FEHLING MI TLIF multi-functional retractor Premia Spine

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

Components

Fixings/guides

NWA-1B..... Coupling rider for spine retractor
NWA-1D ..... Blade guide titan, adjustable angle
NWA-1C ..... Blade guide for spine retractor (optional alternative)

Micro blades

LVC-5..... TLIF microblade 45 mm, Premia Spine
LVC-6..... TLIF microblade 70 mm, Premia Spine
LVC-7..... TLIF microblade 95 mm, Premia Spine

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

Retractor blades

LVC-4..... TLIF retractor blade, 45 x 75 mm, Premia Spine
LVC-3..... TLIF retractor blade, 45 x 90 mm, Premia Spine
LVC-2..... TLIF retractor blade, 55 x 75 mm, Premia Spine
LVC-1..... TLIF retractor blade, 55 x 90 mm, Premia Spine

Accessories

LMT-6 .....Hexagonal screwdriver Size 4 mm, 200 mm (optional)
LMT-4 .....Cardan screwdriver (optional)
NVG-9.....CERAMO hexagon wrench for specula (optional)
NVG-9L.....CERAMO hexagon wrench for specula, long version (optional)
LVB-0.....Storage and sterilization container for TLIF retractor, 400 x 245 x 65 mm

This instrument or medical device is supplied non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).

The MI TLIF multi-functional retractor may only be used, reprocessed and disposed of by qualified medical personnel!

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

1) Intended purpose

The purpose of holding and guiding instruments is to hold products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drainage tubes, holding rods, handles, retractor blades, etc.).

- to hold or fix in a certain position

- to move into or to a certain position

This does not apply to retractors (according to TD retractor class I and class IIa), hooks, vessel and tissue clamps, forceps and needle holders.

Supplementary information on the intended purpose

Duration of application: Holding and guiding instruments are intended for short-term use.

Field of application: Holding and guiding instruments are used for all patients where products and tissue have to be held or fixed in or at a certain position and/or moved in or at a certain position.

User profile: Holding and guiding instruments may only be used by medically trained specialists (e.g. medical specialists).

Application environment: Holding and guiding instruments are only used under controlled environmental conditions (e.g. operating theater).

Anticipated patient population: No restrictions

2) Indications

Treatment methods that require products and tissues to be held and guided.

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual holding and guiding instrument model are considered contraindicated. There are no generally valid contraindications for the use of holding and guiding instruments.

Nevertheless, attention must be paid to increased risks that could arise from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible side effects

The following side effects are described in the medical literature, which may occur during or after a TLIF procedure (oTLIF or miTLIF) despite the intended use of the MI TLIF multi-functional retractor (method-specific complications):

- Cerebrospinal fluid leakage
- Neural injuries (e.g. transient radiculopathy, neurogenic bladder, ileus, paresis)
- Seroma
- Hematoma
- Bone fractures such as spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Lesions of structures (tissue, nerves, vessels)
- Necrosis
- Ischemia of other organs due to compression of blood vessels

The decision to perform an EMB in children – as in adults – can only be made by the treating physician after weighing all the pros and cons.

⚠	Medical devices may contain chromium, nickel and/or titanium, for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Before use

The MI TLIF multifunctional retractor is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before each subsequent use (see chap. *6) Reprocessing*).

⚠	A safety inspection must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see chap. *6) Reprocessing* under *"Maintenance, inspection and testing"*).

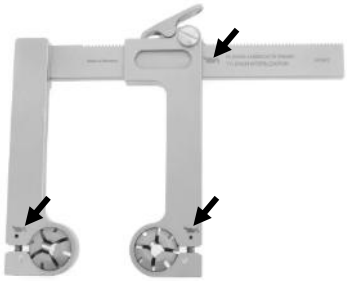
⚠	Handle the MI TLIF multi-functional retractor with care during storage, transportation and cleaning! Avoid impacts and punctual loads on the MI TLIF multi-functional retractor to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!
⚠	The MI TLIF multi-functional retractor is designed for use with standard pedicle screws for rod-screw systems with U-shaped or tulip-shaped receptacles!
⚠	These instructions for use do not replace reading the instructions for use for the additional accessories used (e.g. the pedicle screw).

