



FEHLING CALAFIORE sternal retainer		
Sternal blades, implant steel	PEEK nut	Accessories
Reusable	Single-use device	Reusable
<p><u>Neonate</u></p> <p>MPC-1R 7 x 30 mm Right-hand thread MPC-1L 7 x 30 mm Left-hand thread</p>	<p>MPA-5 Ø 8 mm, Spreading width 25- 35 mm</p>	<p>MPB-1 Open-end wrench (2 pcs.) Wrench size 7 mm MPC-0P Storage container paediatric</p>
<p><u>Paediatric</u></p> <p>MPB-7R10 x 18 mm Right-hand thread MPB-7L.....10 x 18 mm Left-hand thread MPA-2R10 x 50 mm Right-hand thread MPA-2L 10 x 50 mm Left-hand thread</p>	<p>MPA-6 Ø 12 mm, Spreading width 45- 65 mm</p>	<p>MPB-2 Open-end wrench (2 pcs.) Wrench size 10 mm MPC-0P Storage container paediatric</p>
<p><u>Adult</u></p> <p>MPA-3R 15 x 70 mm Right-hand thread MPA-3L 15 x 70 mm Left-hand thread</p>	<p>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</p>	<p>MPB-3 Open-end wrench (2 pcs.) Wrench size 14 mm MPC-0A Storage container adult</p>
<p><u>Obese</u></p> <p>MPA-4R 20 x 100 mm Right-hand thread MPA-4L 20 x 100 mm Left-hand thread</p>		<p>MPB-3 Open-end wrench (2 pcs.) Wrench size 14 mm MPC-0C Storage container curved</p>
<p><u>Osteoporosis</u></p> <p>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</p>		
	<p>These instruments or medical devices are non-sterile when delivered. They must be reprocessed before use. The instrument must undergo risk assessment according to the RKI-Guidelines (non-critical, semi-critical, critical A/B/C) before reprocessing.</p> <p>The CALAFIORE sternal retainer may only be used, reprocessed and disposed of by qualified medical personnel.</p> <p>The CALAFIORE sternal retainer is intended for re-use.</p>	



The PEEK nut is intended for single use and must not be reprocessed and reused after use!

1) Intended purpose

The sternal retainer is used to keep the sternum open after surgery. The system is used in particular for the delayed sternal closure technique following cardiac surgery. The maximum duration of application is 30 days.

Additional information regarding the intended purpose

Duration of application: The sternal retainer is intended for short-term use

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

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

Application environment: Sternal retainers are only to be used in controlled environments (e.g., in the operating room).

Target patient population: No restrictions.

2) Indications

Keeping the sternum open following cardiac surgery:

- Delayed sternal closure technique
- Open chest technique

Intended for use in patients ranging from neonates to obese patients.

3) Contraindication

Any use that is incompatible with the physical and/or mechanical properties of the specific sternal retainer model is contraindicated. There are no generally applicable contraindications for the use of sternal retainers.

Nevertheless, due consideration must be given to increased risks that may result from the patient's anatomical and physiological conditions and underlying disease (e.g., infiltrating tumours, recurrent infections, or osteoporosis).



4) Possible side effects

The medical literature reports the following side effects associated with the delayed sternal closure technique, which may also occur during the intended use of the sternal retainer:

- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Fractures of bones in the event of over-distraction
- Necrosis



Medical devices may contain, for example, PEEK, chromium and/or nickel. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Before use

The sternal blades of the CALAFIORE sternal retainer are supplied non-sterile and must be cleaned and sterilised by the user before first use and before each subsequent use (see section 6) Reprocessing).

The PEEK nut of the CALAFIORE sternal retainer is supplied non-sterile and must be cleaned and sterilised by the user before first use and before each subsequent use (see section 6) Reprocessing).



Perform a safety check before each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section 6) *Reprocessing* under "*Maintenance, Inspection and Testing*").



