FEHLING SUPERFLEX soft-tissue retractor, spatulated	
MTI-0..... SUPERFLEX soft-tissue retractor, spatulated, 25 x 200 mm (material thickness 0.13 mm) MTK-1 .... SUPERFLEX soft-tissue retractor, spatulated, 25 x 200 mm (material thickness 0.25 mm) MTK-2 .... SUPERFLEX soft-tissue retractor, spatulated, 25 x 200 mm (material thickness 0.34 mm) MTK-3 .... SUPERFLEX soft-tissue retractor, spatulated, 25 x 200 mm (material thickness 0.45 mm)	MTK-4 .....SUPERFLEX soft-tissue retractor, spatulated, 30 x 300 mm (material thickness 0.17 mm) MTK-5 .....SUPERFLEX soft-tissue retractor, spatulated, 30 x 300 mm (material thickness 0.22 mm) MTK-6 .....SUPERFLEX soft-tissue retractor, spatulated, 30 x 300 mm (material thickness 0.34 mm)
Accessories MTK-0 .... Sterilisation and storage tray for SUPERFLEX soft-tissue retractor Clamp or grasping forceps (not too sharp and not serrated – please refer to Section 7) Configuration and use (during application))	

⚠	This instrument or medical device is non-sterile when delivered. It is to 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. The SUPERFLEX soft-tissue retractor may only be used, reprocessed and disposed of by qualified medical personnel! The SUPERFLEX soft-tissue retractor is intended for reuse.

1) Intended purpose

Retractors and retractor components used for short-term invasive surgical procedures are intended to spread or retract various tissues, such as skin, bone, muscle, and organs.

Additional information regarding the intended purpose

Duration of application: Retractors and retractor components are intended for short-term use.

Field of application: Retractors and retractor components are used in all patients where tissue must be temporarily retracted to improve the surgeon's view of the underlying structures (max. 24 hours).

User profile: Retractors and retractor components may only be used by medically trained personnel (e.g. specialist surgeon).

Application environment: Retractors and retractor components must only to used in controlled environments (e.g. in the operating room).

Target patient population: no restrictions

2) Indications

Surgical procedures requiring the short-term spreading and retraction of various tissue structures, such as skin, bone, musculature and organs, to access the target anatomical structure. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the retractor and retractor blades used are of the correct size and have adequate stability.

In particular, the SUPERFLEX soft-tissue retractor is intended for
- concentric spreading of soft tissue, for example in abdominal or cardiac surgery
- temporary holding soft tissue open, for example in abdominal or cardiac surgery

3) Contraindication

Any use that is incompatible with the physical and/or mechanical properties of the specific retractor model is contraindicated. There are no generally applicable contraindications for the use of retractors.
Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying condition. These include, for example, increased risk of fracture of the bones in osteoporosis.

4) Possible side effects

The following side effects are reported in the medical literature and may also occur during the intended use of retractors:
- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischaemia

In particular, when the SUPERFLEX soft-tissue retractor is used as intended during or after minimally invasive techniques on the heart, (method-specific complications):
- Postoperative atrial fibrillation
- Postoperative cardiac arrhythmias

and, in rare cases,
- Infections
- Strokes

may occur.

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

5) Before use

The SUPERFLEX soft-tissue retractor is supplied non-sterile and must be cleaned and sterilised by the user before initial 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 the SUPERFLEX soft-tissue retractor with care during storage, transport and cleaning! Avoid mechanical shock and point loading on the SUPERFLEX soft-tissue retractor to prevent any possible secondary damage! Do not overload functional parts!
⚠	Use only intact and sterilised products!
⚠	SUPERFLEX soft-tissue retractors are made of an austenitic nickel-titanium shape memory alloy. They are flexibly deformable at room temperature and return to their original shape (immediately) after the deforming force is removed. Do not kink the device while it is deformed during use and do not go below the permissible minimum diameter of 30 mm. If the device is bent more than this, permanent deformation or irreparable kinking of the material may occur, which may impair the function of the retractor.

6) Reprocessing	
⚠	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.
⚠	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.
⚠	The instruments must be handled with care during storage, transportation and cleaning. Avoid mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts.
Limitations on reprocessing	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"*). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.