6) Reprocessing	
⚠	The medical device must be prepared before use. Before reprocessing, it must be risk-assessed according to the RKI guidelines (non-critical/semicritical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for preparation must be complied with.
⚠	The respective national regulations for the treatment of instruments used on patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants must be observed.
⚠	The instruments may only be used, prepared and disposed of by qualified medical personnel.
⚠	Handle the instruments with care during storage, transportation and cleaning! Avoid impacts and localized pressure on the instruments in order not to cause any possible consequential damage! Do not overload functional parts!
Limitations during reprocessing	Frequent reprocessing has little effect on the label of the instruments and does not impair the function of the instruments. The end of the product's life is normally determined by wear and damage caused by use (e.g. damage, illegible labeling, functional failure - see also *"Maintenance, inspection and testing"*). When used and reprocessed properly, the instruments have been shown to withstand at least 500 processing cycles.
General information on reprocessing	Reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". For validation, the recommended reprocessing agents (cleaning agents: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) is used. Both water of drinking water quality and demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Automated preparation is preferable to manual cleaning because it provides a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with

	regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of cleaning agents and disinfectants. All application instructions of the chemical manufacturer must be strictly adhered to. Otherwise, this can lead to optical material changes or material damage, such as corrosion, fractures or premature aging.
Pre-treatment at the point of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and medication residues are removed from the instruments with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for machine cleaning. Once the instruments have been pre-treated, visual inspections must be carried out to ensure that they are complete. The instruments must be transported from the place of use to the place of preparation in such a way that neither users, 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	It is recommended that the instruments be cleaned immediately after use, as dried residues are difficult to remove from hard-to-reach places. Do not place in NaCl solutions (otherwise risk of pitting or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See chap. *10) Disassembly*
Manual pre-cleaning	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, rinse the instrument in disassembled condition under cold running water (drinking water quality, < 40 °C) until all visible soiling has been removed. Use a soft brush (not a wire brush!) to remove stubborn dirt. • Cavities, gaps, slits and lumen must be rinsed intensively (> 10 seconds) with cold water (drinking water quality, < 40 °C) using a water pressure gun (or similar). • Soak the products for 10 – 30 minutes in a solution containing 0.5 – 2 % Neodisher® MediClean forte with water (drinking water quality, < 40 °C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be observed. • Make sure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!).

	• Rinse the instrument for 1 minute under cold demineralized water (see *"General information on reprocessing"*) and move any moving parts on the instrument back and forth.
Cleaning/ disinfection	If possible, a washer-disinfector that uses thermal disinfection and complies with DIN EN ISO 15883 is preferable.
Cleaning: Machine	Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. • If applicable, relax springs • Make sure that all cavities are completely flushed out, including the inside. • Make sure that no areas are left unwashed. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector. <u>Procedure/parameters:</u> • 3 minutes pre-rinse with cold water (drinking water quality, < 40 °C) • Emptying • 10 minutes cleaning with a solution of 0.5 – 2 % Neodisher® MediClean forte in water (drinking water quality) at 55 °C • Emptying • 2 minutes rinsing with water (drinking water quality, < 40 °C) • Emptying • 1 minute rinse with cold demineralized water (< 30 °C) • Emptying • 5 minutes thermal disinfection with demineralized water (> 90 °C) • 30 minutes drying (90 °C) After machine cleaning, cavities, blind holes, etc. in particular have to be inspected for visible dirt. If necessary, repeat the cycle or clean manually.
Cleaning: Manual	<u>Validated procedure:</u> Equipment: Basin Soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec

	Cleaning agents: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/parameters:</u> • If possible, place the disassembled instruments in cold water (drinking water quality, < 40 °C) for 10 minutes. • Operate moving parts, if any, through their full range of movement. • Clean the instruments with a soft brush (not a wire brush!) until no visible contamination remains. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). <u>Ultrasonic cleaning:</u> • 10 minutes sonication at < 40 °C with 0.5 – 2 % detergent solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments with water (drinking water quality, < 40 °C) for at least 10 seconds. • Deionized water (< 40 °C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/parameters:</u> • After cleaning, immerse the products for 5 minutes in an ultrasonic bath (35 kHz, < 40 °C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med AF). Ensure that all surfaces are wetted with the disinfectant. If necessary, move mobile 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 necessary, move mobile parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded. Then dry with suitable compressed air in accordance with RKI recommendations. Pay particular attention to drying areas that are difficult to access.
Assembly	See chap. *9) Assembly*

