FEHLING CASPAR distractor		
Retractor body	LMJ-5	CASPAR distractor for cervical spine body only, right
	LMJ-6	CASPAR distractor for cervical spine body only, left

Components

Distraction screw

NGN-0..... Distraction screw 12 mm (pair) for CASPAR distractor
LMJ-8..... Distraction screw 14 mm (pair) for CASPAR distractor
LMJ-9..... Distraction screw 16 mm (pair) for CASPAR distractor
NGN-5..... Distraction screw 18 mm (pair) for CASPAR distractor

Accessories

LMK-1 ..... Screwdriver for CASPAR distractor
NGM-7K..... Drill guide for distraction screws left
NGM-8K..... Drill guide for distraction screws right

Extension modules

Possible supplementary retractor systems

ATLAS cervical spine retractors in transverse and longitudinal version

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 CASPAR distractor may only be used, reprocessed and disposed of by qualified medical personnel!

The CASPAR 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 CASPAR 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 CASPAR 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 INSTRUMENTS CASPAR 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 CASPAR distractor must be handled with care during storage, transportation and cleaning! Avoid striking the CASPAR 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 CASPAR distractor (Figs. 1a and 1b) is a U-shaped bar retractor with a fixed (a) and a flexible (b) retractor arm. The flexible retractor arm is freely movable along the toothed rack (c) and is moved via a gear. The proximal end of the flexible retractor arm (b) is the cage (d), on which the wing screw (e) with the gear wheel as well as the lock (f) are located. The fixed, non-replaceable holder tubes for holding the distraction screws are located at the distal end of the two retractor arms.

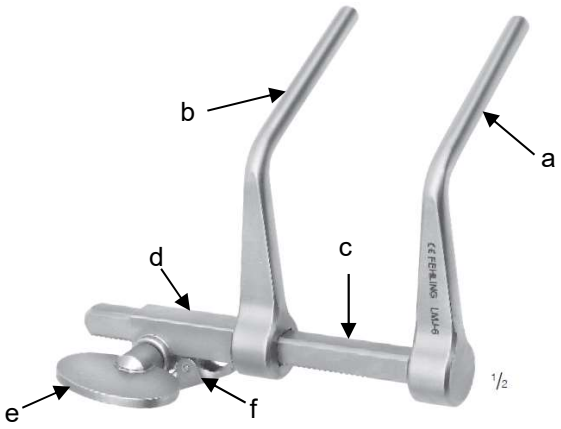


Fig. 1a: LMJ-6 CASPAR distractor left

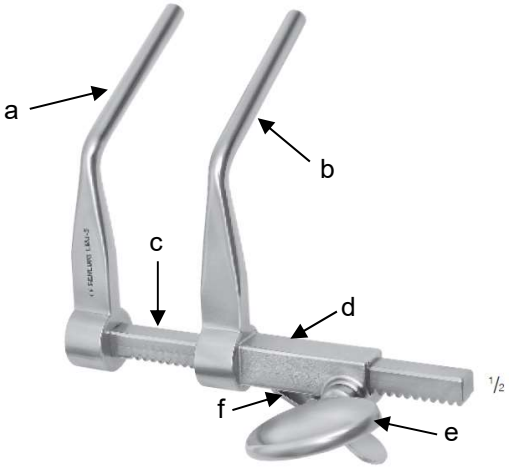


Fig. 1b: LMJ-5 CASPAR distractor right

Figure 2 depicts a configuration example for the CASPAR distractor (1) in combination with a longitudinally (2) and transversely (3) aligned ATLAS cervical spine retractor in each case. Table 1 lists the corresponding components.

Figure 3 depicts an example of a distraction screw, which is screwed into the vertebral body using the screwdriver LMK-1 (see 8) Required accessories).

