FEHLING spreaders class IIa - all FEHLING scissor spreaders

⚠	This instrument or medical device is supplied non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed according to the RKI- guidelines (non-critical/semicritical/critical A/B/C). Spreaders (retractors) and spreader components may only be used, reprocessed and disposed of by qualified medical personnel! Spreaders (retractors) and spreader components are intended for reuse.

1) Intended purpose

Spreaders (retractors) and spreader components, which are used surgically invasively and for short periods, are used to spread or retract various tissue structures, such as skin, bones, muscles and organs.

Supplementary information on the purpose

Duration of use: The spreader (retractors) or spreader component is intended for short-term use.

Field of application: Spreaders (retractors) and spreader components are used in all patients where tissue must be held away for a short time (max. 24 hours) for the surgeon to better see the underlying tissue.

User profile: Spreaders (retractors) and spreader components may only be used by medically trained personnel (e.g., medical specialists).

Application environment: Spreaders (retractors) and spreader components are only used under controlled environmental conditions (e.g., operating room).

2) Indications

Surgical procedures requiring the short-term spreading and holding of various tissue structures, such as skin, bones, muscles and organs to reach the body structure to be treated. The choice of spreader and accessory components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken to ensure that the spreaders or spreader blades used are the correct size and have sufficient stability.

3) Contraindication

Contraindicated are all applications that are contrary to the physical and/or mechanical properties of the individual spreader model. There are no generally valid contraindications for the use of spreaders.
Nevertheless, attention must be paid to increased risks that could result from the anatomical and physiological conditions as well as the patient's clinical picture. These include, for example, increased fracture risk of the bones in osteoporosis.

4) Possible side effects

The medical literature describes the following side effects, which may also occur during the intended use of spreaders:

- Bone fractures; e.g. ribs, sternum, spinous processes, vertebral bodies
- Infections

- Wound healing disorders - Lesions of structures (tissues, nerves, vessels) - Necroses - Ischemia of other organs due to compression of blood vessels
⚠ Medical devices may contain, for example, chromium, nickel and/or titanium. The materials used are biocompatible, but they may cause allergic reactions or intolerances.

5) Before use	
FEHLING INSTRUMENTS spreaders (retractors) and spreader components are supplied non-sterile and must be cleaned and sterilized by the user before initial use and before each subsequent use (see 6) Preparation).	
⚠	A safety check must be performed before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see 6) Preparation under "Maintenance, inspection and testing").
⚠	Handle spreaders (retractors) and spreader components with care during storage, transport and cleaning! Avoid blows and punctual loads on spreaders (retractors) and spreader components to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use faultless and sterilized products!

6) Preparation	
⚠	The medical device must be reprocessed before use. Before reprocessing, it must be risk-assessed according to the RKI guidelines (non-critical/semicritical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing must be observed.
⚠	For the reprocessing of instruments -used in patients with -Creutzfeldt-Jakob disease -(CJD), suspected CJD -or possible variants, the applicable national regulations must be observed.
⚠	The instruments may only be used, reprocessed and disposed of by qualified medical personnel.
⚠	Handle instruments with care during storage, transport and cleaning! Avoid impacts and point loads on instruments to prevent possible consequential damage! Do not overload functional parts!
⚠	Do not clean CERAMO® instruments (recognizable by their black-brown surface) and titanium instruments with oxidative processes (processes with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). The use of these procedures leads to the destruction of titanium instruments or the titanium-containing CERAMO® coating after some time due to the dissolution of titanium.

Limitations during reprocessing	Frequent reprocessing has little effect on these instruments. The end of the product life is normally determined by wear and tear and damage from use (e.g. damage, illegible marking, functional failure - see also "Maintenance, inspection and testing").
General information on preparation	The reprocessing is based on a validated procedure. All the cleaning steps mentioned (manual pre-cleaning, cleaning by machine/manually, disinfection manually and sterilization) were validated with the parameters specified in each case and listed under "Validated procedure". The recommended reprocessing agents (cleaning agent: Neodisher® MediClean forte (Dr. Weigert); disinfectant: Korsolex® med AF (Bode Chemie GmbH)) were used for validation. Both water of drinking water quality and fully demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Machine reprocessing is preferable to manual cleaning due to a better and safer cleaning result. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of the cleaning and disinfecting agents. All application specifications of the chemical manufacturer must be strictly adhered to. Otherwise, this may result in visual material changes or material damage, such as corrosion, fractures or premature aging.
Initial treatment at the point of use	Pre-cleaning: Care must be taken to remove residues of blood, tissue and drugs from the instruments with a disposable cloth/paper towel immediately after completion of the procedure, and these must be immediately sent for machine cleaning. After completion of the initial treatment of the instruments, visual inspections must be carried out to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing in such a way that neither users, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation before cleaning	It is recommended that the instruments are reprocessed immediately after use, as dried residues in hard-to-reach areas are difficult to remove. Do not -place in NaCl solutions -(otherwise risk of pitting or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See 10) Disassembly
Manual Pre-cleaning	<u>Validated procedure:</u> Equipment: Basin soft brush Water pressure gun (or similar) Cleaning agent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u>

