FEHLING POLYTEL/ATLAS modular universal retractor system

Retractor body

NSA-1V	POLYTEL titanium body
NHL-1	ATLAS cervical spine retractor longitudinal version with double joint
NIE-1	ATLAS cervical spine retractor with X-ray end piece, longitudinal
NIE-2	ATLAS cervical spine retractor with X-ray end piece, transversal
NHK-9	ATLAS cervical spine retractor transversal version with double joint
NHK-9L	ATLAS cervical spine retractor transversal version with double joint, 183 mm
NIN-1	ATLAS retractor side load transversal version with double joint
NIN-2	ATLAS retractor side load longitudinal version with double joint

Components

Handle

NIN-3K	Handle for ATLAS front load/side load blades
NIG-1	Radiolucent handle, 200 mm

Fixations/guides

NSA-2V	POLYTEL coupling rider
NSA-3V	POLYTEL blade guides, 140 mm
NSA-5	POLYTEL body joint stabilizer

Parafascial blades POLYTEL/ATLAS

NSS-6	40 x 25 mm, rotatable
NSS-7	60 x 25 mm, rotatable
NSS-8	80 x 25 mm, rotatable
NSS-9	100 x 25 mm, rotatable
NSU-9	120 x 25 mm, rotatable
NSS-0	140 x 25 mm, rotatable
NSM-6	40 x 40 mm, rotatable
NSM-7	60 x 40 mm, rotatable
NSM-8	80 x 40 mm, rotatable
NSM-9	100 x 40 mm, rotatable
NST-9	120 x 40 mm, rotatable
NSO-6	40 x 40 mm, fixed
NSO-7	60 x 40 mm, fixed
NSO-8	80 x 40 mm, fixed
NSO-9	100 x 40 mm, fixed
NSP-6	40 x 80 mm, fixed
NSP-7	60 x 80 mm, fixed
NSP-8	80 x 80 mm, fixed
NSP-9	100 x 80 mm, fixed
NSK-8	120 x 80 mm, fixed

POLYTEL/ATLAS retractor blades

NSO-0	30 x 15 mm, pointed
NSB-0	35 x 15 mm, pointed
NSO-1	40 x 15 mm, pointed
NSB-1	45 x 15 mm, pointed
NSO-2	50 x 15 mm, pointed
NSB-2	55 x 15 mm, pointed
NSO-3	60 x 15 mm, pointed
NSB-3	65 x 15 mm, pointed
NSO-4	70 x 15 mm, pointed
NSB-4	75 x 15 mm, pointed
NSO-5	80 x 15 mm, pointed
NSB-5	85 x 15 mm, pointed
NSB-6	95 x 15 mm, pointed
NSB-7	105 x 15 mm, pointed
NSR-8	20 x 15 mm, blunt
NSR-9	25 x 15 mm, blunt

POLYTEL/ATLAS retractor blades

NSH-4	75 x 24 mm, blunt
NSH-5	85 x 24 mm, blunt
NSH-6	95 x 24 mm, blunt
NSH-7	105 x 24 mm, blunt
NSR-0	35 x 24 mm, pointed, two-pronged
NSR-1	45 x 24 mm, pointed, two-pronged
NSR-2	55 x 24 mm, pointed, two-pronged
NSR-3	65 x 24 mm, pointed, two-pronged
NSR-4	75 x 24 mm, pointed, two-pronged
NSR-5	85 x 24 mm, pointed, two-pronged
NSR-6	95 x 24 mm, pointed, two-pronged
NSR-7	105 x 24 mm, pointed, two-pronged
NSI-8	25 x 40 mm, pointed, three-pronged
NSI-0	35 x 40 mm, pointed, three-pronged
NSI-1	45 x 40 mm, pointed, three-pronged
NSI-2	55 x 40 mm, pointed, three-pronged
NSI-3	65 x 40 mm, pointed, three-pronged
NSI-4	75 x 40 mm, pointed, three-pronged
NSI-5	85 x 40 mm, pointed, three-pronged
NSI-6	95 x 40 mm, pointed, three-pronged
NSI-7	105 x 40 mm, pointed, three-pronged
NSK-0	35 x 56 mm, pointed, four-pronged
NSK-1	45 x 56 mm, pointed, four-pronged
NSK-2	55 x 56 mm, pointed, four-pronged
NSK-3	65 x 56 mm, pointed, four-pronged
NSK-4	75 x 56 mm, pointed, four-pronged
NSK-5	85 x 56 mm, pointed, four-pronged
NSK-6	95 x 56 mm, pointed, four-pronged
NSK-7	105 x 56 mm, pointed, four-pronged
NSG-0	35 x 20/15 mm, conical
NSG-1	45 x 20/15 mm, conical
NSG-2	55 x 20/15 mm, conical
NSG-3	65 x 20/15 mm, conical
NSG-4	75 x 20/15 mm, conical
NSG-5	85 x 20/15 mm, conical
NSG-6	95 x 20/15 mm, conical
NSG-7	105 x 20/15 mm, conical

