



FEHLING RAABE Titanium Hemilaminectomy Retractor

Retractor frame NWA-1A

RAABE Titanium Hemilaminectomy Retractor, frame only

Components

Fixations/guides

NWA-1B..... Fixation carriage for spinal retractor

NWA-1C Blade guide for spinal retractor

RAABE titanium cranial-caudal fixation pins

NWA-2 35 mm

NWA-3 45 mm

NWA-4 55 mm

RAABE titanium cross-over muscle blades 120°

NWC-1R 50 x 20 mm, rotatable

NWC-2R 65 x 20 mm, rotatable

NWC-3R 80 x 20 mm, rotatable

NWC-4R 95 x 20 mm, rotatable

NWC-1 50 x 20 mm

NWC-2 65 x 20 mm

NWC-3 80 x 20 mm

NWC-4 95 x 20 mm

RAABE titanium muscle blades 90°

NWB-2R 65 x 15 mm, rotatable

NWB-3R 80 x 15 mm, rotatable

NWB-1 50 x 15 mm

NWB-2 65 x 15 mm

NWB-3 80 x 15 mm

NWB-4 95 x 15 mm

NWB-5 50 x 30 mm

NWB-6 65 x 30 mm

NWB-7 80 x 30 mm

NWB-8 95 x 30 mm

Accessories

NWA-0 AVR sterilisation and storage container 400 x 260 x 50 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 RAABE Titanium Hemilaminectomy Retractor may only be used, reprocessed and disposed of by qualified medical personnel!

The RAABE Titanium Hemilaminectomy Retractor 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.
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5) Before use

The RAABE Titanium Hemilaminectomy Retractor 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) <i>Reprocessing</i> under "Maintenance, Inspection and Testing").
	The RAABE Titanium Hemilaminectomy Retractor must be handled with care during storage, transportation and cleaning! Avoid impacts and point loading on the FEHLING RAABE Titanium Hemilaminectomy Retractor 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!
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 instruments with tips or sharp edges in particular, safe storage in a closed, puncture and break-proof disposable container must be ensured. Do not use damaged instruments.
Packaging	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

The RAABE Titanium Hemilaminectomy Retractor is a U-shaped bar retractor with an additional centre arm. The movable retractor arm and the centre arm can move freely along the toothed rack. Retracting elements in the form of hooks and flat blades of various sizes can be inserted at the distal ends of both retractor arms and the centre arm.



The movable retractor arm can be adjusted in the cranial-caudal direction by means of a pinion mechanism. The centre arm can be mounted at any position on the toothed rack. The retaining element mounted on the centre arm can be moved laterally by means of a pinion mechanism.

Figure 1 shows an example configuration of the RAABE Titanium Hemilaminectomy Retractor. The corresponding components are listed in Table 1.

The RAABE Titanium Hemilaminectomy Retractor is intended in particular for exposure of the surgical field during unilateral approaches to the spine involving no more than three segments.

Table 1: List of the corresponding components

	Item no.	Description
1	NWA-1A	Hemilaminectomy retractor, frame only
2	NWA-1B	Fixation carriage
3	NWA-1C	Blade guide
4	NWA-2/3/4	Cranial-caudal fixation pins
5	NWB-1/2/3/4	Muscle blade 90°, 15 mm wide
	NWB-5/6/7/8	Muscle blade 90°, 30 mm wide
6	NWC-1/2/3/4	Cross-over muscle blade 120°, 20 mm wide