Maintenance, inspection and testing	For instruments with moving components that are exposed to friction (e.g. joints), an instrument oil based on paraffin/white oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such points may also be indicated by an oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to stiffness and impair the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). If applicable, check the locking mechanisms. All instruments: Visually inspect for damage and wear using a magnifying lamp. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments whose labeling is no longer legible must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs may only be carried out by the manufacturer or workshops authorized 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 in the standard hospital scrap metal disposal system. In this case, especially for surgical instruments with pointed or sharp edges, it is important to ensure safe storage in a closed, puncture- and break-proof disposable container. Do not use damaged instruments!	
⚠	With the MI TLIF multi-functional retractor, instrument oil must be applied to the points marked accordingly. On the underside of the MI TLIF multi-functional retractor, the corresponding points are marked with an oil can symbol (Fig. 1).	 Fig. 1: MI TLIF multi-functional retractor with the correspondingly marked points
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into trays provided for this purpose or place them on all-purpose sterilization trays. A suitable method must be used to pack the trays.	
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance according to DIN EN 285 and DIN EN ISO 17665 (part 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended limit values for the ingredients of feed water and steam condensate are defined in DIN EN 285. <u>Validated procedure:</u> Equipment: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert	

	Procedure/parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see appliance manufacturer's instructions).
Storage	In accordance with Section 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments should be stored in a dry place at room temperature, clean and protected from damage and mechanical influences (avoidance of condensation, damage). If applicable, always store instruments in a tension-free state. This helps to prevent premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are predominantly made of titanium. These must be cleaned before disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care should be taken to ensure that any pointed or sharp edges are protected.

The instructions listed above have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The person carrying out the preparation is responsible for ensuring that the preparation actually carried out with the equipment, materials and personnel used in the preparation facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for effectiveness and possible adverse consequences.

Any modification to the product or 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. The movable retractor arm is moved by a gear drive on the toothed rack. A fixing slide with hook guide is used as a supplement for a 3-point holding system.

At the distal end there are two ball mounts in which the TLIF retractor blades with mount are guided. The TLIF retractor blades are locked in the ball mounts by the clamping screw with external hexagon, which is operated using a suitable screwdriver, e.g. the LMT-6 hexagon screwdriver (see chap. *8) Required accessories*).

Figure 2 shows such a configuration example for the MI TLIF multi-functional retractor with a central arm consisting of a fixing carriage with a hook guide for attaching the blade at the distal end. The corresponding components are listed in Table 1.

Table 1: List of the corresponding components

	Item No.	Designation
1	LVB-1	MI TLIF multi-functional retractor, body only
2	LVC-1/2/3/4	TLIF retractor blade
3	LVC-5/6/7	TLIF microblade
4	NWA-1B/1D	Coupling rider with blade guide
5	LVB-5/6/7/8	Medial blade

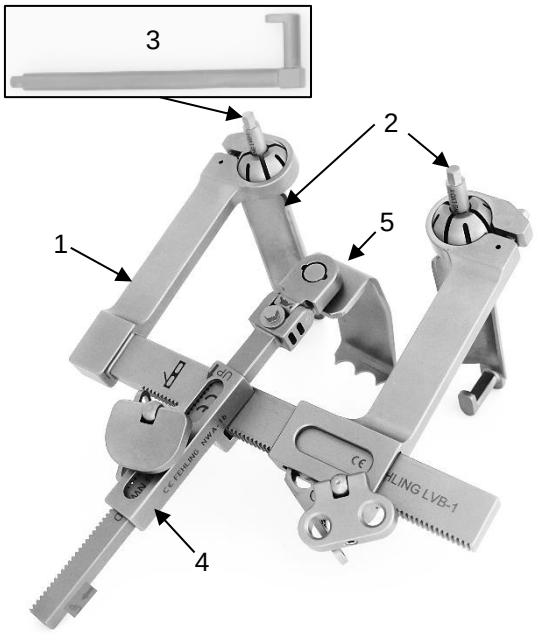


Fig. 2: Configuration example for the MI TLIF multi-functional retractor with center arm

Figure 3 shows an example of a pedicle screw that has a compatible screw shape for the system.

