FEHLING POLYTEL/ATLAS Modular Universal Retractor System

NSA-1V.....U-shaped retractor frame with one hinge per arm
NSA-2V.....Fixation slides (4 to 6)
NSA-3V.....Blade guides (4 to 6)
NHL-1 .....ATLAS retractor for longitudinal exposition
NIE-1 ..... ATLAS retractor with PEEK connection elements
NHK-9..... ATLAS retractor for transversal exposition of the cervical spine
NIE-2 ..... ATLAS retractor with PEEK connection elements

- Spinous pins
- Blunt/sharp blades
- Conical blades
- Sharp blades with 2, 3 and 4 prongs
- Blunt/sharp blades made of PEEK
- Pivoting and rigid parafascial blades

Warning: Do not clean CERAMO® instruments (identifiable by the brownish black surface) and titanium instruments using the Orthovario and Oxivario process: Using the two processes will result in the destruction of titanium instruments or the titanic CERAMO® coating after some time due to oxidative processes (titanium is dissolved out by H_2O_2).

Prior to processing a risk assessment on the instrument must be performed.

Retractor systems may only be used, processed and disposed of by competent medical personal!

Intended use:

The POLYTEL retractor system serves for the exposition of the entire spine from C1 to S1 in case of dorsal access.
The ATLAS retractor system mainly serves for the exposition of the cervical spine in case of ventral access. However, it is also suited for smaller accesses at the entire spine in case of dorsal access, in particular for children, thin and/or older patients as well as surgical operations at the craniocervical junction.

Before use:

FEHLING INSTRUMENTS retractor systems are delivered non-sterile and have to be cleaned and sterilized by the user before their first and any further use (see reprocessing).
Handle retractors with care on storage, transport and cleaning! Avoid impacts and selective loads!
Perform a safety check before each use. Check for cracks, breaks or mechanical malfunctions (see Maintenance, control and functional testing).

Assembly:

Fig. 1

Basic information:

For the assembly the marked side of all components must face the viewer.

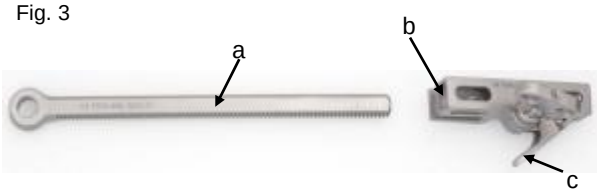
Frame NSA-1V

Position the two components as shown in fig. 1.
Slide the ratchet of the bigger frame part (a) through the socket of the smaller frame part (b). During the sliding procedure the locking lever (c) must be released by pressing with the finger. The big thumbscrew (d) turns automatically during the sliding procedure. The thumbscrew should stand upright as the folded away thumbscrew could collide with the fingers and thus hinder the sliding procedure.

Fig. 2

As shown in fig. 2, the legs of the frame should not be too far apart from each other before the application, so that the frame can then be opened further. To open the frame the upright standing thumbscrew (folded away in the picture) will be turned clockwise.

Fig. 3



Retaining unit (fixation slide and blade guide)

Slide the blade guide (a) through the opening of the fixation slide (b) until the locking lever (c) engages in the ratchet on the blade guide. During the insertion the locking lever must be released by pressing it down.

By turning the upright standing thumbscrew the blade guide can be tensioned in a controlled way.

Fig. 4

As shown in fig. 4, the blade guide should be inserted only half way into the fixation slide before the application. This is the only possibility to be able to further tension the retaining unit placed on the frame.

Fig. 5

The connection pins of the blades are inserted in the blade sockets of the blade guide from below. Although the blades are securely fastened they can still be turned, so that the retractor can take a stable and bio-mechanically optimized position in case of asymmetric load distribution. Dislocations are excluded as far as possible.

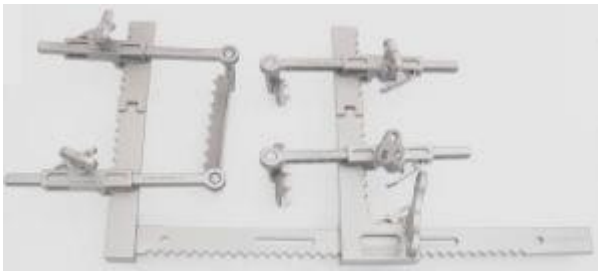


Fig. 6

The retaining units shown in an example configuration in fig. 5 can now be inserted in the wound like Langenbeck's retractors and placed on the profiled parts of the frame at any location.

Depending on the requirement, either the individual retaining units or the entire frame can be opened using the thumbscrews. As soon as the desired configuration is achieved, it is recommended to fold away the thumbscrews in order to optimize the space available.

Fig. 7

ATLAS retractor (fig. 7 and 8)

The transversal ATLAS frame (fig. 8) is assembled in the same way as the POLYTEL retractor. The longitudinal frame (fig. 7) consists only of one piece and needs no assembly.

All pivoting POLYTEL blades can be inserted in the two ATLAS frames. The blades are inserted in the same way as with the POLYTEL frame.

Fig. 8

Reprocessing:

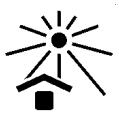
Restriction for reprocessing:
Frequent reprocessing has only minor effects on these instruments.
Usually the end of the product service life is determined by wear and damage due to utilization.

Place of application:	Remove surface contamination with a disposable towel/paper towel – pre-cleaning.

