FEHLING CALAFIORE Sternal Retainer

Sternal blades, implant-quality stainless steel (reusable)	**PEEK nuts (single use)**	**Accessories: (reusable)**
Newborn: MPC-1R 7x30 mm right-hand thread MPC-1L 7x30 mm left-hand thread	MPA-5 D8 spreading width 25-35 mm	MPB-1 Flat wrench (2 units) wrench width 7 mm MPC-0P Storage tray, pediatric
Pediatric: MPB-7R 10x18 mm right-hand thread MPB-7L 10x18 mm left-hand thread MPA-2R 10x50 mm right-hand thread MPA-2L 10x50 mm left-hand thread	MPA-6 D12 spreading width 45-65 mm	MPB-2 Flat wrench (2 units) wrench width 10 mm MPC-0P Storage tray, pediatric
Adult: MPA-3R 15x70 mm right-hand thread MPA-3L 15x70 mm left-hand thread	MPA-7 D16 spreading width 70-90 mm MPA-8 D16 spreading width 95-115 mm MPA-9 D16 spreading width 45-65 mm	MPB-3 Flat wrench (2 units) wrench width 14 mm MPC-0A Storage tray, adult
Obese patient: MPA-4R 20x100 mm right-hand thread MPA-4L 20x100 mm left-hand thread		
Osteoporosis: MPB-5R 15x30 mm right-hand thread MPB-5L 15x30 mm left-hand thread MPB-6R 20x30 mm right-hand thread MPB-6L 20x30 mm left-hand thread		MPB-3 Flat wrench (2 units) wrench width 14 mm MPC-0C Storage tray, curved

Only trained medical personnel may use, reprocess or dispose of spreader systems.

Intended use:

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. The system consists of several reusable sternal blades as well as single-use nuts.

Indications and contraindications:

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

Contraindications

- Not known

Prior to use:

The sternal retainer is a spreader with two sternal blades and a spreader component between the two blades.

The spreader components are single-use nuts made of (M-grade) PEEK suitable for use for up to 30 days. The sternal retainer blades are manufactured completely from implant-quality stainless steel.

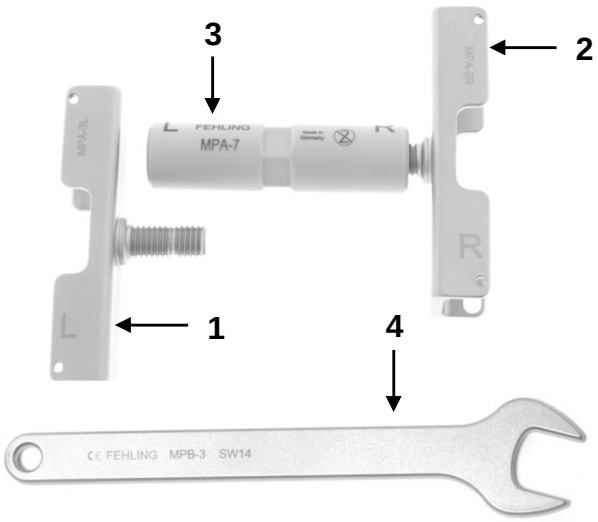
FEHLING INSTRUMENTS sternal retainers are delivered unsterilized and must be cleaned and sterilized by the user prior to initial use and prior to all other further uses (see reprocessing).