Fig. 3: Example pedicle screw with compatible screw shape
Lock nut required!

⚠ The FEHLING INSTRUMENTS product portfolio does not include pedicle screws.

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

The MI TLIF multi-functional retractor is intended in particular for the following procedures:

- Use in fusion operations, for example, often combined with neural decompression.
- Treatment of degenerative instabilities (spondylolisthesis/scoliosis) with or without spinal canal stenosis.
  In a younger patient population, fusion operations are typically performed due to (isthmic) spondylolisthesis or erosive osteochondrosis (e.g. following disc surgery).

⚠ Only use flawless and sterilized products!

⚠	Before inserting the spreaders (retractors) and retractor components, ensure that the surgical site has been properly prepared.
⚠	Before using the spreaders (retractors) and retractor components, make sure that their functionality is not impaired and that there is no damage!
⚠	Medical devices made of ferromagnetic materials must not be exposed to 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 holding and guiding instruments depends on the anatomical and physiological conditions as well as the area of application. It is important to ensure that the holding and guiding instruments used are the right size and geometry and have sufficient stability.

During the application

The use of the MI TLIF multi-functional retractor is preceded by the insertion of the transpedicular screws and the transmuscular preparation in the area of the spinal segment to be treated.
In order 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 is inserted, as this will cause the ball to deform plastically and the shaft can no longer be inserted.
⚠	Do not unscrew the locking screw completely during use, as it could otherwise fall into the patient. To loosen the shaft, it is sufficient to simply loosen the locking screw.

Figure 4 shows the customized tower (a) and an example of a pedicle screw (b) with the corresponding lock nut (c).
These components are not part of the FEHLING INSTRUMENTS product portfolio.

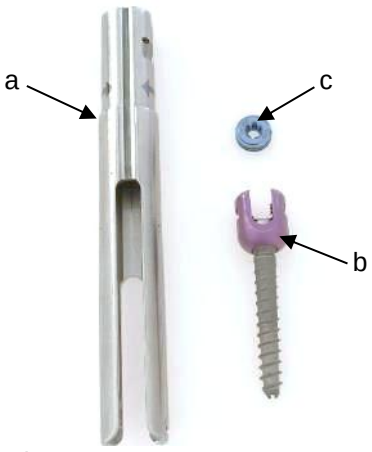


Fig. 4

1	First, the distal end of the tower (a) is pressed over the screw head of the pedicle screw (b) (Fig. 5) until the pedicle screw (b) audibly engages. The tower with the inserted pedicle screw is then inserted into the wound gap to fix the pedicle screw (not shown here).	 Fig. 5
2	The mount of the TLIF retractor blade (d) (Fig. 6a) is inserted into the recess in the tower (e) (Fig. 6b) so that the retractor blade fits snugly against the tower and the shaft is located in the notch (f) provided for this purpose (Fig. 6c). The TLIF retractor blade is guided along the tower until the receptacle is positioned in the head gap of the pedicle screw (Fig. 6c). The holder is screwed tight with the corresponding lock nut of the pedicle screw (Fig. 6d). The lock nut secures the mount of the retractor blade in the head gap of the pedicle screw so that there is a connection between the retractor blade and pedicle screw for distraction.	