Table 1: List of the corresponding components

	Article no.	Description
1	LMJ-6	CASPAR distractor for cervical spine, body only, left
2	NHL-1	ATLAS cervical spine retractor longitudinal version with double joint
3	NHK-9	ATLAS cervical spine retractor transversal version with double joint
4	NGN-0	Distraction screw 12 mm (pair)
	LMJ-8	Distraction screw 14 mm (pair)
	LMJ-9	Distraction screw 16 mm (pair)
	NGN-5	Distraction screw 18 mm (pair)

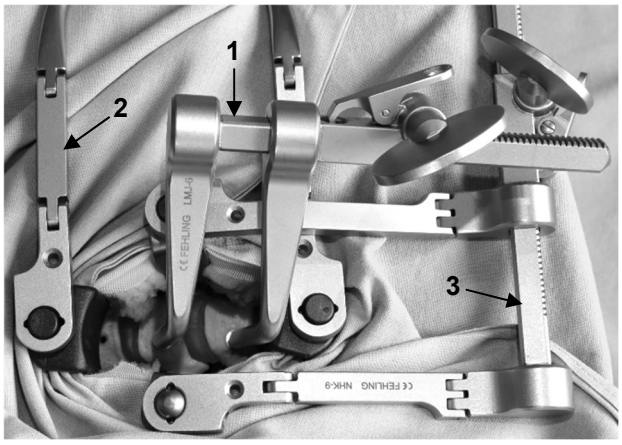


Fig. 2: Configuration example for the CASPAR distractor

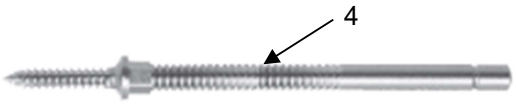


Fig. 3: Distraction screw (example)

⚠	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 CASPAR distractor can be used, the surgical field must be prepared appropriately (Fig. 4). This will not be discussed in detail in the following.
In Figure 4, 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.

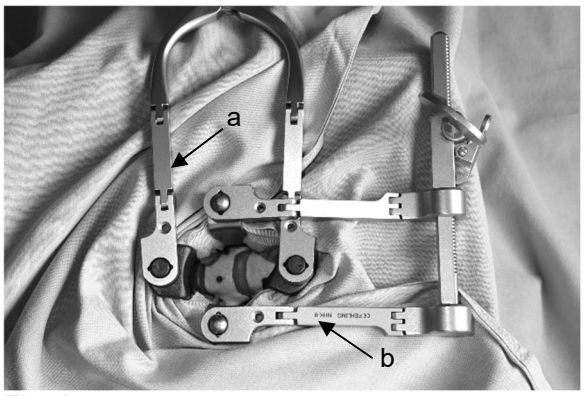


Fig. 4

2. The distraction screw (a) is screwed into the vertebral body using the screwdriver LMK-1 (b).
Prior to inserting the distraction screw into the vertebral body, the distraction screw (a) is inserted into the screwdriver (b) up to the stop, as shown in Figure 5a.

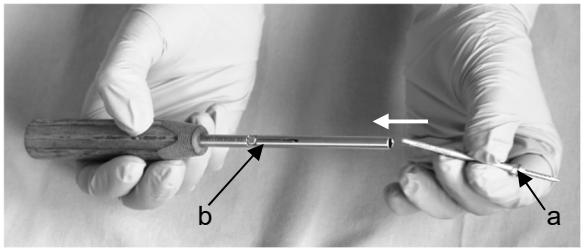


Fig. 5a

⚠ Insert the distraction screw such that the tip of the distraction screw points out of the tube of the screwdriver, as shown in Figure 5b.


Fig. 5b

3. The distraction screw, which is inserted in the screwdriver (Fig. 6a), is screwed completely into the vertebral body in a clockwise manner using the screwdriver (Fig. 6b).

Prior to this step, a hole can be predrilled in the vertebral body for the distraction screw.