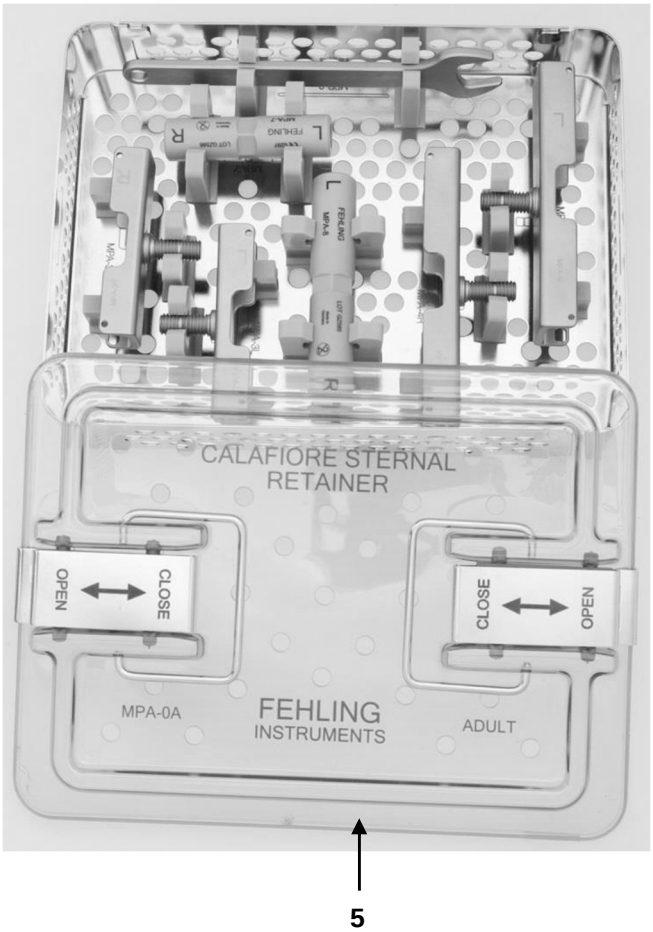
The components of the sternal retainer must be handled with care during storage, transportation and cleaning. Avoid striking the instrument or applying pressure to only parts of it. Perform a safety check prior to each use. Check for cracks or fractures (see also Maintenance, Checking and Functional Testing).

Use only sterilized products of sound quality.

After they have been cleaned and disinfected, sternal blades and PEEK nuts may be sorted into the sterilization and storage trays together and sterilized together. The trays are not intended for use in the washer/disinfector.

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
4	MPB-1,2,3	Flat wrench (2 units each)
5	MPC-0A/C/P	Storage tray

Choosing the suitable model

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

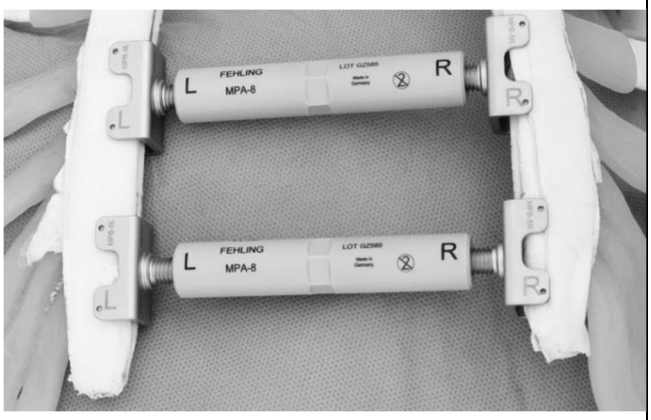
Five different sizes have been defined for the following patient groups:

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

The sternal blades and 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 (MPB-5 R/L, -6 R/L) must be inserted parallel to each other.

Assembly:

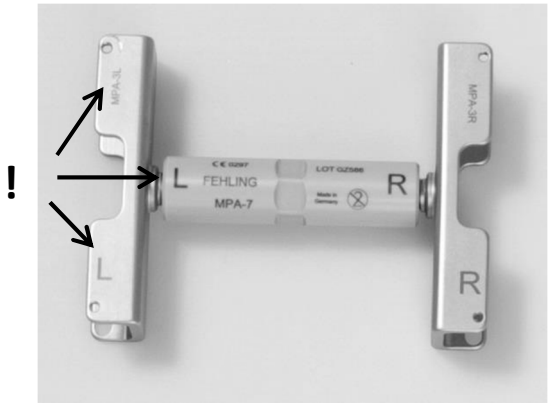
Take one suitable sternal blade with a left-hand thread (1) and one with a right-hand thread (2) and screw into the nut as far as they will go. Arrange the system so it is symmetrical.

