



FEHLING POLYTEL/ATLAS Modular Universal Retractor System

Retractor frames

NSA-1V POLYTEL titanium frame	NHK-9 ATLAS cervical spine retractor, transverse version with double joint
NHL-1 ATLAS cervical spine retractor, longitudinal version with double joint	NHK-9L ATLAS cervical spine retractor, transverse version with double joint, 183 mm
NIE-1 ATLAS cervical spine retractor with X-ray end piece, longitudinal	NIN-1 ATLAS retractor side-load, transverse version with double joint
NIE-2 ATLAS cervical spine retractor with X-ray end piece, transverse	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 fixation carriage
NSA-3V POLYTEL blade guides, 140 mm
NSA-5 POLYTEL frame joint stabiliser

POLYTEL/ATLAS parafascial blades

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, rigid
NSO-7 60 x 40 mm, rigid
NSO-8 80 x 40 mm, rigid
NSO-9 100 x 40 mm, rigid
NSP-6 40 x 80 mm, rigid
NSP-7 60 x 80 mm, rigid
NSP-8 80 x 80 mm, rigid
NSP-9 100 x 80 mm, rigid
NSK-8 120 x 80 mm, rigid

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

POLYTEL/ATLAS retractor blades

NSU-1 135 x 30 mm, pointed
NSU-2 145 x 30 mm, pointed
NSU-3 155 x 30 mm, pointed
NSU-4 165 x 30 mm, pointed
NSU-5 135 x 30 mm, blunt
NSU-6 145 x 30 mm, blunt
NSU-7 155 x 30 mm, blunt
NSU-8 165 x 30 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-7 105 x 56 mm, pointed, four-pronged
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 side-load retractor blades

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



NSB-6..... 95 x 15 mm, pointed
 NSB-7..... 105 x 15 mm, pointed
 NSB-8..... 115 x 15 mm, pointed
 NSB-9..... 125 x 15 mm, pointed
 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
 NSP-0..... 30 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
 NSP-4..... 70 x 20 mm, pointed
 NSL-7 105 x 20 mm, pointed
 NST-8..... 25 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-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
 NSH-4 75 x 24 mm, blunt
 NSH-5 85 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, serrated
 NII-2 30 x 19 mm, serrated
 NII-3 35 x 19 mm, serrated
 NII-4 40 x 19 mm, serrated
 NII-5 45 x 19 mm, serrated
 NII-6 50 x 19 mm, serrated
 NII-7 55 x 19 mm, serrated
 NII-8 60 x 19 mm, serrated
 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-1 35 mm
 NSC-2 40 mm
 NSC-3 45 mm
 NSC-4 50 mm
 NSC-5 55 mm
 NSC-6 65 mm
 NSC-8 25 mm
 NSC-9 30 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



NSH-6 95 x 24 mm, blunt
NSH-7 105 x 24 mm, blunt

NIG-3 85 x 23 mm, blunt, X-ray
NIG-4 95 x 23 mm, blunt, X-ray

Accessories

NSX-0 POLYTEL sterilisation and storage container 530 x 250 x 100 mm

NGM-6 Forceps for blade change (optional)



This instrument or 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

The purpose of holding and guiding instruments is to hold or fix products and tissue (e.g. sizers, 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 to move them into or to a specific position

This does not apply to retractors (as specified in the TD for Classes I and IIa retractors), hooks, vascular and tissue clamps, forceps and needle holders.

Additional information regarding the intended purpose

Duration of application: Holding and guiding instruments are intended for short-term use.

Field of application: Holding and guiding instruments are used in all patients where products and tissue must be held or fixed in or to a specific position and/or moved to or in a specific position.

User profile: Holding and guiding instruments may only be used by medically trained personnel (e.g. specialist surgeons).

Application environment: Holding and guiding instruments are only to be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions.

2) Indications

Treatment methods requiring the holding and guiding of products and tissue.