Handle sternal blades and PEEK nuts with care during storage, transport and cleaning! Avoid mechanical shock and point loading on sternal blades and PEEK nuts to minimize the risk of secondary damage! Do not overload functional parts!



Use only intact and sterilised products!

6) Reprocessing



The PEEK nut is intended for single use and must not be reprocessed and reused after use!



It is to be disposed of properly.



Sternal blades and PEEK nuts can be placed in the corresponding storage containers after cleaning and disinfection and sterilised together. The storage containers are not suitable for use in washer-disinfectors.



The medical device is to be reprocessed before use. It must undergo risk assessment according to the RKI Guidelines (non-critical, semi-critical, critical A/B/C) before 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.



	<p>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.</p>
	<p>The instruments may only be used, reprocessed and disposed of by qualified medical personnel.</p>
	<p>Handle instruments with care during storage, transport and cleaning! Avoid mechanical shock and point loading on instruments to minimise causing any secondary damage! Do not overload functional parts.</p>
	<p>Do not clean instruments with plastic components using oxidative processes (processes with hydrogen peroxide H₂O₂, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative ageing of the material, which may under certain circumstances not be detectable by visible discolouration or embrittlement.</p>
<p>Limitations on reprocessing</p>	<p>Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. 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, Inspection and Testing").</p> <p>Although the PEEK nut may only be used only once on the patient, there is nothing to prevent multiple reprocessing and sterilisation (for example, if it was provided but <u>not</u> used and <u>not</u> contaminated).</p> <p>According to the material manufacturer, the PEEK used for the nut can be sterilised up to 500-times without losing its static properties.</p>
<p>General information on reprocessing</p>	<p>Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilisation) 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 deionised water (deionised water, demineralised, microbiologically at least of potable water quality) are used for cleaning.</p> <p>Automated reprocessing is preferable to manual cleaning due to a better and safer cleaning result.</p> <p>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 of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.</p>



<p>Pre-treatment at the place of use</p>	<p>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).</p> <table border="1" data-bbox="480 584 1474 683"> <tr> <td data-bbox="480 584 587 683"> </td> <td data-bbox="587 584 1474 683"> <p>Dispose of PEEK nut after use in accordance with the hospital's own regulations for infectious waste!</p> </td> </tr> </table>		<p>Dispose of PEEK nut after use in accordance with the hospital's own regulations for infectious waste!</p>
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<p>Preparation before cleaning</p>	<p>Instruments should be reprocessed 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 that were connected to each other during use must be disassembled into their original condition before cleaning.</p>		
<p>Disassembly</p>	<p>See section 10) <i>Disassembly</i></p>		
<p>Manual pre-cleaning:</p>	<p><u>Validated procedure:</u> Equipment: Basin Soft brush Water spray gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> • 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. • If necessary, the moving parts of the instrument may be moved back and forth in the cleaning bath. • Remove coarse contamination using a suitable brush (not a wire brush) during the exposure time. • Rinse the instruments for one minute in cold deionised water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth. 		



<p>Cleaning/ disinfection</p>	<p>If possible, a washer/disinfector according to DIN EN ISO 15883, which uses thermal disinfection, is to be preferred.</p>
<p>Cleaning: automated</p>	<p>Avoid overfilling instrument trays and washing trays - use only suitable instrument holders.</p> <p>When placing instruments in the sterilisation baskets and removing them afterwards, take special precautions to ensure that the tips do not become stuck in the mesh.</p> <p><u>Validated procedure:</u></p> <p>Equipment: Washer/Disinfector G 7835 CD (Miele) / PG 8535 (Miele)</p> <p>Cleaning program: Des-Var-TD (G 7835 CD)</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p> <p><u>Preparation:</u></p> <ul style="list-style-type: none"> • Instruments with joints are to be placed in the device so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the cavities is also completely rinsed. • Ensure that no areas are left unwashed. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the washer/disinfector. <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> • 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 deionised water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionised water (> 90 °C) • Dry for 30 minutes (90 °C) <p>After cleaning in the machine, inspect cavities, blind holes, etc. for visible contamination. If necessary, repeat the cycle or clean manually.</p>
<p>Cleaning: manually</p>	<p><u>Validated procedure:</u></p> <p>Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec</p> <p>Detergent: Neodisher® MediClean forte (Dr. Weigert)</p>



