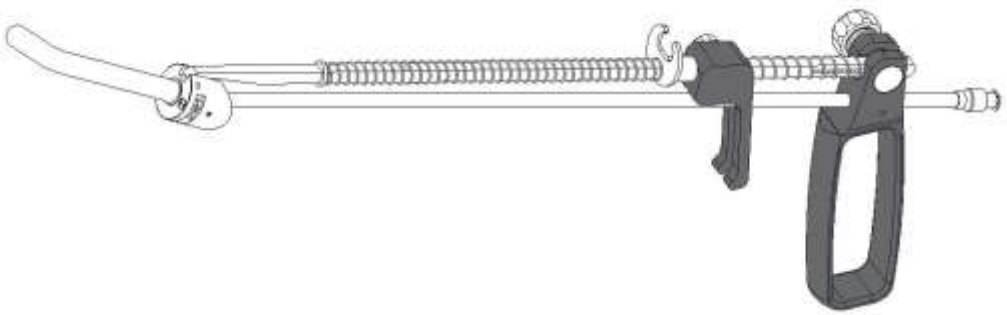
» UTERUS MANIPULATOR «



TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

TEKNO-Medical Optik-Chirurgie GmbH
Sattlerstr. 11
78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Phone: +49 7461 17 01 0
Fax: +49 7461 17 01 50
Mail: mail@tekno-medical.com
Web : www.tekno-medical.com

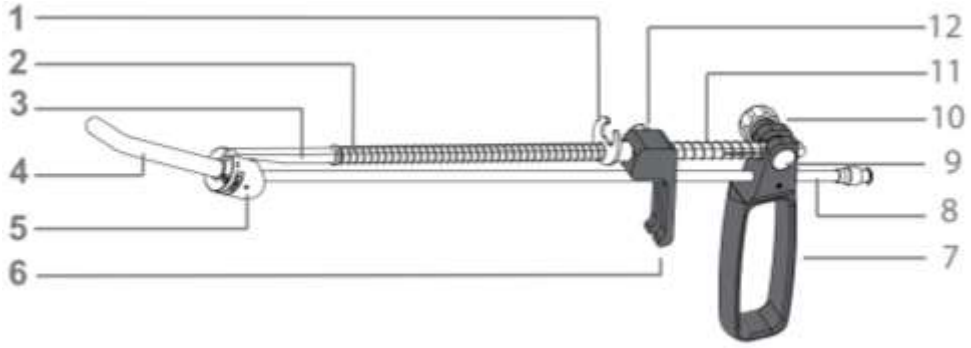
TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully observed. The use, preparation and testing of the instruments may only be carried out by trained specialists.

The uterus manipulators from Tekno-Medical Optik-Chirurgie GmbH are delivered non-sterile and must go through the complete cleaning and sterilization process before the first and every subsequent use.

1 SCOPE

MD This instruction manual applies to the uterus manipulators of Tekno Medical Optik-Chirurgie GmbH (see product list in the appendix).



1	Pusher	**7**	Grip
2	Long spring	**8**	Flushing pipe
3	Square bar	**9**	Clamping screw
4	Adapter	**10**	Tension screw
5	Adapter mount	**11**	Short spring
6	Handle	**12**	Locking screw

2 INSPECTIONS

Before each use of the manipulators, they must be inspected for breaks, cracks, deformations, damage and functionality. Sensitive areas such as springs, sealing surfaces and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged products must be sorted out.
The stainless steels used for production (stainless steels) form specific passive layers as protective layers due to their alloy. These steels are only partially resistant to the attack of chloride ions and aggressive media and liquids!

Damaged products must not be used!
Instruments must be checked for functionality before each use!

3 HANDLING

The instruments must not be overused by twisting or levering, as this can lead to damage or breakage of instrument parts.
The instruments may only be used by trained medical professionals.
These instruments are not intended for use on the heart or the central nervous and circulatory system!

4 PURPOSE

The instrument is used to introduce contrast agents and to position the uterus for the subsequent procedure.

