



FEHLING MI TLIF Multifunctional Retractor

Retractor frame LVB-1 MI TLIF Multifunctional Retractor, frame only

Components

Fixations/guides

NWA-1B Fixation carriage for spinal retractor
NWA-1C Blade guide for spinal retractor

Parafascial blades

LVB-3 MI left parafascial blade for LVB-1 (11 mm wide), Ø4.75 mm
LVB-3B MI left parafascial blade for LVB-1 (11 mm wide), Ø5.5 mm
LVB-3A MI left parafascial blade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø4.75 mm
LVB-3C MI left parafascial blade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø5.5 mm
LVB-4 MI right parafascial blade for LVB-1 (11 mm wide), Ø4.75 mm
LVB-4B MI right parafascial blade for LVB-1 (11 mm wide), Ø5.5 mm
LVB-4A MI right parafascial blade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø4.75 mm
LVB-4C MI right parafascial blade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø5.5 mm
LVG-5 MI Parafascial blade for LVB-1, D4.75 mm x 11, 111 mm
LVG-6 MI Parafascial blade for LVB-1, D4.75 mm x 11, 171 mm
LVG-5A MI Parafascial blade for LVB-1, D4.75 mm x 12.5, 111 mm
LVG-6A MI Parafascial blade for LVB-1, D4.75 mm x 12.5, 171 mm
LVG-5B MI Parafascial blade for LVB-1, D5.5 mm x 11, 111 mm
LVG-6B MI Parafascial blade for LVB-1, D5.5 mm x 11, 171 mm
LVG-5C MI Parafascial blade for LVB-1, D5.5 mm x 12.5, 111 mm
LVG-6C MI Parafascial blade for LVB-1, D5.5 mm x 12.5, 171 mm
LVG-5D MI Parafascial blade for LVB-1, D6.5 mm x 11, 111 mm
LVG-6D MI Parafascial blade for LVB-1, D6.5 mm x 11, 171 mm
LVG-5E MI Parafascial blade for LVB-1, D6.5 mm x 12.5, 111 mm
LVG-6E MI Parafascial blade for LVB-1, D6.5 mm x 12.5, 171 mm

Microblades

LVB-2 MI Microblade for LVB-1 (11 mm wide), Ø4.75 mm
LVB-2B MI Microblade for LVB-1 (11 mm wide), Ø5.5 mm
LVB-2A MI Microblade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø4.75 mm
LVB-2C MI Microblade for LVB-1, wide mounting receptacle (12.2 mm wide), Ø5.5 mm
LVG-7 MI Microblade for LVB-1, D4.75 mm x 11, 108 mm
LVG-8 MI Microblade for LVB-1, D4.75 mm x 11, 168 mm
LVG-7A MI Microblade for LVB-1, D4.75 mm x 12.5, 108 mm
LVG-8A MI Microblade for LVB-1, D4.75 mm x 12.5, 168 mm
LVG-7B MI Microblade for LVB-1, D5.5 mm x 11, 108 mm
LVG-8B MI Microblade for LVB-1, D5.5 mm x 11, 168 mm
LVG-7C MI Microblade for LVB-1, D5.5 mm x 12.5, 108 mm
LVG-8C MI Microblade for LVB-1, D5.5 mm x 12.5, 168 mm
LVG-7D MI Microblade for LVB-1, D6.5 mm x 11, 108 mm
LVG-8D MI Microblade for LVB-1, D6.5 mm x 11, 168 mm
LVG-7E MI Microblade for LVB-1, D6.5 mm x 12.5, 108 mm
LVG-8E MI Microblade for LVB-1, D6.5 mm x 12.5, 171 mm