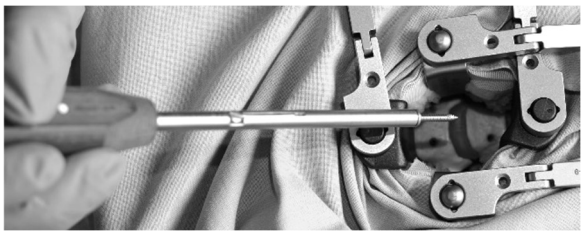


Fig. 6a

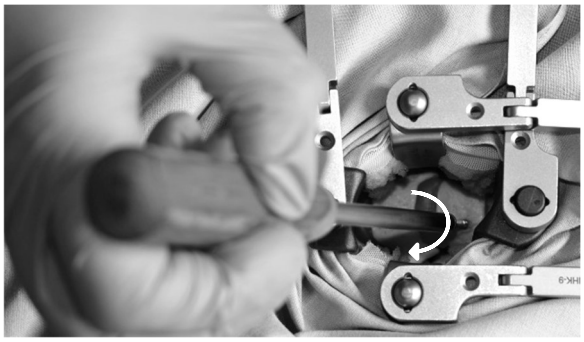


Fig. 6b

4. The CASPAR distractor, right (LMJ-5) is prepared accordingly in order to screw the second distraction screw into the vertebral body. To this purpose, the flexible retractor arm (b) of the CASPAR distractor is advanced outwards on the toothed rack (c) until it can be removed. At the same time, release the lock (f) by pressing in the direction of the toothed rack (c) (Fig. 7a).

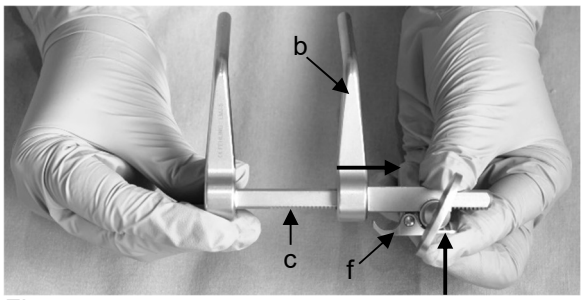


Fig. 7a

⚠ The drill guide is to be used for the second distraction screw, as this is the only way to ensure parallelism of the two distraction screws and thus ensure that the CASPAR distractor can be guided over the distraction screws.

Insert the toothed rack (c) of the CASPAR distractor into the recess of the drill guide, right (NGM-8K) (g) (Fig. 7b). At the same time, release the lock of the drill guide (h) by pressing in the direction of the toothed rack (c).

⚠ Ensure that the fixed retractor arm (f) and the holder of the drill guide (i) point in the same direction and that the sprocket of the drill guide points outwards (Fig. 7b).

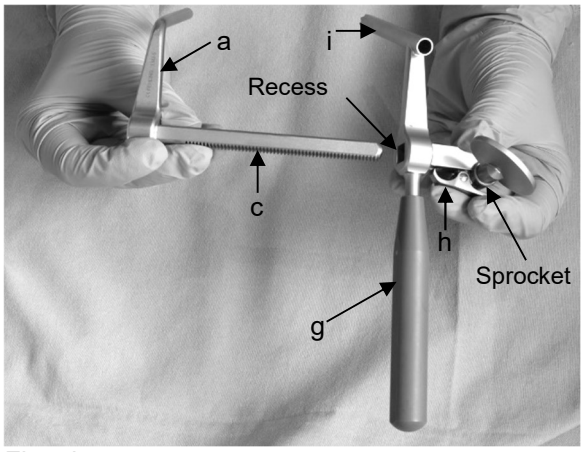


Fig. 7b

Advance the drill guide (g) along the toothed rack (c) inwards in the direction of the fixed retractor arm (a) (Fig. 7c).

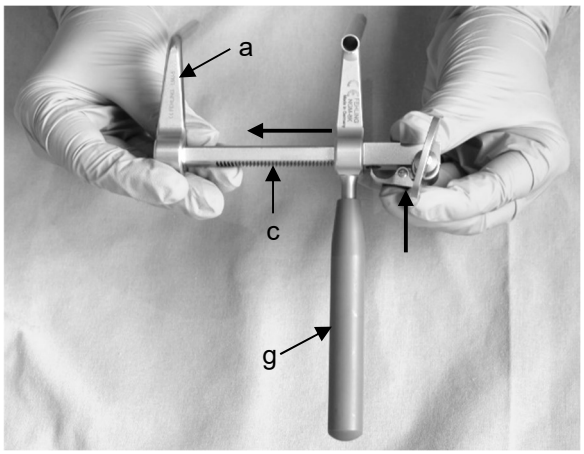


Fig. 7c

Following a functional test, the assembled instrument is now ready for use again (Fig. 7d).

