FEHLING Treede Maxposition Blade
MMZ-7 ..... Treede Maxposition Blade 44 x 40 mm, Ø 60 MMZ-8 ..... Treede Maxposition Blade 44 x 30 mm, Ø 40
Accessories LMT-4 ..... Cardan screwdriver (optional) LMT-4L ..... Cardan screwdriver Size 4 mm, 290 mm (optional) LMT-4T ..... Cardan screwdriver Torx T15, 290 mm (optional) MRN-3 ..... Transthoracic atrial retractor - blade guide, 220 mm MRU-9 ..... Guiding clamp for atrial blade and retainer (optional)

⚠	This instrument or medical device is supplied non-sterile. It must be reprocessed before use. Before reprocessing, the instrument must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C). The Treede Maxposition Blade may only be used, processed and disposed of by qualified medical personnel! The Treede Maxposition Blade is intended for reuse.

1) Intended purpose

Retractors and retractor components, which are used surgically invasively and for short periods of time, are used to spread various tissue structures, such as skin, bones, muscles and organs.

Supplementary information on the intended purpose

Duration of use: The retractor or the retractor component is intended for short-term use.

Field of application: Retractors and retractor components are used for all patients where tissue has to be retracted for a short time (max. 24 hours) to improve visibility of the underlying tissue for the surgeon.

User profile: Retractors and retractor components may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: Retractors and retractor components are only used under controlled environmental conditions (e.g. OR).

2) Indications

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

3) Contraindication

All applications that run counter to the physical and/or mechanical properties of the individual retractor model are contraindicated. There are no general contraindications for the use of retractors.
Nevertheless, attention must be paid to increased risks that could result from the anatomical and physiological conditions and the patient's clinical picture.

4) Possible side effects	
The following side effects are described in the medical literature, which may also occur during the intended use of retractors: - Infections - Wound healing disorders - Lesions of structures (tissue, nerves, vessels) - Necrosis - Ischemia	
⚠	Medical devices may contain PEEK, chromium and nickel, for example. The materials used are biocompatible, but they can trigger allergic reactions or intolerances.

5) Prior to use	
FEHLING INSTRUMENTS Treede Maxposition Blade is supplied non-sterile and must be cleaned and sterilized by the user before first use and before each subsequent use (see section *6) Reprocessing*).	
⚠	A safety check must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components (see section *6) Reprocessing* under "*Maintenance, inspection and testing*").
⚠	Handle the Treede Maxposition Blade with care during storage, transportation and cleaning! Avoid impacts and point loads on the Treede Maxposition Blade to prevent possible consequential damage! Do not overload functional parts!
⚠	Only use flawless and sterilized products!

6) Reprocessing	
⚠	The medical device must be reprocessed before use. Before reprocessing, it must be risk-assessed in accordance with the RKI guidelines (non-critical/semi-critical/critical A/B/C).
⚠	The national legal regulations, national and international standards and guidelines as well as the company's own hygiene regulations for reprocessing must be complied with.
⚠	The applicable national regulations must be observed 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, transportation and cleaning! Avoid impacts and punctual loads on instruments to prevent possible consequential damage! Do not overload functional parts!
⚠	Do not clean instruments with plastic components using oxidative processes (processes with hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario from Miele). These processes lead to oxidative ageing of the material, which may not be recognizable by visible discoloration or embrittlement.
Limitations during reprocessing	Frequent reprocessing has little effect on these instruments. The end of the product's service life is normally determined by wear and damage caused by use (e.g. damage, illegible labeling, functional failure - see also "*Maintenance, inspection and testing*").

