FEHLING CONCEPT cervical spine intervertebral distractor

Retractor body	LMI-9F	CONCEPT cervical spine intervertebral distractor, body only
	LMI-9L	CONCEPT cervical spine intervertebral distractor, body only/deep

Components

Distraction pins

LMI-3F .....CONCEPT pin with thread 12 mm
LMI-4F .....CONCEPT pin with thread 14 mm
LMI-5F .....CONCEPT pin with thread 16 mm
LMH-0F.....CONCEPT pin with thread 18 mm
LMI-3L.....CONCEPT pin with thread 12 mm deep
LMI-4L.....CONCEPT pin with thread 14 mm deep
LMI-5L.....CONCEPT pin with thread 16 mm deep
LMH-0L.....CONCEPT pin with thread 18 mm deep

Fixation of distraction pins

LMJ-0F.....CONCEPT fixation nut for distraction pins

Extension modules

Possible supplementary retractor systems

ATLAS cervical spine retractors in transverse and longitudinal version

Accessories

LMI-6F .....CONCEPT pin driver for LMI-9F
LMI-6L.....CONCEPT pin driver for LMI-9L deep
LMI-8F .....CONCEPT intervertebral retractor forceps with quick-action lock

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.

The CONCEPT cervical spine distractor may only be used, reprocessed and disposed of by qualified medical personnel!

The CONCEPT cervical spine intervertebral distractor is intended for re-use.

1) Intended purpose

Retractors and retractor components, which are used invasively and for short periods in surgery, serve to separate or hold back various tissue structures, such as skin, bone, muscles and organs.

Additional information regarding the intended purpose

Duration of application: The CONCEPT cervical spine intervertebral distractor is only intended for short-term use.

Field of application: retractors and retractor components are used for all patients where tissue has to be retracted for a short period of time (max. 24 hours) to improve visibility of the underlying tissue for the surgeon.

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

Application environment: retractors and retractor components are only to be used in controlled environments (e.g. OR).

2) Indications

Surgical procedures that require the temporary spreading and holding of various tissue structures, such as skin, bones, muscles and organs, to reach the body structure requiring treatment. The choice of retractor and accessory components depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the retractors or retractor blades used are of the correct size and have adequate stability.

3) Contraindication	
All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no generally applicable contraindications for the use of retractors. 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. These include, for example, an increased risk of bone fracture in osteoporosis.	
4) Possible adverse effects	
In medical literature, the following adverse effects are described that can possibly occur during the intended use of the CONCEPT cervical spine intervertebral distractor: - Vertebral body fractures - Infections - Impaired wound healing - Lesions of structures (tissues, nerves, vessels) - Necroses	
⚠	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 CONCEPT cervical spine intervertebral distractors 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 cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	The CONCEPT cervical spine intervertebral distractor must be handled with care during storage, transportation and cleaning! Avoid striking the CONCEPT cervical spine intervertebral distractor or applying pressure to its parts so as not to cause any consequential damage! Do not overstrain functional parts!
⚠	Use only sterilized products of sound quality!
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!

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. • During the exposure time, use appropriate brush (not a wire brush) to remove coarse contamination. • 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 connections of the instruments, if present, to the Luer Lock flushing attachment of the WD. <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 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	<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 no more contamination is visible. • Rinse the instruments for at least 20 seconds with 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 with a water spray gun (or similar) for at least 20 seconds. • 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. Rinse the instruments with deionized water for at least 30 seconds. Ensure that no residues remain on the products.
Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer 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 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. 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!
Packaging	Singly: In accordance with the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953. Sets: sort instruments 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 minutes Drying time: 20 minutes 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 of the German Medical Devices Operator Ordinance (MPBetreibV) and 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 CONCEPT cervical spine intervertebral distractor (Fig. 1) consists of two flexible retractor arms (a) and a toothed rack (b). The two retractor arms can be moved freely on the toothed rack (b) and are moved via a gear. The proximal end of the flexible retractor arms (a) is the cage (c), on which the wing screw (d) with the gear wheel as well as the lock (e) are located. The fixed, non-replaceable holder tubes for holding the distraction pins are located at the distal end of the two retractor arms.