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

5 INDICATION

Uterus manipulators are used in gynaecological procedures.

6 CONTRAINDICATIONS

The use of manipulators in gynaecological procedures is generally contraindicated when the use of other techniques is indicated and in health conditions that inhibit the healing process, such as:

- Impairment of blood supply,
- acute and chronic, local or systemic infections,
- deep or superficial infections,
- systemic diseases and metabolic dysfunction,
- mental states that make it impossible to participate in the rehabilitation program (Parkinson's disease, alcoholism, drug use, etc.),

There are also contraindications,

- in case of general inoperability;
- if the patient is unwilling;
- if the technical requirements are not met.

Not for use on the heart and central circulatory and nervous systems. The responsible physician must decide whether the intended application can be carried out on the basis of the patient's general condition.

7 PATIENT POPULATION

Apart from the contraindicated uses, there are no restrictions on the patient population.

8 DISPOSAL

If the instruments can no longer be repaired and reprocessed, the disposal of the instruments must be carried out in accordance with the applicable country-specific regulations and laws.

9 WARNINGS

Risk of infection from non-sterile instruments.
Prepare before use.
Risk of injury due to angled threaded cone.
Do not angle the adapter when inserting it into the cervix.

10 REPROCESSING

In general, medical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities.
Detailed information on the reprocessing of medical instruments can be found in the "**Red Brochure**" of the AKI. Under www.a-k-i.org you will also find links to laws, standards and publications of treatment committees.
Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is determined by their function and gentle handling. Frequent reprocessing has little impact on the product. The end of product life is usually determined by wear and damage from use.

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

10.1 Preparation on site

Remove coarse dirt from the instruments immediately after application. Do not use fixatives or hot water (>40°C), as this leads to the fixation of residues and can negatively affect the success of cleaning.
Instruments made of stainless steel must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion.
Instruments may only be sterilized after prior cleaning and disinfection.

10.2 Transport

Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination with the environment.

10.3 Preparation for decontamination

The instruments must be dismantled for reprocessing (see Chapter 12.2).
The instruments must be stored on machine-compatible instrument carriers in a dishwasher-friendly manner. The condition of the instrument carriers must not impair the subsequent cleaning and disinfection by sound or flushing shadows.

10.4 Manual pre-cleaning

Soak instruments in cold demineralized water for at least 5 min. If possible, disassemble the instruments and clean them under cold water with a soft brush until no residue is visible. Pressure flush cavities, holes and threads with a water gun for at least 10 seconds (pulsed method, minimum pressure 2 bar).
Place instruments in an ultrasonic bath at 40°C with 0.5% alkaline or enzymatic cleaner for 15 minutes and fill them with sound.
Remove instruments and rinse with cold water.
The cleaning solution should be changed at least once a day, more often if necessary. Too high a degree of soiling impairs the cleaning effect and increases the risk of corrosion. National laws and guidelines must be observed.

10.5 Automated cleaning

Place the instruments in an open sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments into their individual parts as far as possible (see instrument-specific instructions).

Step	Parameter	
Pre-rinse	Flush temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinse	Flush temperature + water quality	Cold tap water
	Exposure time	180 s
Clean	Cleaning temperature	45°C
	Water quality	Tap water
	Exposure time	300 s (worst case condition) / RKI Recommendation 600 s
	Detergent	Neodisher Medizym
	Concentration	0,50 %
Neutralization	Rinsing temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing agent	Neodisher Z
	Concentration	0,10 %
Rinse	Rinsing temperature	40 °C
	Water quality	Demineralized water
	Exposure time	120 s

