» REUSABLE SURGICAL INSTRUMENTS «

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Content

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, preparation 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, sterilisation) before the first and each subsequent use.

1 SCOPE

These instructions for use are valid for the reusable surgical instruments of Tekno-Medical Optik-Chirurgie GmbH (see product listing in the last section).
These instructions for use are valid for surgical instruments made of stainless steel, such as dental instruments, extracting forceps, instruments for bone surgery, scalpels, knifes, scissors, forceps, clamps, retractors, probes, spatulas, suture instruments a s o.
Instruments made of aluminium need to be cleaned/disinfected with non-alkaline, neutral cleaning/disinfection detergents and fully desalinated water, in order to avoid damages to anodized surfaces. Alkaline cleaning procedures will very quickly have negative effects on colour anodized surfaces.

2 BEFORE USE

The instruments must be checked for functionality prior to each use.
Damage 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 in the usual hospital.

Damaged products must not be used!

3 HANDLING

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

4 PURPOSE

Instruments intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

5 CONTRAINDICATIONS

The use of reusable surgical instruments 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.

6 PATIENT POPULATION

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

7 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 remanufacturing process before disposal.

8 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 publications of reprocessing expert committees.

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 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, damaged insulation, bent parts and binding) 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.

10 REPROCESSING INSTRUCTIONS

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 essentially 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.

11 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 coagulate and may affect the success of cleaning.

Dissolve heavy, fixed dirt with a 3% H_2O_2 solution (hydrogen peroxide) and wipe it off with a disposable cloth. Then rinse thoroughly with demineralized water. Reprocess the instruments as soon as possible immediately after use.

11.1 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.

11.2 Preparation for cleaning / decontamination

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.

11.3 Manual pre-cleaning

Soak the instruments in cold de-mineralized 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 mode).

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.

11.4 Automated cleaning

Place the instruments in an open state in a sieve tray on the slide-in carriage and start the cleaning process.
Disassemble instruments into their individual parts as much as possible.

Step	Parameter	
Pre-rinse	Rinsing temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinse	Rinsing 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	City water
	Exposure time	180 s
	Neutralizing agents	Neodisher Z
	Concentration	0,10 %
Rinse	Rinsing temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

11.5 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 instruments with sterile compressed air. Allow products must cool to room temperature.	

11.6 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 errors 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.

11.7 Maintenance of the instruments

Products with movable jaws, 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.)

11.8 Packaging

Select standard-compliant packaging of the instruments for sterilization according to ISO 11607 and EN 868.

11.9 Sterilization

Sterilization of the products with fractionated back-vacuum process (according to .ISO 17665), 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 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.

11.11 Information on the reprocessing-validation

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

Detergent	Neodisher Medizym 0.5% (v/v)
Neutralizer	Neodisher Z 0.1 % (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23279 / 23278 (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, machine cleaning and disinfection are always preferable to manual cleaning. In the case of machine cleaning and disinfection, there is greater safety in the process.
For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents. Highly alkaline cleaning agents damage plastics and anodized layers.
The instruments must not be sterilized in hot air sterilizers.

13 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service.

In accordance with the requirements of the Medical Device Regulation EU MDR 2017/745 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 for reportable events, please send an e-mail to:
safety@tekno-medical.com.

Serious incidents must also be reported to the competent authority in your country!
Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself.
Tekno-Medical accepts no liability for any incidental or consequential damages.
Tekno-Medical assumes no liability if it can be proven that these instructions for use have been violated.

Attention: In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno-Medical declines any responsibility for reuse.

14 SERVICE AND REPAIR

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this.

Defective products must have gone through the entire reprocessing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.
Forms at: https://www.tekno-medical.com/de/service/reparaturservice/

15 SYMBOLS

	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
CE 0483	CE mark with number of the Notified Body mdc		

16 PRODUCT LISTING

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2xxx-xx; 4xxx-xx; 5xxx-xx; 6xxx-xx; 7xxx-xx; 8xxx-xx; 9xxx-xx; 10xxx-xx; 11xxx-xx; 12xxx-xx; 13xxx-xx; 14xxx-xx; 15xxx xx; 16xxx-xx; 17xxx-xx; 18xxx-xx; 19xxx-xx; 20xxx-xx; 21xxx-xx;22xxx-xx; 23xxx-xx; 24xxx-xx; 25xxx-xx; 26xxx-xx; 28xxx-xx; 29xxx-xx; 30xxx-xx; 31xxx-xx,32xxx-xx; 34xxx-xx; 35xxx-xx; 36xxx-xx; 37xxx-xx; 38xxx-xx; 39xxx-xx; 40xxx-xx; 48xxx-xx; 49xxx-xx; 50xxx-xx; 51xxx-xx; 52xxx-xx; 53xxx-xx; 55xxx-xx; 54xxx-xx; 55xxx-xx; 56xxx-xx; 70xxx-xx; 71xxx-xx; 72xxx-xx; 73xxx-xx; 75xxx-xx; 79xxx-xx; 83xxx-xx; 6xx-xxx; 7xx-xxx; 8xx-xxx; Z0000xxxxxx.