“BIPOLAR RESECTOSCOPY”



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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, preparation and testing of the instruments may only be carried out by trained specialists. Before using the electrosurgical instrument, read the entire instructions for use. This also applies to the instructions for use of the accessories used, including the HF generator. The specifications, safety and warnings of the respective instructions for use must be strictly adhered to and followed. The resectoscopes of 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 **bipolar resectoscopes** of Tekno-Medical Optik-Chirurgie GmbH (Tekno-Medical).
(Optics, obturators, RF generators and RF cables are not part of this product group and are therefore not described in these instructions.)

Resectoscopes basically consist of the following parts:

- Working elements (electrode transporters),
- Inner shafts,
- Outer shafts,
- Electrodes.

2 EXAMS

Before each use, resectoscopes and their accessories must be inspected for breaks, cracks, deformations, damage, and functionality. Particular care must be taken to check areas such as locking mechanisms, working channels, working ends, connections, and all moving parts. Worn, corroded, deformed, porous, or otherwise damaged instruments must be discarded.
The stainless steels and aluminium alloys used in the manufacturing process form specific passive layers as protective coatings due to their alloy composition. These materials offer only limited resistance to attack by chloride ions and aggressive media and liquids!
In addition to the efforts made by the manufacturer in selecting the right materials and processing them carefully, the resectoscopes must be subjected to proper and continuous care and reprocessing by the user.

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The attending physician or user is responsible for selecting the instruments for specific applications or surgical use, for ensuring adequate staff training, and for possessing experience in handling the products. This product may only be used in medical facilities by trained medical professionals.

Do not use for other purposes!

4 INTENDED PURPOSE

Resection instruments are used to perform endoscopic diagnostic and therapeutic procedures. Examples of their application include the visualization and manipulation of anatomical structures, ablation, incision, coagulation, cauterization, control of minor bleeding, tissue resection, vaporization, and enucleation.

5 INDICATIONS

5.1 Generally

The instruments are designed for minimally invasive use in general urological and gynaecological surgery, utilizing natural body orifices for access to the surgical area.
The use of these instruments is recommended for, but not limited to, the following types of procedures:

5.2 Urology

- Transurethral incision and resection of the prostate (TURP),
- Transurethral removal of bladder tumours (TUR-B),
- Indications for TURP in benign prostatic syndrome (BPS) or benign prostatic hyperplasia (BPH), urinary retention, bladder obstruction, Palliative care, prostate cancer, etc.

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5.3 Gynaecology (hysteroscopy)

- Endoscopically controlled uterine bleeding ,
- Metrorrhagia / Menorrhagia ,
- Transcervical resection and ablation of the endometrium ,
- Transcervical resection of myomas (myomectomy) ,
- Uterine/endocervical polyp removal ,
- Endometrial hyperplasia ,
- Endoscopic therapy of endometriosis ,
- Intrauterine adhesions/lesions ,
- Uterine malformations, etc.

6 CONTRAINDICATIONS

The instruments must not be used if, in the opinion of a qualified physician, the patient's general condition is insufficient, or if the endoscopic method is contraindicated, or if the patient is unable to undergo surgery or anaesthesia due to their general condition.
Do not use the resectoscopes if one or more of the following conditions are present:

6.1 Urology

- Acute inflammation of the abdominal cavity,
- acute pelvic inflammatory disease (PID),
- unexplained coagulation disorders,
- acute or chronic active urinary tract infections,
- acute prostatitis
- Bladder dysfunction/neurogenic detrusor instability,
- Patients with pacemakers,
- Medically related contraindications.

6.2 Gynaecology (hysteroscopy)

- Acute inflammation of the abdominal cavity,
- acute pelvic inflammatory disease (PID),
- acute inflammatory conditions (cervicitis /vaginitis),
- Cervical/vaginal infection,
- Known/existing pregnancy (if pregnancy is suspected, a pregnancy test should be performed before the resectoscopy),
- Inability to dilate the uterus/cervix,
- Cervical stenosis,
- Uterine bleeding or menstruation,
- invasive cervical cancer,
- In the case of operative hysteroscopy: Unclear histology, exclusion of a malignant tumor,
- newly occurring uterine perforation,
- In the case of synechiae: absence of symptoms, without the desire to have children .
- Patients with pacemakers,
- Medically related contraindications.

A vaginal ultrasound examination prior to hysteroscopy can reveal clinical conditions that may affect the patient's treatment.

