FEHLING MI TLIF Multi-functional Retractor

Retractor body LVB-1 MI TLIF multi-functional retractor, body only

Components

Fixations/guides

NWA-1B	Coupling rider for spine retractors
NWA-1C	Blade guide for spine retractors

Microblades

LVB-2	MI microblade (width 11 mm)
LVB-2A	MI microblade, wide mount (width 12.2 mm)

Parafascial blades

LVB-3	MI parafascial blade left (width 11 mm)
LVB-3A	MI parafascial blade left, wide mount (width 12.2 mm)
LVB-4	MI parafascial blade right (width 11 mm)
LVB-4A	MI parafascial blade right, wide mount (width 12.2 mm)

Titanium medial blades

LVB-5	medial blade, 50 x 24 mm
LVB-6	medial blade, 65 x 24 mm
LVB-7	medial blade, 80 x 24 mm
LVB-8	medial blade, 95 x 24 mm

Accessories

LMT-4	Cardan screwdriver
LMT-6	Screwdriver SW4
NVG-9	CERAMO® hexagonal wrench for specula
NVG-9L	CERAMO® hexagonal wrench for specula, long version
LVB-0	Storage and sterilization container for TLIF retractors, 400 x 245 x 65 mm

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.

Only trained medical personnel may use, reprocess or dispose of the MI TLIF multi-functional retractor!

The MI TLIF multi-functional retractor is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The MI TLIF multi-functional retractor is only intended for short-term use.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
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 the medical literature, the following adverse effects are described that can possibly occur despite the correct use of the FEHLING MI TLIF multi-functional retractor during or after performing a TLIF procedure (oTLIF or miTLIF) (method-specific complications):

- CSF leakage
- Neural damage (e.g., transient radiculopathy, neurogenic bladder, ileus, paresis)
- Seroma
- Hematoma
- Bone fractures such, for example, spinous processes, vertebral bodies
- Infections
- Impaired wound healing
- Lesions of structures (tissues, nerves, vessels)
- Necroses
- Ischemia of other organs due to compression of blood vessels

As for adults, the decision to perform the procedure in children can only be made by the attending physician after considering all the benefits and risks.

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

5) Prior to use

FEHLING INSTRUMENTS MI TLIF multi-functional retractors are non-sterile when delivered and must be cleaned and sterilized by the user before initial use and every time before they are 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").
⚠	The MI TLIF multi-functional retractor must be handled with care during storage, transportation and cleaning! Avoid striking and applying pressure to the MI TLIF multi-functional retractor, so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!
⚠	The MI TLIF multi-functional retractor is intended for use with common pedicle screws for rod-screw systems with U-shaped or tulip-shaped receptacles!

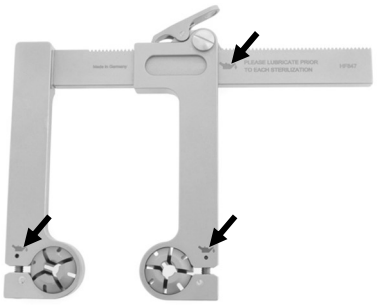
⚠	These Instructions for Use are no substitute for reading the instructions for use for any accessories that may be additionally used (e.g., of the pedicle screws).

6) Reprocessing	
⚠	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!
⚠	Do not clean titanium or titanium-containing instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium or titanium-containing instruments.
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").
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).

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. • If necessary, the moving parts of the instrument are 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 deionized water (see "General Information on Reprocessing") and, if applicable, move movable parts back and forth.
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> • Instruments with joints are to be placed in the device such, that the joints are opened or disassembled if possible, and that the water can flow from the cavities and sac holes. • If applicable, loosen springs

	• Ensure that the inside of all 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 WD. Procedure/Parameters: • 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	Validated procedure: Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) Procedure/Parameters: • 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 no more contamination is visible. • Rinse the instruments for at least 20 seconds using a water spray gun (or similar). Ultrasonic cleaning: • 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). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • 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 deionized 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 9) Assembly
Maintenance, checking and testing	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 sterilizable and steam-permeable is to be applied. Such places are additionally marked by a corresponding symbol of an oil can (see Fig. 1). Instruments must not be treated with care products containing silicone. These can lead to stiffness and question the effect of steam sterilization. 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. Check instruments with movable parts for smooth operation (avoid excessive play). Check locking mechanisms. All instruments: use a magnifying lamp to visually inspect the components for damage and wear and tear. 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 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!