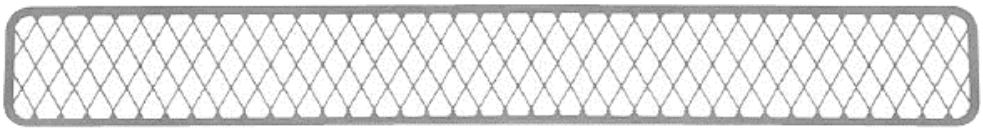
General information on reprocessing	Reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection, and sterilisation) were validated with the respective parameters specified in each case and listed under "Validated 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. 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 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.
Pre-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).
Preparation before cleaning	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.
Disassembly	See section *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. • 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.
Cleaning/ disinfection	If possible, for preference use a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. 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. <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> • 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. <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 deionised water (< 30 °C)

	• Emptying • Thermodisinfection for 5 minutes with deionised 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. • 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). <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). • 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.
Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's 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. 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.
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 section *9) Assembly*
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), apply a biocompatible, steam sterilisable, steam-permeable paraffin-/white oil-based instrument oil (according to the valid European or United States Pharmacopoeias) 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. Check instruments with movable parts for smooth operation (avoid excessive looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. In particular, inspect the critical points on moving parts and 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 authorised by the manufacturer. A confirmation 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	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.

Sterilisation	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. <u>Validated procedure:</u> Equipment: Tuttnauer autoclave Type B 3870 EHS / Lautenschläger ZentraCert <u>Procedure/Parameters:</u> Cycle type: 3 pre-vacuum phases Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	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. 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. Instruments must be transported to their place of use in a closed, puncture-proof sterile container.
Disposal	These products are made of Nitinol. They must 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.
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 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.	
	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	
SUPERFLEX soft-tissue retractors are made of an austenitic nickel-titanium shape-memory alloy (Fig. 1). They are elastically deformable at room temperature and return to their original shape (immediately) after the deforming force is removed. The spatulated SUPERFLEX soft-tissue retractor in particular is intended for self-retaining concentric spreading and temporary holding open of soft tissue. Depending on the specific patient anatomy and the area of application, the spatulated SUPERFLEX soft-tissue retractor is carefully rolled up, grasped using a non-sharp or non-toothed clamp or grasping forceps, and positioned in the soft tissue to be retracted.	
 Fig. 1: SUPERFLEX soft-tissue retractor MTI-0	
⚠	Use only intact and sterilised products!
⚠	Before inserting the SUPERFLEX soft-tissue retractor, ensure that the surgical field has been prepared accordingly.
⚠	Before using the SUPERFLEX soft-tissue retractor, 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 the SUPERFLEX soft-tissue retractor depends on the anatomical and physiological conditions as well as the field of application. Care must be taken to ensure that the SUPERFLEX soft-tissue retractor used is the correct size and geometry, and is sufficiently stable.
During application	
Do not subject the tissue being retracted to greater stress than is unavoidable for the intended surgical purpose.	

In its original shape, the SUPERFLEX soft-tissue retractor is unrolled (Fig. 2a). Before insertion, carefully roll up the spatulated SUPERFLEX soft-tissue retractor (Fig. 2b). Depending on the thickness of the material, this will form a cylinder with a minimum diameter of 30 mm.

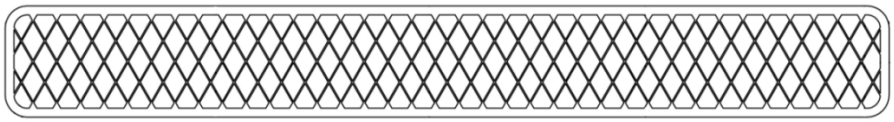


Fig. 2a: The SUPERFLEX soft-tissue retractor in its original shape

Fig. 2b: Illustration of rolling up the SUPERFLEX soft-tissue retractor for use

⚠	SUPERFLEX soft-tissue retractors are made of austenitic NiTi material and have a shape memory. They are flexibly deformable at room temperature and return to their original shape (immediately) after the deforming force is removed. Do not kink the device during shaping in the course of use and do not go below the permissible minimum bending radius of 15 mm. If the device is bent more than this, permanent deformation or irreparable kinking of the material may occur, which may impair the function of the retractor!

Do not use a clamp or grasping forceps that are too sharp or toothed to stabilise the shape, otherwise the SUPERFLEX soft-tissue retractor may be damaged.
Figure 3 shows a configuration example in which the shape of the SUPERFLEX soft-tissue retractor (a) is stabilised with the aid of grasping forceps (b).