	• If possible, rinse the disassembled instruments under cold running water (drinking water quality, <40°C) until all visible dirt has been removed. Remove any stuck dirt with a soft brush (not a wire brush!). • Cavities, crevices, slots and lumens must each be flushed intensively (>10 seconds) with cold water (drinking water quality, <40°C) using a water pressure gun (or similar). • Soak the products for 10 - 30 minutes in a solution containing 0.5 - 2 % Neodisher® MediClean forte with water (drinking water quality, <40°C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be followed. • Make sure that all areas of the instrument are in contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath. • During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). • Rinse the instruments for 1 minute under cold deionized water (see "General information on reprocessing") and, if necessary, move moving parts on the instrument back and forth.
Cleaning/ Disinfection	If possible, a washer/disinfector according to DIN EN ISO 15883 that uses thermal disinfection is preferable.
Cleaning: Machine	Avoid overfilling instrument trays and wash trays - use only suitable instrument trays. Take particular care to ensure that the tips do not become jammed in the grid when inserting and removing the instruments into/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Cleaning agent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Articulated instruments shall be inserted into the instrument so that the joints are open or disassembled, if possible, and water can drain from cavities and blind holes. • Relax springs if necessary • Make sure that all cavities are also completely flushed on the inside. • Care should be taken not to create flushing shadows. • Connect the Luer connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. <u>Procedure/Parameters:</u> • 3 minutes pre-rinse with cold water (drinking water quality, <40°C) • Drainage • 10 minutes Cleaning with a solution of 0.5 - 2% Neodisher® MediClean forte in water (drinking water quality) at 55°C

	• Drainage • 2 minutes rinsing with water (drinking water quality, <40°C) • Drainage • 1 minute rinsing with cold deionized water (<30°C) • Drainage • 5 minutes thermal disinfection with deionized water (>90°C) • 30 minutes drying (90°C) After machine cleaning, especially cavities, blind holes, etc. are checked for visible dirt. If necessary, repeat cycle or clean manually.
Cleaning: Manual	<u>Validated procedure:</u> Equipment: Basin soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Cleaning agent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • If possible, place the disassembled instruments in cold water (drinking water quality, <40°C) for 10 minutes. • Operate moving parts, if any, over the entire range of motion. • Clean the instruments using a soft brush (no wire brush!) until there is no visible contamination. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). <u>Ultrasonic cleaning:</u> • 10 minutes sonication at <40°C with 0.5 - 2 % cleaner solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments with water (drinking water quality, <40°C) for at least 10 seconds. • Deionized water (<40°C) must be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the label instructions (see chemical manufacturer's instructions). <u>Validated procedure:</u> Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) <u>Procedure/Parameters:</u> • After cleaning, place the products in an ultrasonic bath (35 kHz, <40°C) with a suitable disinfectant (e.g. 0.5 % Korsolex® med AF) for 5 minutes. Make sure that all surfaces are wetted with the disinfectant. If necessary,