⚠	With the MI TLIF multi-functional retractor, instrument oil must be applied to the respective marked areas. The corresponding points are marked with an oil can symbol on the underside of the MI TLIF multi-functional retractor (Fig. 1).	 Fig. 1: MI TLIF multi-functional retractor with the respective marked areas
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instructions into dedicated trays or place them in general-purpose sterilization trays. Pack the trays appropriately using a suitable procedure.	
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). 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 largely consist of steel or titanium. 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.	

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

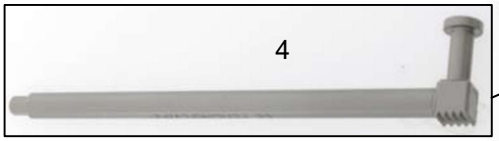
The MI TLIF multi-functional retractor is a U-shaped bar retractor with one fixed and one movable retractor arm. A gear control is used to move the flexible retractor arm along the toothed rack. As a supplement, a coupling rider with a blade guide is used for a three-point holding system.

Two ball mounts are located at the distal end, in which the parafascial blades with mount are guided. The parafascial blades are locked into place in the ball sockets using the clamping screw with a hexagonal head, which is operated with the cardan screwdriver LMT-4 (see 8) Required accessories).

Figure 2 depicts such a configuration example for the MI TLIF multi-functional retractor with a central arm consisting of a coupling rider with a blade guide for attaching the blade at the distal end. Table 1 lists the corresponding components.

Table 1: List of the corresponding components

	Article no.	Description
1	LVB-1	MI TLIF multi-functional retractor, body only
2	LVB-3/3A	Parafascial blade, left
3	LVB-4/4A	Parafascial blade, right
4	LVB-2/2A	MI microblade
5	NWA-1B/1C	Coupling rider with blade guide
6	LVB-5/6/7/8	Medial blade



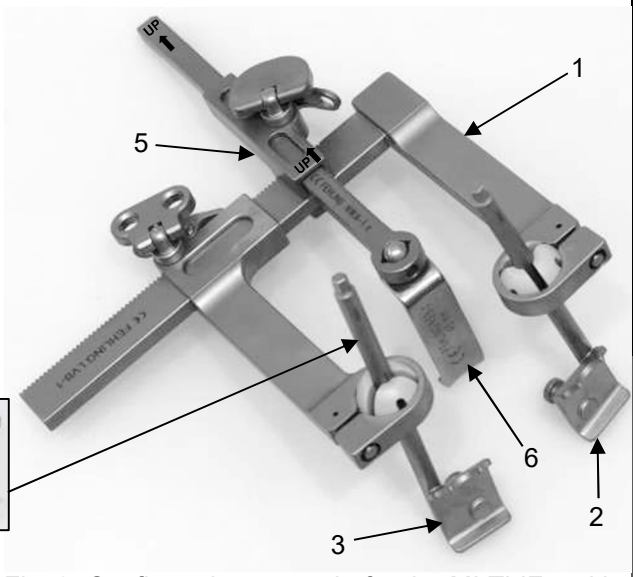


Fig. 2: Configuration example for the MI TLIF multi-functional retractor with center arm

Both the MI parafascial blades left (Fig. 3a) and right (Fig. 3b) and the MI microblades (Fig. 3c) are available in two different mounting widths (a) for the pedicle screws.

Articles LVB-2, LVB-3 and LVB-4 have a mounting width of 11 mm. Articles LVB-2A, LVB-3A and LVB-4A possess a wider mounting width (a = 12.2 mm).

Depending on the size of the pedicle screw, one can choose between the two mounting widths.

The respective blades can be grasped at their proximal hexagonal profile and turned into the optimum position using the CERAMO® hexagonal wrench NVG-9 (see 8) Required accessories).

Fig. 3a

Fig. 3b

Fig. 3c

Figure 4 shows an example of a pedicle screw with a compatible screw shape for the system.

The FEHLING INSTRUMENTS product portfolio does not include pedicle screws.

Fig. 4: Example of pedicle screw with compatible screw shape
Requires self-locking nut!

The MI TLIF multi-functional retractor is designed specifically for visualizing the surgical field during minimally invasive approaches to the lumbar spine and for distraction of the disc space in dorsal transmuscular approaches. The retractor is designed for TLIF application and is used in combination with a pedicle-screw system for rod-screw implants.

In particular, the MI TLIF multi-functional retractor is intended for the following surgical procedures:

- Use in fusion procedures, etc., often combined with neural decompression.
- Treatment of degenerative instabilities (spondylolisthesis/scoliosis) with or without spinal stenosis. In a young patient cohort, spinal fusions are typically performed to treat (isthmic) spondylolisthesis or erosive osteochondrosis (e.g., after disk surgery).

