» BIPOLAR CLAMPS WITH "U" HANDLE «

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483

Tekno-Medical Optik Chirurgie GmbH
Sattlerstr. 11
78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Telephone: +49 (0) 7461 / 17 01 0

E-Mail: mail@tekno-medical.com
Web: www.tekno-medical.com

Content

1 Scope 4
2 Inspections 4
3 Handling 4
4 Purpose 4
5 Indication 4
6 Contraindication 4
7 Side effects and residual risks 5
8 Patient population 5
9 Patient positioning and preparation 5
10 Combinations 6
11 Disposal 6
12 Warnings and Precautions 6
13 Reprocessing instructions 7
13.1 Generally 7
13.2 On-site preparation 7
13.3 Transport 7
13.4 Preparation for cleaning / decontamination 7
13.5 Manual pre-cleaning 7
13.6 Automated cleaning 8
13.7 Automated (thermal) disinfection 8
13.8 Functional testing, maintenance 8
13.9 Maintenance of the instruments 8
13.10 Packaging 8
13.11 Sterilization 9
13.12 Storage 9
13.13 Information on the validation of the reprocessing 9
14 Additional Instructions 9
15 Reporting product issues 9
16 Warranty 10
17 Service and repair 10
18 Symbols 10
19 Product Listing 10

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483

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.

The bipolar clamps from Tekno-Medical Optik-Chirurgie GmbH (Tekno) and their accessories are delivered non-sterile and must go through the complete reprocessing cycle (cleaning, disinfection and sterilization) before the first and each subsequent use.

1 SCOPE

MD These instructions for use are valid for the bipolar clamps with U-handle from Tekno-Medical Optik-Chirurgie GmbH. (See the list of items in the last paragraph of these instructions for use.)

2 INSPECTIONS

Before each use of the HF-instruments, they must be inspected for breaks, cracks, deformations, damage and functionality.
Particular care must be taken to inspect areas such as working ends, connections and all moving parts. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out.
In addition to the efforts made by the manufacturer to select the right materials and to process them carefully, Bipolar clamps must be given professional and continuous care and reconditioning at the user's site.

3 HANDLING

Coagulation is carried out by means of electrical energy generated by HF generators for electrosurgery. The RF voltage must not be activated if the working end is not in contact with the tissue to be coagulated. These instruments can be connected to RF generators from Tekno-Medical, Erbe, Martin, Berchtold, Codman, Valleylab and other similar devices. The instructions for the respective HF generator must be observed.

Attention: Instruments for electrosurgery may only be used by people who are specially trained or instructed for this purpose. **Do not use for other purposes!**

The attending physician or user is responsible for the selection of the instruments for certain applications or surgical use, the appropriate training of the staff and the experience in the handling of the products. This product should only be used in medical facilities by trained healthcare professionals.

4 PURPOSE

The endoscopic electrosurgical forceps (clamps) are primarily used for grasping, compressing and coagulating or thermally sealing tissues in the context of minimally invasive procedures

5 INDICATION

Tekno's bipolar clamps are designed for use in minimally invasive surgery. They must be connected to the bipolar output of an RF generator by means of a suitable bipolar cable and may only be used with bipolar coagulation current and parameters for vessel sealing.

6 CONTRAINDICATION

The use of HF instruments is generally contraindicated when the use of other surgical techniques is indicated and in health conditions that inhibit the healing process, e.g.:

- impaired blood supply,
- acute and chronic, local or systemic infections,
- deep and superficial infections,
- severe muscle, nerve or vascular diseases,
- systemic diseases and metabolic dysfunction,
- Mental conditions that make it impossible to participate in the rehabilitation program (Parkinson's disease, alcoholism, drug addiction, etc.).

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483

In addition, there are contraindications,

- in case of general inoperability;
- in the absence of readiness on the part of the patient;
- if the technical requirements are not met.

Not for use on the heart and on the central circulatory and nervous system within the meaning of the regulation.