General information on reprocessing	Reprocessing is based on a validated procedure. All cleaning steps mentioned (manual pre-cleaning, automated/manual cleaning, manual disinfection and sterilization) were validated with the 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 drinking water quality and fully demineralized water (demineralized, microbiologically at least drinking water quality) are used for cleaning. Mechanical reprocessing is preferable to manual cleaning due to better and safer cleaning results. It is also possible to clean our instruments with other tested and approved chemicals that have been recommended by the chemical manufacturer with regard to their material compatibility. Please always observe the manufacturer's instructions regarding concentration, exposure time, temperature and renewal of the cleaning and disinfecting agents. All application instructions of the chemical manufacturer must be strictly adhered to. Failure to do so may result in visual material changes or material damage, such as corrosion, breakage or premature ageing.
Pre-treatment at the point of use	Pre-cleaning: Care must be taken to ensure that blood, tissue and drug residues are removed from the instruments with a disposable cloth/paper towel immediately after completion of the procedure and that they are immediately sent for automated cleaning. Once the pre-treatment of the instruments has been completed, visual checks must be carried out to ensure that the instruments are complete. The instruments must be transported from the place of use to the place of reprocessing in such a way that neither users, third parties, the environment nor the medical devices are endangered or damaged (placement in closed, puncture-proof containers and - if necessary - use of protective caps).
Preparation prior to cleaning	It is recommended to reprocess the instruments immediately after use, as dried residues in hard-to-reach areas are difficult to remove. Do not place in NaCl solutions (otherwise there is a risk of pitting or stress corrosion cracking). Instruments that have been joined together during use must be disassembled back to their original state before cleaning.
Disassembly	See section *10) Disassembly*
Manual Pre-cleaning	<u>Validated procedure:</u> Equipment: Basin soft brush Water pressure gun (or similar) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Procedure/Parameters:</u> • If possible, rinse instruments under cold running water (drinking water quality, <40°C) when disassembled until all visible dirt has been removed. Stubborn dirt should be removed with a soft brush (not a wire brush!). • Cavities, gaps, slits and lumens must be rinsed intensively (>10 seconds) with cold water (drinking water quality, <40°C) using a water pressure gun (or similar). • Soak the products for 10 - 30 minutes in a solution containing 0.5 - 2 % Neodisher® MediClean forte with water (drinking water quality, <40°C). • Only use an approved solution of a cleaning agent that does not have a protein-fixing effect. The instructions of the cleaning agent and disinfectant manufacturer must be followed. • Ensure that all areas of the instrument come into contact with the solution. • If necessary, moving parts on the instrument are moved back and forth in the cleaning bath.

	• During the exposure time, remove coarse soiling with a suitable brush (not a wire brush!). • Rinse the instruments for 1 minute under cold demineralized water (see "*General information on reprocessing*") and move any moving parts on the instrument back and forth.
Cleaning/ Disinfection	If possible, a washer-disinfector in accordance with DIN EN ISO 15883 that uses thermal disinfection is preferable.
Cleaning: Mechanical	Avoid overfilling instrument trays and wash trays - only use suitable instrument holders. Take particular care to ensure that the tips do not get stuck in the grid when inserting and removing the instruments in/from the sieve baskets. <u>Validated procedure:</u> Equipment: Cleaning and disinfection machine G 7835 CD (Miele) / PG 8535 (Miele) Cleaning program: Des-Var-TD (G 7835 CD) Detergent: Neodisher® MediClean forte (Dr. Weigert) <u>Preparation:</u> • Articulated instruments must be inserted into the appliance in such a way that the joints are open or disassembled, if possible, and the water can drain out of cavities and blind holes. • If necessary, relax the springs • Ensure that all cavities are also completely flushed on the inside. • Make sure that no rinsing shadows are created. • Connect the Luer connections of the instruments, if available, to the Luer lock irrigation attachment of the washer-disinfector. <u>Procedure/Parameters:</u> • 3 minutes pre-rinse with cold water (drinking water quality, <40°C) • Emptying • 10 minutes cleaning with a solution of 0.5 - 2 % Neodisher® MediClean forte in water (drinking water quality) at 55°C • Emptying • 2 minutes rinsing with water (drinking water quality, <40°C) • Emptying • 1 minute rinse with cold demineralized water (<30°C) • Emptying • 5 minutes thermal disinfection with demineralized water (>90°C) • Dry for 30 minutes (90°C) After machine cleaning, check cavities, blind holes etc. in particular for visible dirt. If necessary, repeat the cycle or clean manually.
Cleaning: Manual	<u>Validated procedure:</u> Equipment: Basin soft brush Water pressure gun (or similar) Bandelin Sonorex Digitec Detergent: Neodisher® MediClean forte (Dr. Weigert)