The designations "L" and "R" on the nuts and at the end of the article number indicate the direction of the thread.

Example:

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

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



⚠ **Caution: 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 nut.

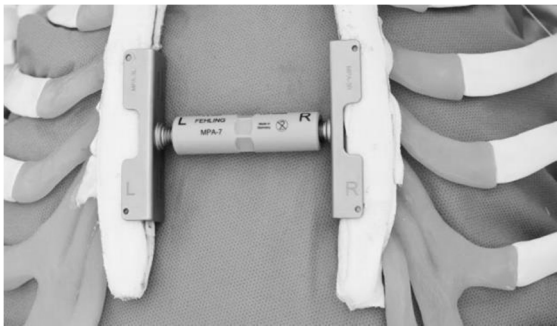
Using force to screw in the blade or tilting the blade while screwing it in can damage the PEEK nut and can compromise the stability of the sternal retainer.

Use:

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

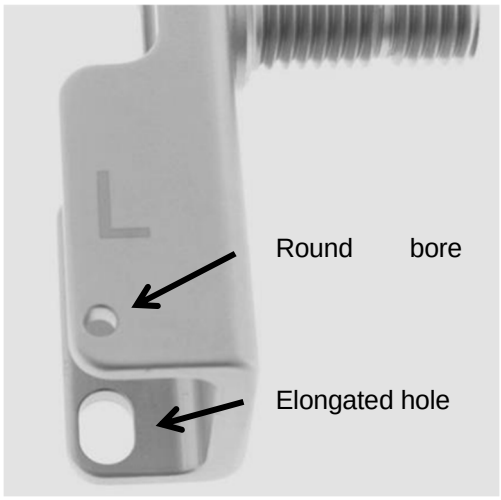
Once the sternal retainer has been assembled, it is inserted such that the entire depth of the upper and lower lip of the bracket-shaped blades is hooked around the edges of the sternum.

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



Important: 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 below. Braided suture of appropriate strength should be punched through these holes, as well as through the sternum located between them.



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. 1). At the exit site (through the elongated hole) guide it down through the retainer. In order 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. 2)

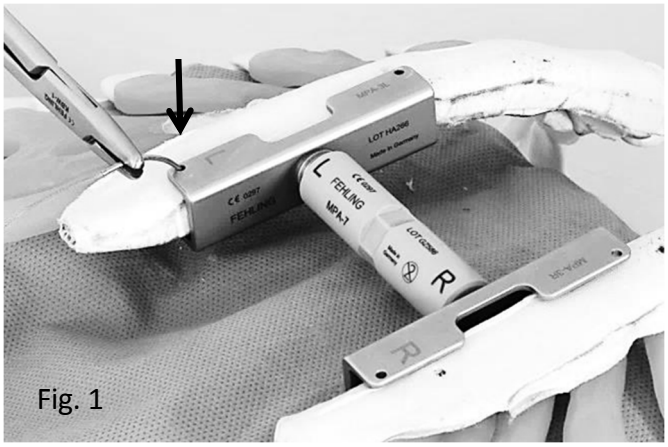


Fig. 1

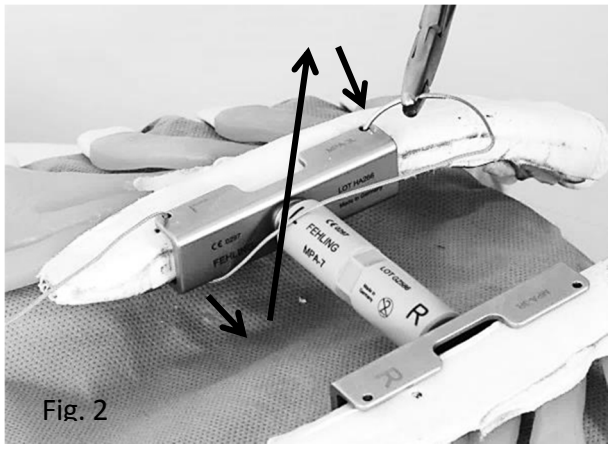


Fig. 2

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. 3)