Titanium medial blades

LVG-1 Titanium medial blade for LVB-1, 50x15 mm
LVG-2 Titanium medial blade for LVB-1, 65x15 mm
LVG-3 Titanium medial blade for LVB-1, 80x15 mm
LVG-4 Titanium medial blade for LVB-1, 95x15 mm
LVB-5 Titanium medial blade for LVB-1, 50x24 mm
LVB-6 Titanium medial blade for LVB-1, 65x24 mm
LVB-7 Titanium medial blade for LVB-1, 80x24 mm
LVB-8 Titanium medial blade for LVB-1, 95x24 mm

Accessories

LMT-4 Cardan screwdriver
LMT-6 Screwdriver SW4



NVG-9 CERAMO® hex wrench for specula
NVG-9L CERAMO® hex wrench for specula, long version
LVB-0 Storage and sterilisation container for TLIF retractor, 400 x 245 x 65 mm



This instrument or 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.

The MI TLIF Multifunctional Retractor may only be used, reprocessed and disposed of by qualified medical personnel!

The MI TLIF Multifunctional Retractor is intended for re-use.

1) Intended purpose

The purpose of holding and guiding instruments is to hold or fix products and tissue (e.g. sizers, 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 to move them into or to a specific position

This does not apply to retractors (as specified in the TD for Classes I and IIa retractors), hooks, vascular and tissue clamps, forceps and needle holders.

Additional information regarding 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 in all patients where products and tissue must be held or fixed in or to a specific position and/or moved to or in a specific position.

User profile: Holding and guiding instruments may only be used by medically trained personnel (e.g. specialist surgeons).

Application environment: Holding and guiding instruments are only to be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions.

2) Indications

Treatment methods requiring the holding and guiding of products and tissue.

3) Contraindication

All applications that are inconsistent with the physical and/or mechanical properties of the specific holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding and guiding instruments.

Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.



4) Possible side effects

The following side effects are described in the medical literature and may also occur during the intended use of holding and guiding instruments:

- Bone fractures, e.g. ribs, sternum, spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Injury to structures (tissues, organs, nerves, vessels)
- Necrosis
- Ischaemia
- Haematoma
- Compression of the nerve roots
- CSF leakage
- Nerve injuries (e.g. transient radiculopathy, neurogenic bladder, ileus, paresis)
- Seroma



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

5) Before use

The TLIF Multifunctional 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 prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section 6) *Reprocessing* under "Maintenance, Inspection and Testing").



The MI TLIF Multifunctional Retractor must be handled with care during storage, transport and cleaning!
Avoid impacts and point loading on the MI TLIF Multifunctional Retractor to prevent any possible secondary damage! Do not overload functional parts!



Use only intact and sterilised products!



The MI TLIF Multifunctional Retractor is intended for use with conventional pedicle screws for rod-screw systems with U-shaped or tulip-shaped head!



These IFU do not replace those supplied with any additional accessories used (e.g. 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 mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts!
Reprocessing limitations	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 labels or 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 automated 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	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) <i>Disassembly</i>
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, preference should be given to 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)

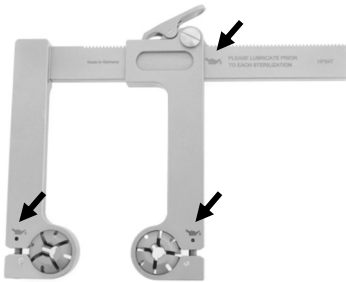


	Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Instruments with joints are to be placed in the device so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area 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) <i>Assembly</i>
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 impair the effectiveness of steam sterilisation. 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 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.	
	Instrument oil must be applied to the relevant marked points on the MI TLIF Multifunctional Retractor. The relevant points on the underside of the MI TLIF Multifunctional Retractor are marked with an oil can symbol  (Fig. 1).	 Fig. 1: MI TLIF Multifunctional Retractor with the relevant marked points
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 using a fractionated vacuum process in a steriliser complying with DIN EN 285 and DIN EN ISO 17665. 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 loss of 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. They must be cleaned prior to 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

The MI TLIF Multifunctional Retractor is a U-shaped bar retractor with one fixed and one movable retractor arm. The movable retractor arm is moved along the toothed rack by means of a pinion mechanism. As an additional component, a fixation carriage with blade guide is used to form a three-point retention system.