	Procedure/Parameters: • If possible, place instruments in cold water (drinking water quality, <40°C) for 10 minutes when disassembled. • Operate moving parts, if present, over the entire range of movement. • Clean the instruments with a soft brush (not a wire brush!) until there is no visible contamination. • Rinse the instruments for at least 20 seconds using a water pressure gun (or similar). Ultrasonic cleaning: • 10 minutes sonication at <40°C with 0.5 - 2 % detergent solution at 35 kHz • After sonication, rinse the instruments for at least 20 seconds using a water pressure gun (or similar). • Rinse the instruments with water (drinking water quality, <40°C) for at least 10 seconds. • Deionized water (<40°C) should be used for the final rinse. The instruments are rinsed with deionized water for at least 30 seconds. It must be ensured that no residues remain on the products.
Disinfection: Manual	Disinfectant solutions can be used in accordance with the instructions on the label (see chemical manufacturer's instructions). 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 (e.g. 0.5% Korsolex® med AF) for 5 minutes. Ensure that all surfaces are wetted with the disinfectant. If necessary, move moving parts in the disinfection bath before switching on the ultrasonic device. • After disinfection, rinse all products thoroughly with deionized water (<40°C) for at least 1 minute to remove the disinfectant and, if necessary, move moving parts back and forth on the instrument. • It must be ensured that no residues remain on the products. • Drying with sterile, oil-free compressed air.
Drying	If drying is achieved as part of the cleaning/disinfection cycle, 120°C should not be exceeded. Then dry with suitable compressed air in accordance with the RKI recommendation. Pay particular attention to drying areas that are difficult to access.
Assembly	See section *9) Assembly*
Maintenance, inspection and testing	For instruments with moving components that are exposed to friction (e.g. joints), a paraffin/white oil-based instrument oil (in accordance with the applicable European or United States Pharmacopoeia) that is biocompatible, steam-sterilizable and steam-permeable must be applied before sterilization. Such areas may also be marked with an appropriate oil can symbol. Instruments must not be treated with silicone-based care products. These can lead to stiffness and compromise the effectiveness of steam sterilization. A safety check of the instruments must be carried out before each use. Check for sharp edges, cracks, fractures, mechanical malfunctions and missing components. Check instruments with moving parts for ease of movement (avoid excessive play). Check locking mechanisms.

	All instruments: Perform a visual inspection with a magnifying lamp for damage and wear. Pay particular attention to critical points on moving parts and in the work area. Defective or damaged instruments or instruments 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 workshops authorized by the manufacturer. A confirmation form for this procedure is available from the manufacturer. Instruments that can no longer be repaired must be disposed of in the standard hospital scrap metal disposal system. Surgical instruments with points or sharp edges in particular must be stored safely in a closed, puncture and break-proof disposable container. Do not use damaged instruments!
Packaging	Individually: in accordance with standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Sets: Sort instruments into trays provided for this purpose or place them on all-purpose sterilization trays. A suitable procedure must be used to pack the trays.
Sterilization	Steam sterilization in a fractionated vacuum process in an appliance in accordance with DIN EN 285 and DIN EN ISO 17665 (parts 1 and 2). To avoid staining and corrosion, the steam must be free of ingredients. The recommended content limits for feed water and steam condensate are specified in 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 several instruments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see device manufacturer's instructions).
Storage	In accordance with § 4 MPBetreibV and standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series. Instruments must be stored dry, at room temperature, clean and protected from damage and mechanical influences (avoid condensation, damage). If applicable, always store instruments in a relaxed state. This counteracts premature fatigue of the spring tension. Instruments must be transported to the place of use in a closed, puncture-proof sterile container.
Waste disposal	These products are mainly made of steel. They must be cleaned before disposal. They can be disposed of at a scrap metal recycling center. To protect employees, care must be taken to protect any spikes and sharp edges.
The instructions listed above have been validated by the medical device manufacturer as suitable for preparing a medical device for reuse. The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Similarly, any deviation from the instructions provided should be carefully evaluated by the reprocessor for effectiveness and potential adverse consequences.	

⚠	Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.

7) Configuration and application

The size-adjustable Treede Maxposition Blade (Fig. 1a) consists of three elements of different sizes: base element (1), primary element (2) and secondary element (3) (Fig. 1b). One element consists of a box module (4) and fan blades (5) (Fig. 1a).

Using a suitable screwdriver, e.g. the Torx LMT-4T cardan screwdriver (see section *8) Required accessories*), the fan blades are adjusted via the gear axis, which is located inside the box module (4), and the desired spreading width can be set.

The primary and secondary elements are marked in gold at the ends of the fan blades (see Fig. 1b). This provides better orientation when extending the individual elements of the Treede Maxposition Blade.

With the MRN-3 blade guide (see section *8) Required accessories*), the angle of the Treede Maxposition Blade is infinitely adjustable and can be raised or lowered. To do this, the MRN-3 blade guide is screwed into the threaded joint (6). A guiding clamp, e.g. the guiding clamp for atrial blade and retainer MRU-9 (see section *8) Required accessories*), can be used for blade removal or blade insertion.

The Treede Maxposition Blade is used in particular for mitral valve surgery to provide better access and an optimal view of the operating field.