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

10.6 Mechanical (thermal) disinfection

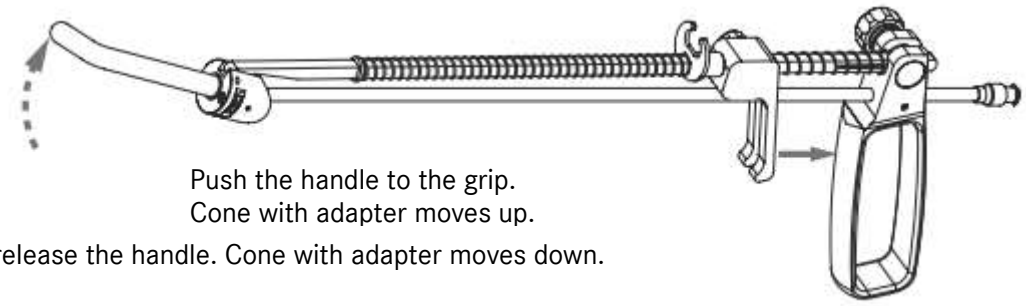
Step	Parameter	
Thermal disinfection	Disinfection temperature	90°C (A0 3000)
	Water quality	Demineralized water
	Exposure time	300 s
Drying	Drying of the outside of the instruments through the drying cycle of the washer/sanitizer. If necessary, manual drying can also be achieved with the help of a lint-free cloth. Dry cavities and channels of instruments with sterile compressed air.	

For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

10.7 Testing

The function test shows whether the proper functioning of the instrument and its components is guaranteed. Perform the functional test immediately after assembly (see Chapter 12.1).

Precondition: The clamping screw on the grip is easily loosened.



Push the handle to the grip.
Cone with adapter moves up.

Slowly release the handle. Cone with adapter moves down.

10.8 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8.

10.9 Sterilization

Sterilization of the products using the fractional pre-vacuum process (in accordance with DIN EN ISO 17665-1), taking into account the respective national requirements.

Pre-vacuum:	3 times
Sterilization Temperature:	134 °C
Sterilization time:	5 min
Drying:	20 min.

The use of any other sterilization method is beyond our responsibility!

Sterilization parameters UK:

Sterilization of the instruments by applying a fractionated pre-vacuum process (according to Health Technical Memorandum 01-01 Part C):

- Heat up to a minimum sterilization temperature of 134° - 137°C (maximum temperature 137°C).
- Minimum holding time: at least 3 min.

10.10 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment at moderate temperatures of +5°C to +40°C and constant humidity. The distance between the shelf and the shelf should be at least 30cm.
The storage period must be determined by the user himself.

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

10.11 Information on the validation of the treatment

The following materials and machines were used in the validation of the machine reprocessing:

Detergent	Neodisher Medizym 0,5 % (v/v)
Neutralisator	Neodisher Z 0.1% (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam-autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

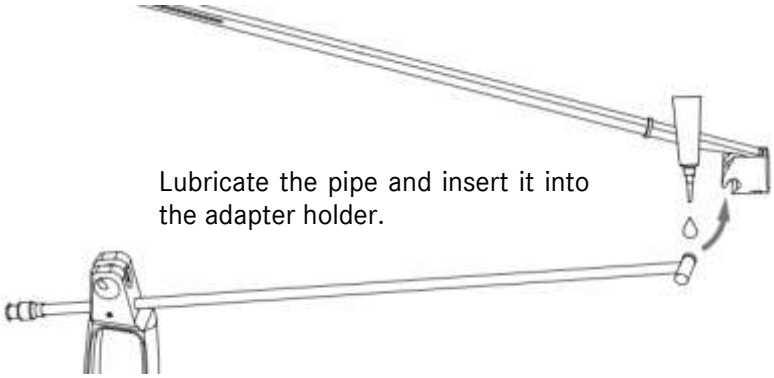
11 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly. The state of the art and national laws require validated processes to be followed.
During reprocessing, the temperature acting on the instrument must **not exceed** 140°C.
In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. In the case of machine cleaning and disinfection, there is greater safety in the process.
Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning / pre-cleaning. Highly alkaline cleaning agents damage plastics and anodizing layers.
The instruments must not be sterilized in hot-air sterilizers.
Do not use corrosive cleaning agents. Do not use strong oxidizing detergents. Agents with a neutral pH value (7.0) are best suited.

