



# » REUSABLE SURGICAL SPREADING AND WIDENING INSTRUMENTS «





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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



These instructions for use are valid for the reusable spreading and widening instruments 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 locks, cutting edges and working tips 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 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 PURPOSES

Medical device for spreading, dilating, holding, fixing and palpating various types of tissues, bones, organs and vessels.

## 5 INDICATIONS

Instruments in this product group are used in all types of surgical procedures, for example:

- when spreading wounds or incisions,
- when dilating vessels or organ ducts,
- when holding vessels, bones, organs and tissues,
- when fixing vessels, bones or peripheral nerves,
- as an auxiliary instrument for touching or probing.

## 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

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

## 8 COMBINATIONS

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

## 9 DISPOSAL

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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

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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

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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](http://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

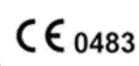
Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination to the environment.

### 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-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	
<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

## 11.6 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.	

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

## 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.: TK95 100-00. 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 17665-1), 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.



## 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 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)	

## 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 REPORTABLE EVENTS



In accordance with the requirements of the Regulation (EU) on Medical Devices 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO.

If you cannot reach us directly for reportable events, 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.

## 14 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno accepts no liability for any incidental or consequential damages.

Tekno 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 declines any responsibility for reuse.

## 15 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 remanufacturing 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/repair\\_service](https://www.tekno-medical.com/de/service/repair_service)





## 16 SYMBOLS

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

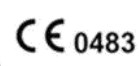
	Attention!		Manufacturer
	Medical device		Date of manufacturing
	Non-sterile		Read the instructions for use
	Catalogue number		Protect from sunlight
	Lot-number		Store in a dry place
	Unique device identification		
	CE mark with the number of the notified body: <b>mdc – medical device certification GmbH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

**REF**

## 17 PRODUCT LISTING

Printed on 20.03.2025

5471-12	17127-02	17302-15	24544-04*	25401-03	50556-25*	760-000-25
5471-14	17127-03	17303-17	24544-17	25401-04	50557-05*	783-750
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17036-03*	17180-01	18106-10	24577-19	30302-22	51620-23	Z0000125470
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17067-04*	17200-10	18147-08	24843-20	40123-01	52719-22*	Z0000129094
17067-06*	17200-12	18147-10	24843-25	40123-02	52723-16	Z0000129389
17071-21	17200-14	18147-12	24843-30	40170-01	52725-08	Z0000129392
17072-21	17200-16	18147-14	24843-35	40170-02	52725-08*	Z0000129599
17073-21	17200-18	18147-30	24843-40	40170-03	52725-10	Z0000129600
17074-21	17201-08	18148-01	24843-45	40170-05	52725-10*	Z0000129601
17076-21	17201-10	18148-02	24843-50	40230-01	52730-06	Z0000129602
17077-04*	17201-12	18148-03	24843-70	40400-14	52730-07	Z0000129661
17077-06*	17201-14	24500-17	24843-90	40410-01	52730-09	Z0000129683
17078-01	17201-16	24501-17	24844-05	40410-02	52730-11	Z0000129684
17078-02	17201-18	24502-01	24844-10	40411-01	52731-05	Z0000129685
17078-03	17202-17*	24502-02	24844-15	40412-01	52731-07	Z0000129686
17078-04	17202-33	24503-19	24844-20	40412-02	52731-08	Z0000129687
17078-06	17202-35	24504-15	24844-25	40412-05	52731-09	Z0000129688
17079-01	17203-08	24505-18	24844-30	40420-01	52733-01	Z0000129689
17079-02	17203-11	24506-15	24844-40	40420-02	52733-02	Z0000129690
17080-15*	17203-15	24510-17	24844-50	40420-03	52733-03	Z0000129691
17080-16	17203-17	24511-17	24847-05	40423-01	52733-04	Z0000129692
17081-16	17203-20	24514-10	24847-10	40425-01	52733-05	Z0000129693
17082-10	17203-23	24514-11	24847-15	40425-04	52733-06	Z0000129694
17082-15	17204-20	24514-12	24847-20	40435-01	52733-07	Z0000129695
17083-01	17205-01	24515-04	24847-25	40435-02	52733-08	Z0000129727
17083-02	17205-02	24515-05	24847-30	40437-04	52733-09	Z0000129728
17084-14	17205-03	24515-06	24847-35	40438-01	52733-10	Z0000129729
17084-15*	17212-28	24515-07	24847-40	40438-02	52733-11	Z0000129773
17085-15	17213-28	24516-08	24847-45	40439-01	52733-12	Z0000129985
17085-21	17214-01	24518-21	24847-50	40470-00	52733-13	Z0000129986
17086-22	17214-02	24519-19	24847-70	48115-14	52733-14	Z0000129987
17087-23	17214-03	24520-15	24848-05	48128-15	52733-15	Z0000130005
17088-11	17215-21	24521-15	24848-10	48130-01	52733-24	Z0000130233
17089-18	17216-24	24522-18	24848-15	48130-02	52735-01	Z0000130440
17090-18	17217-06	24522-21	24848-20	49925-15	52735-01*	Z0000130441
17091-18	17217-07	24523-05	24848-25	49925-16	52738-21	Z0000130442
17092-18	17217-08	24523-10	24848-30	49927-15	52738-21*	Z0000130524
17093-18	17217-09	24523-15	24848-35	49927-16	52740-21	Z0000130720
17094-18	17217-10	24523-20	24848-40	49928-18	52740-21*	Z0000130738
17095-18	17217-26	24523-25	24848-45	49929-18	52749-18	Z0000130739
17096-08	17217-27	24524-01*	24848-50	50530-00	52750-14	Z0000130740
17097-08	17217-28	24524-03*	24849-30	50531-00	52751-23	Z0000130741
17099-21	17217-29	24525-13	25240-07	50532-00	52764-01*	Z0000130742
17100-25	17217-30	24525-16	25240-11	50533-00	52764-02*	Z0000130743
17101-25	17217-40	24526-16	25240-15	50534-00	54410-01	Z0000130797
17102-25	17217-41	24527-05	25240-18	50535-00	54410-02	Z0000130836
17103-25	17218-01	24527-06	25285-17	50536-00	5471-12	Z0000130896