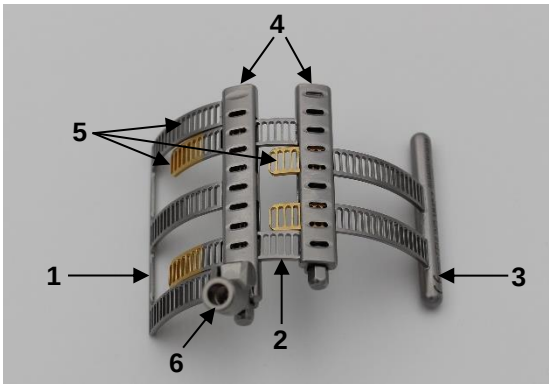


Fig. 1a: Treede Maxposition Blade

Base element (1) | Primary element (2) | Secondary element (3)

Fig. 1b: Treede Maxposition Blade in its individual elements

⚠	Only use flawless and sterilized products!
⚠	Before inserting the Treede Maxposition Blade, ensure that the surgical field has been prepared accordingly.
⚠	Before using the Treede Maxposition Blade, make sure that its functionality is not impaired and that there is no damage!
⚠	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.

During the application	
Before the Treede Maxposition Blade can be used, the surgical field must be prepared accordingly. This will not be discussed in detail below. The Treede Maxposition Blade must be inserted into the atrium when fully retracted.	
⚠	When inserting the Treede Maxposition Blade, make sure that no tissue structures are unintentionally injured (especially nerves and blood vessels)!
⚠	If the pressure on the tissue is too high and too long, necrosis and other lesions can occur!
⚠	Overloading can cause plastic deformation or breakage of the Treede Maxposition Blade!
⚠	Make sure that the appropriate screwdriver is always fully seated on the transport mechanism of the box module when extending or retracting the Treede Maxposition Blade.
⚠	Observe the order in which the primary and secondary elements are extended and retracted!
⚠	When setting the desired spread width of the Treede Maxposition Blade, make sure that the primary and secondary elements are only extended until the first two gold-colored slotted holes in the corresponding box module are fully visible. Once the required spread width of the Treede Maxposition Blade has been set for the operation, this spread width must not be adjusted during the procedure. Do not extend the primary and secondary elements to the end of the box module, as they could then fall out completely and possibly into the patient.

Extending the elements of the Treede Maxposition Blade

To set the desired spreading width of the elements, first extend the secondary element (3) using the appropriate screwdriver (7).

To do this, turn the transport mechanism on the box module of the primary element (4b) clockwise using a suitable screwdriver (7) (Fig. 2a) until the first two gold-colored slotted holes are extended from the box module of the primary element (4b), as shown in Figure 2b.

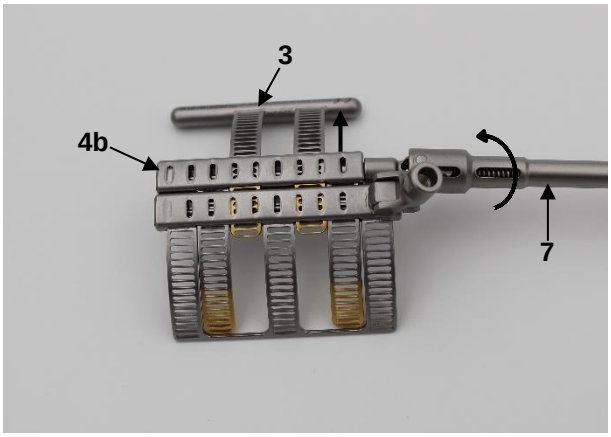


Fig. 2a

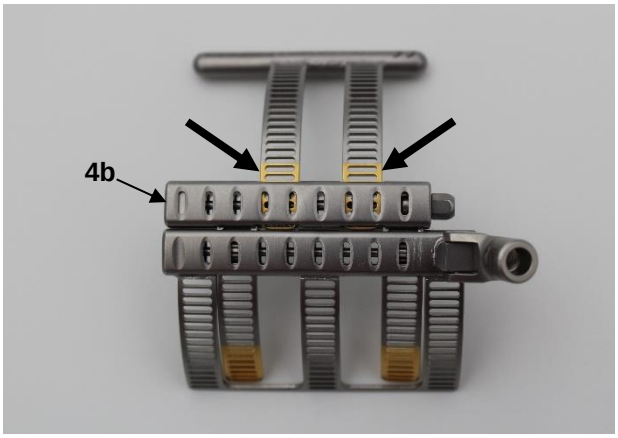


Fig. 2b

Then extend the primary element (2) using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the base element (4a) clockwise using a suitable screwdriver (7) (Fig. 3a). Only extend the primary element (2) until the first two gold-colored slotted holes can be seen from the box module (4a) (see Fig. 3b).

