



» HF-CABLES AND ADAPTORS «





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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. The products are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.



1 SCOPE



These instructions for use are valid for the reusable HF cables and HF adapters from Tekno-Medical Optik-Chirurgie GmbH (hereinafter “Tekno-Medical”).

(See product list in the last section.)

2 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 instruments for specific applications or operational use, the appropriate training of personnel and the experience in handling the products.

3 PURPOSE

HF cables & adapters are used to connect HF accessories for monopolar or bipolar application to an electrosurgical generator.

4 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.

5 SAFETY INSTRUCTIONS

The maximum rated accessory voltage can be found in these instructions for use (Chapter 9), on the label or in the current product catalogue. If anything is unclear, please contact the manufacturer.

A visual and functional check must be carried out before each use. Make sure the RF cable or adapter is securely and correctly connected to the generator. Care must be taken to avoid damaging the RF cables or adapters.

It is important to ensure that there are no flammable substances in the immediate vicinity during the entire application, otherwise there is a risk of explosion.

The use of RF current can cause damage to pacemakers and in vivo cardiac defibrillators, so affected patients must consult a cardiologist before the procedure.

Incidents reported in connection with the use of electrosurgical systems:

- Accidental activation resulting in tissue damage in the wrong location and/or equipment damage.
- 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 sparks in the environment of flammable gases.
- Perforation of organs. Sudden heavy bleeding.

6 PATIENT POPULATION

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

7 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. Steel instruments must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion.

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 essentially 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.





7.1 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.

7.2 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.

7.3 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.

7.4 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.

7.5 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

7.6 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.	

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

7.7 Functional testing

After each cleaning, the products must be macroscopically clean, i.e., free of visible contamination.

Stained products must be sorted out immediately and given special treatment. If errors or damage occur, 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 product must be replaced.



7.8 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.

7.9 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.

7.10 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.

7.11 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

8 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. The instruments must not be sterilized in hot air sterilizers. Strongly alkaline cleaning agents damage plastics and anodized coatings.

9 MAXIMUM RATED VOLTAGE

Designation	U_{max}
Monopolar cables & adapters	5,0 kVp
Bipolar cables & adapters	1,0 kVp
Neutral electrode cable	5,0 kVp

10 REPORTABLE EVENTS




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 their place.





11 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors 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 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.













12 SERVICE AND REPAIR

Do not carry out repairs or modifications of the product on your own. Repairs only by authorized personnel. 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>

13 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



14 PRODUCT LISTING

Printed on: 08.10.2024

707-010	707-317*	707-360*	707-526	Z0000126392
707-300	707-322*	707-361*	707-540*	Z0000126916
707-301	707-330	707-362*	790-310	Z0000126917
707-302	707-331	707-430*	790-311	Z0000127747
707-303	707-332	707-433*	790-312	Z0000127950
707-303-4*	707-333	707-510	790-313	Z0000129902
707-306*	707-338	707-511	90029-08*	Z0000130406
707-309	707-339	707-519	90721-03	Z0000130431
707-310	707-340	707-520	90722-03	Z0000131289
707-311	707-341	707-521	90723-03	Z0000131290
707-312	707-343	707-523*	Z0000124985	
707-315*	707-350	707-525	Z0000126078	