7 SIDE EFFECTS AND RESIDUAL RISKS

Incidents reported in combination with the use of HF systems:

- Unintentional activation resulting in tissue damage in the wrong place and/or damage to the equipment.
- Fire associated with drapes and other flammable materials.
- Alternating current paths that lead to burns in places where the patient or user comes into contact with uninsulated components.
- Explosions caused by the formation of sparks in the vicinity of flammable gases.
- Perforation of organs.
- Sudden severe bleeding.

When electrosurgery is used in patients with pacemakers or other active implants, special requirements apply (e.g., low HF power, patient monitoring). In any case, a cardiologist or appropriate specialist should be consulted.
Do not use in the presence of flammable or explosive substances.

Endogenous burn hazard: Endogenous burns are burns caused by high current density in the patient's tissues. Causes may include:

- The patient inadvertently comes into contact with electrically conductive parts.
- In direct skin contact with the electrode or HF cable, capacitive currents can lead to burns.

Exogenous burn hazard: Exogenous burns are burns caused by the heat of ignited liquids or gases. Explosions are also possible. Causes may include:

- inflammation of skin cleansers and disinfectants,
- Inflammation of anaesthetic gases, etc.

The working end of the instruments can still be hot after the electric current is switched off and cause burns. Unintentional activation or movement of the instruments outside the field of vision can lead to injury to the patient.

⚠ Failure to follow these instructions for use and safety may result in injury, malfunction or other unexpected incidents! The activation of the HF voltage can lead to capacitive couplings if the working end does not touch the tissue to be coagulated or is not properly positioned to deliver energy (fulguration).

8 PATIENT POPULATION

There are no fundamental restrictions on the patient population.

9 PATIENT POSITIONING AND PREPARATION

Ensure proper patient positioning, i.e., use insulating operating table pads that are dry, absorbent and liquid-tight. Isolate conductive surfaces and points of contact with the patient. In skin folds, breast folds and between the extremities, dry cellulose interlayers are required, such as fluids accumulated in body cavities, should be eliminated before starting the procedure. Use non-flammable disinfectants, use non-conductive rinsing solutions where medically possible. As a rule, any type of body jewellery of the patient must be removed before use.

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

10 COMBINATIONS

The bipolar clamps are designed to be connected to HF generators by means of appropriate cables:
(See product list in the last section of this user manual.)
To plug and unplug the cable, always only touch the plug, never pull the cable. The use of damaged cables can lead to significant hazards. Check the cable for visible damage before each use.

Damaged HF cables must not be used!

A faulty combination of the products can lead to injury to the patient, user or third parties or to damage to the products!
The application and safety instructions of the generator manufacturer must be observed!
The maximum output voltage of the generator must not exceed **500 Vp**.

Potential hazardous situations!

Always check the handles and cables for:

- Visibly exposed metal at the connection point of the RF cable,
- poor electrical connection between the handle and the RF cable,
- Poor fit between the handle and the RF cable.

11 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.

12 WARNINGS AND PRECAUTIONS

Always place patient cables (active electrode, neutral electrode) in such a way that there is no contact with the patient or other cables. Instruments that are temporarily unused must always be placed in isolation from the patient in order to avoid patient harm in the event of accidental activation of the HF current.
Consider the possible use of bipolar applications if there is a risk that HF current could flow through relatively small cross-sectional areas of the patient's body (avoiding unwanted tissue damage).
The power of the HF generator must always be set as low as possible to achieve the desired effect.
Activate HF current only when the contact surfaces are in the field of vision and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics, cables or the like.
Brand new products must have gone through the complete reprocessing process once before they are used for the first time. Bipolar clamps are impaired in their function when they come into contact with aggressive substances. For this reason, it is imperative to follow the reprocessing and sterilization instructions.
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. In order to minimize possible health risks, specific fume extraction systems should be used and, if possible, surgical filter masks should be worn. Before use, make sure that the product has been properly prepared and inspected.