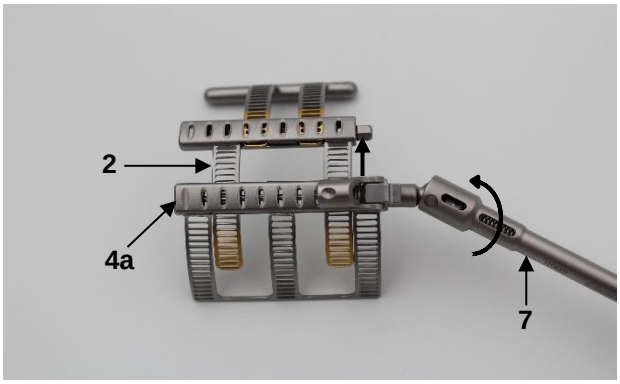


Fig. 3a

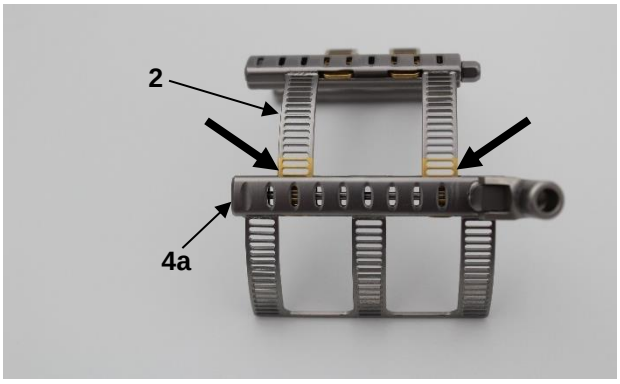


Fig. 3b

Retracting the elements of the Treede Maxposition Blade

⚠ Before removing the Treede Maxposition Blade from the operating field, the primary element (2) is always slowly retracted completely first, followed by the secondary element (3).

First fully retract the primary element (2) using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the base element (4a) counterclockwise using the screwdriver (7) (Fig. 4).

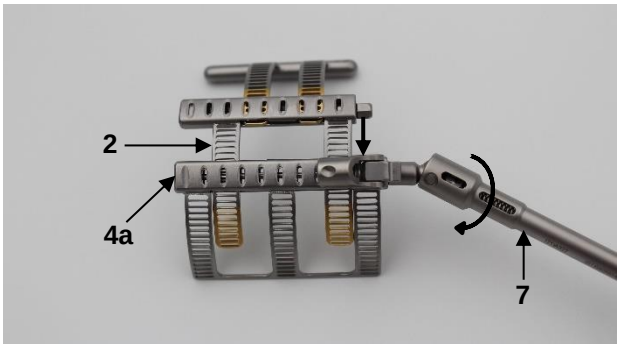


Fig. 4

Then retract the secondary element (3) using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the primary element (4b) counterclockwise using the screwdriver (7) (Fig. 5).

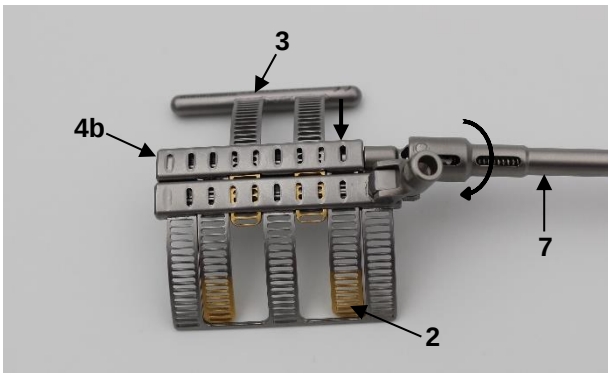


Fig. 5

If the order is not observed, the ends of the fan leaves of the secondary element can be pushed over the box module of the base element (4a) (Fig. 6, **B**) instead of into the box module (Fig. 6, **A**).

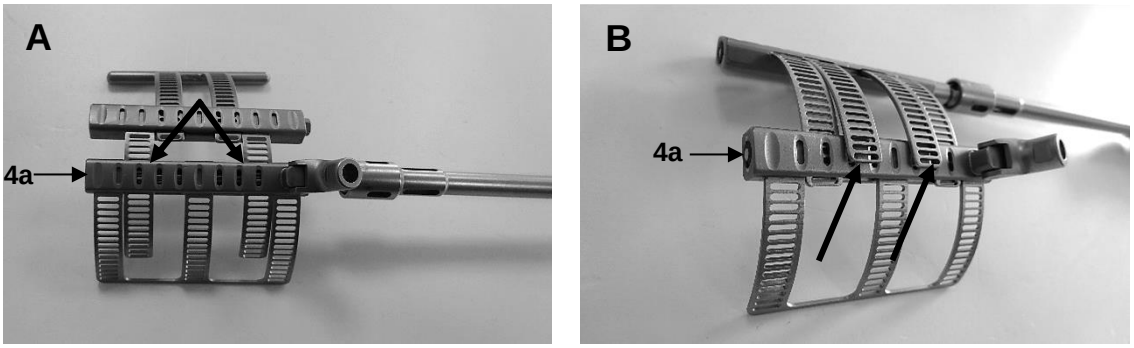


Fig. 6: Exemplary illustration of compliance with the sequence (**A**) and non-compliance with the sequence (**B**)

Application of the transthoracic atrial retractor - blade guide MRN-3

To raise or lower the Treede Maxposition Blade, the blade guide MRN-3 (8) must first be screwed clockwise into the thread of the joint (6) (Fig. 7).