Storage: acc. to § 4 MPBetreibV (regulation on the operation of medical devices)	Store instruments in dry rooms to avoid condensation. It is recommended to start reprocessing the instruments directly after use as dried residues located in areas with limited access are quite difficult to remove.
Preparation of cleaning: Mechanical processing acc. to RKI directives. Mechanical processing should be preferred over manual processing.	Make sure that traces of blood, tissue and medication are removed from the instruments directly after termination of the surgery and that they are immediately forwarded to mechanical cleaning. Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed. Do not place in NaCl solution (risk of hole or stress crack corrosion). Only use an approved solution of a combined cleaning and disinfecting agent without protein fixing effect (observe the recommendation of the chemicals producer when mixing the solution). Avoid overfilling of instrument sets and washing trays – use appropriate instrument carriers only. Be particularly careful that the mouths/points do not get stuck in the mesh when placing and removing the instruments into/from the set baskets. Disassemble dismountable instruments according to the appropriate assembly instructions. Always open joint instruments before processing. Release the springs, if necessary.
Cleaning/Disinfection acc. to DIN EN ISO 15883-1:2009	It is assumed that the products used for cleaning and disinfection are available on the market and approved for the respective application. And that the recommended concentrations, time of exposure and temperatures are observed.
Cleaning: Mechanically acc. to DIN EN ISO 15883-1:2009	Validated procedure: Equipment: Washer/disinfector G 7836 CD (Miele) Process: 2-component process alkaline/enzymatic Detergent: deconex® TWIN PH10 and TWINZYME (Borer Chemie, Switzerland) Preparation: • Joint instruments are to be placed in the device such that the hinges are open and the water can flow off cavities and blind holes. • Make sure that all cavities are completely flushed on the inside as well. • Make sure that no flushing shadows arise. Parameters: • 3 min pre-cleaning with tap water • Drain • 10 min cleaning with tap water and 0.3 % TWIN PH10 at 35 °C, and 0.2 % TWINZYME at 40 °C • Drain • 2 min rinsing with deionized water > 30 °C • Drain • 1 min rinsing with deionized cold water • Drain • 5 min thermal disinfection at 93 °C • After mechanical cleaning check cavities, blind holes, etc. in particular for visible dirt. Repeat cycle or clean manually, if required.
Cleaning/Disinfection: Manually Manual cleaning should be avoided as it cannot be validated.	Equipment: Detergent (active and non protein-fixing cleaner, with or without anti-microbial effect and/or enzymes), compressed-air cleaning gun, soft cloths/sponges, running water. 1. Thoroughly rinse dirt from the surface of the instrument. 2. Apply detergent solution on all surfaces using a soft cloth or sponge. Make sure that joint instruments are cleaned in open as well as in closed position. 3. Thoroughly rinse all cavities and blind holes with a sufficient amount of detergent solution (min. 200 ml) using a syringe. Take special care that enough solution flows to the distal end.

	4. Hold the instrument under running water. The running water must flow through the cavities, and blind holes must be filled and emptied several times. Use deionized water for the final rinsing. For manual cleaning the detergent solution should not be warmer than room temperature. Disinfection: Disinfecting solutions may be used according to the instructions on the label (see indications of the chemicals producer). The automatic cleaning may be followed by a thermal disinfection (min. 5 minutes at 93 °C). (Thermal disinfector, see indications of the device manufacturer.) Demineralized water must be used for the final flushing. Make sure that no residues remain on the products.
Drying:	If the drying is achieved as part of the cleaning/disinfection cycle, 120 °C should not be exceeded.
Maintenance:	Assemble the instruments according to the assembly instructions. Apply a small amount of high-grade, water-soluble instrument spray on the hinges.
Control and function test:	Check instruments for easy operation (avoid too much play). Check locking mechanisms. Using a magnifying lamp visually inspect for damage and wear. Pay special attention to the critical points on movable parts and in the working area. Sort out defective instruments and send them to the manufacturer for repair. Clean and disinfect instruments before sending them to be repaired. A confirmation form for this procedure can be obtained from the manufacturer.
Packaging:	Separate: acc. to standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments in trays provided for that purpose or place them on universal sterilization trays. Use an appropriate procedure to pack the trays.
Sterilization:	Steam-sterilize using the fractional vacuum process at 134 °C (min. 5 minutes holding time) with equipment acc. to DIN EN 285, validated sterilization processes! To avoid formation of stains and corrosion, the steam must be free of components. The recommended limit values of the components for feed-water and steam condensation are defined in DIN EN 285. Validated process: Equipment: Selectomat HP (MMM) 1. Three times pre-vacuum 2. Sterilization temperature 134 °C 3. Holding time: 5 minutes 4. Drying time: min. 10 minutes
Storage:	Acc. to § 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.
Additional information:	Do not exceed the maximum load of the sterilizer when sterilizing several instruments within the same sterilization cycle (see indications of equipment manufacturer).
Contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: +49 (0) 6188-957440 Fax: + 49 (0) 6188-957445 E-mail: info@fehling-instruments.de

Storage / Symbols

 Protect from excessive heat!	 Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	 Observe instructions for use	 Article number	 Attention	CE

! Each modification to the product or deviation from these instructions of use results in exclusion of liability!
Subject to change without notice.

Manufacturer:
FEHLING INSTRUMENTS GmbH & Co. KG, Hanauer Landstr. 7A, 63791 Karlstein/Germany, www.fehling-instruments.de

The instructions above have been validated by the manufacturer of the medical devices as being appropriate for preparation for reuse. The processor is responsible for ensuring that the equipment, material and personnel in the processing facility attain the desired results. Generally, this requires validation and routine monitoring of the process. In the same way, any deviation from the provided instructions should be thoroughly evaluated by the processor with regard to their effectiveness and possible unfavorable consequences.