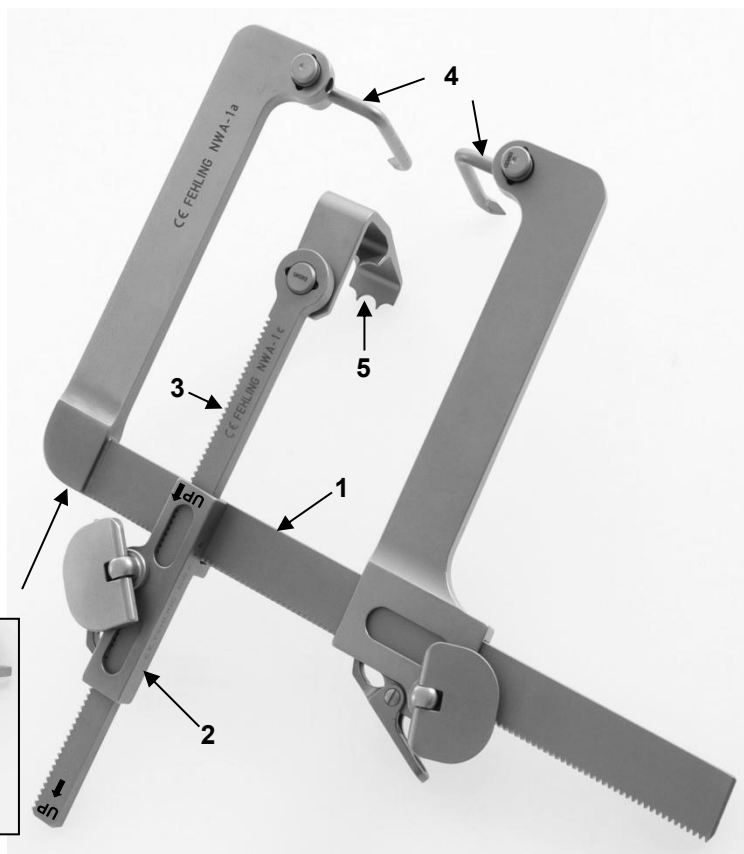


Fig. 1: Example configuration of the RAABE Hemilaminectomy Retractor

The RAABE Titanium Hemilaminectomy Retractor is made entirely of titanium. This allows intraoperative imaging to be performed with the locking lever in place. The titanium elements are visible only as grey shadows, but do not cause artefacts.

The advantages of the RAABE Titanium Hemilaminectomy Retractor are as follows:

- Unlike retractors intended for the same purpose, the RAABE Titanium Hemilaminectomy Retractor offers largely unobstructed access to the surgical field, especially to medial structures that are often concealed by conventional retractors. This is achieved by the arrangement of the retracting elements, particularly the angularly stable soft-tissue hooks, which act in the cranial-caudal direction.
- For unilateral surgical fields, muscle blades available in two widths and four depths reliably keep the surgical-field open at the required width, even during lengthy procedures.
- Obliquely positioned muscle blades permit crossover procedures through a unilateral approach.



Use only intact and sterilised products!



	Before inserting the RAABE Titanium Hemilaminectomy Retractor, ensure that the surgical field has been prepared accordingly beforehand.
	Before using the RAABE Titanium Hemilaminectomy Retractor, ensure that its functionality is not impaired and that there is no damage!
	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.
During application	
Turn the semicircular carriage toggle lever clockwise until the required exposure of the surgical field has been achieved. Options: - For unilateral procedures, use 90° muscle blades of the required depth. - For crossover procedures, use crossover muscle blades of the required depth. The tissue edge is displaced obliquely in a lateral direction, thereby allowing access to the opposite side of the spine.	
	Before removing the retractor from the surgical field, ensure that the retractor arms are slowly pushed back together.

8) Required accessories

No accessories are required for the use of the RAABE Titanium Hemilaminectomy Retractor. However, the optional NGM-6 blade-changing forceps may be used to remove or change blades.

A RAABE sterilisation and storage container (Fig. 2) can be used for sterilisation and storage.



Fig. 2: RAABE sterilisation and storage container – NWA-0

9) Assembly

Please follow the assembly instructions below to assemble the RAABE Titanium Hemilaminectomy Retractor.

	Figures 3 – 5 are for illustrative purposes only and do not correspond to the FEHLING RAABE Titanium Hemilaminectomy Retractor, as the wing of the wing screw does not have a recess. However, the functional principle is the same.
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Figure 3 shows an example of a U-shaped bar retractor with a gear wheel and locking lever. The bar retractor consists of a fixed retractor arm (a), a toothed rack (b) and a movable retractor arm (c).

At the proximal end of the movable retractor arm is the housing (d), which contains the wing screw (e), gear wheel and locking lever (f).

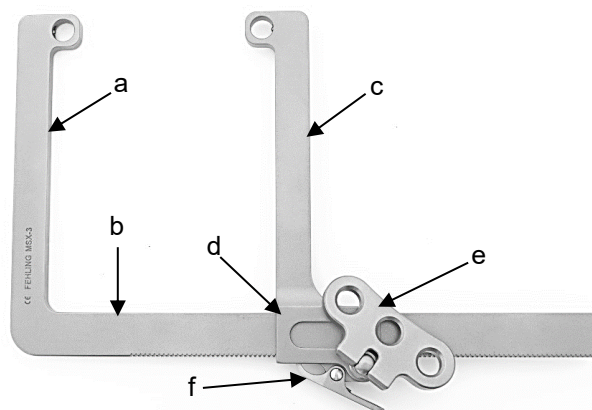


Fig. 3: Example of a U-shaped bar retractor with gear wheel/locking lever

Insert the toothed rack (b) into the recess in the housing (d). At the same time, release the lock (f) by pressing it in the direction of the toothed rack (b) (Fig. 4).

