



» BIPOLAR COAGULATION FORCEPS EVO II & EVO III «





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In order to keep hazards to patients, users or 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 coagulation forceps 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



These instructions for use are valid for the dismantable bipolar coagulation forceps EVO II & EVO III from Tekno-Medical Optik-Chirurgie GmbH.

(See the product listing in the last paragraph of these instructions for use.)

2 INSPECTIONS

Before each use of the coagulation forceps, they must be inspected for fractures, cracks, deformations, damage and functionality.

Particular care must be taken in areas such as interlocks, working channels, 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 in selecting the right materials and processing them with care, the coagulation forceps must be professionally and continuously cared for and reprocessed by the user.

3 HANDLING

The products may only be used for their intended use by appropriately trained and qualified personnel. 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.



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!



Caution: Especially when using scissors, deflagration can occur during the coagulation of parenchyma tissue.

Maximum output voltage of Umax generator: 500 Vp.

The power of the HF generator must always be set as low as possible to achieve the desired effect.

4 INTENDED PURPOSE

The endoscopic electrosurgical forceps are primarily used for grasping, compressing and coagulating or thermal sealing of tissues in the context of minimally invasive procedures.

5 INDICATION

The bipolar coagulation forceps EVO II & EVO III were developed 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 CONTRAINDICATIONS

The use of coagulation forceps is generally contraindicated when the use of other surgical techniques is indicated. 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.

Do not use for tube sterilization or tube coagulation for sterilization.

The doctor in charge must decide on the basis of the patient's general condition whether the intended application can be carried out. The instrument should not be used if, in the opinion of the responsible physician, the risks to the patient exceed the benefits.

Not for use on the central circulatory and nervous system within the meaning of the Medical Device Regulation (EU) 2017/745 (MDR).



7 SIDE EFFECTS AND RESIDUAL RISKS

When direct current or low-frequency alternating current enters the body, electrolysis can occur at the point of contact with the electrode. This chemical effect disappears at higher frequencies.

Direct current or low-frequency alternating current can depolarize cell membranes and cause neuromuscular arousal states.

Electrosection leads to higher collateral tissue damage compared to incisions with a scalpel and can therefore lead to histological changes at the incision site.

Thermal damage can lead to carbonation at the exit site, vascular thrombosis and collagen changes; a thorough assessment of the benefits and appropriateness of the proposed application is therefore appropriate.

Incidents reported in connection 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.

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 or the like.

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 RF 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 electrode can still be hot after the electric current is switched off and cause burns. Unintentional activation or movement of the instrument outside the field of vision could result in injury to the patient.



Failure to follow these instructions for use and safety may result in injury, malfunction or other unexpected incidents!

8 PATIENT POPULATION

There are no fundamental restrictions on the patient population.

9 COMBINATIONS

9.1 General

The coagulation forceps are designed to be combined with the following products:

- Inserts (electrodes)
- Connection cable (RF cable)

(See product list in the last section of this user manual.)



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!

Potential hazardous situations!

Always check the handles 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.



9.2 Length of accessories

Note (in accordance with DIN EN IEC 60601-2-2, subsection 202.7.9.2.14 k):

**The length of the connection cables, which are considered antennas, is between 3 – 5 meters.
The working length of the complete instruments is 340 mm.**

10 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.

11 WARNINGS



- 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).
- 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. Coagulation forceps corrode and become 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. Especially when handling 3 mm instruments for use in minimally invasive surgery, special care must be taken.

To plug in and out, always touch the cable only at the plug, never pull on 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!

In order to minimize possible health risks, specific fume extraction systems should be used and, if possible, surgical filter masks should be worn.