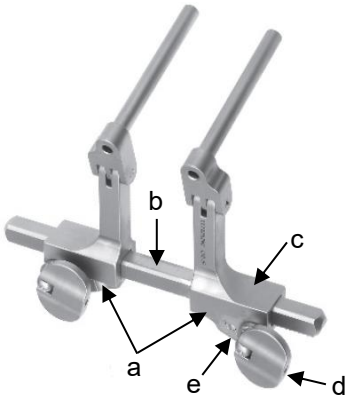


Fig. 1: CONCEPT cervical spine intervertebral distractor (LMI-9F resp. LMI-9L)

Figure 2 depicts s a configuration example for the CONCEPT cervical spine intervertebral distractor (1) in combination with a longitudinally (3) and transversely (4) aligned ATLAS cervical retractor in each case. Table 1 lists the corresponding components. Figure 3 shows an example of a distraction pin, which is screwed into the vertebral body using the pin driver (see 8) Required accessories). The distraction pins feature a thread at the proximal end with which they are fixated using a fixation nut (Fig. 4).

Table 1: List of the corresponding components

	Article no.	Description
1	LMI-9F/9L	CONCEPT cervical spine intervertebral distractor, body only/deep
2	LMJ-0F	Fixation nut for distraction pins (see also Fig. 4)
3	NIE-1	ATLAS cervical spine retractor with X-ray end part, longitudinal
4	NHK-9	ATLAS cervical spine retractor transversal version with double joint
5	LMI-3F/3L	CONCEPT pin with thread 12 mm/deep
	LMI-4F/4L	CONCEPT pin with thread 14 mm/deep
	LMI-5F/5L	CONCEPT pin with thread 16 mm/deep
	LMH-0F/0L	CONCEPT pin with thread 18 mm/deep

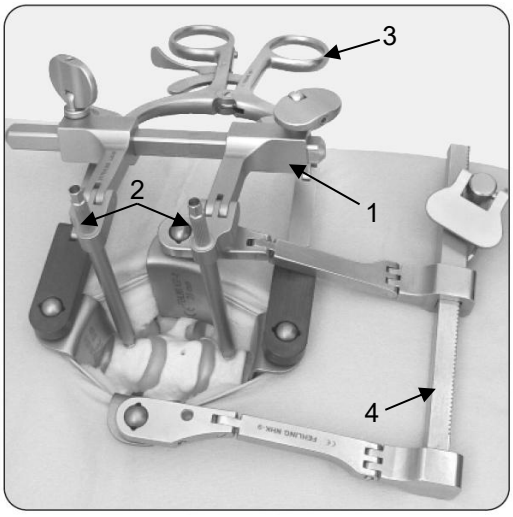


Fig. 2: Configuration example for the CONCEPT cervical spine intervertebral distractor (LMI-9F resp. LMI-9L)

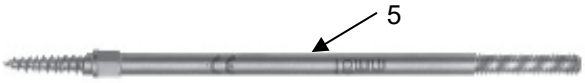


Fig. 3: Distraction pin (example)

Fig. 4: Fixation nut for distraction pins LMJ-0F

The main advantages of the CONCEPT intervertebral retractor system include the following:

- The CONCEPT cervical spine intervertebral distractor is suitable for access from both the right and the left side.
- Both pin holders can be moved via the common toothed rack.
- Both pin holders are equipped with a joint which allows adjustment for pins not arranged in parallel.
- The pin holders are open on both sides, so that the proximal end of the pin protrudes from the holder tube.
- The pins feature a proximal thread to accept fixation nuts (Fig. 4), which prevent any dislocation of the pins during surgery.
- The CONCEPT intervertebral retractor forceps allows temporary expansion of the intervertebral disc space. The retraction width is secured or released with a quick action nut.