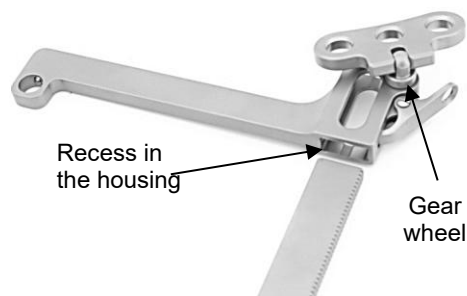


Fig. 4



Ensure that both retractor arms point in the same direction and that the gear wheel on the movable retractor arm faces outwards.

Slide the movable retractor arm (c) inwards along the toothed rack (b) towards the fixed retractor arm (a) (Fig. 5).

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

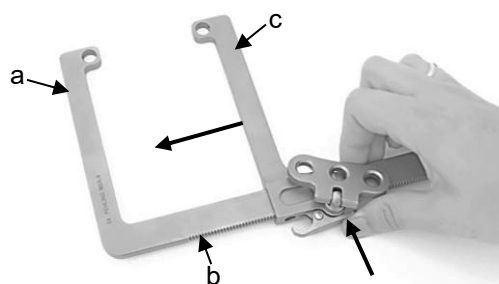


Fig. 5

Select the length of the cranial-caudal fixation pins (4, see Table 1) according to the patient's specific anatomy and insert the pins into the receptacles provided at the distal ends of the retractor arms. The tip of the pin on the cranial retractor arm must point cranially, and the tip of the pin on the caudal retractor arm must point caudally. The pins are fixed in the receptacles in an angularly stable manner.

Then bring the two retractor arms together enough to allow them to be inserted easily into the tissue incision. Then spread the two retractor arms just far enough for the pin tips to engage the tissue cranially and caudally.

Important: The cranial-caudal fixation pins must not spread the wound edges under tension, as the traction exerted by the muscle blade could otherwise overstretch them.



Next, insert the blade guide (a) for the muscle blade into the fixation carriage (b) (see Fig. 6).

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. 6). 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.

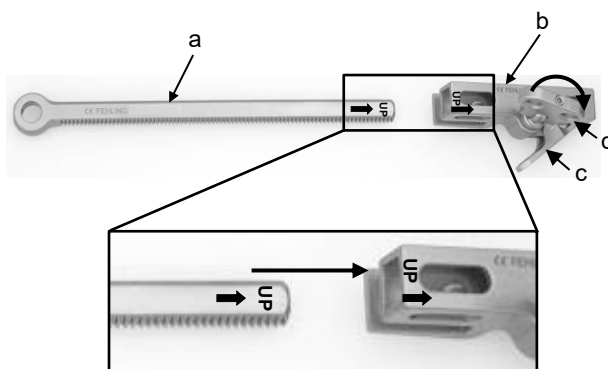


Fig. 6

Important: Align the fixation carriage (b) so that its U-shaped profile is open towards the spine (Fig. 7).

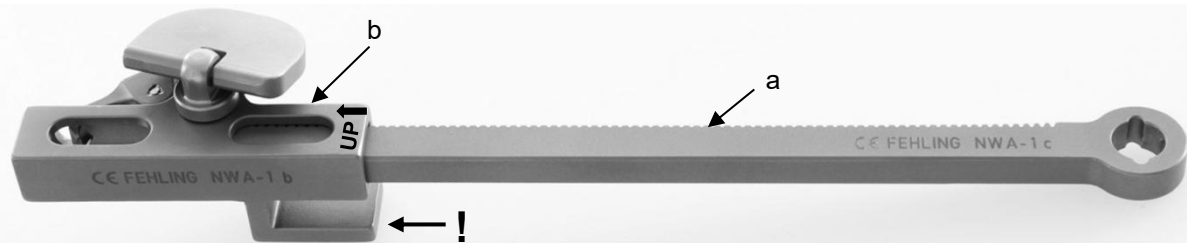


Fig. 7

The blade guide (a) should protrude as far as possible from the fixation carriage (b) (see Fig. 8).

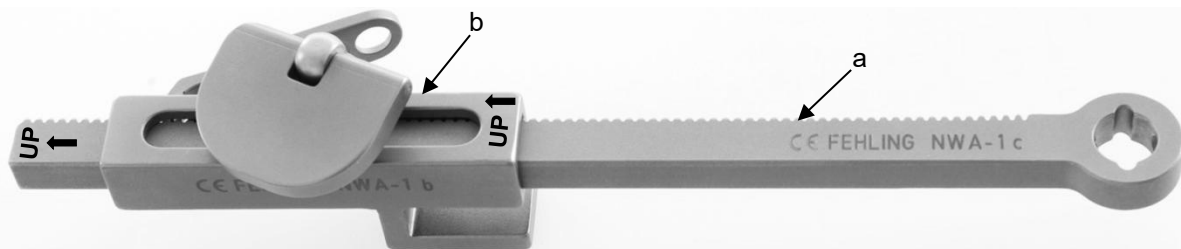


Fig. 8



Next, select the optimal muscle blade (e) (5/6, see Table 1) for the patient-specific application and insert it into the angularly stable blade guide (a). Align the tissue claws of the muscle blade laterally (see Fig. 9).