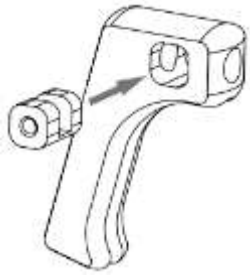
12 ASSEMBLY & DISASSEMBLY

12.1 Assembly

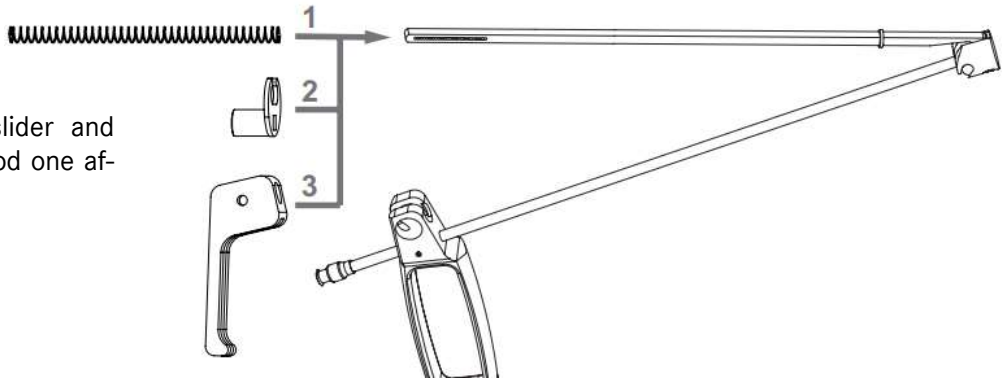
The size of the adapter is determined immediately before the procedure.
Precondition: O-ring is mounted on the flushing pipe.



Lubricate the pipe and insert it into the adapter holder.

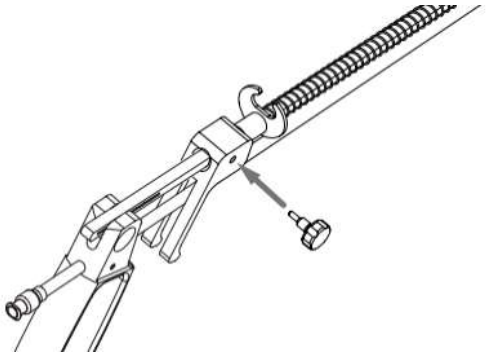


Insert the latch into the handle.



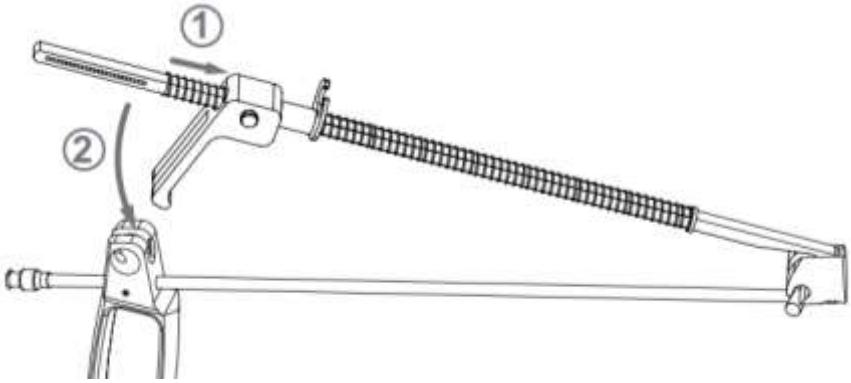
Slide the long spring, slider and handle onto the square rod one after the other.