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the MI TLIF multi-functional retractor, 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 components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

During use

Before the MI TLIF multi-functional retractor is used, the transpedicular screws must be inserted and transmuscular exposure must be carried out in the area of the spinal segment to be treated.

To be able to insert the pedicle screw, the surrounding tissue must be kept away accordingly.

⚠	The locking screw at the distal end of the retractor arms must not be screwed in if no shaft has been inserted, as this will cause plastic deformation of the ball and the shaft can no longer be inserted.
⚠	Do not unscrew the locking screw completely during use, otherwise it could drop into the patient's body. To release the shaft, it is sufficient to only loosen the locking screw.
1	Parafascial blades LVB-3/3A and LVB-4/4A are inserted into the wound opening. For an approach from the right, the left blade LBV-3/3A is in caudal position and the right blade LBV-4/4A is in cranial position. For an approach from the left, the left blade LBV-3/3A is in cranial position and the right blade LBV-4/4A is in caudal position.
2	Each parafascial blade (a) must be aligned with its tooth side facing laterally. The cylindrical shaft attached to the back of the blade (arrow in Fig. 5) is inserted into the slit on the head of the pedicle screw.

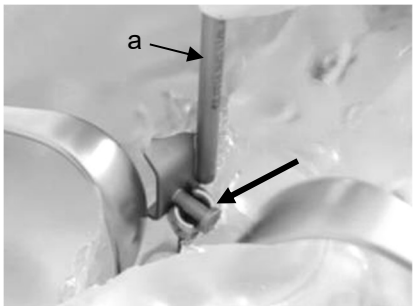
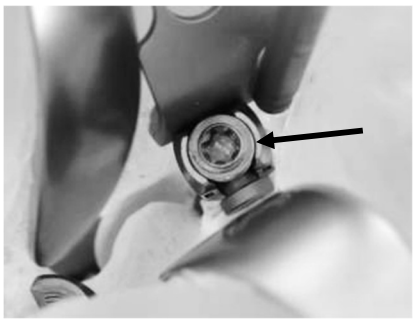
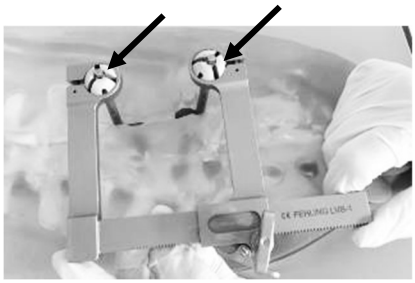
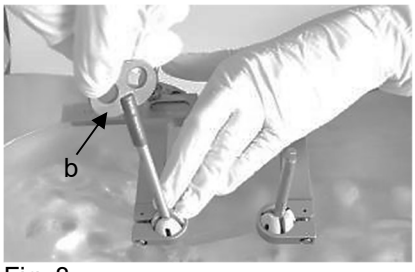
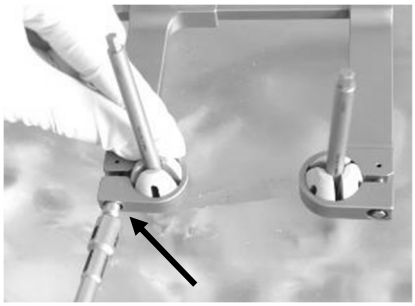
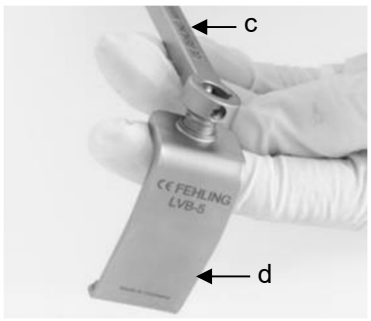