There are two ball sockets at the distal end that receive the mounting elements of the parafascial blades. The parafascial blades are locked in the ball sockets using the clamping screw with an external hex head, which is operated with the LMT-4 Cardan screwdriver (see Section 8) Required Accessories).

Figure 2 shows an example configuration of the MI TLIF Multifunctional Retractor with a centre arm consisting of a fixation carriage and blade guide for attaching a blade at the distal end. The corresponding components are listed in Table 1.

Table 1: List of the corresponding components

	Item no.	Description
1	LVB-1	MI TLIF Multifunctional Retractor, frame only
2	LVB-3/3A/3B/3C	Parafascial blade left
3	LVB-4/4A/4B/4C	Parafascial blade right
2/3	LVG-5/5A/5B/5C/5D/5E LVG-6/6A/6B/6C/6D/6E	Parafascial blade
4	LVB-2/2A/2B/2C, LVG-7/7A/7B/7C/7D/7E LVG-8/8A/8B/8C/8D/8E	MI microblade
5	NWA-1B/1C	Fixation carriage with blade guide
6	LVB-5/6/7/8, LVG-1/2/3/4	Medial blade

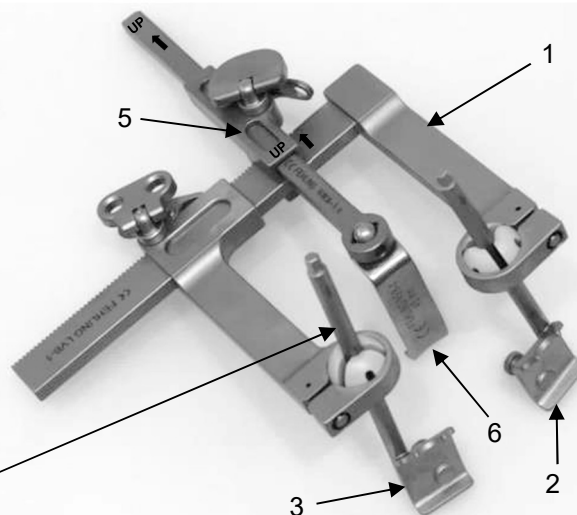


Fig. 2: Example configuration of the MI TLIF Multifunctional Retractor with centre arm



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

The corresponding variants are listed in Tables 2 and 3.

Different mounting widths and diameters are available, depending on the size of the pedicle screw. The CERAMO® NVG-9 hex wrench (see Section 8, Required Accessories) can be fitted onto the proximal hexagonal profile of each blade to rotate it into the optimal position.

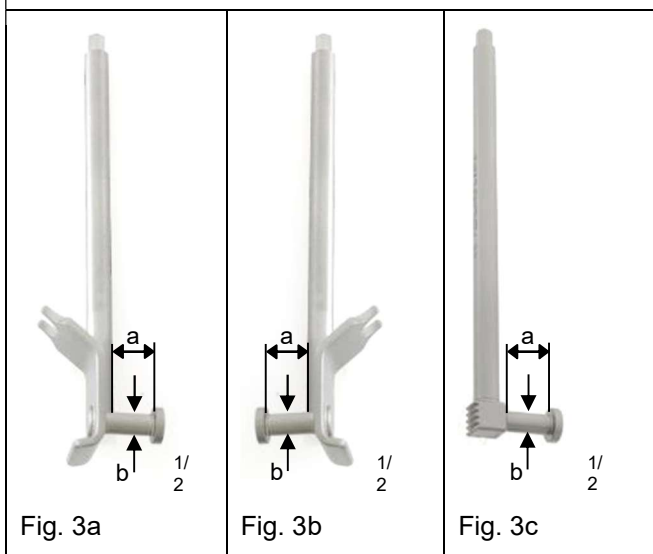


Table 2: List of blade variants with different mounting widths (a) and diameters (b)