⚠	Use only sterilized products of sound quality!
⚠	Prior to inserting the retractors and retractor components, ensure that the surgical field has been prepared accordingly beforehand.
⚠	Before using retractors and retractor components, ensure that their functionality is not impaired and that there is no damage!
⚠	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 retractors and retractor components depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the retractors and retractor components used are of the correct size and have adequate stability.
During use	
⚠	When inserting the retractor blades, ensure that no tissue structures are unintentionally damaged (especially nerves and blood vessels)!
⚠	Too long and too high pressure on the tissue can cause necroses, ruptures, fractures and other lesions!
⚠	Excessive load can cause plastic deformation or breakage of the retractors and retractor components!

1. Before the CONCEPT cervical spine intervertebral distractor can be used, the surgical field must be prepared appropriately (Fig. 5). This will not be discussed in detail in the following.
In Figure 5, the ATLAS cervical spine retractor longitudinal version with double joint NHL-1 (a) and the ATLAS cervical retractor transversal version with double joint NHK-9 (b) are used to distract the surrounding tissue.

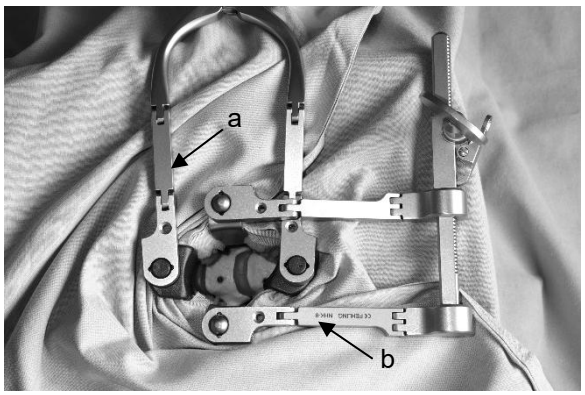


Fig. 5

2. The distraction pin (a) is screwed into the vertebral body using the pin driver (b).
Prior to inserting the distraction pin into the vertebral body, the distraction pin (a) is inserted into the pin driver (b) up to the stop, as shown in Figure 6a.

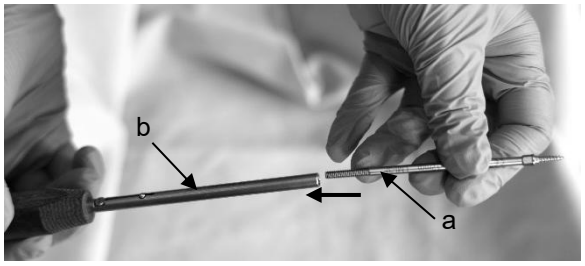


Fig. 6a

⚠ The distraction pin is to be inserted such that the tip of the distraction pin protrudes from the tube of the pin driver (Fig. 6b).

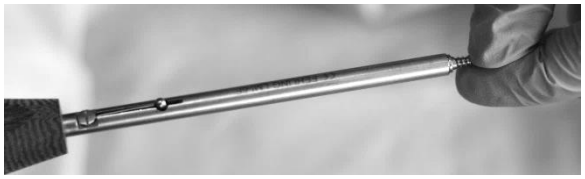


Fig. 6b

3. The distraction pin, which is inserted in the pin driver (Fig. 7a), is screwed completely into the vertebral body in a clockwise manner using the pin driver (Fig. 7b).

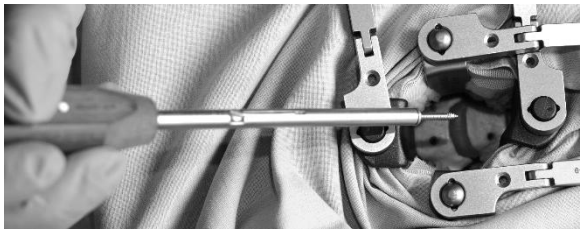


Fig. 7a

Fig. 7b

4. The same procedure applies to the second distraction pin as for the first distraction pin (see steps 2 and 3).

Figure 8 depicts the two distraction pins (a) in the vertebral bodies.