	<p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> Place instruments, if possible in disassembled condition, in cold water (potable water quality, < 40 °C) for 10 minutes. Move any movable parts, if present, back and forth over the entire range of movement. Use a soft brush (not a wire brush) to clean the instruments until contamination is no longer visible. Rinse the instruments for at least 20 seconds using a water spray gun (or similar). <p><u>Ultrasonic cleaning:</u></p> <ul style="list-style-type: none"> 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). Deionised water (< 40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.
<p>Disinfection: manually</p>	<p>Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's information).</p> <p><u>Validated procedure:</u></p> <p>Equipment: Basin Bandelin Sonorex Digitec</p> <p>Disinfectant: Korsolex® med AF (Bode Chemie GmbH)</p> <p><u>Procedure/Parameters:</u></p> <ul style="list-style-type: none"> 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. If applicable, move the moving parts in the disinfection bath before switching on the ultrasonic cleaner. After disinfection, rinse all products thoroughly with deionised water (< 40 °C) for at least 1 minute to remove the disinfectant and, if applicable, move the moveable parts of the instrument back and forth. Ensure that no residues remain on the products. Dry with sterile, oil-free compressed air.
<p>Drying</p>	<p>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.</p>
<p>Assembly</p>	<p>See section 9) <i>Assembly</i></p>



<p>Maintenance, inspection and testing</p>	<p>For instruments with movable components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (according to the valid European or United States Pharmacopoeias) which is biocompatible, steam sterilisable and steam-permeable is to be applied before sterilisation. Such places are additionally marked by a corresponding symbol of an oil can. Instruments must not be treated with care products containing silicone. These can lead to stiffness and compromise the effect of steam sterilisation. Perform a safety check of the instruments before each use. When doing so, check for sharp edges, cracks, fractures and mechanical malfunctions and missing components.</p> <p>Check instruments with movable parts for smooth operation (avoid excessive looseness). Check locking mechanisms.</p> <p>All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp.</p> <p>In particular, inspect the critical points on moving parts and in the working area.</p> <p>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 authorised by the manufacturer. A confirmation form for this process is available from the manufacturer.</p> <p>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.</p>
<p>Packaging</p>	<p>Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953.</p> <p>Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure. One open-end wrench should be packaged separately, sterilised and kept available in the area of the intensive care unit.</p>
<p>Sterilisation</p>	<p>Steam sterilisation in a fractionated vacuum process in a device complying with DIN EN 285 and DIN EN ISO 17665 (Parts 1 and 2). 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.</p> <p><u>Validated procedure:</u></p> <p>Equipment: Tuttnauer autoclave Type B 3870 EHS / Lautenschläger ZentraCert</p> <p><u>Procedure/Parameters:</u></p> <p>Cycle type: 3 pre-vacuum phases</p> <p>Sterilisation temperature: 132 – 134 °C</p> <p>Holding time: 4 – 5 minutes</p> <p>Drying time: 20 minutes</p>



	When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	<p>In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953.</p> <p>Instruments must be stored dry, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage). Always keep instruments, if applicable, in a released state. This counteracts premature fatigue of the spring tension.</p> <p>Instruments must be transported to their place of use in a closed, puncture-proof sterile container.</p>
Disposal	<p>These products largely consist of steel. They are to be cleaned before disposal. They can be disposed of at a scrap metal recycling facility. To protect employees, care must be taken to ensure that any pointed tips or sharp edges are protected.</p>
	<div style="display: flex; align-items: center;"> <p>Dispose of PEEK nut in accordance with the hospital's own regulations for infectious waste!</p> </div>
<p>The above instructions have been validated by the medical device manufacturer as suitable for reprocessing the 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 result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy and potential adverse consequences.</p>	
	<p>Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability.</p> <p>Subject to change without notice.</p>



7) Configuration and application

The CALAFIORE sternal retainer (Fig. 1) is a retractor with two sternal blades and an expansion element between them. The expansion elements are single-use nuts made of PEEK (M-Grade), suitable for use for up to 30 days. The sternal blades of the CALAFIORE sternal retainer are made entirely of implant steel.