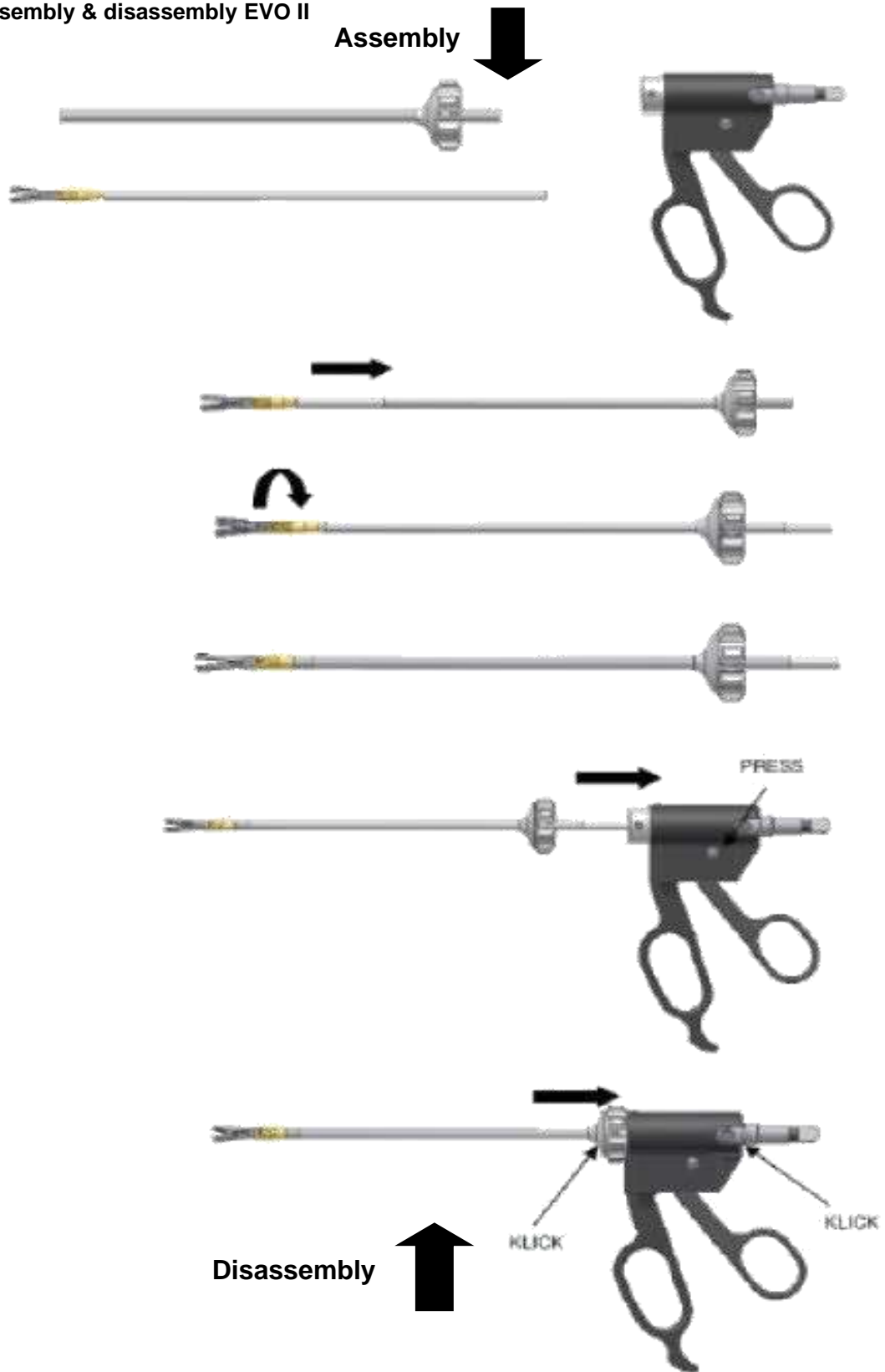
Before use, make sure that the product has been properly reprocessed and inspected.