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17105-03	17218-02	24527-07	25285-21	50537-00	5471-14	Z0000130897
17105-04	17218-03	24528-01	25289-22	50543-01	5471-16	Z0000130898
17107-02*	17219-01	24528-02	25301-19	50543-02	56775-13	Z0000130921
17110-01	17219-02	24528-06*	25301-28	50543-03	56775-13 W	Z0000130922
17110-02	17219-03	24529-19	25302-19	50544-04	56905-02 W	Z0000130924
17110-02 LARGE	17219-04	24530-13*	25302-28	50544-06	704-110	Z0000130925
17110-02 SMALL	17219-05	24532-16	25308-01	50544-08	704-111	Z0000130926
17110-03	17219-06	24533-17	25308-02	50544-10	704-112	Z0000130927
17110-04	17219-07	24534-21	25315-20	50544-17*	704-113	Z0000130928
17110-05	17219-08	24535-01	25316-20	50545-02	704-123	Z0000130929
17112-01	17219-09	24535-02	25317-20	50545-04	704-123-45	Z0000130930
17112-02	17219-10	24535-03	25322-00	50545-06	704-124	Z0000130935
17112-03	17219-18	24535-04	25322-02	50545-08	704-124-45	Z0000130938
17112-04	17222-21	24536-01	25322-04	50545-10	704-800	Z0000130955
17112-05	17225-23	24536-02	25322-06	50545-15	704-801	Z0000130956
17113-16	17225-30	24536-03	25325-19	50545-30	704-802	Z0000131015
17114-01	17225-33	24536-04	25326-19	50546-10	704-803	Z0000131020
17114-02	17225-36	24536-05	25327-19	50546-25	704-860	Z0000131021
17114-03	17238-30	24536-06	25329-18	50548-01	71181-01	Z0000131022
17114-04	17250-30	24537-18	25340-13	50549-01	71181-02	Z0000131043
17114-05	17255-01	24538-19	25342-20	50553-01	71181-03	Z0000131047
17114-06	17264-22*	24539-20	25399-01	50553-02	71181-04	Z0000131048
17114-07	17273-22*	24540-20	25399-02	50553-03	71181-05	Z0000131065
17114-08	17275-30	24541-50	25400-01	50553-04	71182-01	Z0000131066
17114-09	17275-30*	24541-53	25400-02	50554-03*	71182-02	Z0000131101
17115-21	17279-31	24541-59	25400-03	50554-06*	71182-03	Z0000131158
17116-21	17285-25	24541-65	25400-04	50554-10*	72502-01	Z0000131273
17117-60	17285-38	24541-72	25400-05	50555-03*	72502-02	Z0000131327
17117-85	17285-50	24541-78	25400-06	50555-12*	72502-03	Z0000131449
17117-95	17285-75	24542-20	25400-07	50555-15*	72502-04	Z0000131450
17118-19	17286-10	24543-01	25400-08	50555-20*	72502-05	Z0000131451
17120-22	17298-18	24543-02	25400-09	50556-03*	72505-01	Z0000131452
17121-22	17298-20	24543-03	25400-10	50556-06*	72505-02	Z0000131485
17122-22	17298-23	24543-04	25400-11	50556-10*	72505-03	Z0000131488
17125-01	17299-01	24544-01*	25400-21*	50556-12*	72505-04	Z0000131518
17125-02	17300-00	24544-02*	25401-01	50556-15*	72505-05	Z0000138478
17127-01	17301-14	24544-03*	25401-02	50556-20*	760-000	