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483

13 REPROCESSING INSTRUCTIONS

13.1 Generally

In general, surgical instruments may only be reprocessed by individuals who possess the necessary expertise for the intended tasks. Detailed instructions for instrument reprocessing can be found in the AKI's "Red Brochure." Links to laws, standards, and reprocessing expert committees can also be found at www.aki.org .

The lifespan of medical devices is primarily determined by their function and careful handling. Frequent reprocessing has little impact on the product. The end of the product's lifespan is typically determined by wear and tear and damage from use.

The legibility of the marking has been verified over 200 reprocessing cycles.

The cleanability and sterilizability of the instruments have been proven through 200 reprocessing cycles and are valid. Accumulation of cleaning agents or other harmful substances can be ruled out with the reprocessing procedures described in these instructions.

13.2 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.

Dissolve heavy soiling (coagulation residues) with a **3% H_2O_2** solution (hydrogen peroxide) and wipe with a disposable cloth. Then rinse thoroughly with demineralized water. Reprocess the instruments as soon as possible immediately after use. These instruments cannot be disassembled, but have a flush connection.

13.3 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.

13.4 Preparation for cleaning / decontamination

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.

13.5 Manual pre-cleaning

Soak the instruments in cold water for at least 5 minutes. If possible, clean the instruments under cold water with a soft brush until no residue is visible. Pressure flush cavities, holes and threads for at least 10 seconds with a water gun (pulsed method, minimum pressure 2 bar). The shaft should be rinsed several times via the flush connection.

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.

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483

13.6 Automated cleaning

Place the instruments in a sieve tray on the slide-in trolley, connect the flushing port of the shaft to the corresponding port of the cleaning machine and start the cleaning process.

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

13.7 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 to cool to room temperature.	

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

13.8 Functional testing, maintenance

The products must be macroscopically clean, i.e., free of visible dirt, after each cleaning.

- 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.
- Live parts must always be undamaged and in perfect condition.
- All plastic components must be checked before sterilization. The plastic parts must not be cracked, brittle or worn. In these cases, the electrode must be replaced.

Functional testing and maintenance of the instruments must be carried out extremely thoroughly. A proper maintenance procedure increases the service life of the instruments.

13.9 Maintenance of the instruments

Products with movable jaws, joints, locks 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.)

13.10 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607, DIN EN 868-2 and DIN EN 868-8.

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

13.11 Sterilization

Sterilization of the products with fractionated pre-vacuum process (according to DIN EN 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.

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.

13.12 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.

Protect from sunlight!

13.13 Information on the validation of the reprocessing

The following test instructions, materials and machines were used in the validation:

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)	

14 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 reprocessing 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.

The bipolar clamps must not be placed in disinfectant solution. Moisture or residues of disinfectant/cleaning agents on the HF ports may cause interference during operation.

For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents. Highly alkaline detergents damage plastics. The instruments must not be sterilized in hot air sterilizers.

Do not use corrosive cleaning agents. Do not use highly oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

15 REPORTING PRODUCT ISSUES

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 competent authority in their locality.

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

16 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. If errors still occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself.
Tekno-Medical assumes no liability for incidental or resulting damages.
Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.
Attention: In the case of the use of the instruments in patients with Creutzfeldt-Jakob disease, Tekno-Medical declines any responsibility for reuse.

17 SERVICE AND REPAIR

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this.
Defective products must have gone through the entire remanufacturing process before being returned for repair.
For returns, use our RMA application form and the decontamination certificate. The forms can be found on our homepage: https://www.tekno-medical.com/de/service/reparaturservice/

18 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	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 0483	CE marking with number of the Notified Body 0483: **mdc – medical device certification GmbH** Kriegerstrasse 6, 70191 Stuttgart, Germany		

REF

19 PRODUCT LISTING

Printed on: 13.01.2025

These instructions for use are valid for the following products:

707-000	707-001	707-001-45E*	707-001E	707-002

Combination products (cables)

707-300
707-301
707-303

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com
CE 0483