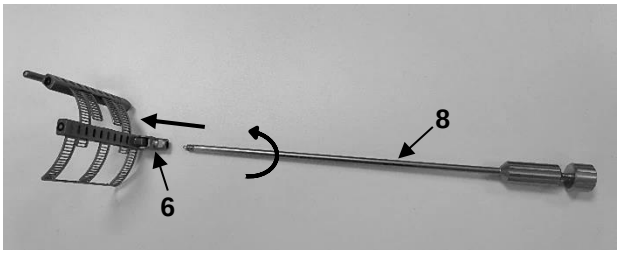


Fig. 7

The Treede Maxposition Blade can be raised or lowered using the blade guide (8) by turning the fixing nut (9) clockwise or anticlockwise (Fig. 8).

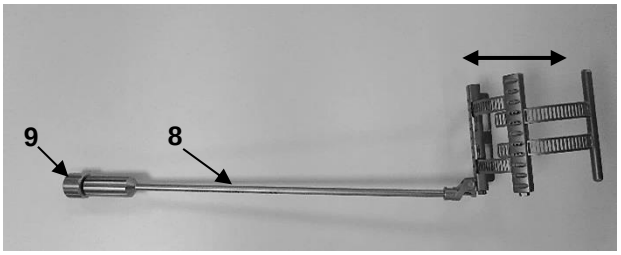


Fig. 8

To remove the blade guide MRN-3 (8), it must be unscrewed completely from the thread of the joint (6) in an anticlockwise direction (Fig. 9).

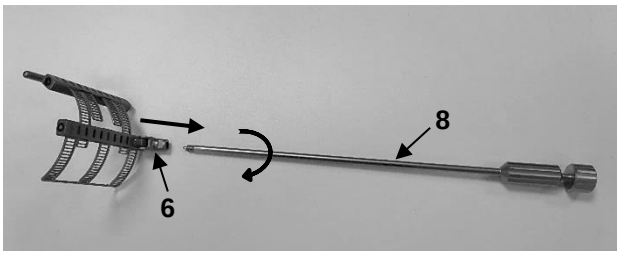


Fig. 9

Application of the guiding clamp for atrial blade and retainer MRU-9

The guiding clamp for atrial blade and retainer MRU-9 (10) can be used to insert or remove the Treede Maxposition Blade into the operating field. The Treede Maxposition Blade is held in the closed state on the threaded joint (6) using the guiding clamp (10) and can be inserted into or removed from the atrium.