Due to variations in anatomical and physiological conditions, the CALAFIORE sternal retainer is available with different specific properties, such as length and height of the sternal blades or length and diameter of the PEEK nuts.

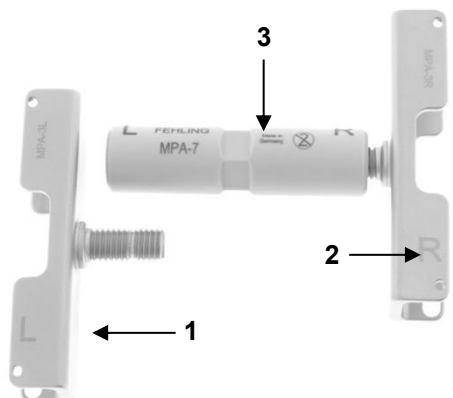


Fig. 1: CALAFIORE sternal retainer for adults (example)

Table: List of the corresponding components

	Item 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 intact and sterilised products!



Before using the CALAFIORE sternal retainer, ensure that the surgical field has been prepared accordingly beforehand.



Before using the CALAFIORE sternal retainer, ensure that it is fully functional and not damaged!



Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.



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 nut depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the sternal blades and PEEK nut used are of the correct size and have adequate stability.

Selection of the appropriate model

An appropriate retractor system, consisting of a PEEK nut (3) and two sternal blades (1/2), must be selected based on patient's anatomy and body weight/height.

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

- Neonates
- Paediatric: Standard and double support
- Adults



- 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.

The decision to perform delayed sternal closure and to select an appropriate model must be made by the treating surgeon after weighing up all weighing all benefits and risks.

Use in patients with osteoporosis

In the case of severely curved sternums or patients with osteoporosis, the set specially designed for this patient group should be used.



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

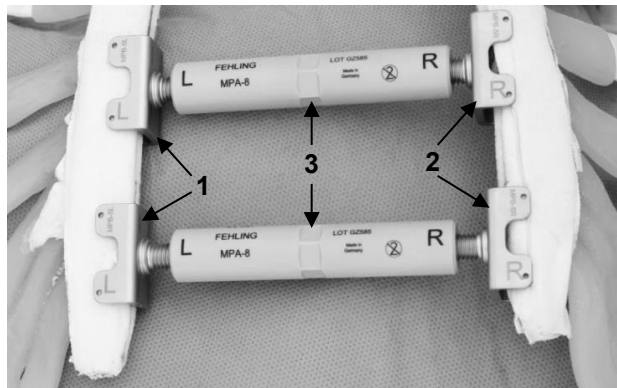


Fig. 2: Configuration example for use in patients with osteoporosis

During application

After removal of the sternal retractor used intraoperatively and the other surgical-instruments, the sternal retainer can then be positioned.

The assembled sternal retainer is inserted in such a way that the upper and lower lips of the clamp-shaped blades grasp the sternum with the full depth of the blades (Fig. 3).

The upper lip of the blade must be inserted between the outer soft tissue and the sternum.

