»Self-retaining retractors«

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In order to keep hazards to patients, users or, if necessary, third parties as low as possible, the instructions for use must be carefully observed. The application, reprocessing and testing of the instruments may only be carried out by trained specialists.
Reusable instruments from Tekno-Medical are delivered non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and, if necessary, disinfection) before the first and each subsequent use. sterilization).

1 SCOPE

MD These instructions for use are valid for the retractors, spreaders and ring-retractors of Tekno-Medical Optik-Chirurgie GmbH (see product listing in the last section).

2 INSPECTIONS

The instruments must be checked for functionality prior to every use.
Damages to the surfaces such as scratches, cracks, nicks, notches, etc., as well as bent parts mean that the instrument must not be used. The products must then be repaired by an authorized repair service or disposed of according to hospital standards.

Damaged products must not be used!

3 HANDLING

The products may only be used for their intended use by appropriately trained and qualified personnel.
Responsible for the selection of instruments for specific applications, the appropriate training of the staff and the experience in the handling of the products lies with the user. This product may only be used in medical facilities by trained healthcare professionals.

4 PURPOSE

4.1 Retractors

Retractors are used to keep the surgical field open. This means holding out tissues, muscles, organs or bones during the Operation.

4.2 Spreaders

Spreaders are used to keep the surgical field open. This means keeping tissues, muscles, organs, or bones out during surgery.

4.3 Ring-retractors

Ring-retractors are attached to the table to keep the surgical field open. This means keeping tissues, muscles, organs, or bones out during surgery. Accessories can be attached to the retractor.

5 INDICATIONS

5.1 Retractors

Retractors are used to keep the surgical field open. This means holding back tissue, muscles, organs or bones during the operation.

5.2 Spreaders

Spreaders are used to hold the surgical field open. This means holding back tissue, muscles, organs or bones during the operation.

5.3 Ring retractors

Ring-retractors are attached to the table to hold the surgical field open. This means holding back tissue, muscles, organs or bones during the operation.

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6 CONTRAINDICATION

The use of self-retaining retractors is generally contraindicated when the use of other techniques is indicated.
In addition, there are contraindications:

- in case of unwillingness of the patient;
- if the technical requirements are not met.

Not for use on the central circulatory and nervous system within the meaning of the regulation.
The responsible physician or user must decide on the basis of the patient's general condition whether the intended application can be carried out.

7 PATIENT POPULATION

Apart from the contraindicated uses listed in these instructions for use, there are no restrictions on the patient population.

8 COMBINATIONS

The products are not intended to be combined with or connected to other products.

9 DISPOSAL

If the instruments can no longer be repaired and reconditioned, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.
Defective products must usually have gone through the entire reprocessing process before disposal.

10 WARNINGS

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.
Instruments made of pure titanium or titanium alloys are to be treated in the same way as instruments made of stainless steel. There are no special instructions to be observed beyond that. Instruments made of aluminum must only be treated with non-alkaline, neutral disinfectants and cleaning agents and fully desalinated water, otherwise damage to the anodized surface may occur. Alkaline cleaning processes lead to color fading and stains on color anodized surfaces after a few cycles.

⚠ Brand new products must have gone through the complete reprocessing process once before they are used for the first time. A new medical device must be subjected to a thorough visual and functional inspection after it has been delivered. If the medical device has externally recognizable defects (scratches, breaks, cracks, notches, bent parts and stiffness) or if it does not work as described in these instructions for use, we as the manufacturer or your distributor must be notified immediately.

In order to ensure the safe operation of the products mentioned, correct maintenance and care of the products is essential. Therefore, a functional or visual inspection should be carried out before each application. For this reason, we refer to the relevant sections in this instruction manual.
There are no specific requirements for the storage of products before sterilization. Nevertheless, we recommend storing the medical devices in a clean and dry environment.
All surgical instruments should always be handled with the utmost care when transporting, cleaning, caring for, sterilizing and storing.
This is especially true for cutting edges, fine tips and other sensitive areas.

11 INSTRUCTIONS FOR REPROCESSING

In general, medical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the preparation of 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 reprocessing expert committees.
Instruments made of steel must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion.

11.1 On-site preparation

Immediately after use, remove coarse dirt from the instruments. Do not use any fixing agents or hot water (>40°C), as this will cause residues to freeze and may affect the success of cleaning.

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11.2 Transport

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

11.3 Preparation for decontamination

If possible, the instruments must be disassembled or opened for reprocessing.
The instruments must be stored on machine-compatible instrument carriers in a dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

11.4 Manual pre-cleaning

For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents.
Place the instruments in cold water for at least 5 minutes. 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 for 15 minutes with 0.5% alkaline or enzymatic cleaner and sonicate. Remove instruments and rinse with cold water.
The cleaning solution should be changed at least once a day, more often if necessary. Too much contamination impairs the cleaning effect and increases the risk of corrosion.
National laws and guidelines must be observed.

11.5 Automated cleaning

Place the opened instruments in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments as much as possible.