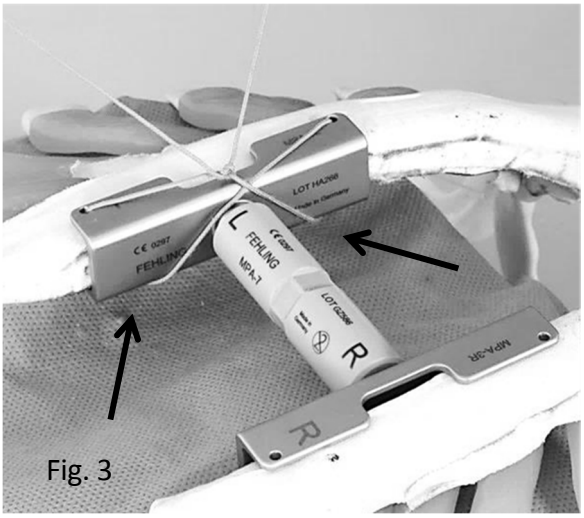


Fig. 3

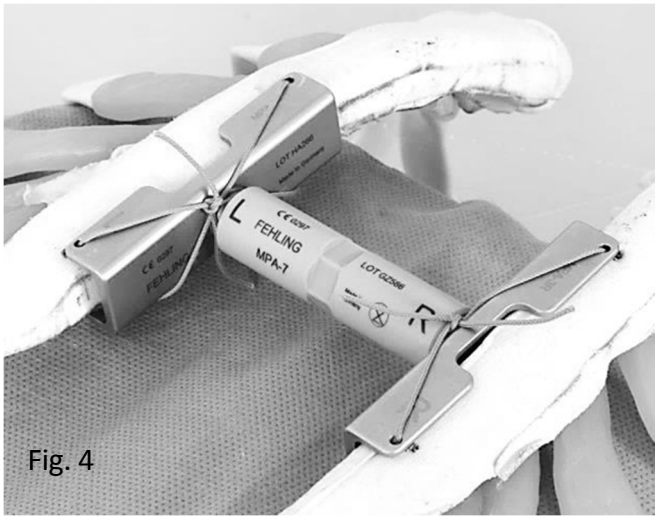
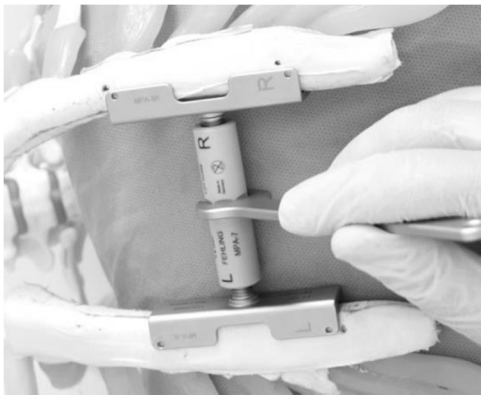
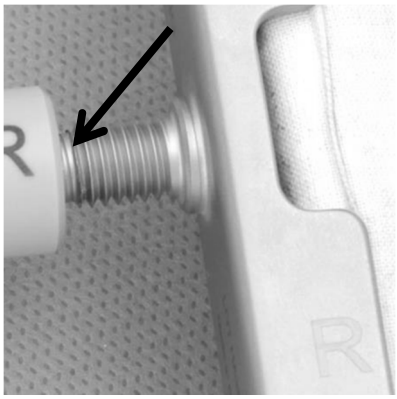


Fig. 4

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. 4)

The width of the sternal opening must be adapted to the surgical requirements. The distance between the sternal blades can be varied by rotating the nuts with the flat wrench.





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.

⚠ **Important: 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 the 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.