ATLAS retractor blades side load

NIJ-1	25 x 19 mm, blunt
NIJ-2	30 x 19 mm, blunt
NIJ-3	35 x 19 mm, blunt
NIJ-4	40 x 19 mm, blunt
NIJ-5	45 x 19 mm, blunt
NIJ-6	50 x 19 mm, blunt
NIJ-7	55 x 19 mm, blunt
NIJ-8	60 x 19 mm, blunt

NSN-0	30 x 15 mm, blunt
NSN-1	35 x 15 mm, blunt
NSN-2	40 x 15 mm, blunt
NSN-3	45 x 15 mm, blunt
NSN-4	50 x 15 mm, blunt
NSN-5	55 x 15 mm, blunt
NSN-6	60 x 15 mm, blunt
NSN-7	65 x 15 mm, blunt
NSN-8	70 x 15 mm, blunt
NSN-9	75 x 15 mm, blunt
NSL-8	25 x 20 mm, pointed
NSP-0	30 x 20 mm, pointed
NSL-0	35 x 20 mm, pointed
NSP-1	40 x 20 mm, pointed
NSL-1	45 x 20 mm, pointed
NSP-2	50 x 20 mm, pointed
NSL-2	55 x 20 mm, pointed
NSP-3	60 x 20 mm, pointed
NSL-3	65 x 20 mm, pointed
NSP-4	70 x 20 mm, pointed
NSL-4	75 x 20 mm, pointed
NSL-5	85 x 20 mm, pointed
NSL-6	95 x 20 mm, pointed
NSL-7	105 x 20 mm, pointed
NST-8	25 x 20 mm, blunt
NSY-4	30 x 20 mm, blunt
NST-0	35 x 20 mm, blunt
NSY-5	40 x 20 mm, blunt
NST-1	45 x 20 mm, blunt
NSY-6	50 x 20 mm, blunt
NST-2	55 x 20 mm, blunt
NSQ-7	60 x 20 mm, blunt
NST-3	65 x 20 mm, blunt
NST-4	75 x 20 mm, blunt
NST-5	85 x 20 mm, blunt
NST-6	95 x 20 mm, blunt
NST-7	105 x 20 mm, blunt
NSF-8	25 x 24 mm, pointed
NSM-0	30 x 24 mm, pointed
NSF-0	35 x 24 mm, pointed
NSM-1	40 x 24 mm, pointed
NSF-1	45 x 24 mm, pointed
NSM-2	50 x 24 mm, pointed
NSF-2	55 x 24 mm, pointed
NSM-3	60 x 24 mm, pointed
NSF-3	65 x 24 mm, pointed
NSM-4	70 x 24 mm, pointed
NSF-4	75 x 24 mm, pointed
NSM-5	80 x 24 mm, pointed
NSF-5	85 x 24 mm, pointed
NSF-6	95 x 24 mm, pointed
NSF-7	105 x 24 mm, pointed
NSG-8	20 x 24 mm, blunt
NSG-9	25 x 24 mm, blunt
NSH-8	30 x 24 mm, blunt
NSH-0	35 x 24 mm, blunt
NSH-9	40 x 24 mm, blunt
NSH-1	45 x 24 mm, blunt
NSQ-8	50 x 24 mm, blunt
NSH-2	55 x 24 mm, blunt
NSQ-9	60 x 24 mm, blunt
NSH-3	65 x 24 mm, blunt
NSQ-0	70 x 24 mm, blunt
NIM-1	35 x 24 mm, blunt
NIM-2	40 x 24 mm, blunt
NIM-3	45 x 24 mm, blunt
NIM-4	50 x 24 mm, blunt
NIM-5	55 x 24 mm, blunt
NIM-6	60 x 24 mm, blunt
NIM-7	65 x 24 mm, blunt
NIM-8	70 x 24 mm, blunt
NIM-9	75 x 24 mm, blunt
NII-1	25 x 19 mm, toothed
NII-2	30 x 19 mm, toothed
NII-3	35 x 19 mm, toothed
NII-4	40 x 19 mm, toothed
NII-5	45 x 19 mm, toothed
NII-6	50 x 19 mm, toothed
NII-7	55 x 19 mm, toothed
NII-8	60 x 19 mm, toothed
NIK-1	30 x 24 mm, lateral
NIK-2	35 x 24 mm, lateral
NIK-3	40 x 24 mm, lateral
NIK-4	45 x 24 mm, lateral
NIK-5	50 x 24 mm, lateral
NIK-6	55 x 24 mm, lateral
NIK-7	60 x 24 mm, lateral
NIK-8	65 x 24 mm, lateral
NIK-9	70 x 24 mm, lateral
NIL-1	30 x 24 mm, medial
NIL-2	35 x 24 mm, medial
NIL-3	40 x 24 mm, medial
NIL-4	45 x 24 mm, medial
NIL-5	50 x 24 mm, medial
NIL-6	55 x 24 mm, medial
NIL-7	60 x 24 mm, medial
NIL-8	65 x 24 mm, medial
NIL-9	70 x 24 mm, medial