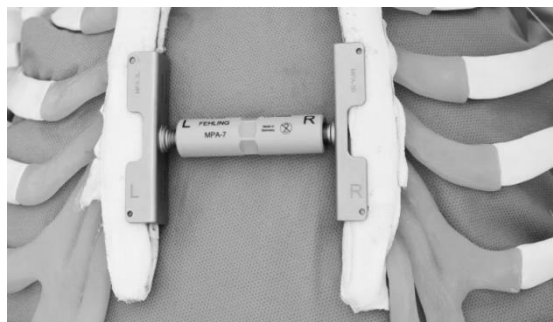


Fig. 3: Configuration example for a sternal retainer



Ensure that the sternal blades are correctly positioned. The sternal blades must enclose the sternum as flush as possible to prevent the formation of air pockets under the sterile cover and thus increased risk of infection. Then secure the blades with sutures to prevent the sternal blades from dislocating during transport and/or repositioning.



	<p>Position locking: All sternal blades have round holes on the upper side and elongated slots on the lower side (Fig. 4), through which, and through the sternum between them, sufficiently strong braided sutures must be passed.</p>	<p>Fig. 4</p>
	<p>Position locking of the sternal retainer should ideally be carried out as follows: A sufficiently strong braided suture is passed on one side through the hole on the upper side of the sternal retainer and through the sternum (Fig. 5), and on the exit side (through the slot) is guided downward through the device. To prevent dislocation, the thread is then reinserted from above into the second hole of the same blade. The exit is again through the intended elongated slot on the lower side of the blade (Fig. 6).</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="331 1048 873 1435"> <p>Fig. 5</p> </div> <div data-bbox="906 1048 1447 1435"> <p>Fig. 6</p> </div> </div>	
<p>The two ends of the threads must be tied tightly and securely on the upper side of the sternal blades. Particular care must be taken to ensure that the threads do not catch on the front edges on the lower side (Fig. 7).</p>		

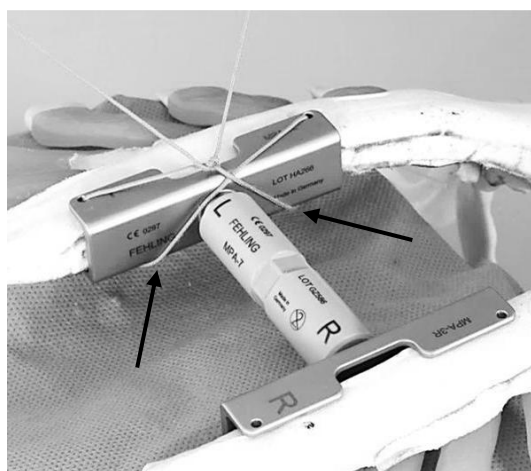


Fig. 7



Fig. 8

This suture securing further reduces the risk of dislocation of the sternal blades in the event of improper repositioning of the patient (Fig. 8).

Adjust the opening width of the sternum to the surgical requirements. The distance between the sternal blades is varied by rotating the PEEK nut (1) with the open-end wrench (2) (see section 8) Required accessories) (Fig. 9).

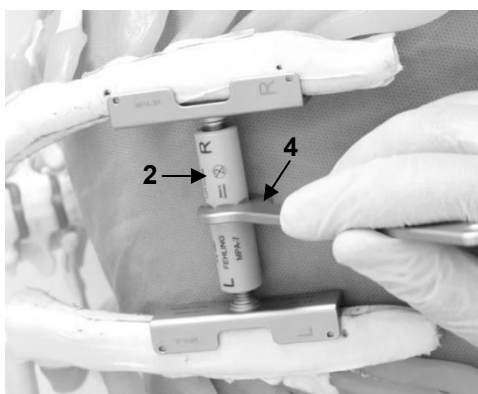


Fig. 9

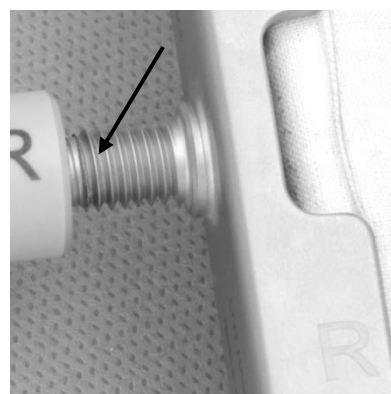


Fig. 10

The maximum opening width is reached when the circumferential groove in the thread of the sternal blades (area without external thread) becomes visible – see arrow in Figure 10.