Fig. 6a

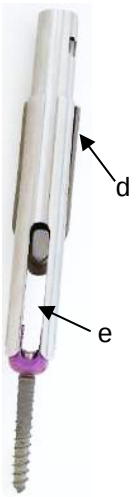


Fig. 6b

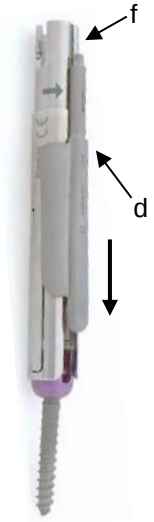
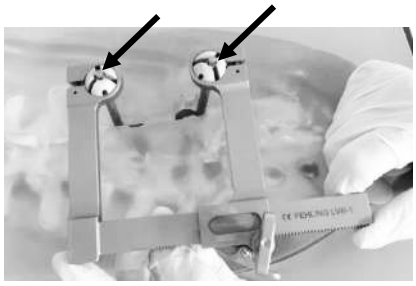
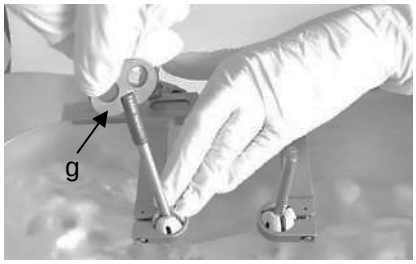
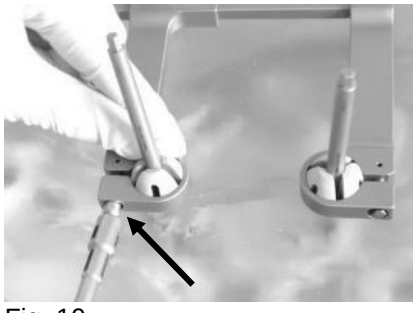
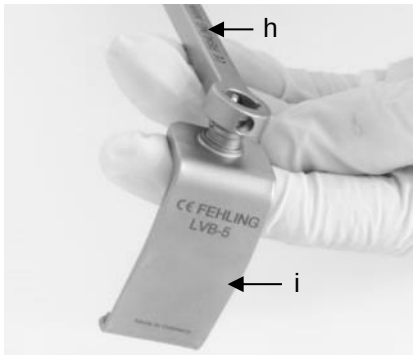


Fig. 6c


Fig. 6d

3	After securing the holder with the pedicle screw, the tower can be removed (Fig. 7).	 Fig. 7
4	The cylindrical shafts of the TLIF retractor blades or the TLIF micro blades protruding from the wound are used to insert the central holes of the spheres (see arrows in Fig. 8) of the retractor frame, with the toothed rack of the retractor always in the medial position.	 Fig. 8
	The balls are guided as close as possible to the wound edge and positioned in such a way that the soft tissue is safely retracted and there is sufficient space between the blade shafts for further preparation. Use the CERAMO hexagon wrench NVG-9 (g) (Fig. 9), the blades can be gripped at their proximal hexagonal profile and rotated into the optimum position.	 Fig. 9
	As soon as this position is reached, the balls are compressed using a suitable screwdriver, e.g. the LMT-6 screwdriver (see chap. *8) Required accessories*), until a stable ball/leaf shaft connection is achieved (Fig. 10). Figure 10 shows the LMT-4 Cardan screwdriver. In contrast, the LMT-6 screwdriver has a rigid shaft and no universal joint.	 Fig. 10
5	In order to widen the situs medially, the hook guide (h) is fitted with a muscle blade (i) (LVB-5/6/7/8) of the appropriate depth (Fig. 11). Figure 11 shows an example of this using the NWA-1C hook guide.	 Fig. 11

The hook guide NWA-1D (h) is then guided through the central opening of the fixing carriage NWA-1B (j) in the direction indicated by the arrow (Fig. 12).

Make sure that the U-shaped part of the fixing carriage (j) is open at the bottom and towards the situs.

The fixing carriage (j) should be close to the proximal end of the hook guide (h).

To insert the hook guide into the fixing carriage, please follow the assembly instructions (see chap. *9) Assembly*).

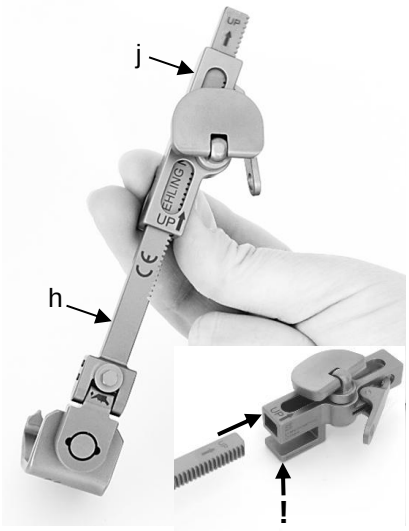


Fig. 12

The hook guide (h) (Fig. 13a) can be angled at the distal end using the LMT-6 screwdriver (k) to obtain a better view of the deeper surgical field (Fig. 13b).

To angle the blade holder, the hexagon head screw of the hook guide (h) must be turned clockwise (Fig. 13c).