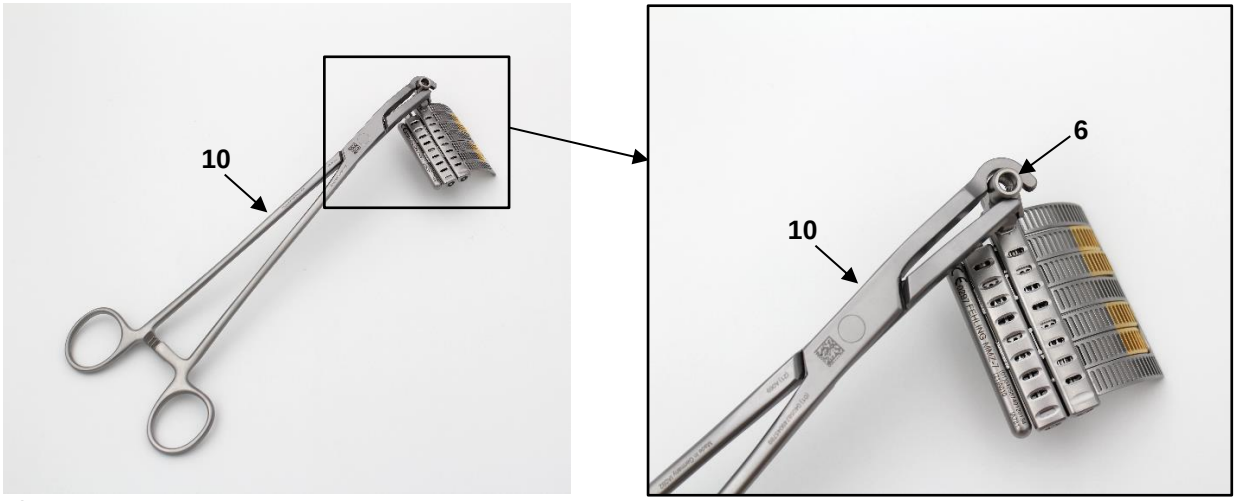


Fig. 10

8) Required accessories

A screwdriver, e.g. the LMT-4 (Fig. 11), LMT-4L (Fig. 12) or LMT-4T (Fig. 13) cardan screwdriver, is required to use the Treede Maxposition Blade. To raise or lower the Treede Maxposition Blade, the transthoracic atrial retractor blade guide MRN-3 (Fig. 14) is required. A guiding clamp, e.g. the guiding clamp for atrial blade and retainer MRU-9 (Fig. 15), can be used for blade removal or insertion.

Fig. 11: Cardan screwdriver LMT-4

Fig. 12: Cardan screwdriver LMT-4L

Fig. 13: Cardan screwdriver LMT-4T

Fig. 14: Transthoracic atrial retractor - blade guide MRN-3

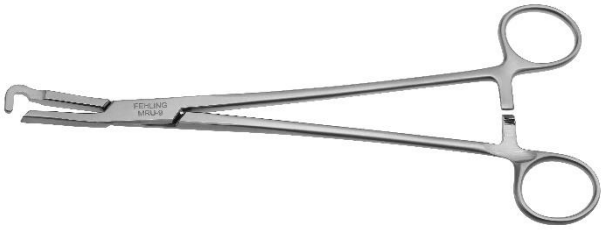


Fig. 15: Guiding clamp for atrial blade and retainer MRU-9

9) Assembly

For assembly and disassembly of the transthoracic atrial retractor blade guide, please follow the assembly instructions M36.

To install the Treede Maxposition Blade, please observe the following installation instructions.

Figure 16a shows the Treede Maxposition Blade, which is made up of three elements of different sizes. It consists of a base element (1), a primary element (2) and a secondary element (3) (Fig. 16b).

A suitable screwdriver, e.g. the LMT-4L cardan screwdriver (see section *8) Required accessories*), is required for assembly/disassembly. The suitable screwdriver is used to adjust the fan blades (5) via the gear axis, which is located inside the box module (4).

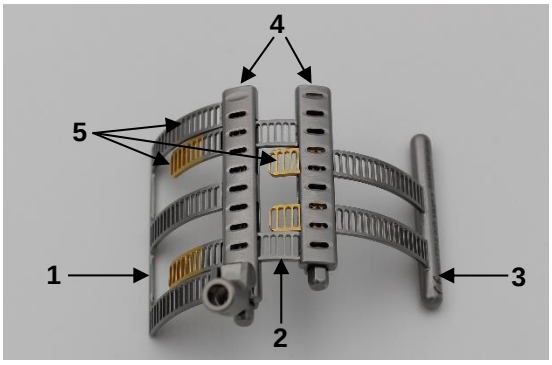
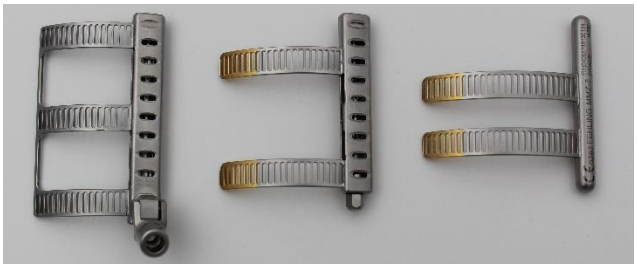


Fig. 16a: Treede Maxposition Blade



Base element (1) | Primary element (2) | Secondary element (3)

Fig. 16b: Treede Maxposition Blade in its individual elements

1. Insert the primary element (2) into the base element (1) and retract using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the base element (4a) counterclockwise using the screwdriver (7) (Fig. 17).

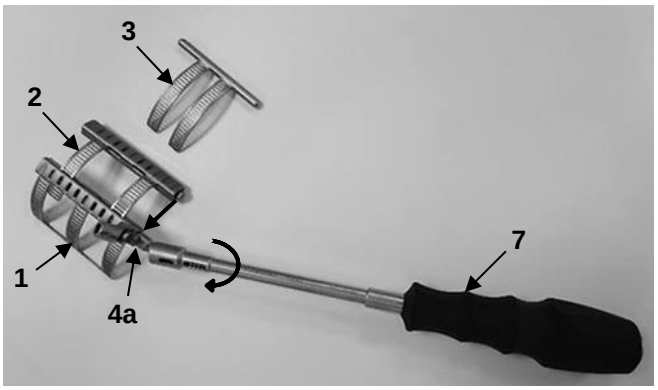


Fig. 17

⚠ Always fit the primary element (2) first.