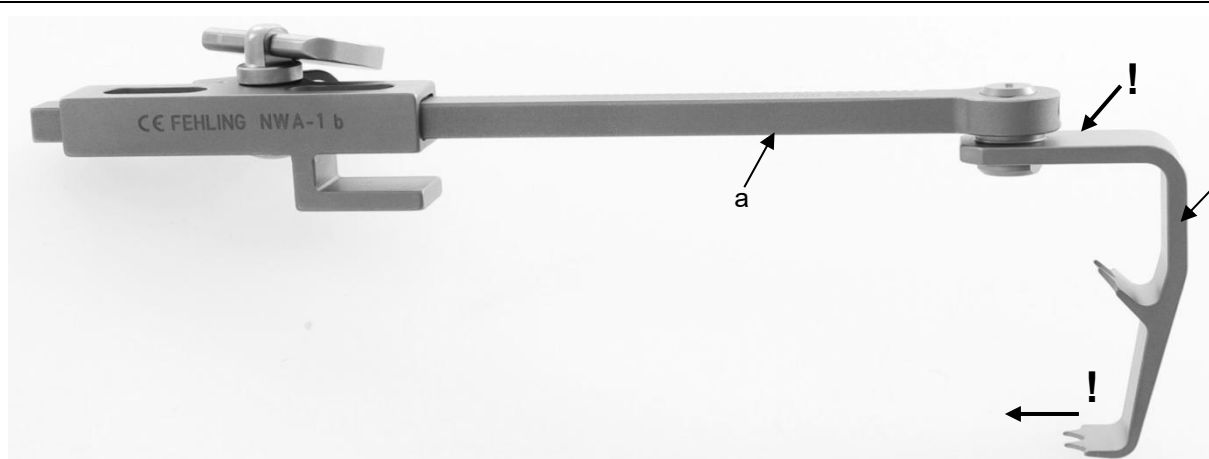


Fig. 9

Insert the muscle blade (e) into the incision. Then move the entire centre arm together with the muscle laterally and guide the U-shaped profile of the fixation carriage (b) over the toothed rack (f) from the lateral side (see Fig. 10).

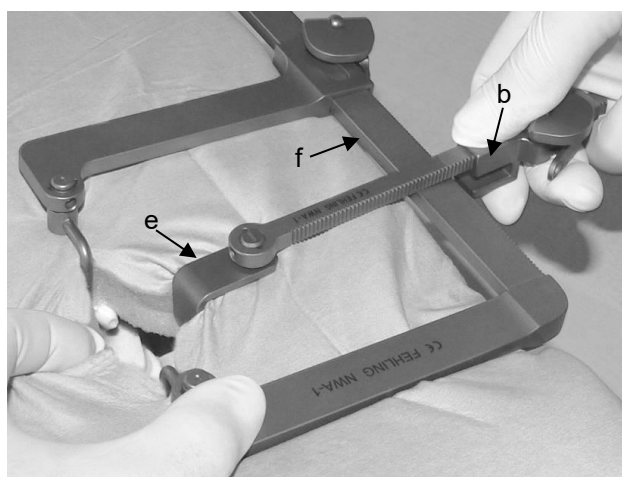


Fig. 10

10) Disassembly

For reprocessing, the RAABE Titanium Hemilaminectomy Retractor must be disassembled as follows.

To disassemble the centre arm, please follow the corresponding assembly instructions (see Section 9) Assembly).



Figures 11 and 12 are examples only and do not depict the RAABE Titanium Hemilaminectomy Retractor, as the wing of its wing screw has no recess. However, the functional principle is the same.



Figure 11 shows an example of a U-shaped bar retractor with a gear wheel and locking lever to illustrate the disassembly procedure. Slide the movable retractor arm (c) outwards along the toothed rack (b) until it can be removed. At the same time, release the lock (f) by pressing it in the direction of the toothed rack (b).

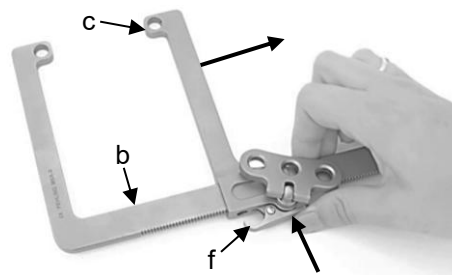


Fig. 11: Example of a U-shaped bar retractor with gear wheel/locking lever

The instrument, now disassembled into its individual components (Fig. 12), can be reprocessed.



Fig. 12



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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