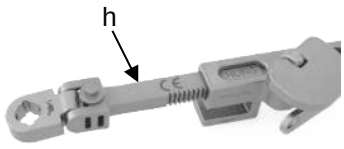


Fig. 13a

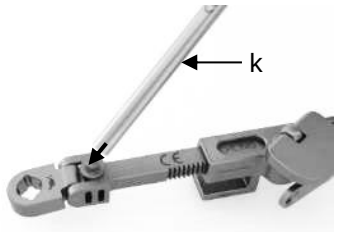


Fig. 13b


Fig. 13c

The medial muscle blade is inserted into the situs at a central point until it encompasses the medial muscle as deeply as possible.

Pull the hook guide together with the fixing carriage and muscle blade medially, slide the U-profile of the fixing carriage over the retractor toothed rack from the outside of the retractor (Fig. 14).

By turning the wing screw of the fixing carriage clockwise, the medial muscle is pulled as far medially as necessary. The result is a trapezoidal situs.

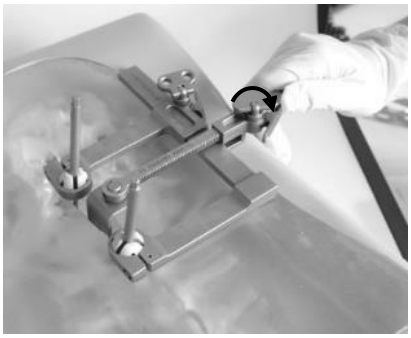
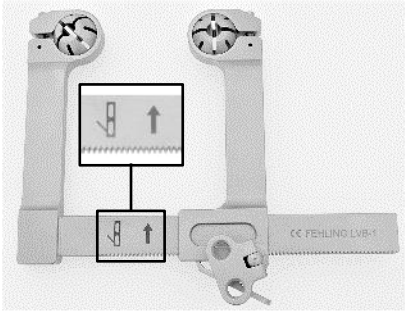
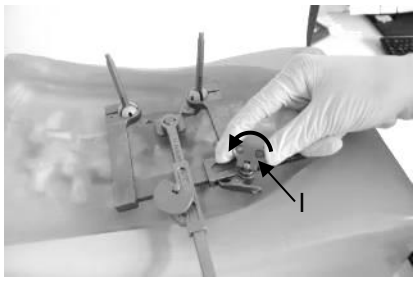


Fig. 14

	The fixing carriage must be attached to the retractor label in accordance with the symbolic marking (Fig. 15a). Make sure that the U-profile of the fixing carriage is open towards the situs so that the fixing carriage can be pushed over the retractor toothed rack from the outside of the retractor in the direction indicated by the arrow (Fig. 15b). Figure 15c shows the correct installation of the fixing carriage with hook guide on the retractor frame.	 Abb.15a
	⚠ The label of the fixing carriage and the hook guide applies exclusively to these two components and has no connection with the label of the MI TLIF multi-functional retractor.	
	 Fig. 15b	 Fig. 15c
6	To expand the intervertebral disc space, remove the wing screw (l) (Fig. 16) of the retractor frame counter-clockwise. This simultaneously distracts the soft tissue and intervertebral disc space in steps of approx. 2 mm in the cranial-caudal axis.	 Fig. 16
7	Subsequently, unilateral facettectomy with subsequent disc resection and insertion of a TLIF cage can be performed.	
8	After completion of the measures in accordance with cl. (7) - Release the pressure on the medial muscle retraction by pressing on the lock of the fixing carriage - Remove the fixing carriage together with the hook guide and muscle blade - Remove the lock nuts from the screw heads of the pedicle screws - Release the compression of the retractor balls using a suitable screwdriver, e.g. the LMT-6 hexagonal screwdriver (see chap. *8) Required accessories*) - Lift the TLIF retractor or TLIF micro blades out of the pedicle screws - Release the retractor frame by pressing on the lock of the movable retractor arm and simultaneously turning the wing screw clockwise - Remove the retractor from the situs.	