2. Then insert the secondary element (3) into the primary element (2) and retract it using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the primary element (4b) counterclockwise using the screwdriver (7) (Fig. 18).

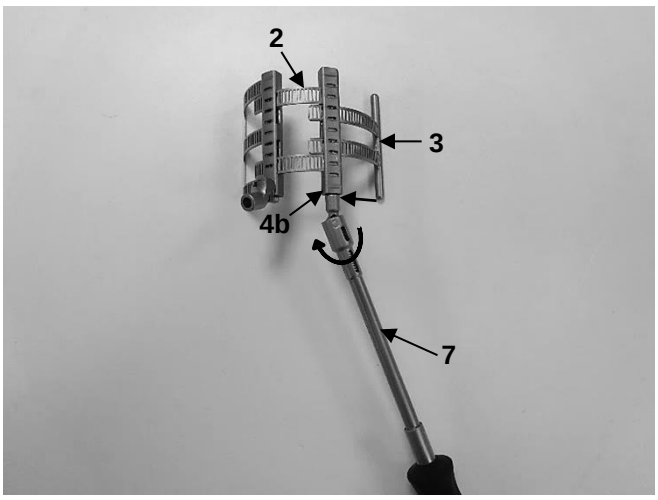


Fig. 18

3. The assembled instrument (Fig. 19) is now ready for use again after a function test.

Fig. 19

10) Disassembly

For reprocessing, the Treede Maxposition Blade must be disassembled as follows.

1. First remove the secondary element (3) from the primary element (2) using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the primary element (4b) clockwise using the suitable screwdriver (7) until it can be removed (Fig. 20).

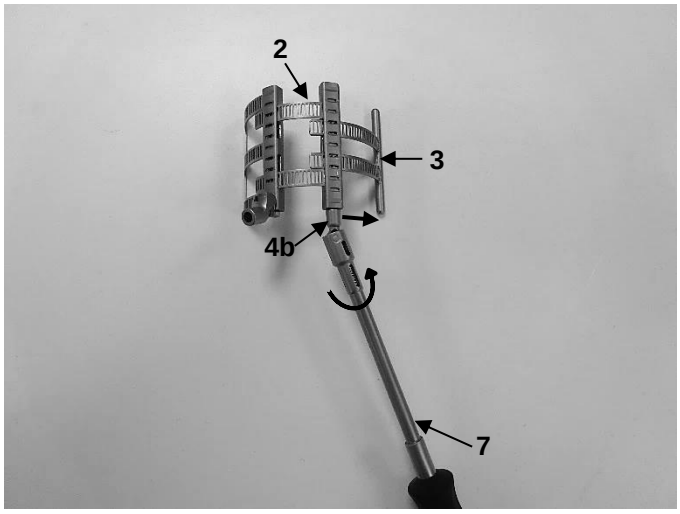


Fig. 20

⚠ Always extend the secondary element (3) first.

2. Then remove the primary element (2) from the base element (1) using the appropriate screwdriver (7). To do this, turn the transport mechanism on the box module of the base element (4a) clockwise using the suitable screwdriver (7) until it can be removed (Fig. 21).

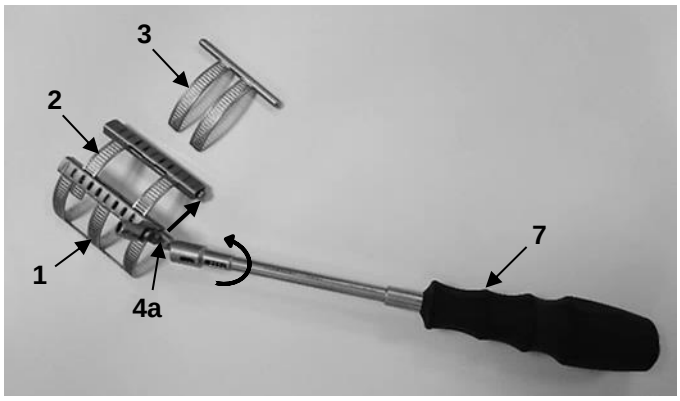


Fig. 21

3. The instrument disassembled into its individual parts (Fig. 22) can now be reconditioned.

Fig. 22

⚠ 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 that 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/ to the competent authority of the Member State in which the user is established.

Symbols

Where shown on the medical device or medical device label or instructions for use, the symbols have the following meaning in accordance with DIN EN ISO 15223-1:

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

Contact the manufacturer:

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CE 0297