POLYTEL/ATLAS spinous pins

NSC-8	25 mm
NSC-9	30 mm
NSC-1	35 mm
NSC-2	40 mm
NSC-3	45 mm
NSC-4	50 mm
NSC-5	55 mm

POLYTEL/ATLAS radiolucent blades

NIE-4	40 x 23 mm, pointed, X-ray
NIE-5	45 x 23 mm, pointed, X-ray
NIE-6	50 x 23 mm, pointed, X-ray
NIE-7	55 x 23 mm, pointed, X-ray
NIE-8	60 x 23 mm, pointed, X-ray
NIE-9	65 x 23 mm, pointed, X-ray
NIF-0	75 x 23 mm, pointed, X-ray
NIF-2	40 x 23 mm, blunt, X-ray
NIF-3	45 x 23 mm, blunt, X-ray
NIF-4	50 x 23 mm, blunt, X-ray
NIF-5	55 x 23 mm, blunt, X-ray
NIF-6	60 x 23 mm, blunt, X-ray
NIF-7	65 x 23 mm, blunt, X-ray
NIF-8	75 x 23 mm, blunt, X-ray
NIG-3	85 x 23 mm, blunt, X-ray
NIG-4	95 x 23 mm, blunt, X-ray

Accessories

NSX-0	POLYTEL Sterilizing and storage container 530 x 250 x 100 mm
NGM-6	Forceps for changing blades (optional)

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 POLYTEL/ATLAS modular universal retractor system may only be used, reprocessed and disposed of by qualified medical personnel!

The POLYTEL/ATLAS modular universal retractor system is intended for reuse.

1) Intended purpose

Retracting and guiding instruments have the purpose of keeping or fixing products and tissue (e.g. sizers, absorbent cotton, swabs, clips, wire, screws, nuts, drills, bone substance, implants, cannulas, drains, holding rods, handles, retractor blades, etc.)

- in or at a specific position
- or moving into or to a specific position.

With the exception of retractors (according to PHA retractor Class Ir and Class IIa), hooks, vascular and tissue clamps, forceps, and needle holders.

Additional information regarding the intended purpose

Duration of application: The POLYTEL/ATLAS modular universal retractor system is intended for short-term application.

Field of application: Retracting and guiding instruments are used in all patients where products and tissues must be held or fixed in or at a specific position and/or moved into or at a specific position.

User profile: Retracting and guiding instruments may only be used by medically trained personnel (e.g., a medical specialist).

Application environment: Retracting and guiding instruments are only used under controlled environmental conditions (e.g., an operating room).

2) Indications

Treatment methods which require retracting and guiding of products and tissues.

3) Contraindication

All applications which run contrary to the physical and/or mechanical properties of the individual retracting and guiding instrument models are contraindicated. There are no generally applicable contraindications for the use of retracting and guiding instruments.
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.