	move moving parts in the disinfection bath before switching on the ultrasonic unit. • After disinfection, rinse all products thoroughly with deionized water (<40°C) for at least 1 minute to remove the disinfectant and, if necessary, move moving parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120°C should not be exceeded. In accordance with the RKI recommendation, subsequently dry with suitable compressed air. Pay particular attention to drying areas that are difficult to access.
Mounting	See 9) Mounting
Maintenance, control and testing	In the case of instruments with moving components which are subject to stress due to friction (e.g. joints), a paraffin/white oil-based instrument oil -(according to the valid European or United States Pharmacopoeia), which is biocompatible, steam-sterilizable and steam-permeable, must be applied prior to sterilization. Such areas may additionally be marked with an appropriate oil can symbol. Instruments must not be treated with care products containing silicone. These can lead to sluggishness and call into question the effect of steam sterilization. A safety check of the instruments must be performed before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). Check locking mechanisms. All instruments: Perform visual inspection with magnifying lamp for damage and wear. Pay particular attention to critical points on moving parts and in the work area. Defective, damaged instruments or instruments whose marking is no longer legible must be sorted out and cleaned and disinfected before being returned to the manufacturer. Repairs are to be carried out exclusively by the manufacturer or workshops authorized by the manufacturer. A confirmation form about this procedure is available from the manufacturer. Instruments that can no longer be repaired must be disposed of in the usual hospital waste metal disposal system. Care must be taken to ensure safe storage in a closed, puncture- and break-proof disposable container, especially for surgical instruments with tips or sharp edges. Do not use any damaged instruments!
Packing	Single: according to standards of the series DIN EN 868, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into designated trays or place on general purpose sterilization trays. A suitable procedure must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in a device according to DIN EN 285 and DIN EN ISO 17665 (Parts 1 and 2). To prevent staining and corrosion, the steam must be free of ingredients. The recommended limits of the ingredients for feed water and steam condensate are defined by DIN EN 285.

	Validated procedure: Equipment: Tuttnauer autoclave type B 3870 EHS / Lautenschläger ZentraCert Procedure/Parameters: Cycle type: 3 pre-vacuum phases Sterilization temperature: 132 - 134°C Holding time: 4 - 5 min. Drying time: 20 min. When sterilizing several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see specifications of the device manufacturer).
Storage	According to § 4 MPBetreibV and standards of the 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). If applicable, always store instruments in a relaxed state. This counteracts premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Disposal	These products are mainly made of steel or titanium. They must be cleaned before disposal. Disposal can take place at a scrap metal recycling center. To protect employees, care must be taken to protect any points and sharp edges that may be present.
The above instructions have been validated by the medical device manufacturer as suitable for preparing a medical device for reuse. The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided should be carefully evaluated by the reprocessor for effectiveness and potential adverse consequences.	
	Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The scissor spreader models with ring handle are gripped and opened like household scissors. A locking device prevents unintentional closing of the spreader under load.
To close the scissors spreader, the locking lever, which engages the teeth of the locking rod due to the spring force, must be actuated in the direction of the ring handle. Figure 1 shows an example of a shear spreader.
Due to the variety of possible anatomical and physiological conditions, beam spreaders differ in their specific characteristics, such as the length and

Fig. 1: WINKING spine spreader for transmuscular approach

shape of the blades and the length and design of the working end, etc.	
⚠	Only use faultless and sterilized products!
⚠	Before inserting the spreaders (retractors) and spreader components, ensure that the surgical field is appropriately prepared.
⚠	Before using spreaders (retractors) and spreader components, make sure that their functionality is not impaired and that there is no damage!
⚠	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or electromagnetic external influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of spreaders (retractors) and spreader components depends on the anatomical and physiological conditions and the area of application. Care must be taken to ensure that the spreaders (retractors) and spreader components used are the correct size and have sufficient stability.
During the application	
⚠	When inserting the spreader blades, make sure that no tissue structures are unintentionally injured (especially nerves and blood vessels)!
⚠	Too long and too high pressure on the tissue can cause necrosis, ruptures, fractures and other lesions!
⚠	Overloading can cause plastic deformation or breakage of spreaders (retractors) and spreader components!
⚠	Before removing spreaders (retractors) and spreader components from the operating field, make -sure that the spreader arms are slowly pushed back together.

7.1) Configuration sheets

The spreader has fixed blades that cannot be replaced.

8) Required accessories

No accessories are required to use the spreader. The spreaders are stand-alone instruments and therefore no combination with other products is intended.

9) Mounting

No assembly of the spreader necessary.
No assembly of the spreader blade necessary.

10) Disassembly
No disassembly of the spreader necessary. No disassembly of the spreader blade necessary.
11) Obligation to report serious incidents
The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer 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 established.
Symbols
Insofar as on the medical device or medical device label or instructions for use shown, the symbols have the following meaning according to DIN EN ISO 15223-1:

 Manufacturer	 Oil can for points to be lubricated	 Caution
 Catalogue number	 Batch code	 Serial number
 Medical device	 Unique Device Identifier	 Consult instructions for use or consult electronic instructions for use
 CE marking	 0297 CE marking	

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	 0297