Item no.	a in mm	b in mm
LVB-2/3/4	11	4.75
LVB-2A/3A/4A	12.2	4.75
LVB-2B/3B/4B	11	5.5
LVB-2C/3C/4C	12.2	5.5



Available blade variants



Fig. 3d: Alternative parafascial blade



Fig. 3e: Alternative microblade

Table 3: List of alternative blade variants with different mounting widths (a) and diameters (b), as illustrated in Figs. 3a, 3b and 3c

Item no.	a in mm	b in mm
LVG-5/-6/-7/-8	11	4.75
LVG-5A/-6A/-7A/-8A	12.5	4.75
LVG-5B/-6B/-7B/-8B	11	5.5
LVG-5C/-6C/-7C/-8C	12.5	5.5
LVG-5D/-6D/-7D/-8D	11	6.5
LVG-5E/-6E/-7E/-8E	12.5	6.5

The alternative blade variants include a symmetrical parafascial blade (Fig. 3d), in addition to the existing left and right versions. The blades are not serrated.

Furthermore, the parafascial blade and microblade (Fig. 3e) have no washer on the mounting pin.

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



Fig. 4: Example of a pedicle screw with a compatible screw shape
Locking nut required!



The FEHLING INSTRUMENTS product portfolio does not include pedicle screws.

The MI TLIF Multifunctional Retractor is specifically intended for exposure of the surgical field during minimally invasive access to the lumbar spine and for distraction of the intervertebral disc space via a posterior transmuscular approach. The retractor is designed for TLIF procedures and is used in conjunction with a pedicle screw system for rod-screw implants.

The MI TLIF Multifunctional Retractor is intended in particular for the following procedures:

- Fusion procedures, often combined with nerve decompression
- Treatment of degenerative instability (spondylolisthesis/scoliosis), with or without spinal canal stenosis

In younger patients, fusion procedures are typically performed for (isthmic) spondylolisthesis or erosive osteochondrosis (e.g. following intervertebral disc surgery).



Use only intact and sterilised products!



Before inserting the MI TLIF Multifunctional Retractor, ensure that the surgical field has been appropriately prepared.

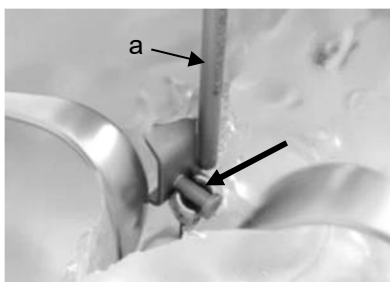


Before using the MI TLIF Multifunctional Retractor, ensure that it is fully functional and not damaged!

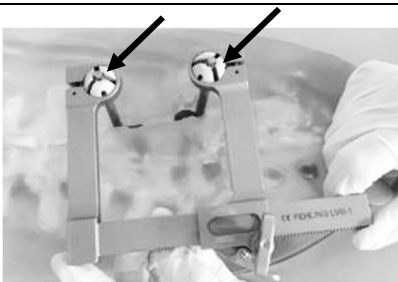
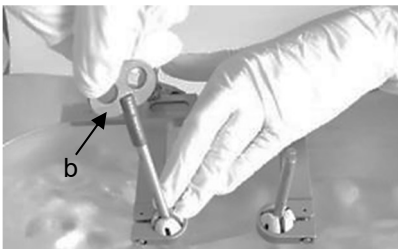
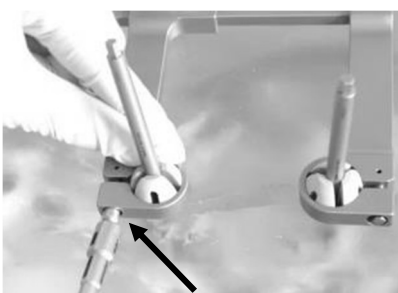
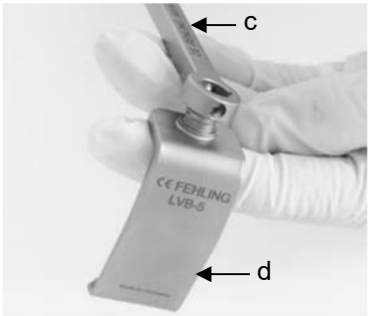
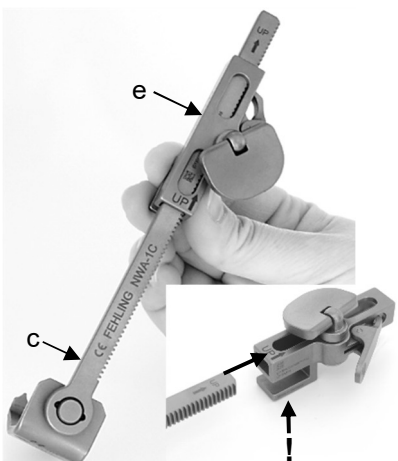


Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.

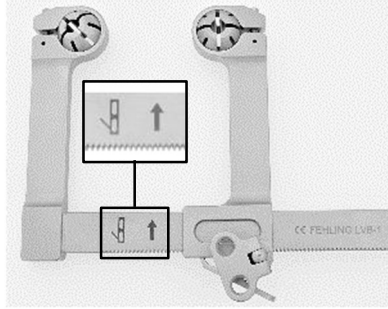
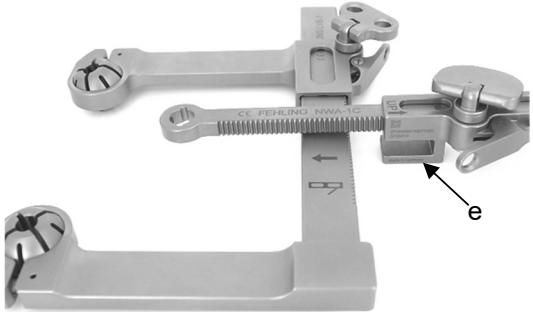
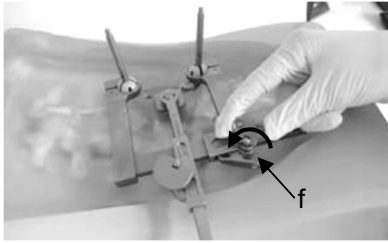


	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
	The choice of components depends on the anatomical and physiological conditions as well as the field of application. Care must be taken to ensure that the components used have the correct size and geometry, as well as sufficient stability.
During application	
Insertion of the pedicle screws and transmuscular dissection in the region of the spinal segment to be treated must be completed before the MI TLIF Multifunctional Retractor is used. The surrounding tissue must be retracted appropriately before the pedicle screw is inserted.	
	The locking screw at the distal end of the retractor arms must not be tightened unless a shaft has been inserted, as this may plastically deform the ball and prevent subsequent insertion of the shaft.
	Do not unscrew the locking screw completely during use, as it could otherwise fall into the patient. To release the shaft, it is sufficient to simply loosen the locking screw.
1	Insert the LVB-3/3A/3B/3C and LVB-4/4A/4B/4C parafascial blades into the surgical wound. For a right-sided approach, position the left LVB-3/3A/3B/3C blade caudally and the right LVB-4/4A/4B/4C blade cranially. For a left-sided approach, position the left LVB-3/3A/3B/3C blade cranially and the right LVB-4/4A/4B/4C blade caudally. Alternatively, the parafascial blades LVG-5/5A/5B/5C/5D/5E/6/6A/6B/6C/6D/6E may be used. There is no distinction here between left and right versions.
2	Align each parafascial blade (a) with its serrated side or blade curvature facing laterally. Insert the mounting pin on the back of the blade (arrow in Fig. 5) into the head slot of the pedicle screw.  Fig. 5
	The nut of the pedicle screw (arrow in Fig. 6) secures the mounting pin of the parafascial blade in position.  Fig. 6
During procedures at the lumbosacral junction, the soft tissue over S1 may be too thin to accommodate a parafascial blade. In such cases, use the microblade LVB-2/2A/2B/2C instead. Alternatively, the microblades LVG-7/7A/7B/7C/7D/7E/8/8A/8B/8C/8D/8E may be used.	