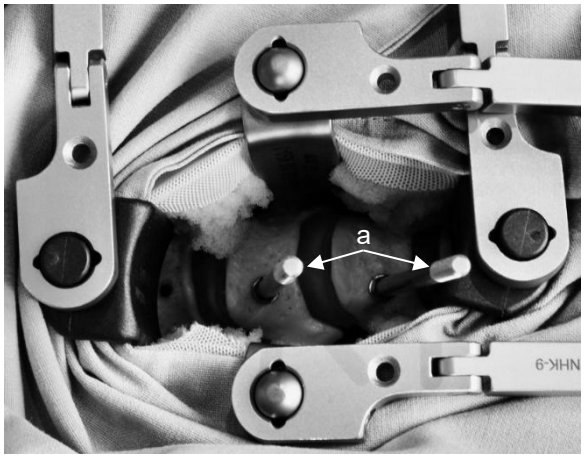


Fig. 8

5. The CONCEPT cervical spine intervertebral distractor (Fig. 9) consists of two flexible retractor arms (a) and a toothed rack (b).

The special feature of the two retractor arms (a) is that they are equipped with a joint. This allows for the adjustment of pins which are not arranged in parallel.

⚠ For assembly of the CONCEPT cervical spine intervertebral distractor please observe 9) Assembly.

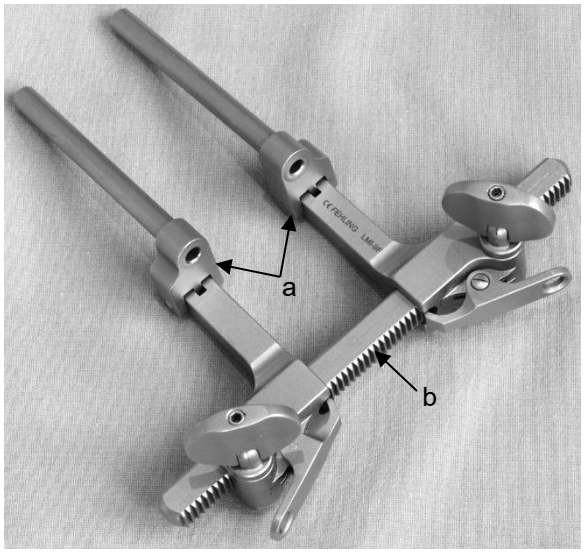
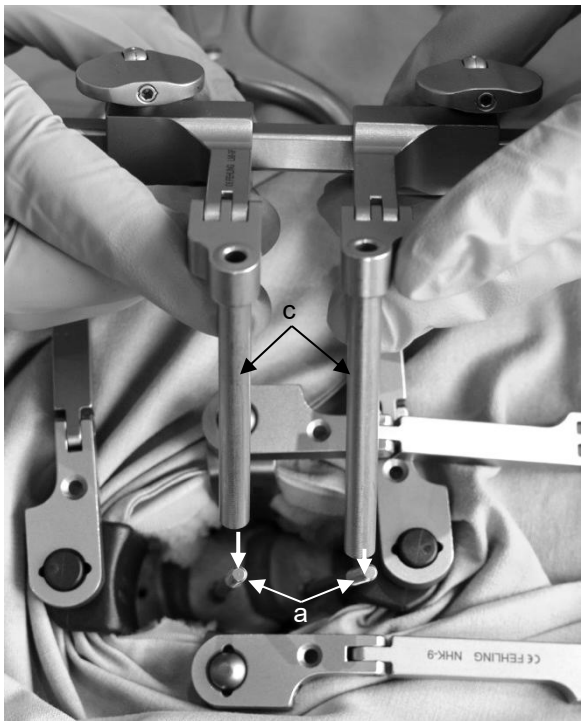
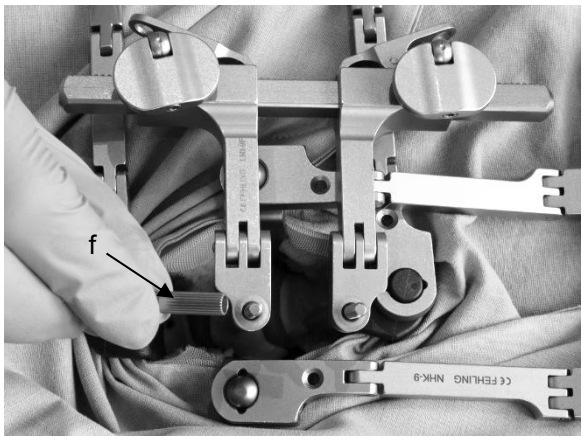