12 ASSEMBLY & DISASSEMBLY

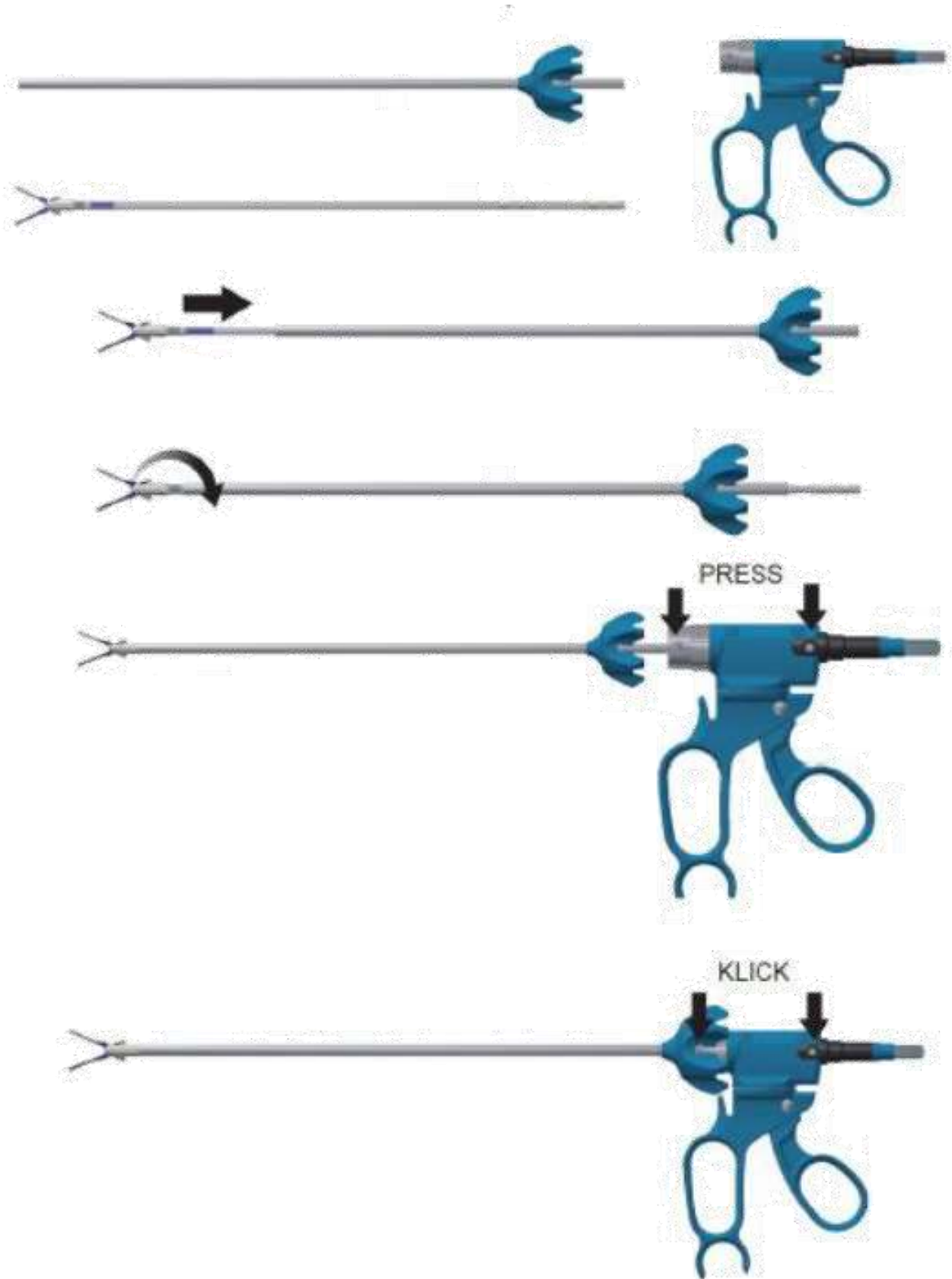
After correct assembly, the instrument can be held in both the right and left hands.
The cutting or coagulation current is triggered by means of a foot pedal, which is part of the HF surgical device.