3	Slide the central bores of the balls (arrow in Fig. 7) on the retractor arms over the cylindrical shafts of the parafascial blades or microblades protruding from the wound, ensuring that the toothed rack of the retractor is always positioned medially. Guide the balls as close as possible to the wound edge and position them so that the soft tissue is securely retracted and sufficient clearance remains between the blade shafts for further dissection. The blades can be grasped at their proximal hexagonal profiles using the CERAMO® NVG-9 hex wrench (b) (Fig. 8) and rotated into the optimal position. Once this position has been reached, compress the balls using the LMT-4- Cardan screwdriver until a stable connection between each ball and blade shaft has been achieved (Fig. 9).	 Fig. 7  Fig. 8  Fig. 9
4	To extend the surgical site medially, fit the NWA-1C blade guide (c) with a muscle blade of an appropriate depth (d) (LVB-5/6/7/8 or LVG-1/2/3/4) (Fig. 10).	 Fig. 10
	Then insert the blade guide (c) through the central opening of the NWA-1B fixation carriage (e) in the direction indicated by the arrow (Fig. 11). Ensure that the U-shaped part of the fixation carriage (e) is at the bottom and open towards the surgical site. The fixation carriage (e) should be positioned close to the proximal end of the blade guide (c). Please refer to the assembly instructions (see 9 Assembly) when inserting the blade guide into the fixation carriage.	 Fig. 11



	Insert the medial muscle blade centrally into the surgical site until it fits securely around the medial muscle at the greatest possible depth. Pull the blade guide, together with the fixation carriage and muscle blade, medially and slide the U-shaped profile of the fixation carriage over the toothed rack of the retractor from the outside (Fig. 12a). Turn the wing screw of the fixation carriage clockwise to retract the medial muscle medially as far as required. This creates a trapezoidal surgical site.	 Fig. 12a
	Attach the fixation carriage  as indicated by the symbol on the retractor arm (Fig. 12b). Ensure that the U-shaped profile of the fixation carriage (e) is open towards the surgical site so that the fixation carriage can be slid over the toothed rack of the retractor from the outside in the direction indicated by the arrow (Fig. 12c). Figure 12d shows the correct assembly of the fixation carriage with blade guide on the retractor arm.	 Fig. 12b
	 The markings on the fixation carriage and blade guide apply exclusively to these two components and are unrelated to the marking on the MI TLIF Multifunctional Retractor.	
	 Fig. 12c	 Fig. 12d
5	To distract the intervertebral disc space, turn the wing screw (f) on the retractor arm anticlockwise (Fig. 13). This simultaneously distracts the soft tissue and intervertebral disc space in increments of approx. 2 mm along the craniocaudal axis.	 Fig. 13
6	Unilateral facetectomy can then be performed, followed by discectomy and insertion of a TLIF cage.	
7	Upon completion of the steps explained in Section 6 - press the locking lever of the fixation carriage to release the tension on the medially retracted muscle	



	- remove the fixation carriage together with the blade guide and muscle blade - remove the locking nuts from the screw heads of the pedicle screws - release the compression of the retractor balls using the LMT-4 Cardan screwdriver - lift the mounting pins of the parafascial blades or microblades out of the pedicle screws - release the retractor frame by pressing the locking lever on the movable retractor arm while simultaneously turning the wing screw clockwise - remove the retractor from the surgical site.
	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.
8	Continue the operation as planned.