Fig. 9

6.	The holder tubes (c) of the CONCEPT cervical spine intervertebral distractor are guided via the two distraction pins (a) (Fig. 10) and then the CONCEPT cervical intervertebral distractor can be positioned on the two ATLAS cervical retractors.  Fig. 10
7.	The proximal ends of the distraction pins protrude from the holder tube of the retractor arms and are tightened clockwise (Fig. 11b) with the aid of the fixation nut (f) (Fig. 11a) to prevent dislocation of the distraction pins during surgery.  Fig. 11a  Fig. 11b
8.	The desired retraction width can be set by turning the wing screw (d) at the proximal ends of the retractor arm (a). Please note here that the wing screw shown in Figure 12a on the left must be turned counterclockwise and the wing screw shown on the right must be turned clockwise (arrows in Fig. 12a). Afterwards the wing screw (d) of the two flexible retractor arms (a) can be folded down (Fig. 12a) so that the view of the surgical field is unobstructed (Fig. 12b).

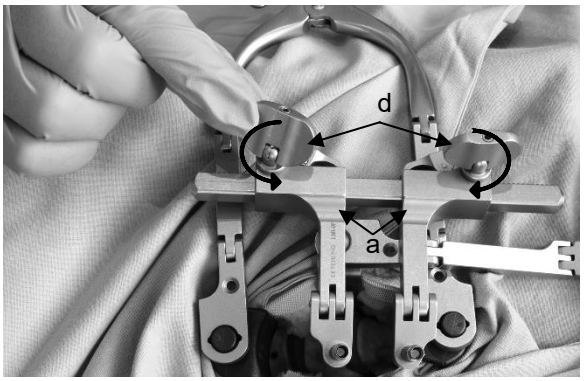


Fig. 12a


Fig. 12b

9. Both retractor arms (a) can be moved along the entire toothed rack (b). This makes full use of the toothed rack possible and allows having different positions of the retractor arms, as the retractor arms can be positioned centrally (Fig. 12b), at one end of the toothed rack (Fig. 13a) or at the other end (Fig. 13b).