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7 SIDE EFFECTS AND RESIDUAL RISKS

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 carbonization at the exit site, vascular thrombosis, and collagen changes; therefore, a thorough assessment of the benefits and appropriateness of the planned application is advisable.
Incidents reported in connection with the use of RF systems:

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

Special requirements apply when using electrosurgery in patients with pacemakers or other active implants (including low RF power and patient monitoring). In every case, a cardiologist or other relevant specialist must be consulted.
Instruments not in use must be stored away from the patient. Activate the RF current only when the contact surfaces are within the field of vision and have good contact with the tissue being treated. Do not touch any other metallic instruments, trocar sleeves, optics, or similar items.
Do not use in the presence of flammable or explosive substances.

Endogenous burn risk: Endogenous burns are burns caused by high current density in the patient's tissue.
Causes can include, but are not limited to:

- The patient unintentionally comes into contact with electrically conductive parts.
- Direct skin contacts with the electrode or the RF cable can cause capacitive currents to lead to burns.

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

- Inflammation from skin cleansing and disinfecting agents,
- Inflammation from anaesthetic gases, etc.

The working end of the electrode may remain hot after the electric current is switched off and cause burns.
Unintentional activation or movement of the electrode outside the field of vision may result in patient injury. Failure to observe these application and safety instructions may lead to injuries, malfunctions, or other unexpected incidents.

8 PATIENT POPULATION

There are no fundamental restrictions regarding the patient population.

9 PATIENT POSITIONING AND PATIENT PREPARATION

Ensure proper patient positioning, i.e., use insulating operating table pads that are dry, absorbent, and leak-proof. Isolate conductive surfaces and points of contact with the patient. Dry cellulose pads are required in skin folds, breast folds, and between the extremities. Any fluids that have accumulated in body cavities should be removed before the procedure begins. Use non-flammable disinfectants. Use non-conductive irrigation solutions where medically feasible. Before the procedure, it is usually necessary to remove all types of body jewellery from the patient.

10 COMBINATIONS

10.1 Generally

Our instruments are designed for use with the following products:

- Rigid endoscopes (uroscopes, cystoscopes)
- RF generators (bipolar) via specific RF cables
- Obturators (enable atraumatic insertion of the resectoscope).

Bipolar resectoscopes are designed for use with bipolar resectoscopy electrodes. It is essential to ensure that the correct electrode size is selected so that the electrode fits securely into the inner shaft.

An incorrect combination of the products can lead to injuries to the patient, user or third parties, or to damage to the products!
Observe the generator manufacturer's application and safety instructions!

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10.2 Bipolar electrodes
The bipolar electrodes (24 Charr.) have a black colour coding.

10.3 RF cable
Tekno's RF cables are compatible with all our working elements and electrodes. The type of RF generator determines the connector design on the device side.
RF cables are described in more detail in **GebA 40 RF Cables .**

10.4 RF generators
Electrical safety tests were conducted using a KLS Martin ME MB2 RF generator. Comparable RF generators can be used with our products, provided that the maximum output voltage is not exceeded and a suitable cable is used for the connection.
Excessive power settings can lead to significantly increased electrode wear. It is recommended to start with a low power level and gradually increase it until the desired mode is reached. Applications with higher device settings than described here may result in damaged instruments.

Maximum output voltage: 500 V_p !

10.5 Potentially dangerous situations!
Always check active electrodes and handles for:
- Visibly exposed metal of the shaft of the active electrode at the connection point to the active handle,
- poor electrical connection between the active handle and the shaft of the active electrode,
- Poor fit between the active handle and the shaft of the active electrode.

10.6 Length of the accessories
Notes (according to DIN EN IEC 60601-2-2, subsection 202.7.9.2.14 k):

The length of the connecting cables, which act as antennas, is between 3 and 5 meters.
The working length of the instruments is approximately 200 mm.
The total length of the fully assembled resectoscope is approximately 330 mm.

11 DISPOSAL
If the instruments can no longer be repaired and refurbished, their disposal must be carried out in accordance with the applicable country-specific regulations and laws.

12 WARNING NOTICES
- Always position patient lines in such a way that there is no contact with the patient or other lines.
- Instruments that are not in use for a period of time must always be stored in isolation from the patient to avoid patient injury in case of accidental activation of the RF current.
- The power output of the RF generator must always be set as low as possible to achieve the desired effect.
- Activate the RF current only when the contact surfaces are within sight and have good contact with the tissue being treated. Do not touch any other metallic instruments, trocar sleeves, optics, cables, or similar items.
- Upon delivery, a new medical device must undergo a thorough visual and functional inspection. If the medical device exhibits any externally visible defects (scratches, breaks, cracks, notches, damaged insulation, bent parts, or stiffness) or does not function as described in these instructions for use, we as the manufacturer or your distributor must be notified immediately.
- To ensure the safe operation of the aforementioned products, proper maintenance and care are essential. Therefore, a functional and/or visual inspection should be carried out before each use. For this reason, we refer you to the relevant sections in these operating instructions.
- Ensure that there is no moisture in the sliding part (white part) of the working element before inserting the electrode. Furthermore, the sliding part must remain completely dry throughout the entire application.
- There are no specific requirements for storing the products before sterilization. However, we recommend storing the medical devices in a clean and dry environment.
- Brand new products must undergo the complete reprocessing process before their first use. Resectoscopes corrode and their function is impaired if they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilization instructions.