12.1 Assembly & disassembly EVO II



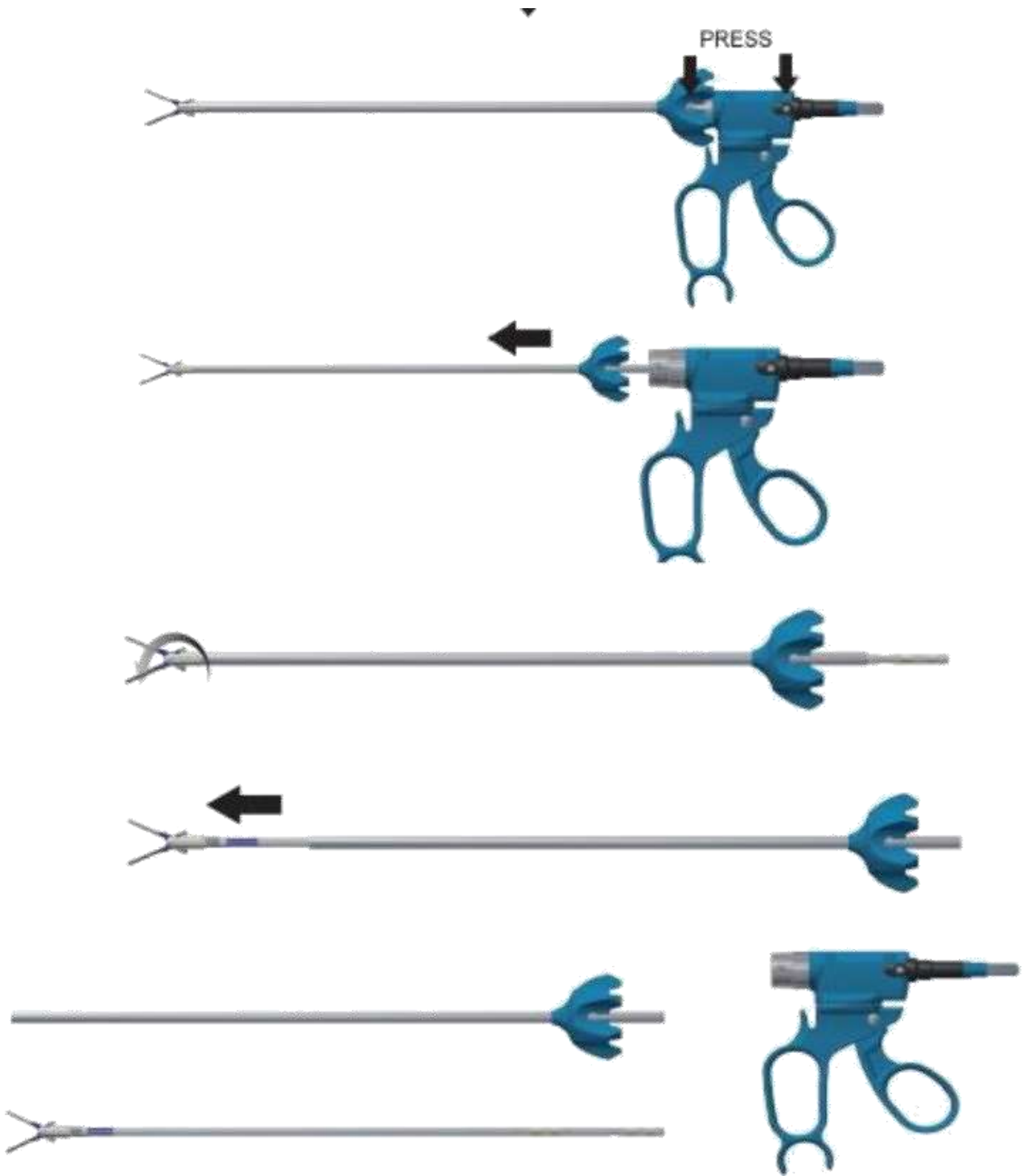


12.2 Assembly EVO III





12.3 Disassembly EVO III



**13 REPROCESSING INSTRUCTIONS**

In general, surgical 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. The service life of medical devices is essentially 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 is verified over 200 reprocessing cycles.)

13.1 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.

Dissolve heavy soiling (coagulation residues) with a **3% H₂O₂** 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.

13.2 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.

13.3 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.

13.4 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).

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.

13.5 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-rinse	Rinsing temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinse	Rinsing temperature + water quality	Cold tap water
	Exposure time	180 s
Clean	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 %
Rinse	Rinsing temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s



13.6 Automated (thermal) disinfection

Step	Parameter	
Thermal disinfection	Disinfection temperature	90°C (A ₀ 3000)
	Water quality	Deionized water
	Exposure time	300 s
Dry	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.	

13.7 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.

13.8 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.)

13.9 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.

13.10 Sterilization

Sterilization of the products with fractionated back-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.

13.11 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!

13.12 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)	



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 handles 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.

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
	Medical device		Manufacturing date
	Non-sterile		Observe the instructions for use
	Article number		Protect from sunlight
	Batch designation		Store in a dry place
	CE mark with number of the Notified Body mdc 0483: mdc – medical device certification GmbH Kriegerstrasse 6, D – 70191 Stuttgart		



19 PRODUCT LISTING

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19.1 Articles

707-000-45E*	707-009E	707-020-25	707-024-25	707-044	707-071	707-140
707-000E	707-012 E	707-020-45	707-024-45	707-045	707-072	707-141
707-001E	707-013	707-021	707-025	707-046	707-073	707-142
707-003-45E*	707-013 E	707-021-25	707-025-25	707-047	707-131	Z0000123830
707-003E	707-013-45*	707-021-45	707-025-45	707-050	707-131-25	Z0000127433
707-005-45E*	707-014	707-022	707-026	707-055	707-131-45	Z0000127434
707-005E	707-014-45*	707-022-45	707-026-45	707-056	707-132	Z0000127973
707-006E	707-015	707-023	707-040	707-058	707-133	
707-008-45E*	707-016	707-023-45	707-041	707-059	707-133-45	
707-008E	707-020	707-024	707-042	707-070	707-134	

19.2 HF cables

707-340
707-341
707-342
707-343