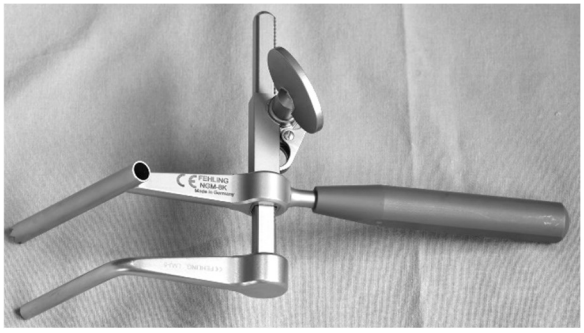


Fig. 7d

5. The retractor system with drill guide is now used. The holder tube of the fixed retractor arm (a) is guided over the distraction screw (b) (Fig. 8a).

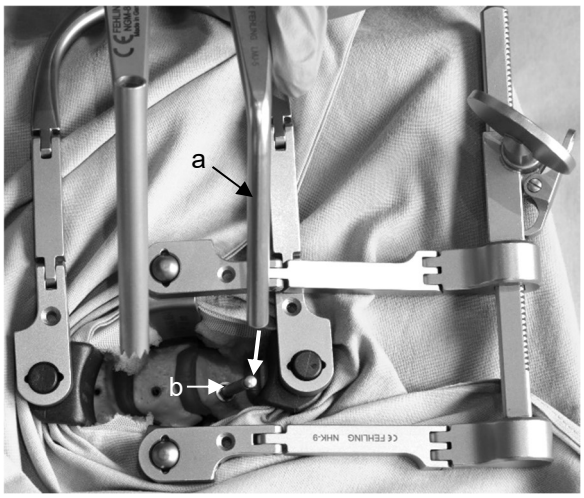


Fig. 8a

By turning the wing screw of the retractor system counterclockwise, the retraction width of the drill guide can be adjusted to determine the position of the second distraction screw (Fig. 8b).

A hole can be predrilled for the second distraction screw by guiding an appropriate drill bit through the holder tube of the drill guide.

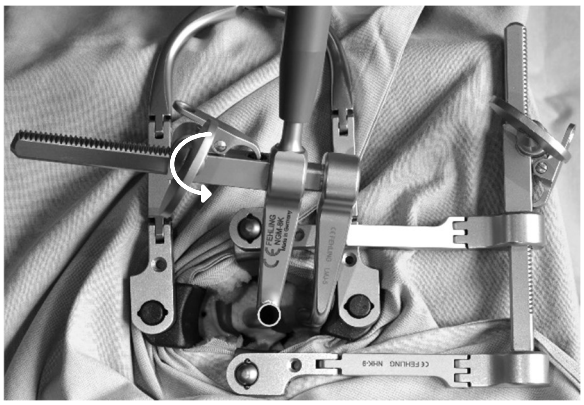


Fig. 8b

6. The same procedure as for the first distraction screw applies to the second distraction screw (see steps 2 and 3).
The distraction screw is inserted directly with the screwdriver through the holder tube of the drill guide (Fig. 9a) and screwed clockwise into the vertebral body (Fig. 9b).

Fig. 9a

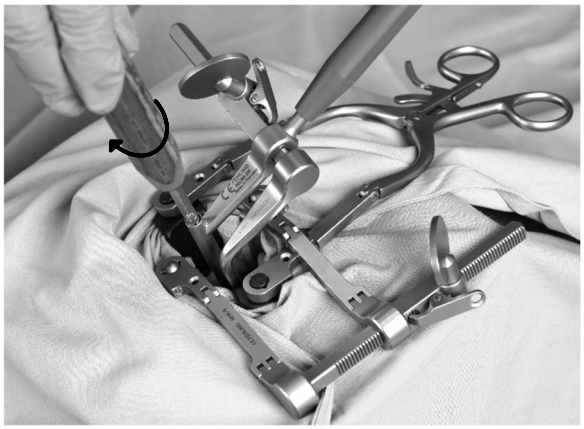


Fig. 9b

7. After the second distraction screw has been applied, the retractor system is removed with the drill guide and the retractor system is returned to its original position.
To this purpose, the drill guide (g) is advanced outwards on the toothed rack (c) until it can be removed (Fig. 10a). At the same time, release the lock of the drill guide (h) by pressing in the direction of the toothed rack (c).