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- The cable insulation must be undamaged along its entire length. There must be no cracks, breaks, or delamination of the insulation along the cable or at the connection point to the plug. The cable must not show any chips, cracks, or signs of burning.
- Avoid kinking or sharply bending the cables, or damaging the insulation. Otherwise, wire breaks may occur, which can lead to cable failure.
- Always grasp the plug when inserting and unplugging the cable; never pull on the cable itself. Using damaged cables can pose significant risks. Check the cable for visible damage before each use.

Damaged RF cables must not be used!

- Shafts with ceramic tips must be handled with great care. The shafts must be inspected for cracks or other damage before each use. Damaged shafts (chips, protrusions, or cracks) must never be used, as this could lead to malfunctions that could injure the patient.
- Use only obturators specifically designed for cases with ceramic tips. Unsuitable obturators can damage the ceramic tip.
- Ensure continuous irrigation during the procedure. The distal tip of the electrode should be immersed in the irrigation fluid and remain in view at all times. This keeps the distal tip cool and the view clear, preventing accidental burns and ensuring proper instrument function.

⚠ Do not press the release button during use. Doing so may cause sparking and damage to the instrument when the RF current is switched on.

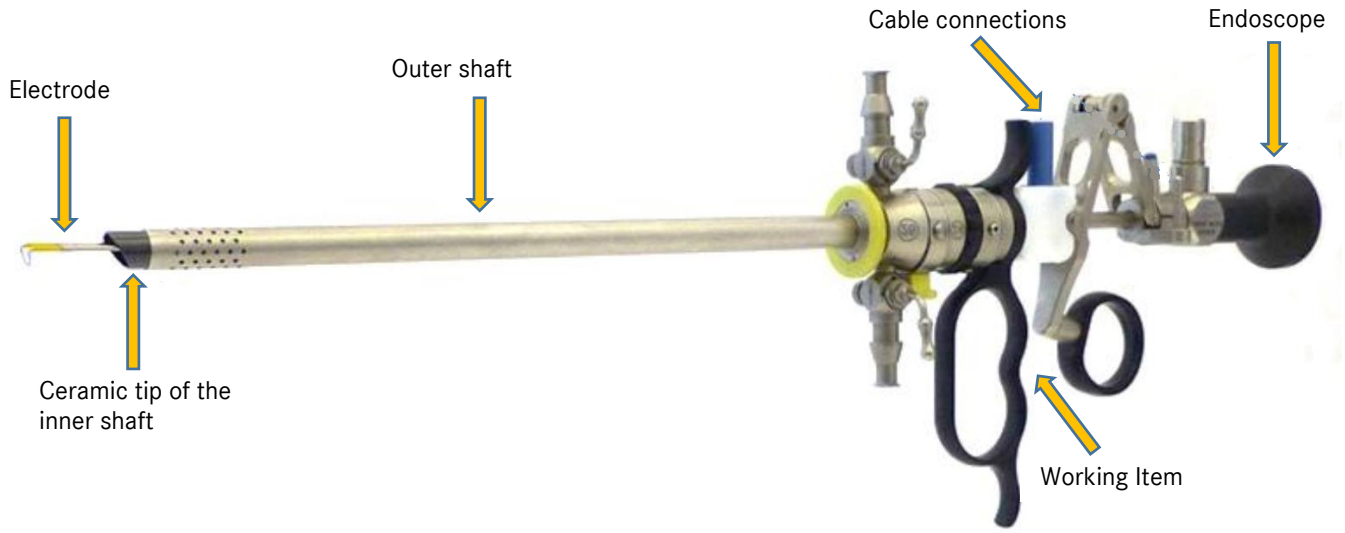
Risk of injury to patient and user!

Resectoscopes should only be inserted with the obturator in place (atraumatic ally), otherwise unintentional tissue damage may result.

Do not insert the resectoscope shaft without an obturator!

To minimize potential health risks, specific smoke extraction systems should be used and, if possible, surgical filter masks should be worn.
Before use, ensure that the product has been properly prepared and inspected.

13 ASSEMBLY & DISASSEMBLY



13.1 Assembly

- Push the RF electrode through the small tube of the working element until it stops and clicks into place.
- Slide the inner shaft onto the working element and lock it with the fastener.
- Slide the outer shaft onto the inner shaft and lock it by confirming the printhead.
- Push the endoscope through the working element and lock it with the fastener.