4) Possible adverse effects	
The medical literature describes the following side effects, which may also possibly occur during the intended use of the POLYTEL/ATLAS modular universal retractor system. - Bone fractures such, for example, spinous processes, vertebral bodies - Infections - Impaired wound healing - Lesions of structures (tissues, nerves, vessels) - Necroses - Ischemia of other organs due to compression of blood vessels	
⚠	Medical devices may, for example, contain PEEK, chromium, nickel and/or titanium. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
The FEHLING INSTRUMENTS POLYTEL/ATLAS modular universal retractor system is supplied non-sterile and must be cleaned and sterilized by the user before initial use and before any further use (see 6) Reprocessing).	
⚠	Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see 6) Reprocessing under "Maintenance, Checking and Testing").
⚠	Handle the POLYTEL/ATLAS modular universal retractor system with care during storage, transport and cleaning! Avoid striking and applying pressure to the POLYTEL/ATLAS modular universal retractor system, 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!

⚠	Do not clean titanium or titanium-containing instruments with oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). By dissolving titanium, the application of these procedures leads to the destruction of titanium or titanium-containing instruments. In the same meaning, do not clean instruments containing plastic components with oxidative processes. These processes lead to thermal-oxidative aging of the material, which may under certain circumstances not be detectable by visible discoloration or embrittlement.
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. • Remove coarse contamination using a suitable brush (not a wire brush!) during the exposure time. • 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 connectors of the instruments, if present, to the Luer lock rinsing attachment of the WD. Procedure/Parameters: • 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	Validated procedure: Equipment: Basin Soft brush Water spray gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert) Procedure/Parameters: • 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 using a water spray gun (or similar). Ultrasonic cleaning: • Clean for 10 minutes at <40 °C with 0.5 - 2 % cleaning solution at 35 kHz • After ultrasonic cleaning, rinse the instruments for at least 20 seconds using a water spray gun (or similar). • Rinse the instruments for at least 10 seconds with water (potable water quality, <40 °C). • Deionized water (<40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionized water. Ensure that no residues remain on the products.

Disinfection: Manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer information). Validated procedure: Equipment: Basin Bandelin Sonorex Digitec Disinfectant: Korsolex® med AF (Bode Chemie GmbH) Procedure/Parameters: • 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 instru-

	ments 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 min. Drying time: 20 min. 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 MPBetreibV (Medical Devices Operator Ordinance) and the 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

Figure 1 gives a configuration example for a POLYTEL retractor system.

The POLYTEL retractor system consists of one fixed retractor arm (a), a toothed rack (b) and one movable retractor arm with wing screw and lock (c).

Blade guides (d) with a coupling rider (e) can be attached to the retractor arms (a, c). The blades are attached to the distal end of the blade guides. In this example, both two rotatable parafascial blades (f) as well as one fixed parafascial blade (g) are used.

The POLYTEL retractor system in particular is used to expose the entire spinal column from C1 to S1 when using a dorsal access.

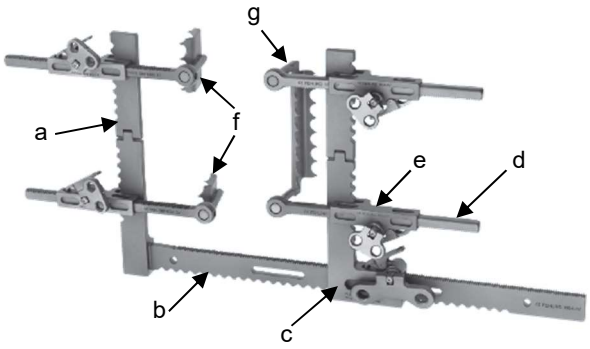

Fig. 1: Configuration example for a POLYTEL retractor system

Fig. 2: Example of an ATLAS retractor, longitudinal version

Figure 2 shows an example of a longitudinal ATLAS rectractor, which consists of a single piece and therefore does not need to be assembled. The respective blades are attached to the distal end of the longitudinal ATLAS retractor (a).

Figure 3 gives a configuration example for an ATLAS side load retractor system.

The respective blades are also attached to the distal end of the longitudinal ATLAS side load retractor (a). Blunt ATLAS side load blades (b) are used in this example. A transversal ATLAS side load retractor (c) is placed over the longitudinal ATLAS side load retractor. Here too, the blades are attached to the distal end of the transversal ATLAS side load retractor. Toothed ATLAS side load blades (d) are used in this example.

This combination has the advantage that retraction can be performed two-dimensionally.