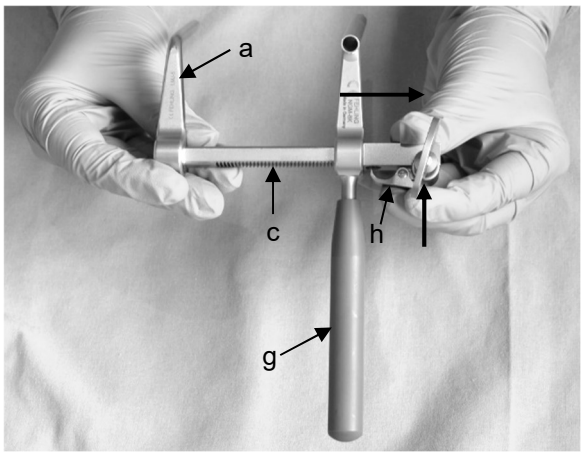


Fig. 10a

Now the retractor system with the drill guide is disassembled into its individual components (Fig. 10b) and the toothed rack (c) is free again to guide the flexible retractor arm (b) of the CASPAR distractor along the toothed rack (c) (Fig. 10c).

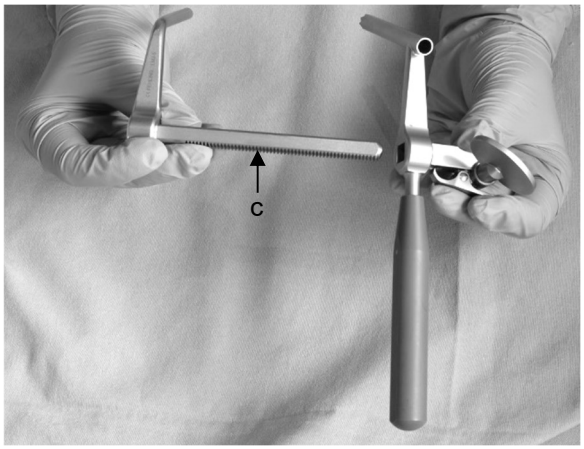


Fig. 10b

Insert the toothed rack (c) of the CASPAR distractor into the recess of the flexible retractor arm (b). At the same time, release the lock (f) by pressing in the direction of the toothed rack (c) (Fig. 10c).

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

Advance the flexible retractor arm (b) along the toothed rack (c) inwards in the direction of the fixed retractor arm (a) (Fig. 10c).

Following a functional test, the CASPAR distractor is now ready for use again.

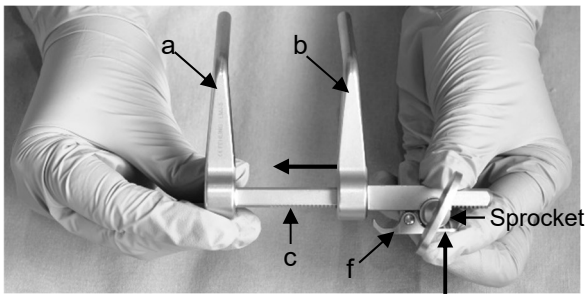


Fig. 10c

8.	The holder tubes of the CASPAR distractor are now guided over the two distraction screws, as shown in Figure 11a. By turning the wing screw counterclockwise, the distraction screw is distracted to the desired position (Fig. 11b). When using the CASPAR distractor left, LMJ-6, turn the wing screw clockwise to distract to the desired position of the distraction screw (Fig. 11c). ⚠ During distraction, care must be taken to ensure that the holder tubes do not slip off the distraction screws.