⚠	When inserting the retractor blades, make sure that no tissue structures are unintentionally injured (especially nerves and blood vessels)!
⚠	Excessive and prolonged pressure on the tissue can cause necrosis, ruptures, fractures and other lesions!
⚠	Overloading can cause plastic deformation or breakage of the spreaders (retractors) and retractor components!
⚠	Before removing the spreaders (retractors) and retractor components from the operating field, ensure that the retractor arms are slowly pushed together again.
9	OP to continue as planned.

8) Required accessories

To use the MI TLIF multi-functional retractor and the NWA-1D hook guide, a hexagonal screwdriver, e.g. LMT-6 (Fig. 17), is required.
The CERAMO hexagon wrench NVG-9 (Fig. 18) or NVG-9L (long version) can be used to grip the blades by their hexagonal profile and rotate them into the optimum position.
The LVB-0 storage and sterilization container can be used for sterilization and storage.

Fig. 17: Hexagon screwdriver LMT-6

Fig. 18: CERAMO hexagon wrench NVG-9

9) Assembly

To install the MI TLIF multi-functional retractor, please follow the installation instructions below.

Figure 19 shows the MI TLIF multi-functional retractor, which is a U-shaped bar retractor with wing screw. The bar retractor consists of a fixed retractor arm (a), a toothed rack (b) and a movable retractor arm (c).
The proximal end of the movable retractor arm is the box (d), on which the wing screw (e) with the toothed wheel and the catch (f) are located.
At the distal ends of the fixed and movable retractor arm there is a ball holder (g) in which the TLIF retractor blades with holder or the TLIF micro blade are guided.

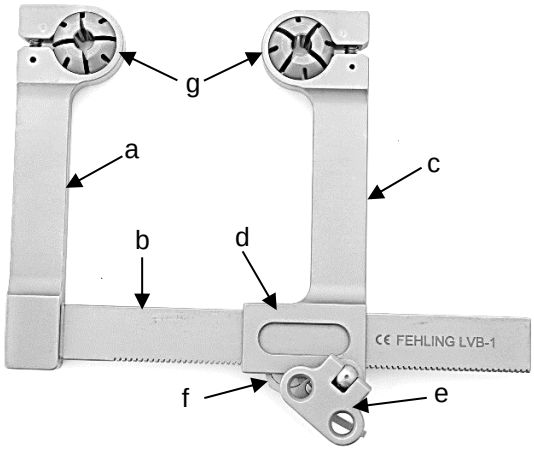


Fig. 19: Exemplary bar frame with toothed wheel/ Lock

Insert the toothed rack (b) into the recess in the box (d). In the meantime, release the lock (f) by pressing in the direction of the toothed rack (b) (Fig. 20).

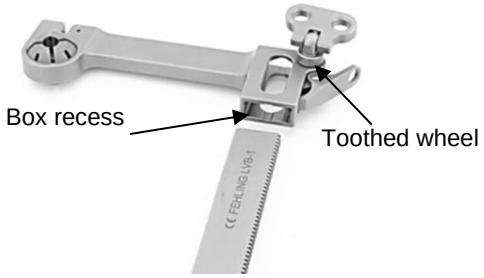


Fig. 20

⚠ Ensure that both retractor arms are pointing in the same direction and that the toothed wheel of the movable retractor arm is pointing outwards.

Move the movable retractor arm (c) on the toothed rack (b) inwards towards the fixed retractor arm (a) (Fig. 21).

The assembled instrument is now ready for use again after a functional test.

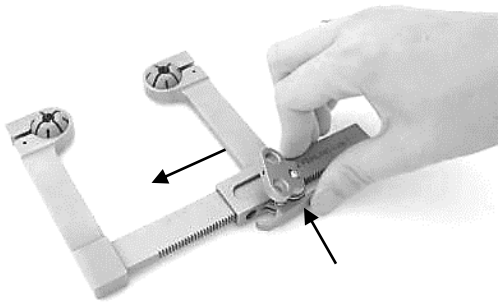


Fig. 21

Please observe the following assembly instructions for inserting the hook guide into the fixing slide.

Both the hook guide (a) and the fixing slide (b) have a side marked "arrow" and "UP". Before inserting the hook guide (a) into the fixing carriage (b), make sure that the two marked sides are facing upwards. The hook guide (a) is inserted into the fixing carriage (b) in the direction indicated by the arrow (Fig. 22). The arrow on the fixing carriage (b) refers exclusively to the insertion of the hook guide (a) and not to the mounting of the retractor frame.

