



## » Skull holder«





**TEKNO-MEDICAL Optik Chirurgie GmbH**

Sattlerstr. 11  
78532 Tuttlingen  
GERMANY  
SRN: DE-MF-000005822

Phone: +49 (0) 7461 / 17 01 0  
Fax: +49 (0) 7461 / 17 01 50

Mail: [mail@tekno-medical.com](mailto:mail@tekno-medical.com)  
Web: [www.tekno-medical.com](http://www.tekno-medical.com)





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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

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These instructions for use are valid for the skull holders of Tekno-Medical Optik-Chirurgie GmbH (see product listing in the last section).

## 2 INSPECTIONS

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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

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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

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The skull holding system is used for self-retaining fixation of the head, neck and spine during a surgical procedure.

The products are not intended for use on the heart or the central nervous and circulatory system

## 5 INDICATIONS

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For rigid fixation of the head during surgical procedures on the head, neck or spine.

## 6 CONTRAINDICATION

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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.

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 COMPLICATIONS

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- Tear of the scalp.
- Skull fracture.
- Epidural hematoma.
- Dural tear.
- Loss of cerebrospinal fluid.
- Infection on the pin puncture site.
- Breakage of the holder.



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**8 COMBINATIONS**

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The system can be connected to a complete attachment holding system for adapting accessories (Viridis®, Leyla®, etc.). This means that the system can be moved in all directions and is height-adjustable. Four adaptation interfaces for attaching target devices, as well as further connection options for stereotactic procedures are available. Please refer to the instructions for use of the respective combination products.

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**9 PATIENT POPULATION**

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

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**10 DISPOSAL**

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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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**11 WARNINGS**

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**11.1 Functional impairment**

Skull holders corrode and their function is impaired if they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilisation instructions. The stainless steels used for production form specific passive layers as protective coatings due to their alloy. These steels are only partially resistant to attack by chloride ions and aggressive media and liquids!

**11.2 Operating conditions**

Correct maintenance and care of the products is essential to ensure safe operation of the aforementioned products. In addition, a functional and visual inspection should be carried out before each use. For this reason, please refer to the relevant sections in these instructions for use.

**11.3 Storage**

There are no specific requirements for storing the products prior to sterilisation. However, we recommend storing the medical devices in a clean and dry environment.

**11.4 Preparation of a procedure**

Antibacterial ointment must be applied to the pins.

**11.5 Use on children**

Pins for children must be used for children.

**11.6 Positioning with pins**

When positioning the skull clamps, the thickness of the skull bone must be taken into account if possible. The pins should not be placed near a large vessel of the cranial vault, a previous wound or in front of a sinus.

**11.7 Fixation of the skull holder**

After fixation of the skull holder, all joints must be checked for a firm hold.

**11.8 Removal of the pins**

The pins must not be removed while the patient is in a sitting position.



**12 INSTRUCTIONS FOR REPROCESSING**

Aluminium instruments must only be reprocessed with non-alkaline, neutral disinfectants and cleaning agents and fully demineralised water, otherwise the anodised surface may be damaged. Alkaline cleaning methods lead to colour fading and stains on colour-anodised surfaces after a few cycles. Due to the product design and the materials used, no defined limit can be set for the maximum number of applications that can be carried out. The service life of medical devices is determined by their function and careful handling. Frequent reprocessing has little effect on the product. The end of the product's service life is normally determined by wear and damage caused by use. The legibility of the labelling has been verified over 200 reprocessing cycles. Detailed information on the preparation of instruments can be found in the "Red Brochure" of the AKI. Under [www.a-k-i.org](http://www.a-k-i.org) you will also find links to laws, standards and reprocessing expert committees.

**12.1 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.

**12.2 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.

**12.3 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.

**12.4 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, minimal 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.

**12.5 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	
<b>Pre-rinsing 1</b>	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
<b>Pre-rinsing 2</b>	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
<b>Cleaning</b>	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 %
<b>Neutralization</b>	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
<b>Post-rinsing</b>	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

**12.6 Automated (thermal) disinfection**

Step	Parameter	
<b>Thermal Disinfection</b>	Disinfection-temperature	90°C (A <sub>0</sub> 3000)
	Water quality	Deionized water
	Exposure time	300 s
<b>Dry</b>	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.

**12.7 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.

**12.8 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.)

**12.9 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.

**12.10 Sterilization**

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

<b>Pre-vacuum</b>	3 times
<b>Sterilization temperature</b>	134 °C
<b>Sterilization time</b>	5 min
<b>Drying time</b>	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.

**12.11 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.

**12.12 Information on the validation of the reprocessing**

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

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



### 13 ADDITIONAL INSTRUCTIONS

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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.

### 14 REPORTING PRODUCT PROBLEMS

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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](mailto:safety@tekno-medical.com)

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

### 15 WARRANTY

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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.

### 16 SERVICE AND REPAIR

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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 undergo the entire reprocessing procedure before being returned for repair. Please use our RMA request form and decontamination certificate for returns.

You can find the forms on our homepage:

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



**17 SYMBOLS**

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

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

**REF**

**18 PRODUCT LISTING**

Printed on: 09.02.2024

24900-00	24910-05	24910-13	24910-30	24910-54	24910-65
24901-00	24910-06	24910-14	24910-31	24910-55	24910-66
24903-00	24910-07	24910-15	24910-32	24910-56	24910-67
24910-00	24910-08	24910-16	24910-33	24910-60	
24910-01	24910-09	24910-17	24910-50	24910-61	
24910-02	24910-10	24910-18	24910-51	24910-62	
24910-03	24910-11	24910-19	24910-52	24910-63	
24910-04	24910-12	24910-20	24910-53	24910-64	