# » Reusable surgical cutting 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.

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

These instructions for use are valid for the reusable surgical cutting instruments of Tekno-Medical Optik-Chirurgie GmbH (see product listing in the last section).

## 2 INSPECTIONS

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

This instruction manual applies to instruments made of stainless steel, aluminium and titanium. Instruments made of pure titanium or titanium alloys should be treated in the same way as instruments made of stainless steel. There are no special instructions to follow.
Aluminium instruments must only be processed with non-alkaline, neutral disinfectants and cleaning agents and fully demineralized water, otherwise damage to the anodized surface can occur. Alkaline cleaning processes lead to colour fading and stains on colour-anodized surfaces after just a few cycles.
The instruments must not be subjected to excessive strain by twisting or levering, as this may result in damage or breakage of instrument parts. This product may only be used in medical facilities by trained healthcare professionals.

## 4 PURPOSE

Medical device with cutting or abrasive edges, with straight or curved blades for smoothing surfaces and/or cutting, separating or removing tissue such as skin, organs, bones or for removing foreign bodies., making incisions in the patient's body to allow the introduction of instruments into the surgical field.
The user decides on the basis of his expertise whether the instrument is suitable for the respective application.
Duration of use: Transient (intended for continuous use under normal conditions for a period of less than 60 minutes.) according to Regulation (EU) 2017/745

## 5 INDICATIONS

Instruments in this product group are used in almost all surgical procedures, e.g.

- Skin and tissue incision as well as other incisions with knives,
- making access to the surgical site,
- preparation of tissue and organ parts with scissors and clamps,
- Cutting and partial removal of bones or bone parts with saws, chisels, files, punches, bone spoons, also in the dental field,
- loosening of foreign bodies in or on the human body,
- Micro-scissors for fine, small procedures on tissue as well as on the eye,
- Snares / curettes: Separation of polyps of any kind with appropriate polyp lacers, snares, spoons, lancet needles for foreign body removal or sharp/blunt curettes for scraping out the uterus,
- Knives for amputation.


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## 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.
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 COMBINATIONS

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

## 8 PATIENT POPULATION

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

## 9 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.

## 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.

## 11 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.
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 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.
The readability of the labelling 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 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.

### 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 |
| **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.<br>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.

### 11.7 Functional testing, maintenance

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 17665-1), 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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### 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:

| | |
|---|---|
| **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, 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 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.

## 14 WARRANTY

The products are manufactured from high-quality materials and undergo quality control before delivery. Should any defects occur, please contact our service department. Tekno-Medical cannot guarantee that the products are suitable for any specific procedure. 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 or its variants (vCJD, BSE, TSE), Tekno-Medical disclaims all responsibility for reuse.

## 15 SERVICE AND REPAIR

Do not attempt any repairs or modifications to the product yourself. This work should only be carried out by Tekno-Medical or Tekno-Medical authorized personnel.
Defective products must undergo the entire reprocessing procedure before being returned for repair. Please use our RMA application form and decontamination certificate for returns.
Forms available at: 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 |
|  | 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 marking with number of the Notified Body<br>**mdc – medical device certification GmbH**<br>Kriegerstrasse 6, D – 70191 Stuttgart | | |

## 17 PRODUCT LISTING

REF

Printed on: 10.11.2026

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6500-08 | 8469-12* | 21121-01 | 24472-05 | 28002-04 | 34814-30 | 50338-28 | 52689-04 |
| 6500-10 | 8477-24 | 21121-02 | 24472-06 | 28002-04A | 35000-00 | 50340-28 | 52689-22 |
| 6500-12 | 8523-12 | 21121-03 | 24473-00 | 28002-04ZA | 35000-01 | 50342-28 | 52691-06* |
| 6500-14 | 8524-12 | 21229-24 | 24473-01 | 28002-05 | 35000-02 | 50345-40 | 52692-01 |
| 6500-16 | 8525-12 | 21232-21 | 24473-02 | 28002-05A | 35000-03 | 50345-50 | 52696-01 |
| 6500-18 | 8533-12 | 21233-21 | 24474-00 | 28002-05ZA | 35000-04 | 50347-01 | 52730-06 |
| 6500-28 | 8534-12 | 21234-24 | 24474-01 | 28002-06 | 35000-05 | 50347-02 | 52730-07 |
| 6500-30 | 8535-12 | 21235-24 | 24474-02 | 28002-06A | 35000-06 | 50351-01 | 52730-09 |
| 6500-32 | 8542-12 | 21236-01 | 24474-03 | 28002-06ZA | 35000-07 | 50424-01 | 52730-11 |
| 6500-34 | 8543-12 | 21236-02 | 24474-04 | 28003-01 | 35000-08 | 50424-02 | 52731-05 |
| 6500-36 | 8544-12 | 21236-03 | 24474-05 | 28003-01A | 35000-09 | 50424-03 | 52731-07 |
| 6500-38 | 8553-12 | 21236-04 | 24474-06 | 28003-01Z | 35000-10 | 50424-04 | 52731-08 |
| 6501-06 | 8562-11 | 21236-05 | 24480-11 | 28003-02 | 35000-11 | 50424-10 | 52731-09 |
| 6501-08 | 8562-12 | 21236-06 | 24480-22 | 28003-02A | 35000-12 | 50424-11 | 52733-03 |
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| 6501-12 | 8571-11 | 21236-08 | 24485-00 | 28003-03 | 35001-00 | 50424-13 | 52733-05 |
| 6501-14 | 8571-14 | 21236-09 | 24485-01 | 28003-03A | 35001-01 | 50424-14 | 52733-06 |
| 6501-16 | 8572-14 | 24001-12 | 24485-12 | 28003-03ZA | 35001-02 | 50425-01 | 52733-07 |
| 6501-18 | 8573-14 | 24001-35 | 24487-00 | 28003-04 | 35001-03 | 50425-02 | 52733-08 |
| 6502-08 | 8582-16 | 24002-03 | 24487-01 | 28003-04A | 35001-04 | 50425-03 | 52733-09 |
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| 6502-12 | 8589-16 | 24002-07 | 24489-01 | 28003-05 | 35001-06 | 50425-52* | 52733-11 |
| 6502-14 | 8591-16 | 24002-39 | 24489-10 | 28003-05A | 35001-07 | 50426-02 | 52733-12 |
| 6502-16 | 8592-12 | 24003-31 | 24489-20 | 28003-05ZA | 35001-08 | 50426-05 | 52733-13 |
| 6502-18 | 8597-12 | 24004-23 | 24490-01 | 28003-06 | 35001-09 | 50426-06 | 52733-14 |
| 6505-08* | 8602-16 | 24005-27 | 24490-10 | 28003-06A | 35001-10 | 50426-07 | 52733-24 |