8) Required accessories

An LMT-4 Cardan screwdriver (Fig. 14) is required to use the MI TLIF Multifunctional Retractor. The CERAMO® NVG-9 hexagonal key (Fig. 15) or NVG-9L hex wrench (long version) can be used to grasp the blades by their hexagonal profile and rotate them to the optimal position. The LVB-0 storage and sterilisation container can be used for sterilisation and storage.



Fig. 14: LMT-4 Cardan screwdriver



Fig. 15: CERAMO® NVG-9 hexagonal key

9) Assembly

Please follow the instructions below to assemble the MI TLIF Multifunctional Retractor.

Figure 16 shows the MI TLIF Multifunctional Retractor, a U-shaped bar retractor with a wing screw. The bar retractor consists of a fixed retractor arm (a), a toothed rack (b) and a movable retractor arm (c).

At the proximal end of the movable retractor arm is the housing (d), which contains the wing screw (e), gear wheel and locking lever (f). At the distal end of both the fixed and movable retractor arms is a ball socket (g), which receives the mounting element of a parafascial blade or an MI microblade.

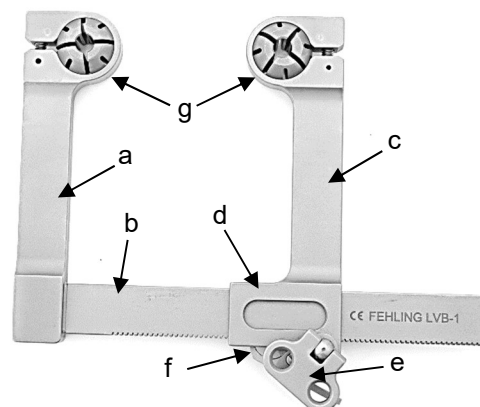


Abb. 16: Example of a bar frame with gear wheel/locking lever



Insert the toothed rack (b) into the recess in the housing (d). At the same time, release the lock (f) by pressing it in the direction of the toothed rack (b) (Fig. 17).

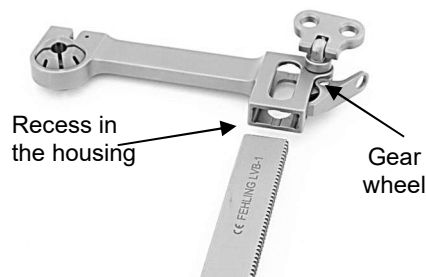


Fig. 17



Ensure that both retractor arms point in the same direction and that the gear wheel on the movable retractor arm faces outwards.

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

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

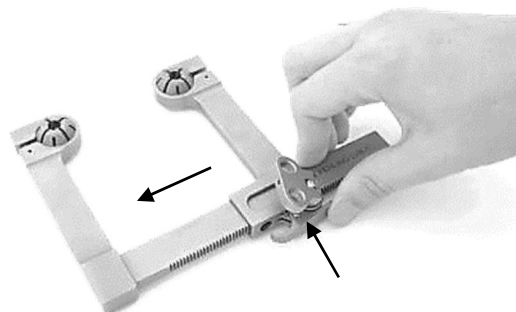


Fig. 18

Please refer to the assembly instructions below when inserting the blade guide into the fixation carriage.

Both the blade guide (a) and the fixation carriage (b) have a side marked with "arrow" and "UP". Before inserting the blade guide (a) into the fixation carriage (b), ensure that both marked sides face upwards. Insert the blade guide (a) into the fixation carriage (b) in the direction indicated by the arrow (Fig. 19). The arrow on the fixation carriage (b) refers exclusively to the insertion of the blade guide (a) and not to attachment of the retractor frame.

Push the blade guide (a) through the opening in the fixation carriage (b) until the locking lever (c) engages with the toothed rack of the blade guide (a). During insertion, press down the locking lever (c) to release it.