Step	Parameter	
Pre-rinsing 1	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinsing 2	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
Cleaning	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 detergent	Neodisher Z
	Concentration	0,10 %
Post-rinsing	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

11.6 Automated (thermal) disinfection

Step	Parameter	
Thermal Disinfection	Disinfection-temperature	90°C (A_0 3000)
	Water quality	Deionized water
	Exposure time	300 s
Dry	Drying of the outside of the instruments by the drying cycle of the washer-disinfector. If necessary, manual drying can also be achieved with the help of a lint-free cloth. Dry cavities and channels of the instruments with sterile compressed air. Allow products need to cool down to room temperature.	

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

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11.7 Functional testing

The products must be macroscopically clean, i.e., free of visible dirt, after each cleaning cycle
Stained products must be sorted out immediately and given special treatment. Particular attention must be paid to all moving parts. In the event of failures or damage, the products must be sorted out immediately. All plastic components must be checked before sterilization. The plastic parts must not be cracked, brittle or worn. In these cases, the instrument must be replaced.

11.8 Maintenance of the instruments

"Maintenance" basically means the application of instrument oil or instrument milk (emulsion of white oil in water). Products with movable jaws, joints, joints or with metallic sliding surfaces must be treated with steam-sterilizable care products based on paraffin oil. The paraffin oil must comply with the applicable pharmacopoeia and be physiologically harmless. (Further information can be found in DIN 96298-4.)

11.9 Packaging

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

11.10 Sterilization

Sterilization of the products using a fractionated pre-vacuum process (according to DIN EN ISO 17665) taking into account the respective national requirements.

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

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

11.11 Storage

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

11.12 Information on the validation of the processing

The following materials and machines were used in the validation of the automated processing:

Cleaning agents:	Neodisher Medizym 0.5% (v/v)	See test reports for details: 23277 / 23279 / 23278 CleanControlling Medical GmbH & Co. KG
Neutralizer:	Neodisher Z 0.1% (v/v)	
Cleaning/disinfection device:	Miele PG 8535	
Steam autoclave:	Lautenschläger ZentraCert	

12 ADDITIONAL INSTRUCTIONS

Should the chemicals and machinery described above not be available, it is the user's responsibility to validate their process accordingly. It is the user's duty to ensure that the reprocessing process, including resources, materials, and personnel, is suitable for achieving the required results. State-of-the-art technology and national laws require adherence to validated processes.
During reprocessing, the temperature acting on the instrument should be **140°C. do not** exceed.
In principle, automated cleaning and disinfection are always preferable to manual methods. Automated cleaning and disinfection offer greater process safety.
Never use metal brushes, metal sponges, or abrasive cleaning agents for manual cleaning/pre-cleaning. Strongly alkaline cleaning agents will damage plastics and anodized coatings. The instruments must not be sterilized in hot air sterilizers.
Do not use corrosive cleaning agents. Do not use strongly oxidizing cleaning agents. Products with a neutral pH value (7.0) are best suited.

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13 REPORTING PRODUCT PROBLEMS

In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.

During business hours you can reach us by phone at +49 (0) 07461 / 1701-0.
Outside of regular business hours, please send an email to
safety@tekno-medical.com .

Serious incidents must also be reported to the local authority responsible for their location.

14 WARRANTY

The products are manufactured from high-quality materials and undergo quality control before delivery. Should any defects occur, please contact our customer service.
Tekno-Medical cannot guarantee that the products are suitable for any given procedure. This must be determined by the user.
Tekno-Medical accepts no liability for accidental or consequential damages.
Tekno-Medical accepts no liability if it can be proven that these instructions for use have been violated.

Caution: In the event of use of the instruments on patients with Creutzfeldt-Jakob disease, Tekno-Medical disclaims all responsibility for reuse.

15 SERVICE AND REPAIR

Do not attempt any repairs or modifications to the product yourself. This is the sole responsibility and intended use of authorized manufacturer personnel.
Defective products must have undergone the entire refurbishment process before being returned for repair.
For returns, please use our RMA application form and decontamination certificate.
You can find the forms on our homepage:
https://www.tekno-medical.com/de/service/reparaturservice/

16 SYMBOLS

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

	Attention!		Manufacturer
MD	Medical device		Date of manufacturing
NON STERILE	Non-sterile		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification		
CE 0483	CE mark with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

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17 PRODUCT LISTING

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17320-05*	17550-09	17827-01	17920-16	17982-45	17987-18	17988-70	17992-65
17321-05*	17560-25	17827-02	17920-17	17982-50	17987-19	17988-71	17992-75
17322-07*	17570-18	17827-03	17920-18	17982-55	17987-20	17988-72	17993-35
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17500-22	17824-01	17920-01	17981-50	17987-08	17988-59	17990-01	34138-00
17501-22	17824-02	17920-02	17981-55	17987-09	17988-60	17991-35	34138-03
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17503-22	17824-04	17920-04	17981-65	17987-11	17988-62	17991-45	34138-05
17504-00	17824-05	17920-05	17981-70	17987-12	17988-63	17991-55	34139-10
17507-00	17826-01	17920-06	17981-75	17987-13	17988-64	17991-65	38599-00
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17540-20	17826-05	17920-15	17982-40	17987-17	17988-69	17992-55	

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