» REUSABLE SPREADING AND WIDENING INSTRUMENTS «

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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. The products are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.

1 SCOPE

These instructions for use are valid for the following spreading and dilating instruments from Tekno-Medical Optik-Chirurgie GmbH (hereinafter “Tekno-Medical”):

MD

- Tongue depressors, tongue depressors, mouth gags
- Specula (rectum, vagina, nose, ear, eye),
- Dilators, bougies and probes (urethra, uterus, eye).

(See product list in the last section.)

2 INSPECTIONS

Before using the products, they must be inspected for breaks, cracks, deformations, damage and functionality. Areas such as cutting edges, working ends, connections and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

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 instruments for specific applications or operational use, the appropriate training of personnel and the experience in handling the products.

4 PURPOSE

Medical device for spreading, fixing, holding open, widening and manipulating various anatomical structures and natural body openings as part of non-surgical-invasive treatments on humans.
The duration of use is temporary (intended for uninterrupted use for a period of less than 60 minutes under normal conditions) in accordance with Regulation (EU) 2017/745.

5 INDICATIONS

The spreading and widening instruments are part of the standard instrumentation for general treatments and for procedures on natural body openings. They are used as spreading, positioning, palpating and fixing instruments in almost all standard applications.

6 CONTRAINDICATION

In general, the use of the head support system is contra-indicated in cases where the use of other surgical 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.

7 PATIENT POPULATION

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

8 DISPOSAL

If the instruments can no longer be repaired and reprocessed, 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.

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9 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.
Brand-new products must go through the entire processing process once before being used for the first time. 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, 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. For this reason, we refer to the relevant sections in these instructions for use. There are no specific requirements for storing products before sterilization. We still recommend storing the medical devices in a clean and dry environment.
All medical instruments should always be handled with the greatest care when transporting, cleaning, maintaining, sterilizing and storing. This applies in particular to work ends, barriers and other sensitive areas.

10 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. Steel instruments must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion.
Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The lifespan of medical devices is essentially determined by their function and careful handling. Frequent reprocessing has little impact on the product. End of product life is typically determined by wear and damage from use.

10.1 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.

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 to the environment.

10.3 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 washer-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of ultra-sound or rinsing shadows.

10.4 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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10.5 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

10.6 Automated (thermal) disinfection

Step	Parameter	
Thermal Disinfection	Disinfection-temperature	90°C (A_0 3000)
	Water quality	Deionized water
	Exposure time	300 s
Drying	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.

10.7 Functional testing

After each cleaning, the products must be macroscopically clean, i.e. free of visible contamination. Stained products must be sorted out immediately and given special treatment. All moving parts must be checked with particular attention. If errors or damage occur, the products must be sorted out immediately.

10.8 Care of the instruments

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

10.9 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.

10.10 Sterilization

Sterilization of the products using a fractionated vacuum process (according to 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 time	20 min.

The use of other sterilization methods 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.

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10.11 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.

10.12 Information on the validation of the reprocessing

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

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)	

11 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. The instruments must not be sterilized in hot air sterilizers. Strongly alkaline cleaning agents damage plastics and anodized coatings.

12 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.

13 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 these instructions for use have been demonstrably violated.
Caution: In the event of use of the instruments on patients with Creutzfeldt-Jakob disease, Tekno-Medical disclaims all responsibility for reuse.

14 SERVICE AND REPAIR

Do not attempt any repairs or modifications to the product yourself. Only authorized manufacturer personnel are responsible for this. Defective products must complete the entire reprocessing procedure before being returned for repair. For returns, please use our RMA application form and decontamination certificate. These forms can be found on our website. https://www.tekno-medical.com/de/service/reparaturservice/

15 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		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification	CE	CE marking

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16 PRODUCT LISTING

REF

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