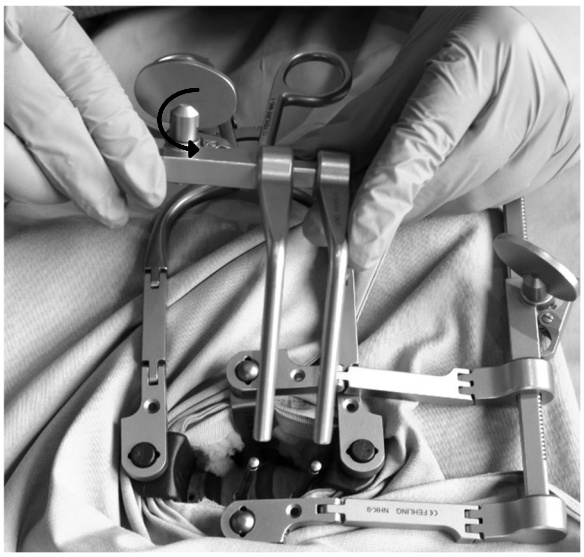


Fig. 11a

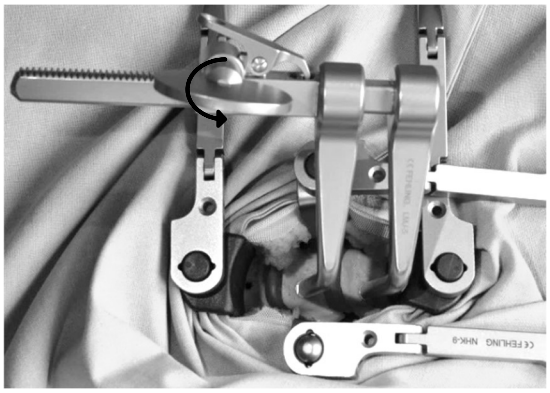


Fig. 11b: LMJ-5 CASPAR distractor right

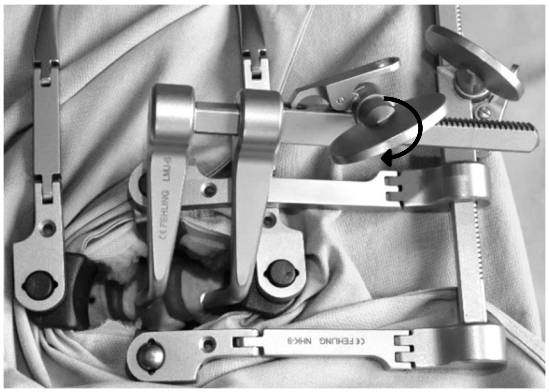


Fig. 11c: LMJ-6 CASPAR distractor left

	The CASPAR distractor is available in right (LMJ-5, Fig. 11b) and left (LMJ-6, Fig. 11c) versions. Whether the LMJ-5 or the LMJ-6 are used depends on the position of the first distraction screw, as the holder of the fixed retractor arm is always guided over the first distraction screw. Accordingly, the drill guide is also available in right and left versions, so that the appropriate drill guide is available for both CASPAR distractors. For the LMJ-5 this is the drill guide right (NGM-8K) and for the LMJ-6 the drill guide left (NGM-7K) (see 8) Required accessories).
9.	In the following, intervertebral disc resection and insertion of a cage can be performed.
10.	After performing surgery according to step 9 - Slowly push the retractor arms of the CASPAR distractor together by pressing on the lock of the flexible retractor arm and simultaneously turning the wing screw - Remove the CASPAR distractor from the distraction screws - Completely unscrew the distraction screws counterclockwise with the aid of the screwdriver and remove them from the vertebral body
	⚠ Prior to removing the CASPAR distractor from the surgical field, ensure that the retractor arms are slowly pushed together again.
11.	Continue the surgical procedure as planned.

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 CASPAR distractor.

8) Required accessories

To use the distraction screw, an LMK-1 screwdriver (Fig. 12) and a drill guide right (NGM-8K, Fig. 13) or left (NGM-7K, Fig. 14), are required depending on the retractor version.

Fig. 12: LMK-1 Screwdriver for CASPAR distractor

Fig. 13: NGM-8K drill guide for distraction screw, right

Fig. 14: NGM-7K drill guide for distraction screw, left

9) Assembly

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

For assembly of the CASPAR distractor please observe the following assembly instructions.

Figure 15 depicts the CASPAR distractor which is a U-shaped bar retractor. The bar retractor consists of a fixed retractor arm (a), a flexible retractor arm (b) and a toothed rack (c).
The proximal end of the flexible retractor arm (b) is the cage (d), on which the wing screw (e) with the gear wheel as well as the lock (f) are located.