3) Contraindication

All applications that are inconsistent with the physical and/or mechanical properties of the specific holding and guiding instrument model are contraindicated. There are no generally applicable contraindications for the use of holding and guiding instruments.

Nevertheless, due consideration must be given to increased risks that may arise from the patient's anatomical and physiological characteristics and underlying conditions.



4) Possible side effects

The following side effects are described in the medical literature and may also occur during the intended use of holding and guiding instruments:

- Bone fractures, e.g. ribs, sternum, spinous processes, vertebral bodies
- Infections
- Wound healing disorders
- Injury to structures (tissues, organs, nerves, vessels)
- Necrosis
- Ischaemia
- Haematoma



Medical devices may contain, for example, PEEK, chromium, nickel and/or titanium. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.

5) Before use

The POLYTEL/ATLAS Modular Universal Retractor System is supplied non-sterile and must be cleaned and sterilised by the user before initial use and before each subsequent use (see Section 6) Reprocessing).



Perform a safety check prior to each use. Check for sharp edges, cracks, fractures or mechanical malfunctions and missing components (see section 6) *Reprocessing* under "*Maintenance, Inspection and Testing*").



Handle the POLYTEL/ATLAS Modular Universal Retractor System with care during storage, transport and cleaning!
Avoid impacts and point loading on the POLYTEL/ATLAS Modular Universal Retractor System to prevent any possible secondary damage! Do not overload functional parts!



Use only intact and sterilised products!

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 mechanical shock and point loading on instruments to avoid causing any secondary damage! Do not overload functional parts!



	Do not clean instruments with plastic components using oxidative processes (processes with hydrogen peroxide H₂O₂, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative ageing of the material, which may under certain circumstances not be detectable by visible discolouration or embrittlement.
Reprocessing limitations	Frequent reprocessing has little effect on the labelling of the instruments and does not impair their function. The end of product life is normally determined by wear and tear and damage occurring through use (e.g. damage, illegible labels or marking, functional failure – also see "Maintenance, inspection and testing"). If used and reprocessed correctly, the instruments have been validated for at least 500 reprocessing cycles.
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 sterilisation) 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 deionised water (deionised water, demineralised, 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 of the chemical manufacturer's instructions for use must be strictly observed. Otherwise, this can lead to visual material changes or material damage, such as, for example, corrosion, fractures or premature ageing.
Pre-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 automated 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	Instruments should be reprocessed 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 that were connected to each other during use must be disassembled into their original condition before cleaning.
Disassembly	See section 10) <i>Disassembly</i>



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 may be 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 deionised water (see “General Information on Reprocessing”) and, if applicable, move movable parts back and forth.
Cleaning/ disinfection	If possible, preference should be given to a washer/disinfector which uses thermal disinfection, in accordance with DIN EN ISO 15883.
Cleaning: automated	Avoid overfilling instrument trays and washing trays - use only suitable instrument holders. When placing instruments in the sterilisation 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 so that the joints are opened or disassembled if possible, and the water can flow from the cavities and blind holes. • If applicable, loosen springs. • Ensure that the area inside all the 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 washer/disinfector. <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 deionised water (< 30 °C) • Emptying • Thermodisinfection for 5 minutes with deionised 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 contamination is no longer visible. • Rinse the instruments for at least 20 seconds using 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 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). • Deionised water (< 40 °C) is to be used for the final rinse. The instruments are rinsed for at least 30 seconds with deionised water. Ensure that no residues remain on the products.