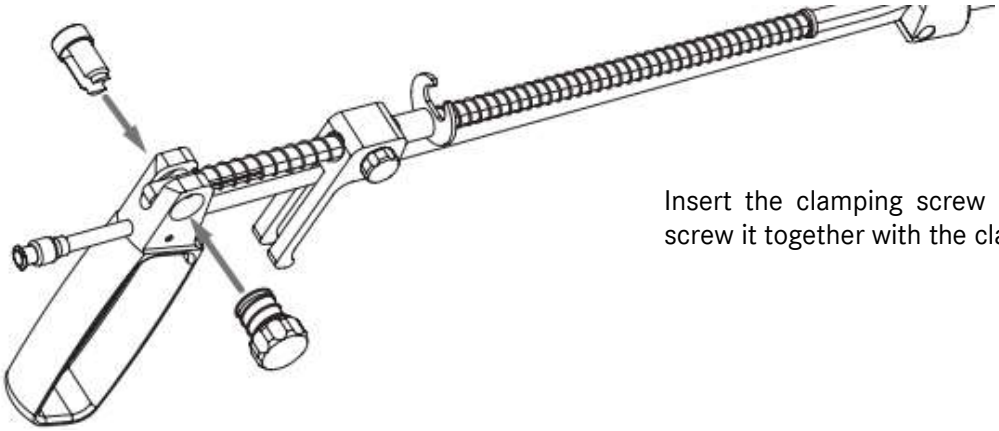
TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com



Position the handle so that the hole in the square bar and the hole in the handle are on top of each other. Insert the locking screw and screw it down.

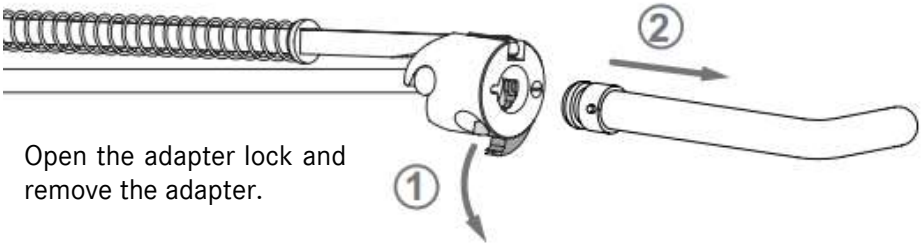
Slide the short spring over the square bar and press against the handle until the square bar fits into the guide of the grip.
Insert a square bar into the grip.



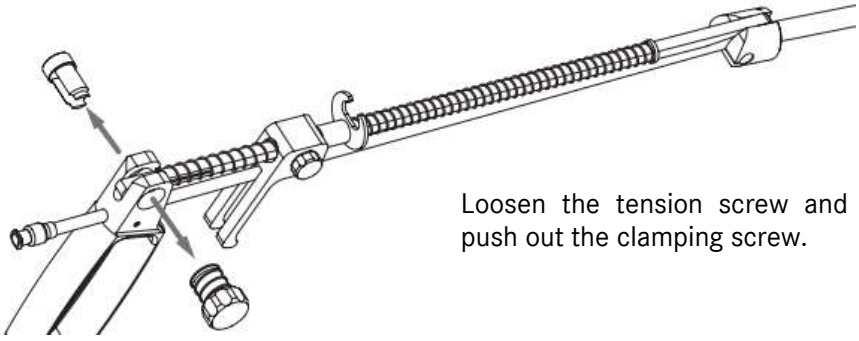


Insert the clamping screw into the grip and screw it together with the clamping screw.

12.2 Disassembly

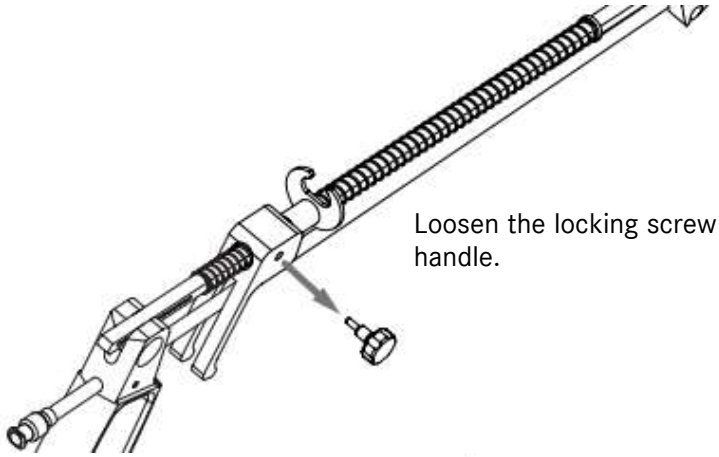


Open the adapter lock and remove the adapter.