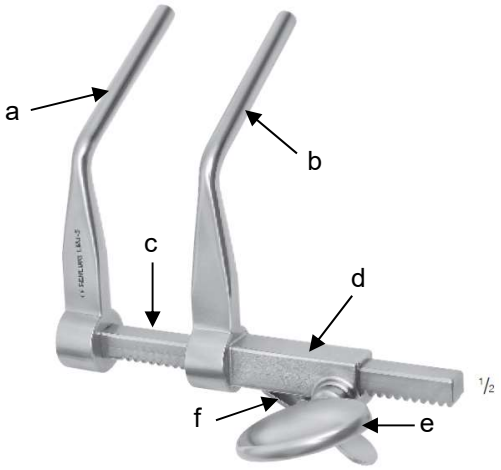


Fig. 15: LMJ-5 CASPAR distractor right

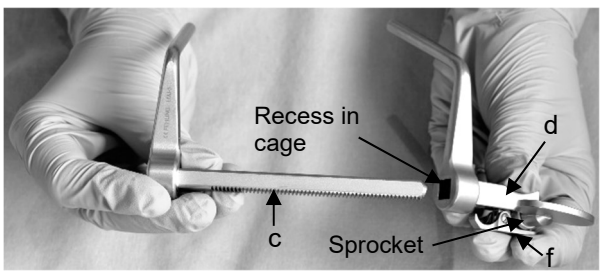
1.	Insert the toothed rack (c) into the recess of the cage (d). At the same time, release the lock (f) by pressing in the direction of the toothed rack (c) (Fig. 16).	

Fig. 16

⚠	Ensure that both retractor arms point in the same direction and the sprocket of the flexile retractor arm points outwards.
2.	Advance the flexible retractor arm (b) along the toothed rack (c) inwards in the direction of the fixed retractor arm (a) (Fig. 17). Following a functional test, the assembled instrument is now ready for use again.

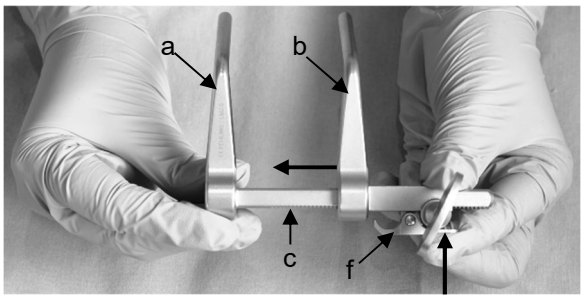


Fig. 17

10) Disassembly

The CASPAR distractor must be disassembled as follows for reprocessing.

1.	Advance the flexible retractor arm (b) outwards along the toothed rack (c) until it can be removed. At the same time, release the lock (f) by pressing in the direction of the toothed rack (c) (Fig. 18).

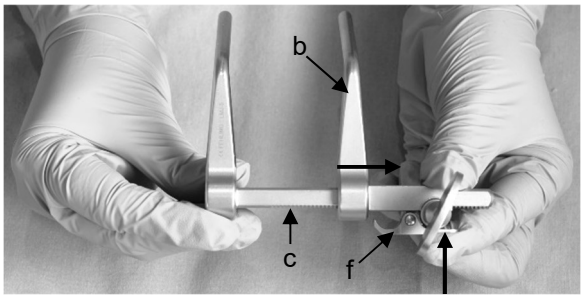


Fig. 18

2.	The instrument is now disassembled into its separate parts (Fig. 19) and can be reprocessed.

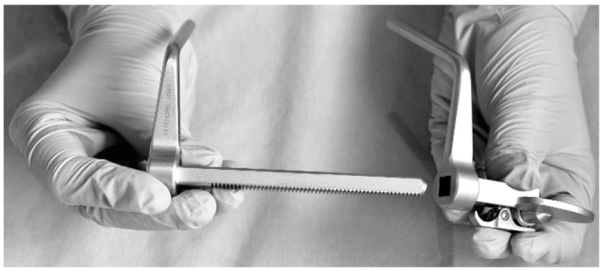


Fig. 19

⚠	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	Instructions for Use are to be observed	Warning
REF Article number	LOT Batch code	SN Serial number
CE labeling	CE 0297 CE labeling	Oil can for points to be lubricated

To contact the manufacturer:	
	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de

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