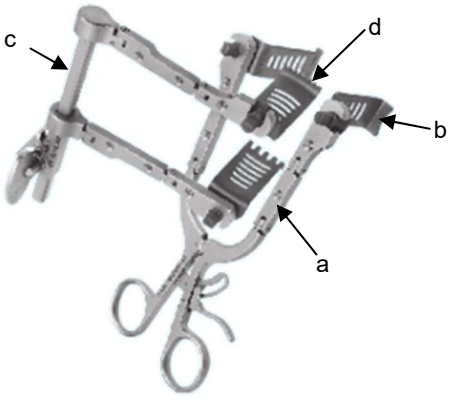

Fig. 3: Configuration example for an ATLAS side load retractor system.

In addition to the ATLAS blades, all rotatable POLYTEL blades can also be used in both ATLAS bodies.

The ATLAS retractor system in particular is mainly used to expose the cervical spine when using a ventral access. However, it is also suitable for smaller accesses along the entire spine from the dorsal, especially for children, lean and/or elderly patients, as well as for procedures at the craniocervical junction.

Fig. 4: Handle for ATLAS side load blades

<u>Handle for ATLAS side load blades (Fig. 4)</u>

The handle does not require assembly and can be used in addition to the POLYTEL or ATLAS retractors.

Only the side load blades can be inserted into this handle.

⚠	Use only sterilized products of sound quality!
⚠	Before employing the POLYTEL/ATLAS modular universal retractor system, ensure that the surgical field is prepared accordingly.
⚠	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 components depends on the anatomical and physiological conditions as well as the area of application. Care must be taken here to ensure that the components used are of the correct size and provide sufficient stability.

8) Required accessories

No accessories are necessary as a matter of principle for using the POLYTEL/ATLAS modular universal retractor system. However, the NGM-6 blade ejector can be used as an option for removing or changing blades.
A POLYTEL sterilization and storage container can be used for sterilization or storage.

9) Assembly

For assembly of the transversal POLYTEL/ATLAS modular universal retractor system, please observe the following assembly instructions.

<u>Retractor body NSA-1V</u>

Position the two individual parts of the instrument as shown in Figure 5.

The toothed rack (a) with the fixed retractor arm (b) is pushed through the cage of the movable retractor arm (c). While sliding, the lock (d) must be unlocked by applying finger pressure. The large wing screw (e) rotates automatically during the sliding process. Here, the wing screw should be in an upright position, as the folded wing screw could collide with the fingers and thus obstruct the sliding process.

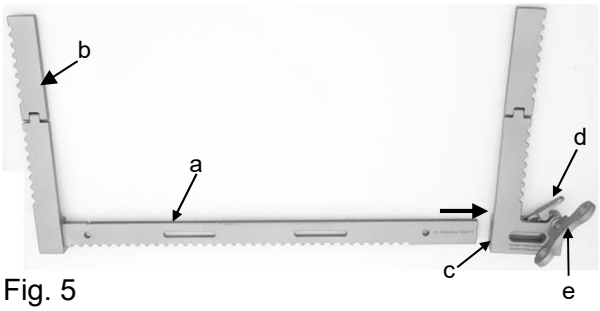

Fig. 5

As shown in Figure 6, the retractor arms should not be too far apart before use so that the retractor body can be expanded further later on. To retraction, rotate the upright wing screw (e) (folded down in the illustration) clockwise.

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

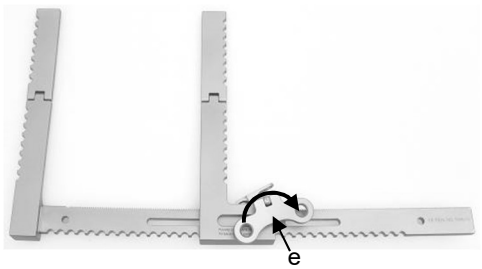

Fig. 6

Fixation unit (coupling rider and blade guide)

Both the blade guide (a) as well as the coupling rider (b) have a side marked with an "arrow" and "UP". Before inserting the blade guide (a) into the coupling rider (b), make sure that the two marked sides are facing upwards. The blade guide (a) is inserted into the coupling rider (b) in the direction indicated by the arrow (Fig. 7). The arrow on the coupling rider (b) refers exclusively to the insertion of the blade guide (a) and not for mounting the retractor body.

The blade guide (a) is pushed through the opening of the coupling rider (b) until the lock (c) on the toothed rack of the blade guide (a) engages. While inserting, the lock (c) must be unlocked by pressing down.

By rotating the upright thumb screw (d) clockwise, the blade guide (a) can be tightened in a controlled manner.