Disinfection: manually	Consult the instructions on the label when selecting a disinfectant (see chemical manufacturer's 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 deionised 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 section 9) <i>Assembly</i>
Maintenance, inspection and testing	For instruments with movable components that are exposed to friction (e.g. joints), apply a biocompatible, steam sterilisable, steam-permeable paraffin-/white oil-based instrument oil (according to the valid European or United States Pharmacopoeias) before sterilisation. 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 impair the effectiveness of steam sterilisation. 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 looseness). Check locking mechanisms, if applicable. All instruments: Visually inspect the instruments for damage and wear using a magnifying lamp. 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 authorised by the manufacturer. A confirmation 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	Individually: in accordance with the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Sets: Sort instruments into dedicated trays or place them in general-purpose sterilisation trays. Pack the trays appropriately using a suitable procedure.
Sterilisation	Steam sterilisation using a fractionated vacuum process in a steriliser complying with DIN EN 285 and DIN EN ISO 17665. 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 Sterilisation temperature: 132 – 134 °C Holding time: 4 – 5 minutes Drying time: 20 minutes When sterilising more than one instrument in a sterilisation cycle, do not exceed the maximum load of the steriliser (see manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, 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 loss of 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. They must be cleaned prior to disposal. They can be disposed of 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 result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the provided instructions should be carefully evaluated for efficacy 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 shows a configuration example for the POLYTEL Retractor System.

The POLYTEL Retractor System consists of a fixed retractor arm (a), a toothed rack (b), and a movable retractor arm with a wing screw and locking lever (c).

Blade guides (d) can be attached to the retractor arms (a, c) using a fixation carriage (e). The blades are attached to the distal end of the blade guide. In the example shown here, two rotatable parafascial blades (f) and one rigid parafascial blade (g) are used.

The POLYTEL Retractor System is specifically intended to expose the entire spine from C1 to S1 via a posterior approach.

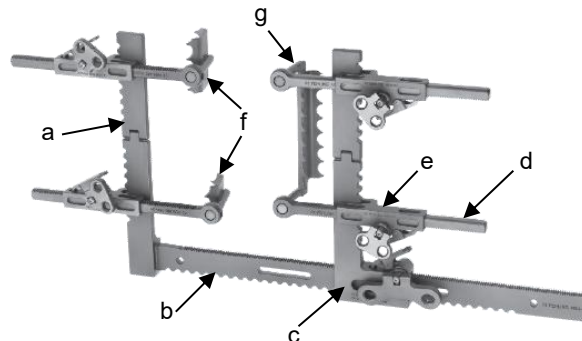


Fig. 1: Example configuration for the POLYTEL Retractor System



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

Figure 2 shows an example of a longitudinal ATLAS Retractor, which consists of a single piece and therefore does not require assembly. The respective blades are attached to the distal end of the longitudinal ATLAS Retractor (a).

Figure 3 shows an example configuration of an ATLAS side-load retractor system.

The 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 the example shown. A transverse ATLAS side-load retractor (c) is positioned on top of the longitudinal ATLAS side-load retractor. Here, too, the blades are attached to the distal end of the transverse ATLAS side-load retractor. Serrated ATLAS side-load blades (d) are used in the example shown here.

This combination has the advantage of allowing retraction in two dimensions.

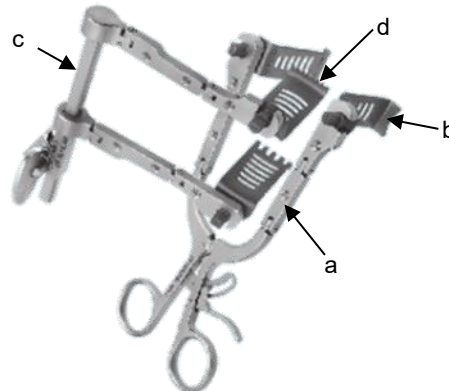


Fig. 3: Example configuration for an ATLAS Side-Load Retractor System

Both ATLAS frames accommodate all rotatable POLYTEL blades as well as the ATLAS blades. The ATLAS Retractor System is primarily used to expose the cervical spine via an anterior approach. However, it is also suitable for smaller posterior approaches throughout the spine, particularly in paediatric, thin 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 with either the POLYTEL or the ATLAS retractor. Only side-load blades can be fitted to this specific handle.
	Use only intact and sterilised products!
	Before inserting the POLYTEL/ATLAS Modular Universal Retractor System, ensure that the surgical site has been prepared accordingly beforehand.
	Before using the POLYTEL/ATLAS Modular Universal Retractor System, ensure that it is fully functional and not damaged!
	Medical devices made of ferromagnetic materials must not be exposed to magnetic fields or external electromagnetic interference.
	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 and the field of application. Care must be taken to ensure that the components used have the correct size and geometry, as well as sufficient stability.