The hook guide (a) is pushed through the opening of the fixing carriage (b) until the catch (c) engages on the toothed rack of the hook guide (a). During insertion, the lock (c) must be unlocked by pressing it down.

The hook guide (a) can be tightened in a controlled manner by turning the wing screw (d) clockwise.

Important: The fixing carriage (b) must be aligned so that its U-profile is open towards the situs (Fig. 22).

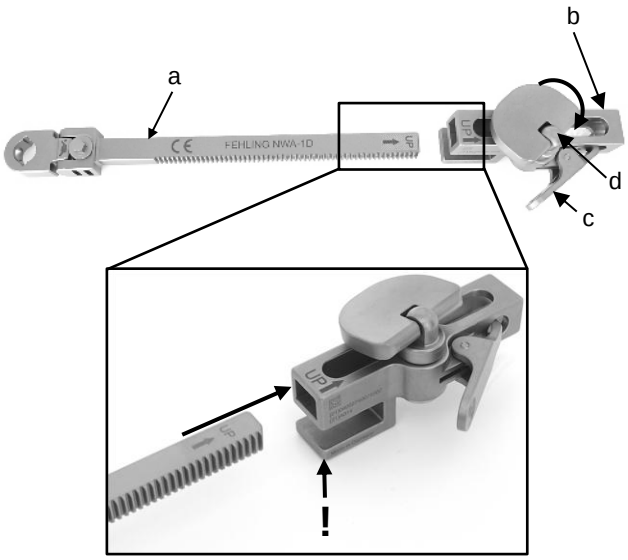


Fig. 22

The hook guide (a) should protrude as far as possible from the fixing carriage (b) (see Fig. 23).

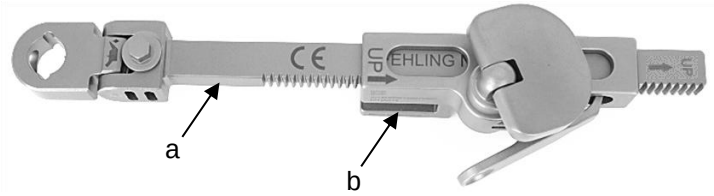


Fig. 23

Next, determine the optimum muscle blade (LVB-5/6/7/8) for the patient-specific application and insert it into the hook guide (a) (see chap. *7) Configuration and application* under *"During application"*).

10) Disassembly

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

To remove the center arm, please follow the corresponding assembly instructions (see chap. 9*) Assembly*).

Figure 24 shows an example of a retractor frame to illustrate disassembly.
Move the movable retractor arm (c) outwards on the toothed rack (b) until it can be removed. In the meantime, release the lock (f) by pressing in the direction of the toothed rack (b).

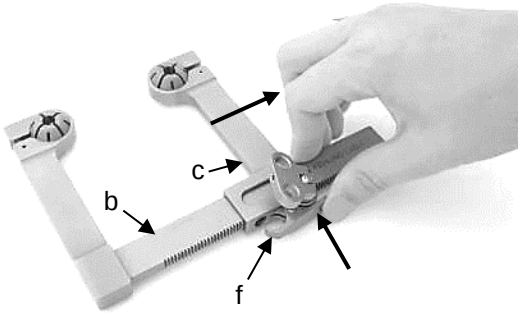


Fig. 24

The instrument disassembled into its individual parts (Fig. 25) can now be reprocessed.

Fig. 25

Figure 26 shows an example of the retractor with dismantled components.

Fig. 26

⚠ 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 that have occurred in connection with the medical device to the manufacturer, either by email to vigilance@fehling-instruments.de or via the complaints form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the member state in which the user is established.

Symbols		
If displayed on the medical device, the label of the medical device or the instructions for use, the symbols according to DIN EN ISO 15223-1 have the following meaning:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalog number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	CE 0297 CE marking
Oil can for points that require lubrication	CE marking	

Contact the manufacturer		
	FEHLING INSTRUMENTS GmbH Hanauer Landstr. 7A D-63791 Karlstein/Germany Tel.: +49 (6188) 9574-40 Fax: +49 (6188) 9574-45 E-Mail: info@fehling-instruments.de www.fehling-instruments.de	CE