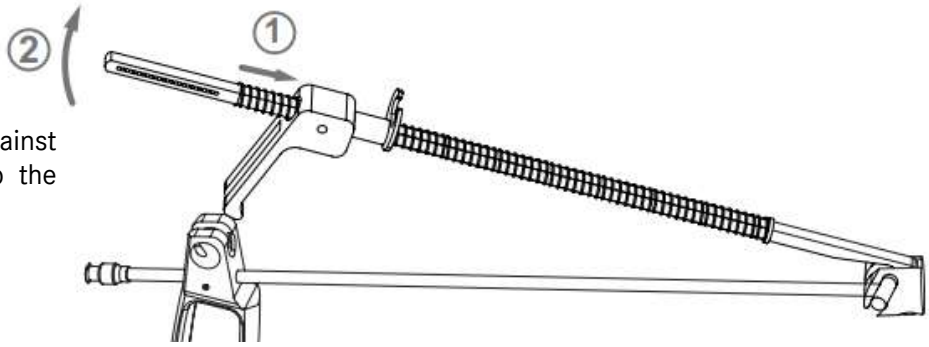


Loosen the tension screw and push out the clamping screw.

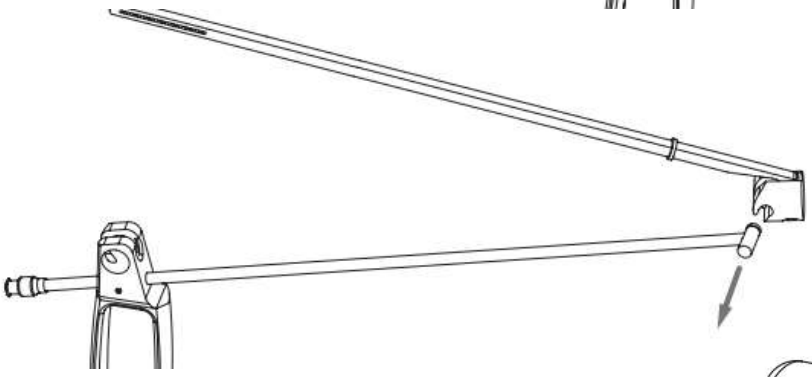
TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com



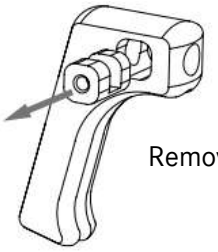
Loosen the locking screw on the handle.



Press the short spring against the handle and fold up the square bar.



Remove the spring, handle and slider.
Pull the flushing pipe out of the adapter holder.



Remove the latch from the handle.

13 REPORTABLE EVENTS

In accordance with the requirements of the Medical Devices Regulation (EU) 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO-MEDICAL.

If you cannot reach us directly in the event of reportable events, please send an e-mail to:

safety@tekno-medical.com

Serious incidents must also be reported to the competent authority in their locality.

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

14 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. If errors still occur, please contact our service.
Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical assumes no liability for incidental or resulting damages. Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.
Attention: In the case of the use of the instruments in patients with Creutzfeldt-Jakob disease, Tekno-Medical declines any responsibility for reuse.

15 SERVICE AND REPAIR

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this.
Defective products must have gone through the entire remanufacturing process before being returned for repair.
For returns, use our RMA application form and decontamination certificate.
Forms at: https://www.tekno-medical.com/de/service/reparaturservice/

16 SYMBOLS

The symbols used in this instruction and on the label have the following meaning in accordance with DIN EN ISO 15223-1:

	Attention!		Manufacturer
	Medical		Manufacture
	Non-sterile		Follow the instructions for use
	Catalogue		Protect from sunlight
	Batch designation		Store in a dry place
	Unique product identification		CE mark

17 PRODUCT LIST FOR INSTRUCTIONS FOR USE

Printed on: 27.03.2025

791-151	791-153	791-155	791-156-60*
791-152	791-154	791-156	791-157

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com