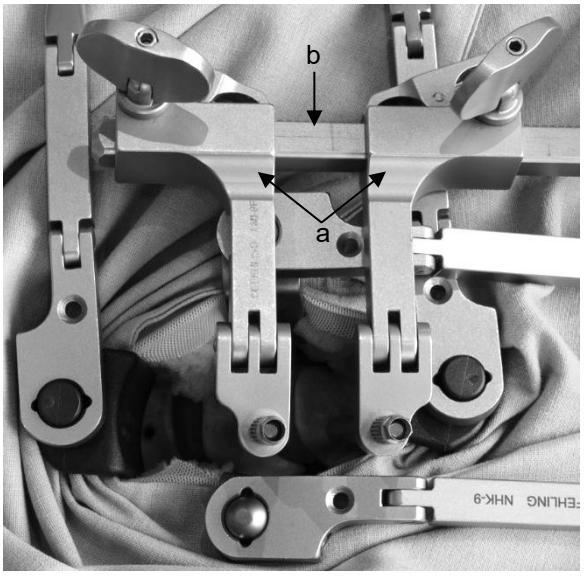


Fig. 13a

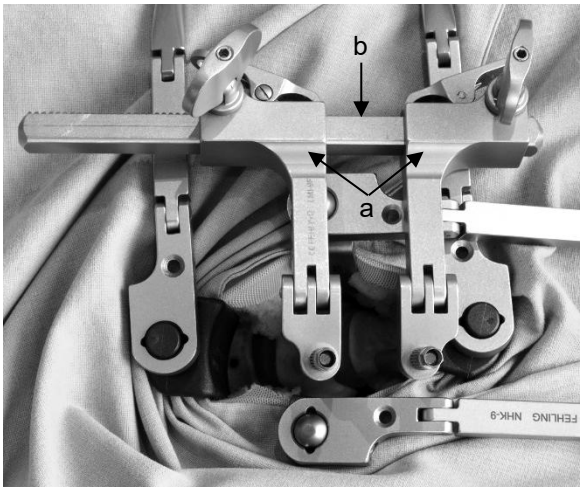


Fig. 13b

10. In the following, intervertebral disc resection and insertion of a cage can be performed.

11. After performing surgery according to step 10
- Slowly push the retractor arms of the CONCEPT cervical spine intervertebral distractor together by pressing on the lock of the flexible retractor arm and simultaneously turning the wing screw.
- Unscrew the fixation nut from the distraction pins counterclockwise.
- Remove the CONCEPT cervical spine intervertebral distractor from the distraction pins.
- Completely unscrew the distraction pins counterclockwise with the aid of the pin driver and remove them from the vertebral body.

⚠ Prior to removing the CONCEPT cervical spine intervertebral distractor from the surgical field, ensure that the retractor arms are slowly pushed together again.

12. Continue the surgical procedure as planned.

CONCEPT intervertebral retractor forceps – application

The CONCEPT intervertebral retractor forceps allows both pre-distraction as well as temporary expansion of the intervertebral disc space. Use of the CONCEPT intervertebral retractor forceps is described in the following.

Press the jaws (a) of the CONCEPT intervertebral retractor forceps (Fig. 14a) together to set the desired retraction width at the distal end.
To fixate the retraction width, the quick-action nut (b) (Fig. 14b) is screwed clockwise (Fig. 14b) until the jaw is reached (Fig. 14c).

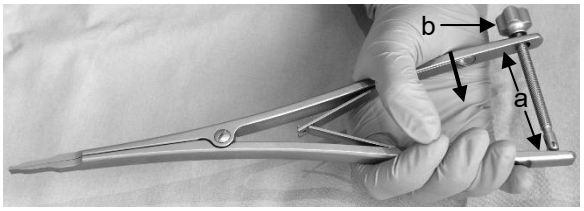


Fig. 14a

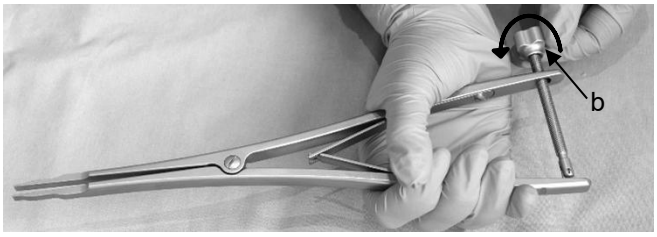


Fig. 14b

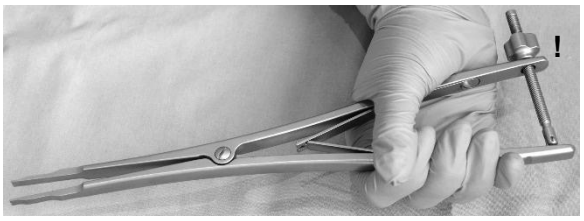


Fig. 14c

The jaws of the CONCEPT intervertebral retractor forceps are placed between the vertebral bodies and the intervertebral disc to temporarily retract the intervertebral disc space (Figs. 15a and 15b). The CONCEPT intervertebral retractor forceps are to be operated during use as described before (see Figs. 14a-14c).