Fig. 5

	The nut belonging to the pedicle screw (arrow in Fig. 6) secures the cylindrical shaft of the parafascial blade in its position.	 Fig. 6
	For surgical procedures in the lumbosacral transition, the soft tissue located over S1 is sometimes too thin to accommodate a parafascial blade. In such cases, microblade LVB-2/2A is used instead.	
3	The central drill holes of the balls (arrows in Fig. 7) of the retractor body are pushed across the cylindrical shafts of the respective parafascial blades or microblades extending out of the wound, whereby the toothed rack of the retractor is always in a medial position.	 Fig. 7
	The balls are inserted as close as possible to the wound edge and are positioned so that the soft tissue is securely retracted and a space is created between the blade shafts that is large enough to allow further dissection. The CERAMO® hexagonal wrench NVG-9 (b) (Fig. 8) may be used to grasp the blades on their proximal hexagonal profile and screw them into the optimum position.	 Fig. 8
	As soon as this position is reached, the cardan screwdriver LMT-4 is used to compress the balls until a stable ball-blade shaft connection is created (Fig. 9).	 Fig. 9
4	In order to widen the surgical site towards medial, blade guide NWA-1C (c) is fitted with a muscle blade (d) (LVB-5/6/7/8) suitable for the depth (Fig. 10).	 Fig. 10

Then pass the blade guide (c) through the central opening of the NWA-1B coupling rider (e) in the direction indicated by the arrow (Fig. 11).

In so doing, care must be taken that U-shaped part of the coupling rider (e) is open below and towards the surgical site.

The coupling rider (e) should be located close to the proximal end of the blade guide (c).

To insert the blade guide into the coupling rider, please follow the assembly instructions (see 9) Assembly).

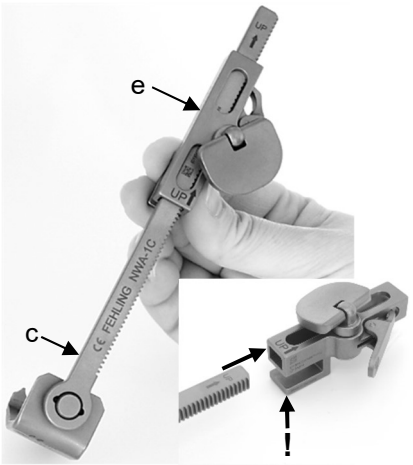


Fig. 11

The medial muscle blade is inserted into the center of the surgical site until it surrounds the medial muscle as deeply as possible.

Pull the blade guide along with the coupling rider and the muscle blade towards medial and push the U-profile of the coupling rider over the toothed rack of the retractor starting from the outer side (Fig. 12a).

The medial muscle is pulled as far as required in a medial direction by turning the wing screw of the coupling rider clock-wise. The surgical site now has a trapezoidal shape.

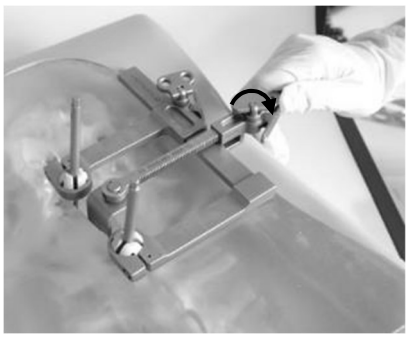


Fig. 12a

The coupling rider must be attached to the retractor body according to the symbolic marking (Fig. 12b).

Here it should be ensured that the U-profile of the coupling rider (e) is open towards the surgical site so that the coupling rider can be pushed over the toothed rack of the retractor from the outer side of the retractor in the direction indicated by the arrow (Fig. 12c).

Figure 12d depicts the proper assembly of the coupling rider with blade guide on the retractor body.

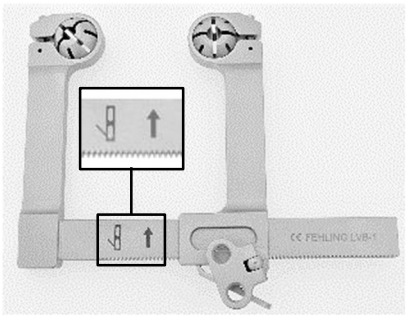


Fig. 12b

⚠ The marking of the coupling rider and the blade guide applies exclusively to these two components and is not related to the marking of the MI TLIF multi-functional retractor.

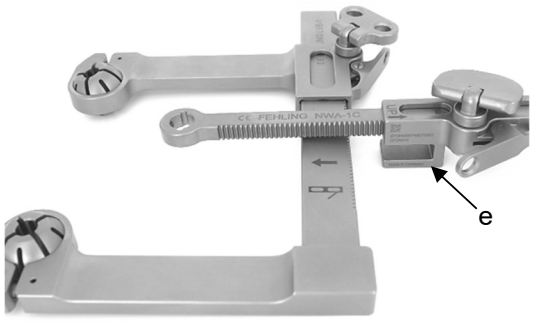
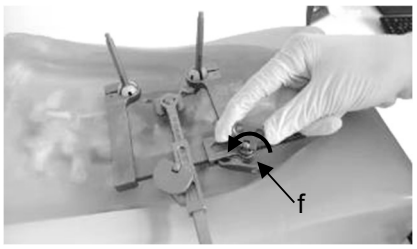


