up the respective thread direction. Keep the blade thread shafts straight while inserting and slowly screw into the PEEK nut. Using force to screw in the blade or tilting the blade while screwing it in can damage the PEEK nut and can compromise the stability of the sternal retainer.
Following a functional test, the assembled instrument is now ready for use again.	

10) Disassembly

For disassembly of the sternal retainer please observe the following assembly instructions (see 9) Assembly).

⚠	Place small parts in suitable containers (e.g. sterilization baskets) for storage, cleaning 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 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

In as far as the medical device or medical device label or instructions for use are labeled, the symbols have the following meaning:

Manufacturer	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Instrument for single use - do not reuse!
Protect from sunlight	Store in a dry place	NON STERILE Non-sterile

To contact the manufacturer:		
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 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 0297