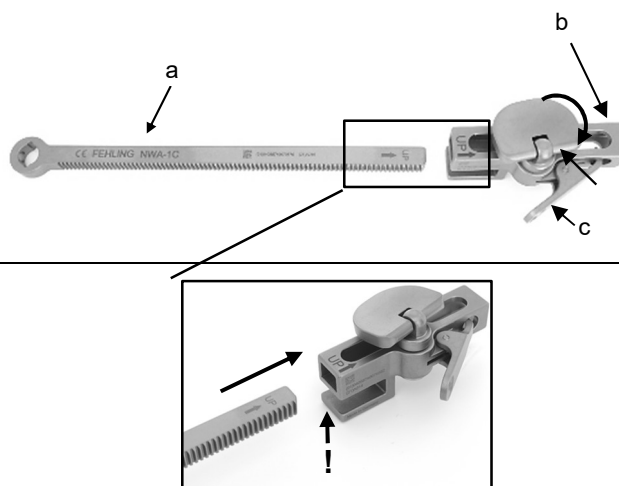


Fig. 19

Turn the wing screw (d) clockwise to tension the blade guide (a) in a controlled manner. Important: Align the fixation carriage (b) so that its U-shaped profile is open towards the surgical site (Fig. 19).



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

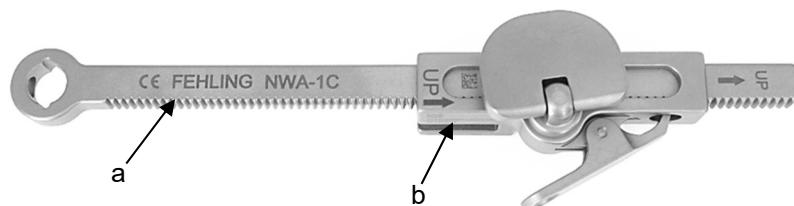


Fig. 20

Next, select the optimal muscle blade (LVB-5/6/7/8 or LVG-1/2/3/4) for the patient-specific application and insert it into the blade guide (a) (see Section 7) Configuration and use – During use).

10) Disassembly

For reprocessing, the MI TLIF Multifunctional Retractor must be disassembled as follows.

To disassemble the centre arm, please follow the corresponding assembly instructions (see Section 9) Assembly).

Figure 21 shows an example of a retractor frame to illustrate disassembly.

Slide the movable retractor arm (c) outwards along the toothed rack (b) until it can be removed. At the same time, release the lock (f) by pressing it in the direction of the toothed rack (b).

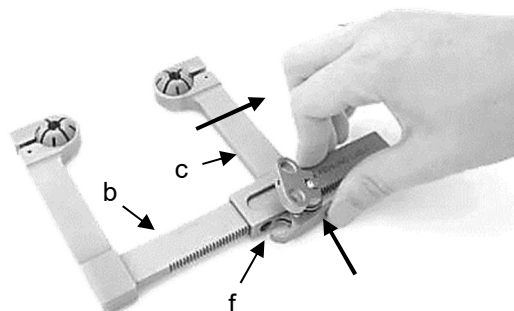


Fig. 21

The instrument, now disassembled into its individual components (Fig. 22), can be reprocessed.

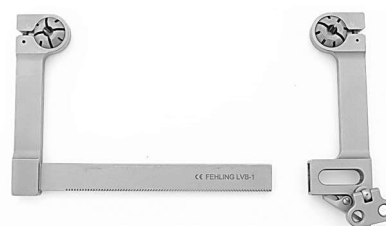


Fig. 22

Figure 23 shows the retractor with its components disassembled.



Fig. 23



Place small parts in suitable containers (e.g., needle box) for storage and reprocessing!



11) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at <https://www.fehling-instruments.de/en/complaint/> and to the competent authority of the Member State in which the user is domiciled.

Symbols

Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:

 Manufacturer	 Consult instructions for use or consult electronic instructions for use	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique device identifier	 Oil can for points to be lubricated
 Positioning mark	 CE marking	 CE marking
 Positioning mark		

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	
---	--	---