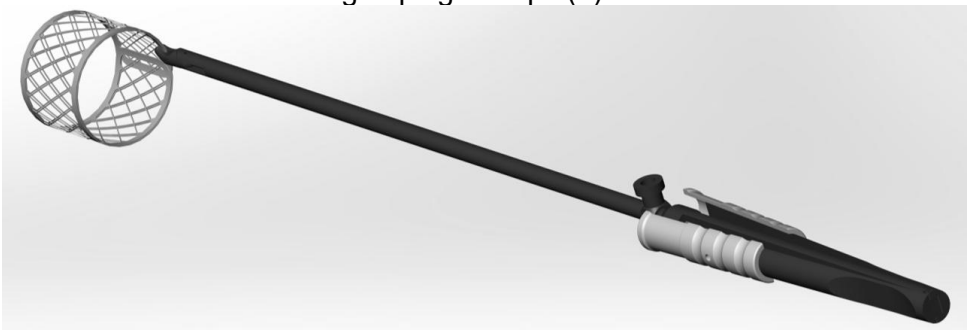


Fig. 3: Configuration example for the SUPERFLEX soft-tissue retractor

Position the rolled-up SUPERFLEX soft-tissue retractor in the soft tissue to be retracted and release the clamp/grasping forceps.

⚠	When inserting the SUPERFLEX soft-tissue retractor, care must be taken not to injure any tissue structures unintentionally (in particular nerves and blood vessels)!
⚠	Do not rotate or tilt the holding instrument during insertion of the SUPERFLEX soft-tissue retractor, as this may damage the retractor.
⚠	Risk of injury! The SUPERFLEX soft-tissue retractor returns to its original shape (immediately) after the holding instrument is removed. The clamp/grasping forceps must only be opened after correct placement in the soft tissue.
⚠	Excessive and prolonged pressure on the tissue can cause necrosis and other lesions!

⚠	Overloading may cause plastic deformation or breakage of the SUPERFLEX soft-tissue retractor!
To remove the SUPERFLEX soft-tissue retractor, grasp the overlapping ends with a non-sharp or non-toothed clamp/grasping forceps and **carefully** withdraw the retractor from the surgical site.	

8) Required accessories

A non-sharp or non-toothed clamp or grasping forceps are required to stabilise the shape for use of the SUPERFLEX soft-tissue retractor.
For sterilisation and storage, a storage and sterilisation container (MTK-0) may be used for the safe storage of the 200 mm SUPERFLEX soft tissue retractor (MTI-0, MTK-1, MTK-2, and MTK-3) (Fig. 4).
SUPERFLEX soft-tissue retractors are stand-alone instruments and combination with other products is therefore not intended.

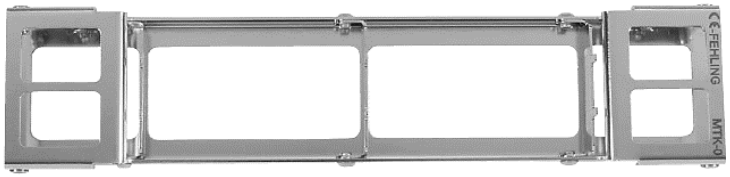


Fig. 4: Storage and sterilisation container MTK-0 for SUPERFLEX soft-tissue retractor with a length of 200 mm

Use of the storage and sterilisation container MTK-0 for MTI-0, MTK-1, MTK-2 and MTK-3

The storage and sterilisation container MTK-0 (a) is used for the safe storage of the flexible soft-tissue retractor (b) during sterilisation and storage (Fig. 5).

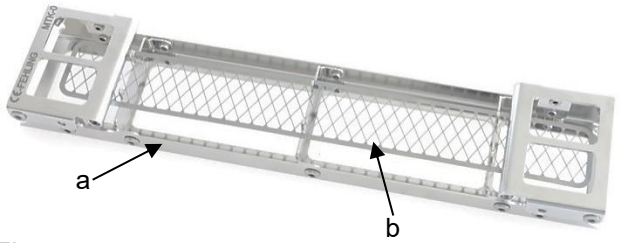


Fig. 5

Before the flexible soft-tissue retractor can be placed in the storage and sterilisation container, the uprights (c) must be checked to ensure that they are perpendicular to the base (d) (Fig. 6).

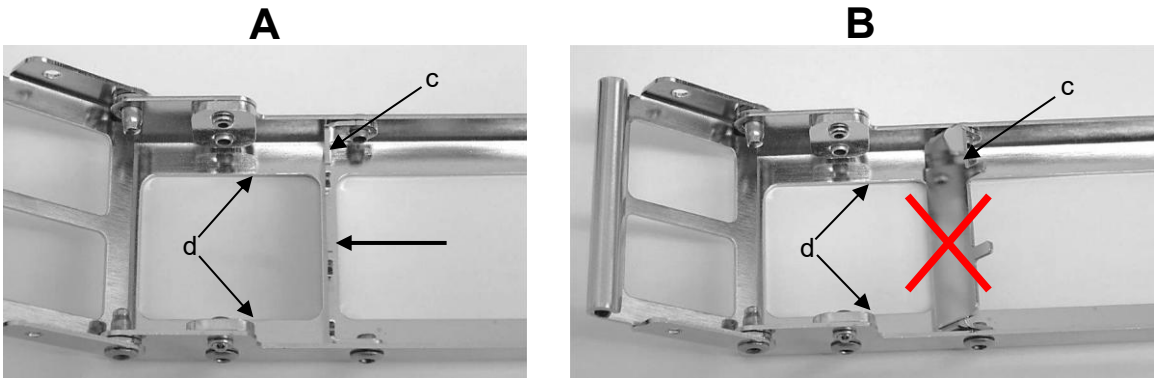


Fig. 6: Illustration of the correct (**A**) and incorrect (**B**) position of the uprights (c).