8) Required accessories

No accessories are required for the use of the POLYTEL/ATLAS Modular Universal Retractor System. However, the optional NGM-6 blade-changing forceps may be used to remove or change blades.

A POLYTEL sterilisation and storage container can be used for sterilisation and storage.

9) Assembly

- Please follow the instructions below when assembling the transverse POLYTEL/ATLAS Modular Universal Retractor System.

Retractor frame NSA-1V

Position the two components of the instrument as shown in Figure 5.

Push the toothed rack (a), together with the fixed retractor arm (b), through the housing of the movable retractor arm (c). While sliding the components together, apply finger pressure to release the locking lever (d). The large wing screw (e) rotates automatically during this sliding movement. The wing screw should remain upright; otherwise, when folded down, it could come into contact with the fingers and impede the sliding movement.

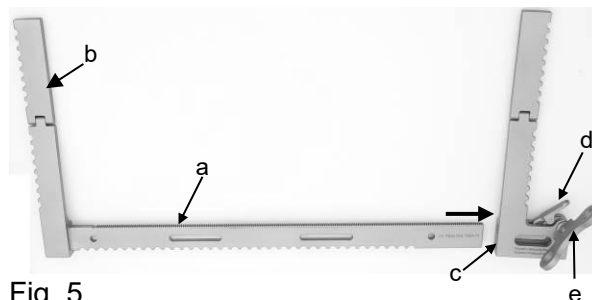


Fig. 5



As shown in Figure 6, the retractor arms should not be positioned too far apart before use, so that the retractor frame can subsequently be opened further. To open the retractor frame, turn the upright wing screw (e) clockwise (shown folded down in the Figure).

After performing a functional test, the assembled instrument is ready for use again.

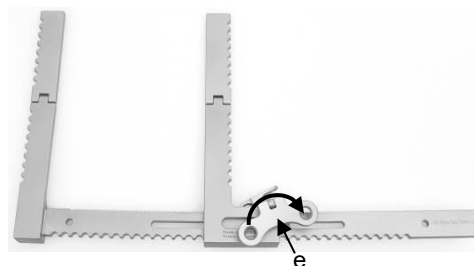


Fig. 6

Retaining unit (fixation carriage and blade guide)

Both the blade guide (a) and the fixation carriage (b) have a side marked with "arrow" and "UP". Before inserting the blade guide (a) into the fixation carriage (b), ensure that both marked sides face upwards. Insert the blade guide (a) into the fixation carriage (b) in the direction indicated by the arrow (Fig. 7). The arrow on the fixation carriage (b) refers exclusively to the insertion of the blade guide (a) and not to attachment of the retractor frame.

Push the blade guide (a) through the opening in the fixation carriage (b) until the locking lever (c) engages with the toothed rack of the blade guide (a). During insertion, press down the locking lever (c) to release it.

Turn the upright wing screw (d) clockwise to tighten the blade guide (a) in a controlled manner.

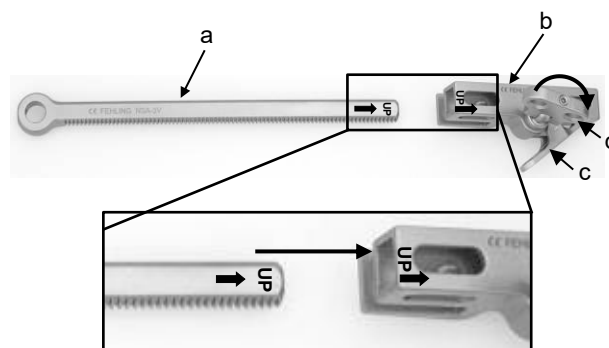


Fig. 7

As shown in Figure 8, insert the blade guide (a) no more than halfway into the fixation carriage (b) before use. Only then can the retaining unit fitted to the retractor frame be tensioned further at a later stage.