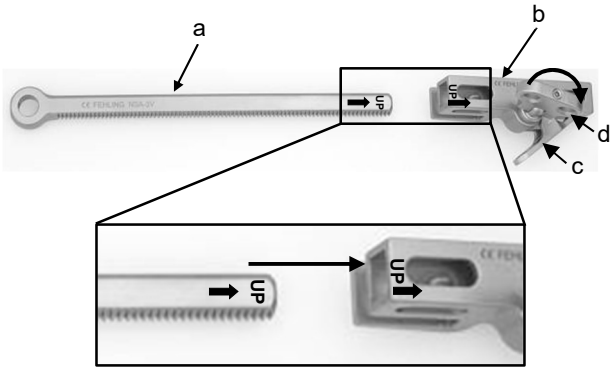

Fig. 7

As shown in Figure 8, the blade guide (a) should be pushed into the coupling rider (b) no more than halfway before being used. This is the only way that the fixation unit placed on the retractor body can be further tightened at a later stage.

Fig. 8

The blades (e) are inserted from below with their connecting pins into the blade mounts of the blade guide (f). And although the blades are securely fixed, they can be rotated, thus giving the retractor the ability to assume a stable and biomechanically optimized position when the load is distributed asymmetrically. Dislocation is more or less impossible.

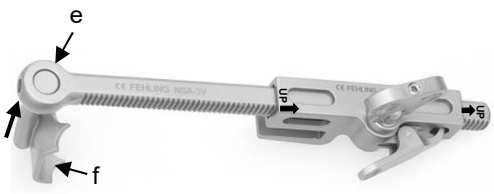

Fig. 9

The fixation units, assembled as illustrated in Figure 9 as an example, can now be inserted into the wound like Langenbeck blades and placed anywhere on the profiled parts of the retractor body.

A configuration example with the assembled individual components described previously is given in Figure 10.

Depending on requirements, both the individual fixation units or the entire retractor body can be opened as options by using the wing screws. Once the desired configuration has been achieved, it is recommended to flip the wing screws for reasons of space optimization.

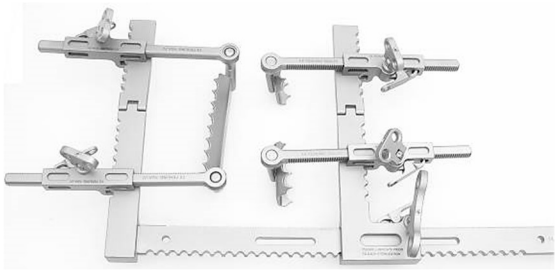

Fig. 10

ATLAS retractors

Figure 11 illustrates an example of a transverse ATLAS body.

The assembly of the ATLAS transversal body is the same as for the POLYTEL retractor, as the movable retractor arm (a) is slid onto the toothed rack (b) with the fixed retractor arm (c).

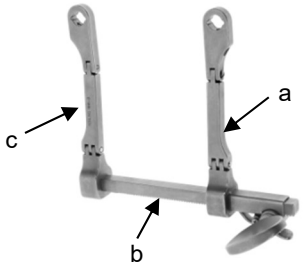

Fig. 11

⚠	Before removing the retractor from the operating field, make sure that the retractor arms are slowly pushed back together.

10) Disassembly

For reprocessing, the POLYTEL/ATLAS modular universal retractor system must be disassembled as follows.

For disassembly of the fixation unit, please observe the corresponding assembly instructions (see 9) Assembly).

Figure 12 depicts a transversal POLYTEL/ ATLAS modular universal retractor system to illustrate disassembly.

Advance the movable retractor arm (a) outwards along the toothed rack (b) until it can be removed. During this process, release the lock (c) by pressing in direction of the toothed rack (b).

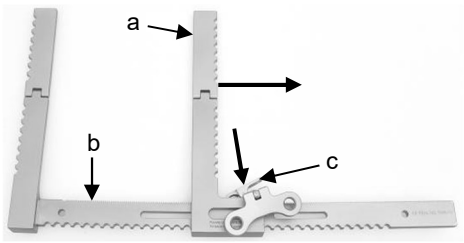

Fig. 12

The instrument is now disassembled into its separate parts (Fig. 13) and can be reprocessed.

Fig. 13

⚠	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 which 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 domiciled.

Symbols		
In as far as the medical device or medical device label or instructions for use are labeled, the symbols represent the following meaning:		
 Manufacturer	 Instructions for Use are to be observed	 Warning
 Article number	 Batch code	 Serial number
 CE labeling	 CE labeling	 Oil can for points to be lubricated
		UP Marking of position

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