Fig. 12c


Fig. 12d

5	To retract the disk gap, turn the wing screw (f) (Fig. 13) of the retractor body anticlockwise. This will simultaneously distract soft tissue and the disk gap at approx. 2-mm intervals in the cranial-caudal axis.	 Fig. 13
6	A unilateral facetectomy may now be performed followed by a disk resection and the insertion of a TLIF cage.	
7	After completing the steps described in item 6, - press the lock of the coupling rider to release the pressure on the medial muscle retraction - remove the coupling rider along with the blade guide and the muscle blade - remove the self-locking nuts from the screw heads of the pedicle screws - use the cardan screwdriver LMT-4 to release the compression of the balls of the retractor - lift the cylindrical shafts of the respective parafascial blades or microblades from the pedicle screws - release the retractor body by pressing the lock of the movable retractor arm and simultaneously turning the wing screw clockwise - remove the retractor from the surgical site.	
⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.	
8	Continue the surgical procedure as planned.	

8) Required accessories	
A cardan screwdriver LMT-4 (Fig. 14) is required for application of the MI TLIF multi-functional retractor. The CERAMO® hexagonal wrench NVG-9 (Fig. 15) or NVG-9L (long version) can be used to grasp the blades by their hexagonal profile and rotate them to their optimum position. The LVB-0 storage and sterilization container can be used for sterilization or storage.	
 Fig. 14: Cardan screwdriver LMT-4	 Fig. 15: CERAMO® hexagonal wrench NVG-9

9) Assembly

For assembly of the MI TLIF multi-functional retractor please observe the following assembly instructions.

Figure 16 illustrates the MI TLIF multi-functional retractor, which is a U-shaped bar retractor with wing screw. The bar retractor consists of one fixed retractor arm (a), a toothed rack (b) and one movable retractor arm (c).
The proximal end of the movable retractor arm is the cage (d) where the wing screw (e) with the gear as well as the lock (f) are located. A ball mount (g) is located at the distal ends of each of the fixed and movable retractor arms, in which the parafascial blades with mount and the MI microblade are guided.

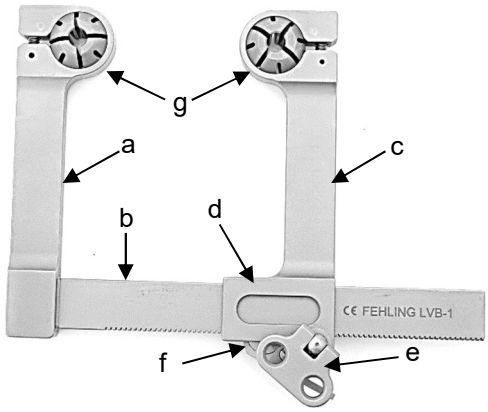


Fig. 16: Exemplary bar body with sprocket/lock

Insert the toothed rack (b) into the recess of the cage (d). During this process, release the lock (f) by pressing in direction of the toothed rack (b) (Fig. 17).

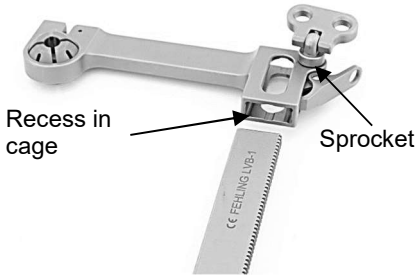


Fig. 17

⚠ Ensure that both retractor arms point in the same direction and the sprocket of the flexile retractor arm points outwards.

Advance the movable retractor arm (c) on the toothed rack (b) inwards towards the fixed retractor arm (a) (Fig. 18).

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

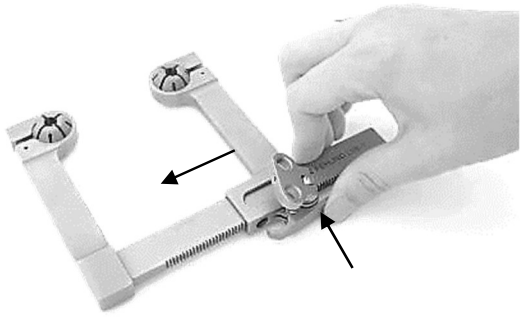


Fig. 18

To insert the blade guide into the coupling rider, please observe the following assembly instructions.