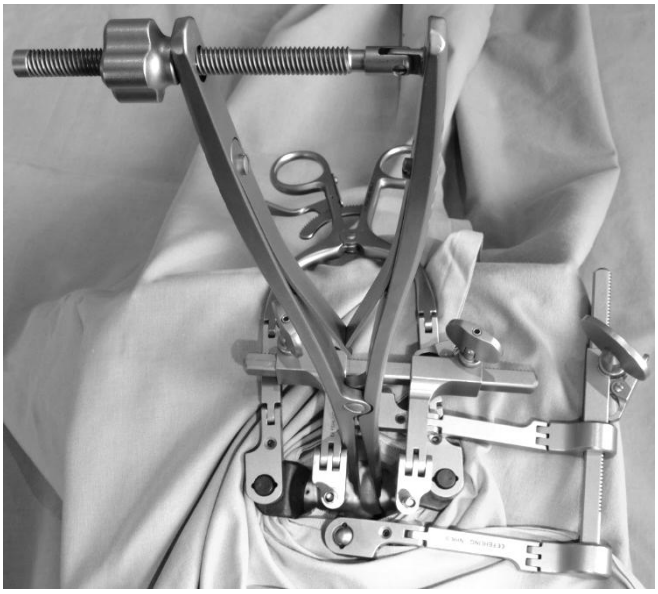


Fig. 15a

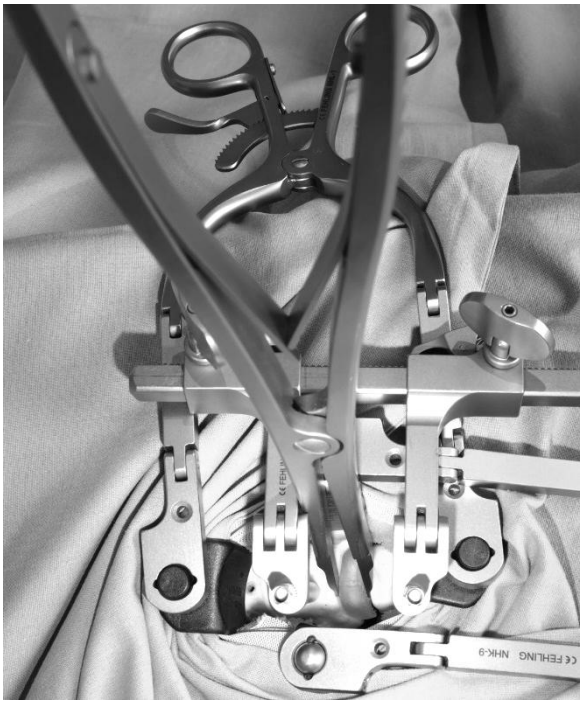


Fig. 15b

7.2) Extension module

The ATLAS cervical spine retractor system in its transversal and longitudinal versions can be used as a possible extension module for the CONCEPT intervertebral retractor system.

8) Required accessories

The CONCEPT pin driver LMI-6F (Fig. 16) is required for use of the CONCEPT distraction pins. The CONCEPT pin driver deep LMI-6L is required for use of the CONCEPT distraction pins deep.
The intervertebral retractor forceps with quick-action lock (Fig. 17) are required when used for pre-distraction or temporary retraction of the intervertebral disc space.

Fig. 16: LMI-6F CONCEPT pin driver for LMI-9F

Fig. 17: LMI-8F CONCEPT intervertebral retractor forceps with quick-action lock

9) Assembly

For assembly and disassembly of the distraction pins, please observe 7) Configuration and application - During application.

For assembly of the CONCEPT cervical spine intervertebral distractor please observe the following assembly instructions.

Figure 18 depicts the CONCEPT cervical spine intervertebral distractor which is a U-shaped bar retractor. The bar retractor consists of two flexible retractor arms (a) and a toothed rack.
The proximal end of the flexible retractor arms (a) is the cage (c), on which the wing screw (d) with the gear wheel as well as the lock (e) are located.

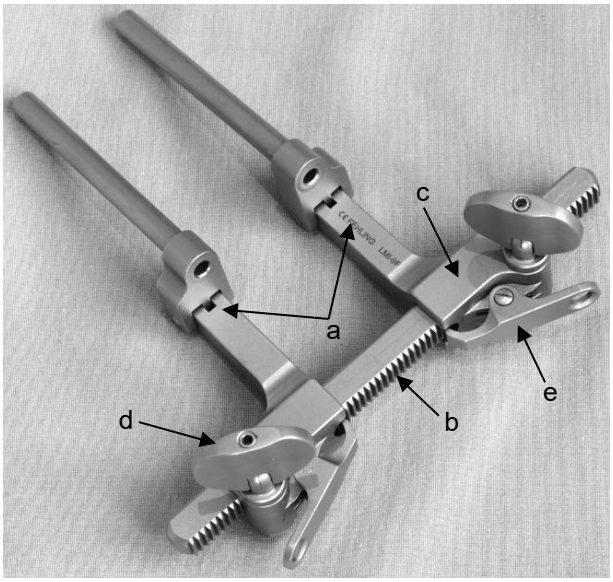


Fig. 18: CONCEPT cervical spine intervertebral distractor (LMI-9F resp. LMI-9L)