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|---|---|---|---|---|---|---|---|
| 6506-10 | 8602-16SU | 24005-30 | 24490-20 | 28003-06ZA | 35001-11 | 50426-08 | 52734-41 |
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| 7000-18* | 8603-16 | 24014-28 | 24502-02 | 28004-04 | 35002-01 | 50427-03 | 52740-21 |
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| 7907-00 | 8688-10 | 24082-09 | 24532-16 | 28007-01A | 35004-12 | 50552-03 | 53410-13 |
| 7907-01* | 8689-10 | 24082-12* | 24533-17 | 28007-01Z | 35004-13 | 50552-04 | 53410-14 |


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|---|---|---|---|---|---|---|---|
| 7908-00 | 8692-14 | 24082-13* | 24534-21 | 28007-02 | 35004-14 | 50552-05 | 53410-16 |
| 8023-10 | 8692-14SU | 24082-14* | 24535-01 | 28007-02A | 35004-15 | 50552-07 | 53550-20 |
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| 8023-16 | 8694-09 | 24083-13* | 24536-02 | 28007-04 | 35005-02 | 50569-02 | 54118-12 |
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| 8023-20 | 8697-12 | 24083-25 | 24536-05 | 28007-05 | 35005-05 | 50573-01 | 56100-04 W |
| 8024-10 | 8697-12SU | 24084-05 | 24536-06 | 28007-05A | 35005-06 | 50573-02 | 56155-01 W |
| 8024-11 | 8697-15 | 24084-10 | 24537-18 | 28007-05ZA | 35005-07 | 50574-01 | 56155-02 W |
| 8024-13 | 8697-15SU | 24084-16 | 24538-19 | 28007-06 | 35005-08 | 50574-02 | 56158-01 W |
| 8024-14 | 8697-18SU | 24084-25 | 24539-20 | 28007-06A | 35005-09 | 50575-01 | 56158-02 W |
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| 8282-17 | 9179-11 | 24221-13 | 24855-07 | 28038-18 | 39599-18 | 51196-12 | AJ 023-14 |
| 8282-17-E* | 9179-14 SU TC | 24221-19 | 24855-08 | 28038-18Z | 39599-19S | 51197-12 | AJ 023-15 |
| 8282-17L* | 9179-18 SU TC | 24221-25 | 24855-09 | 28038-22 | 39599-19W | 51198-04 | AJ 023-16 |
| 8282-17SU | 9179-23 SU TC | 24221-32 | 24855-10 | 28039-13 | 39600-00 | 51230-02 | AJ 023-17 |
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| 8282-21 | 9181-14SU | 24222-13 | 24855-12 | 28039-15 | 39600-02 | 51230-05 | AJ 024-11 |
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| 8283-17-D | 9183-18 SU TC | 24224-06 | 24915-40 | 28042-18 | 39600-12 | 51302-02 | AJ 025-14 |
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| 8292-14 | 9188-14 SU TC | 24227-06 | 25360-24 | 28053-04 | 39600-26 | 51321-21+ | AJ 033-18 |
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| 8293-14 | 9189-11 SU TC | 24228-04 | 25379-20 | 28074-25 | 39600-28 | 51330-11 | AJ 034-13 |
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| 8353-23-A | 9452-12* | 24391-06 | 25603-03 | 30285-08 | 40011-08 | 51730-13 | Z0000123818 |


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