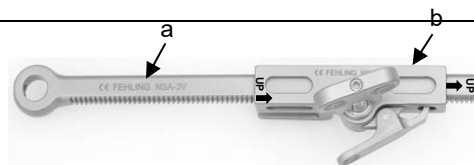


Fig. 8

Insert the three connecting pins of the blades (e) from below into the blade sockets of the blade guide (f). Despite being securely fixed, the blades remain rotatable, allowing the retractor to assume a stable, biomechanically optimised position under asymmetrical loading. This largely prevents displacement.

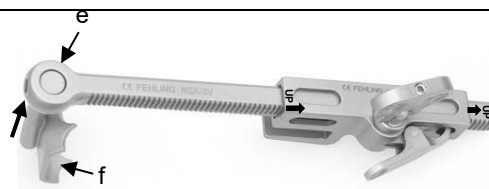


Fig. 9



The retaining units assembled as shown by way of example in Figure 9 can now be inserted into the wound as with Langenbeck retractors and mounted at any desired position on the profiled sections of the retractor frame.

Figure 10 shows an example configuration comprising the assembled individual components described above.

Depending on the requirements, either the individual retaining units or the entire retractor frame can be spread using the wing screws. Once the desired configuration has been achieved, it is advisable to fold down the wing screws to optimise the available space.

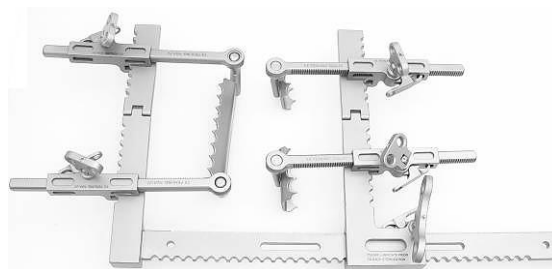


Fig. 10

ATLAS Retractor

Figure 11 shows an example of a transverse ATLAS frame.

The transverse ATLAS frame is assembled in the same manner as the POLYTEL retractor: the movable retractor arm (a) is slid onto the toothed rack (b) with the fixed retractor arm (c).

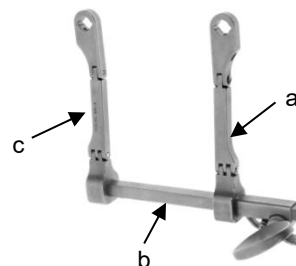


Fig. 11



Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.

10) Disassembly

For reprocessing, the transverse POLYTEL/ATLAS Modular Universal Retractor System must be disassembled as follows.

To disassemble the retaining unit, please follow the corresponding assembly instructions (see 9) Assembly).

Figure 12 shows a transverse POLYTEL/ATLAS Modular Universal Retractor System to illustrate disassembly.

Slide the movable retractor arm (a) outwards along the toothed rack (b) until it can be removed. At the same time, release the lock (c) by pressing it in the direction of the toothed rack (b).

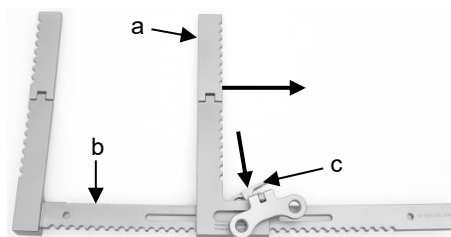


Fig. 12

The instrument, now disassembled into its individual components (Fig. 13), can be reprocessed.



Fig. 13



Place small parts in suitable containers (e.g., needle box) for storage 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 either 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

Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:

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

Manufacturer's contact information

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