⚠ **We recommend keeping an extra flat 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 nut and can then be reprocessed. The PEEK nut is intended for single use and must be disposed of by properly trained personnel.
Caution: Do not exceed the maximum use period of 30 days.
Reprocessing:
The PEEK nut is intended for single use and must not be reprocessed or reused after use. It must be disposed of properly.
Reprocessing restrictions: Frequent reprocessing has little impact on the spreader components. The end of product life is normally determined by wear and tear and damage occurring through use. 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.

Point of use:	Disassemble sternal retainer. **Dispose of the PEEK nuts in accordance with the hospital's own regulations.** Use a disposable cloth/paper towel to remove surface contamination on the sternal blades – pre-cleaning.
Storage:	Store in a dry place in order to avoid condensation. 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.
Cleaning preparation: mechanical cleaning in accordance with Robert Koch Institute (RKI) guidelines. Mechanical cleaning is preferable to manual cleaning.	Ensure that blood, tissue and drug residues are removed from the instruments immediately after completion of the procedure and that they undergo mechanical cleaning immediately. To this end, use suitable soft brushes to clean the instruments under running water until no residues are visible. Do not immerse in normal saline solutions (risk of pitting or stress corrosion). Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemical manufacturer's recommendation for the mixture). Avoid overfilling instrument trays and washing trays. Use only suitable instrument holders. When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck in the grid.
Cleaning/Disinfection in accordance with EN ISO 17664:2004 CDD in accordance with EN ISO 15883-1:2009	It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with.

Cleaning/Disinfection: Mechanical in accordance with EN ISO 17664:2004 CDD in accordance with EN ISO 15883-1:2009	Validated procedure: Equipment: Washer-disinfector G7836CD (Miele) Detergent: neodisher MediClean forte, Dr. Weigert (Hamburg) Preparation: • Ensure that no unwashed areas are left. Parameters: • 2-minute prewash with cold drinking water • Empty • Wash for 10 minutes with tap water with 0.8% neodisher MediClean forte at 55 °C and deionized water. • Empty • Neutralize for 3 minutes with cold deionized water. • Empty • Rinse for 2 minutes with cold bacteria-free deionized water. • Empty • After mechanical cleaning, inspect the instrument for visible contamination. Repeat the cycle or manually clean as necessary.
Cleaning/Disinfection: Manual in accordance with EN ISO 17664:2004	Validated procedure: Equipment: Bandelin Sonorex RK 1028 H Detergent/Disinfectant: Bomix plus, 2 % (Bode Chemie) Preparation: • Soak in cold tap water for 10 minutes. • Brush until no more residues are visible. • Use a spray gun to rinse the parts for at least 20 s. Ultrasonic treatment: • Treat in an ultrasonic bath at room temperature with 2% Bomix plus solution at 35 kHz for 10 minutes. • Then rinse with a spray gun for at least 20 s. • Rinse with tap water. Bacteria-free deionized water must be used for the final rinse. Ensure that no residues remain on the products.
Drying	If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.
Maintenance:	N/A The sternal retainer is assembled as part of a surgical procedure (see "Assembly" section).
Inspection and functionality test:	Use a magnifying lamp to visually inspect the components for damage (e.g. cracks) and wear and tear. Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.
Packaging:	Single: in accordance with the standard series EN 868, EN ISO 11607 Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately. 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 at 134 °C (holding time at least 5 minutes) in a device complying with EN 285; validated sterilization

	processes! 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 EN 285. Validated procedure: Equipment: Selectomat HP (MMM) 1. 3 pre-vacuum phases 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: at least 10 minutes
Storage:	In accordance with standard series EN 868, EN ISO 11607.
Additional information:	When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a medical device for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.

Any modification to the device or deviation from these instructions for use will result in exclusion of liability.
Subject to change without notice.

Storage / Symbols

Store in a dry place. No long-term storage below +5 °C or above +40 °C!	Protect from excessive heat!	Follow the instructions for use	Article number	Batch number
Manufacturer	Notified Bodies	Warning	Do not reuse!	

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