Both the blade guide (a) as well as the coupling rider (b) have a side marked with an "arrow" and "UP". Before inserting the blade guide (a) into the coupling rider (b), make sure that the two marked sides are facing upwards. The blade guide (a) is inserted into the coupling rider (b) in the direction indicated by the arrow (Fig. 19). The arrow on the coupling rider (b) refers exclusively to the insertion of the blade guide (a) and not for mounting the retractor body.

The blade guide (a) is pushed through the opening of the coupling rider (b) until the lock (c) on the toothed rack of the blade guide (a) engages. While inserting, the lock (c) must be unlocked by pressing down.

By rotating the thumb screw (d) clockwise, the blade guide (a) can be tightened in a controlled manner.

Important: The coupling rider (b) must be aligned such that its U-profile is open in direction of the site (Fig. 19).

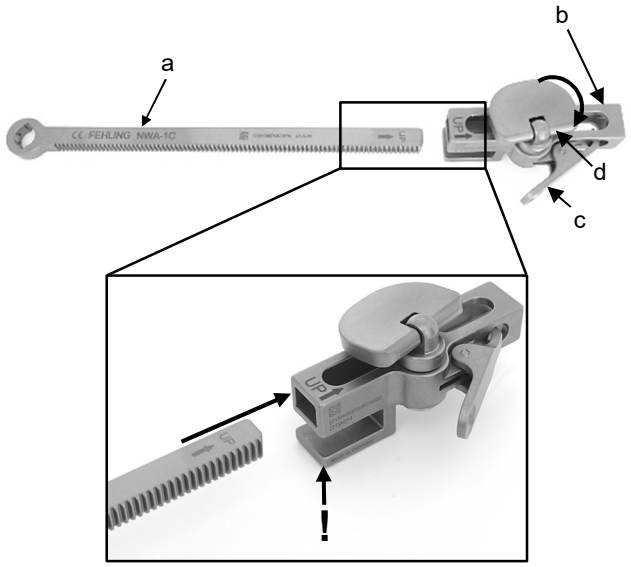


Fig. 19

The blade guide (a) should protrude as far as possible from the coupling rider (b) (see Fig. 20).

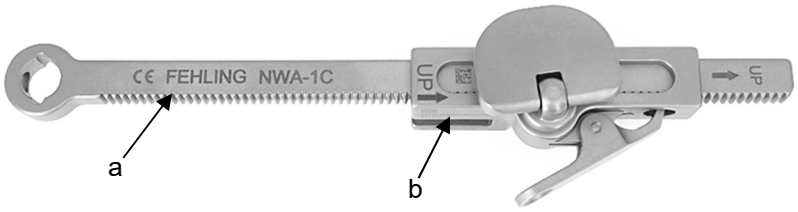


Fig. 20

Next, determine the optimal muscle blade (LVB-5/6/7/8) for the patient-specific application and insert it into the blade guide (a) (see 7) Configuration and application - during use).

10) Disassembly

The MI TLIF multi-functional retractor must be disassembled as follows for reprocessing.

For disassembly of the center arm, please observe the corresponding assembly instructions (see 9) Assembly).

Figure 21 gives an example of a retractor body to illustrate disassembly.

Advance the movable retractor arm (c) outwards along the toothed rack (b) until it can be removed. During this process, release the lock (f) by pressing in direction of the toothed rack (b).

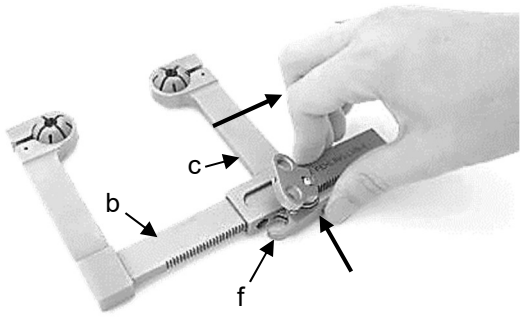
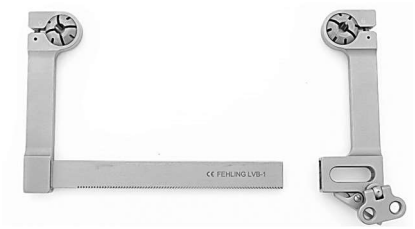


Fig. 21

The instrument is now disassembled into its separate parts (Fig. 22) and can be reprocessed.	 Fig. 22
Figure 23 shows the retractor with disassembled components.	 Fig. 23
⚠	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 CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated
	Marking of position	UP Marking of position

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