» RETRACTORS WITH FIBRE-OPTICS AND IRRIGATION «

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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, preparation and testing of the instruments may only be carried out by trained specialists. Unless otherwise stated, reusable surgical instruments from Tekno-Medical are delivered non-sterile and must go through the complete cleaning and sterilization cycle before the first and every subsequent use.

1 SCOPE

MD This instruction manual is valid for the retractors with fibre-optics and irrigation tube from Tekno-Medical Optik-Chirurgie GmbH (see product list in the last section).

2 INSPECTIONS

Before each use of the instruments, they must be inspected for breaks, cracks, deformations, damage and functionality. Areas such as connections, adapters and working ends must be checked with particular care. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out.

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The treating physician or user is responsible for the selection of the instruments for specific applications or surgical use, the appropriate training of the staff and the experience in handling the products. All surgical instruments should always be handled with the utmost care when transporting, cleaning, maintaining, sterilizing and storing. This applies in particular to fine tips and other sensitive areas.

4 INTENDED PURPOSE

The retractors are used to keep the surgical field open, to flush and to illuminate the surgical field.

5 INDICATIONS

Application for keeping the surgical field open in general surgical procedures, abdominal procedures or thorax procedures.

6 CONTRAINDICATIONS

The use of holding instruments is generally contraindicated when the use of other surgical techniques is indicated and in health conditions that inhibit the healing process, such as:

- impairment of blood supply,
- extreme obesity,
- acute and chronic, local or systemic infections,
- deep or superficial infections,
- systemic diseases and metabolic dysfunctions,
- Mental conditions that make participation in the rehabilitation program impossible (Parkinson's disease, alcoholism, drug use, etc.),
- Allergies or other reactions to the material used.

There are also contraindications,

- with general inoperability;
- if the patient is not prepared;
- if the technical requirements are not met.

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

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.

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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.

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.
A new medical device must be subjected to a thorough visual and functional inspection after delivery. If the medical device has externally visible defects (scratches, breaks, cracks, notches, damaged insulation, bent parts and stiffness) or if it does not work as described in these instructions for use, we as the manufacturer or your sales partner must be notified immediately. To ensure the safe operation of the products mentioned, correct maintenance and care of the products is essential. Therefore, a functional or visual test should be carried out before each use.
There are no specific requirements for storing products before sterilization. We still recommend storing the medical devices in a clean and dry environment.

11 REPROCESSING

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the reprocessing of surgical 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 processing expert 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 effect on the product. The end of product life is usually determined by wear and damage caused by use. The legibility of the marking has been verified over 200 preparations.

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.

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-friendly manner. The condition of the instrument carriers must not impair the subsequent cleaning and disinfection by sound or flushing 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.

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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.	

11.7 Functional testing

Visual inspection of cleanliness; If necessary, assembly of the instruments, maintenance and functional testing.
If necessary, repeat the reprocessing process until the instrument is visually clean.
Treat instruments with moving parts with care oil, e.g.: TK95100-00. Only close instruments with locks in the first notch. Defective or damaged instruments must be discarded immediately.

11.8 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.

11.9 Sterilization

Sterilization of the products using a fractionated 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 other sterilization methods is beyond our responsibility.

11.10 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant level of humidity. The distance between the floor and the shelf should be at least 30cm.
The storage period is to be determined by the user himself.
Protect from sunlight!

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11.11 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/h)
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)	

12 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly.

It is the responsibility of the user to ensure that the remanufacturing process, including resources, materials and personnel, is suitable to achieve the required results.

The state of the art and national laws require the following of validated processes.

During reprocessing, the temperature acting on the instrument should **not** exceed **140°C**.

In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. With mechanical 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. Strongly alkaline cleaning agents damage plastics.

The instruments must not be sterilized in hot air sterilizers. Do not use caustic cleaning agents. Do not use strong oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

13 REPORTING PRODUCT ISSUES

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 competent authority in their locality.

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 the decontamination certificate.

You can find the forms on our homepage:

https://www.tekno-medical.com/de/service/reparaturservice/

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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, 70191 Stuttgart		

17 PRODUCT LISTING

REF

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17217-01	17217-03	17217-05	17217-22	17217-24	17217-60
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