Insert the toothed rack (b) into the recess of the cage (c). At the same time, release the lock (e) by pressing in the direction of the toothed rack (b) (Fig. 19).

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

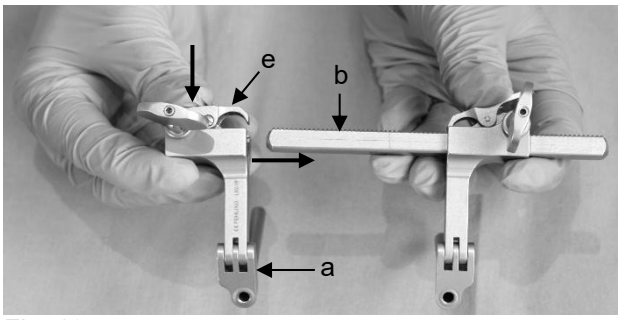


Fig. 19

Advance the flexible retractor arm (a) along the toothed rack to the center (Fig. 20).
The same procedure applies to the other flexible retractor arm, except that it is inserted from the other side of the toothed rack.

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


Fig. 20

10) Disassembly

The CONCEPT cervical spine intervertebral distractor must be disassembled as follows for reprocessing.

Advance the flexible retractor arm (a) outwards along the toothed rack (b) until it can be removed (Fig. 21). At the same time, release the lock (e) by pressing in the direction of the toothed rack (b).

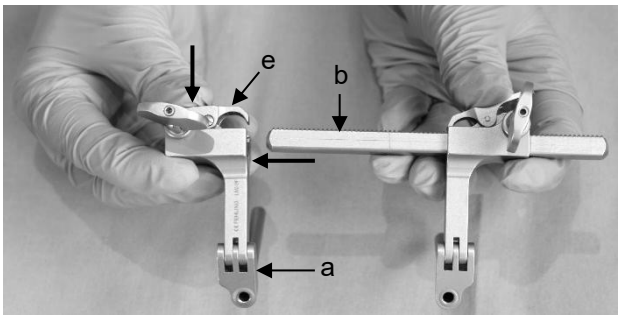


Fig. 21

The instrument is now disassembled into its separate parts (Fig. 22) and can be reprocessed.

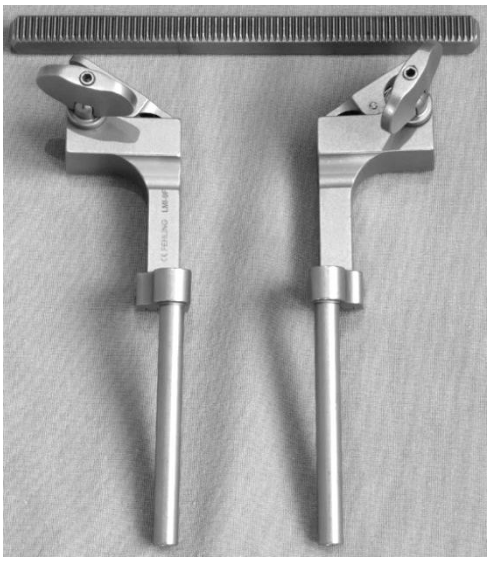


Fig. 22

⚠ 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 relating to the medical device to the manufacturer per e-mail to vigilance@fehling-instruments.de or via the report form at https://www.fehling-instruments.de/en/complaint/ and the competent authority of the Member State where the user is registered.

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	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
CE marking	CE 0297 CE marking	Oil can for points to be lubricated

To contact the manufacturer:

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CE 0297