If the uprights (c) are not perpendicular, the mesh profile of the flexible soft-tissue retractor (b) may be kinked or damaged when inserted (Fig. 6a). The uprights (c) must therefore always be perpendicular.

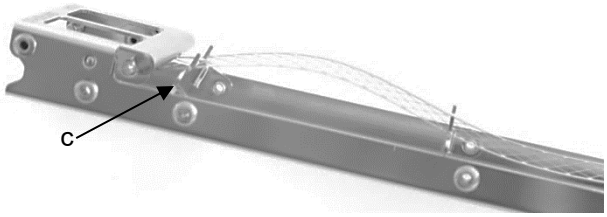


Fig. 6a

The flexible soft-tissue retractor is placed centrally on the uprights (c) with the safety covers (e) open (Fig. 7).

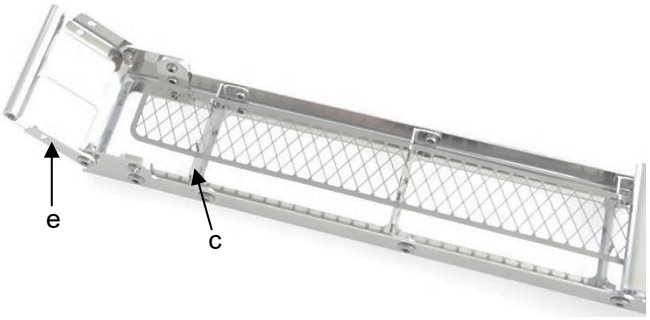


Fig. 7

It is important to ensure that the fixing pins (f) protrude through the mesh profile (g) of the soft-tissue retractor (see arrows in Fig. 7a).

When positioning on the fixing pins (f), ensure that the retractor does not touch or is not pulled against the fixing pins when being placed in the storage and sterilisation container.

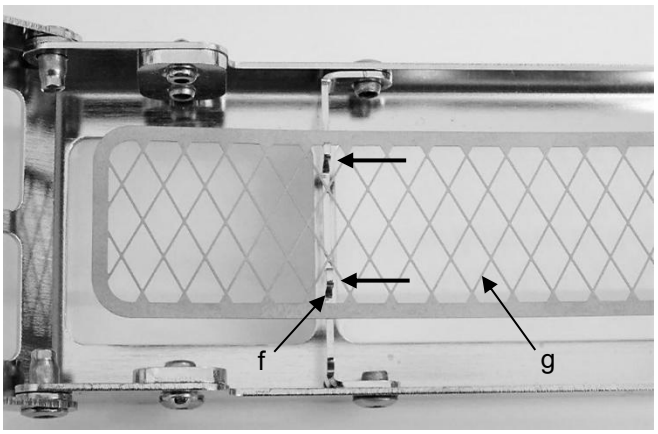


Fig. 7a

When closed and locked, the two locking covers (e) prevent the retractor from detaching from the uprights (c) (Fig. 8). This prevents loss and possible damage.

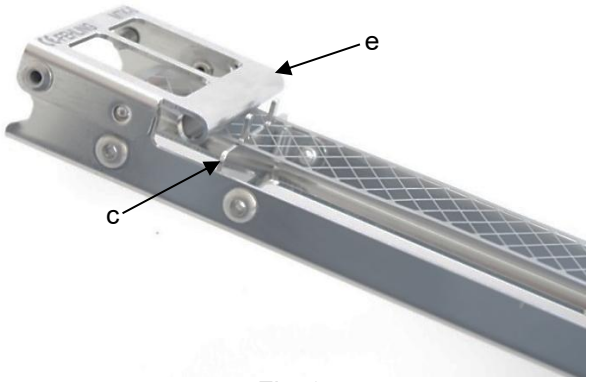


Fig. 8

9) Assembly

No assembly of the SUPERFLEX soft-tissue retractor is necessary.

10) Disassembly

No disassembly of the SUPERFLEX soft-tissue retractor is necessary.

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
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points to be lubricated	CE CE marking	

Manufacturer's contact information		
	FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 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