13.1.1 Insert electrode

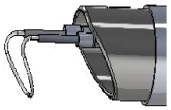
- Insert the proximal end of the electrode into the distal opening of the electrode guide tube.
- Slide the electrode into the carriage of the working element until it clicks into place.
- Grasp the electrode at the stabilizing cuff and pull it distally. The electrode must be firmly fixed.

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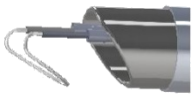
13.1.2 Check electrode:



Never bend the working end of the electrode.
Tampering with the electrode can lead to damage.
Danger to patient and user!



Correct shape



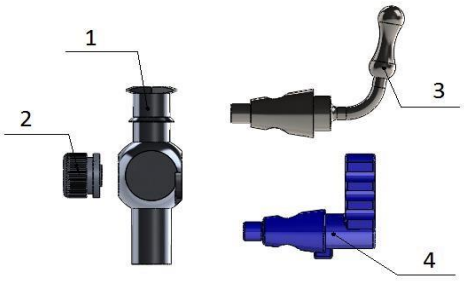
Incorrect shape

13.2 Disassembly

- Unlock the endoscope and pull it out of the working element.
- Unlock the outer shaft by pressing the push button and pull it out.
- Unlock and pull out the inner shaft
- Unlock the RF electrode by pressing the push button and pull it out.

13.3 Shafts with connectors

The taps should be disassembled before autoclaving to ensure sterility.
After sterilization, it should be reassembled under sterile conditions.
The outer shafts are available with two different tap options (stainless steel or plastic).



1 Port
2 Spring cap
3 Lever (steel version)
4 Lever (plastic version)

The suction/flushing connections (taps) must be serviced as follows after each use of the instrument:

- loosen the spring cap
- remove the lever
- thoroughly clean all parts and thinly coat them with special tap grease.
- re-insert the levers
- tighten the spring cap securely.
- functional test.

14 PREPARATION

14.1 Introducing optics

Insert a compatible optic through the optical channel of the working element and ensure that the optic is properly locked.

14.2 Replace electrode

Disconnect the RF cable from the working element before each insertion or replacement of the RF electrode.
Reconnect the RF cable only after inserting the electrode.

14.3 Introduce work element / conveyor

Unlock the obturator from the shaft and pull it out.
Insert the working element / transporter with optics into the resectoscope shaft and lock it with the locking ring / Quick-Lock.

14.4 Connect the cable

Connect the connecting cable to the cable terminals. Please note that the bipolar working element has **two** terminals to which **two** cable connectors must be attached.

14.5 Visual and functional inspection

The optic must be easy to insert into the working element and lock via the bayonet locking mechanism.

Check the locking mechanism of the shaft lock!

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15 REPROCESSINGINSTRUCTIONS

15.1 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.

15.2 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.

15.3 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.

15.4 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.

15.5 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). 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.

15.6 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
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 %
Rinsing	Rinsing temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

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15.7 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 down to room temperature.	

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

15.8 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.

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.)

15.9 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.

15.10 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.

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.

15.11 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.

15.11.1 Storage conditions

Parameter	Application	Transport / Storage
Temperature [°C]	10 – 40	-40 - 70
Relative humidity [%]	5 – 75	5 - 95
Air pressure [kPa]	70 – 106	70 - 106

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15.12 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)	

16 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 resectoscopes 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.

17 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.

18 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.

19 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.
You can find the forms on our homepage: https://www.tekno-medical.com/de/service/reparaturservice/

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CE 0483

20 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		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

21 Product Listing

Printed on: 30.09.2026

21.1 Working elements

800-301	BIPOLAR WORKING ELEMENT, PASSIV,
800-306	BIPOLAR WORKING ELEMENT, ACTIVE,

21.2 Shafts

800-331	BIPOLAR RESECTOSCOPE OUTER SHEATH
800-332	BIPOLAR RESECTOSCOPE,INNER SHEATH

21.3 Electrodes

800-351	BIPOLAR LOOP ELECTRODE, 0° STRAIGHT
800-352	BIPOLAR LOOP ELECTRODE, ANGLED 30°
800-353	BIPOLAR LOOP ELECTRODE, 90°, 24 CHARR.
800-354	BIPOLAR LOOP ELECTRODE, ANGLED 60°
800-355	BIPOLAR BALL ELECTRODE,
800-356	BIPOLAR ROLLER ELECTRODE, SMOOTH, D. 3MM
800-369	BIPOLAR MUSHROOM ELECTRODE, CONVEX,
800-370	BIPOLAR MUSHROOM ELECTRODE, BLUNT,
800-371	BIPOLAR MUSHROOM ELECTRODE,
800-372	BIPOLAR LOOP ELECTRODE, TOUGH,

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