Only open the sternal retainer up to the groove in the thread of the sternal blades. If the minimum screw-in depth of the sternal blades into the PEEK nut is not observed, sufficient stability of the sternal retainer can no longer be ensured!

Close the wound with a suitable wound cover, for example a sterile, occlusive wound dressing. It is possible to gradually reduce the spreading width of the inserted CALAFIORE sternal retainer during use (progressive stent downsizing). Remove the CALAFIORE sternal retainer as soon as the medical condition permits. To remove the complete system, the opening width should be reduced to a minimum.

During use of the CALAFIORE sternal retainer, care must be taken to avoid any possible movement of the patient; sedation of the patient may be necessary to prevent the CALAFIORE sternal retainer from becoming loose or slipping.



It is recommended to stock one additional open-end wrench per set and to store it separately from the set in a sterile manner in the ICU area to allow revisions 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 suitably qualified personnel.



The maximum duration of application of 30 days must not be exceeded!

8) Required accessories

A suitable open-end wrench, e.g. MPB-1, MPB-2 or MPB-3 (Fig. 11), is required for the use of the CALAFIORE sternal retainer.

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



Fig. 11: Open-end wrench MPB-3 (2 pcs. each) (example)

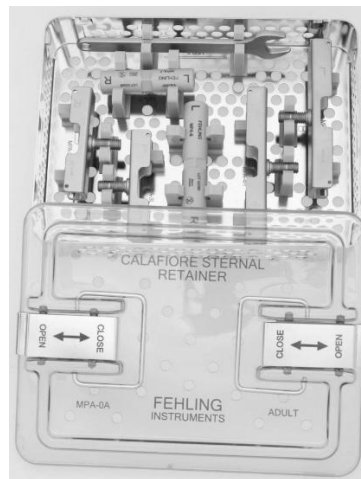


Fig. 12: Storage container adult MPA-0A (example)

9) Assembly

Please follow the assembly instructions below for assembling the CALAFIORE sternal retainer.

Screw one suitable sternal blade with left-hand thread (1) and one with right-hand thread (2) into the PEEK nut (3) as far as they will go (Fig. 13, curved arrow). Align the system in such a way that a symmetrical arrangement is achieved.

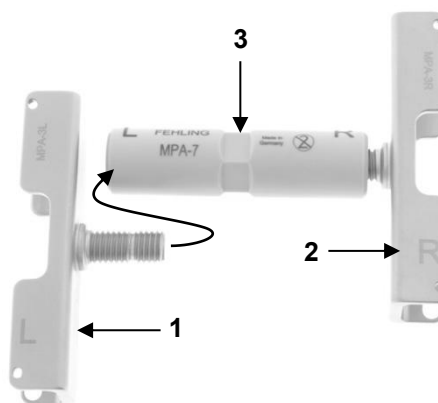


Fig. 13: CALAFIORE sternal retainer with sternal blade mounted on one side



The marking "L" or "R" on the PEEK nut and behind the article number indicates 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: CALAFIORE sternal retainer with both sternal blades mounted



When screwing in the blades, ensure that they are correctly assigned to the respective thread direction. Place the threaded pins of the blades straight and slowly screw them into the PEEK-nut.

Forceful or misaligned tightening may damage the thread of the PEEK nut and impair the stability of the CALAFIORE sternal retainer.

After a functional test, the assembled instrument is ready for use again.

10) Disassembly

To disassemble the CALAFIORE sternal retainer, please follow the corresponding assembly instructions (see 9) Assembly).



Place small parts in suitable containers (e.g., needle box) for storage 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 either 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		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 Single-use instrument – do not re-use!
 Keep away from sunlight	 Keep dry	 CE marking
 Non-sterile	 CE marking	
Manufacturer's contact information		 CE marking
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