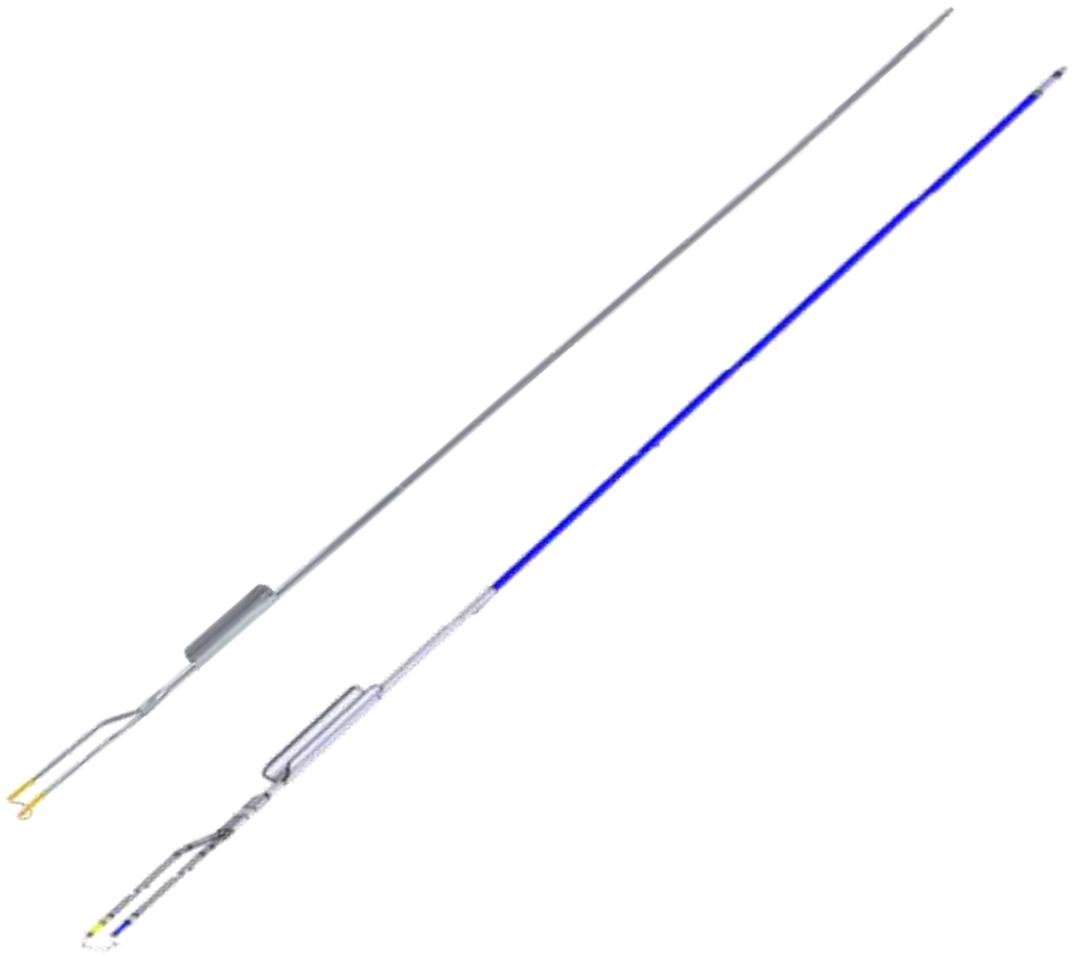
» RESECTOSCOPY ELECTRODES «



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Content

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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, reprocessing and testing of the instruments may only be carried out by trained specialists. Before using the instrument, the entire instructions for use must be read.
The electrodes from Tekno-Medical Optik-Chirurgie GmbH (Tekno) and their accessories are supplied non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and sterilisation) before the first and each subsequent use.

1 SCOPE

MD

These instructions for use are valid for the **monopolar** and **bipolar** resectoscopy-electrodes (hereinafter referred to as "**electrodes**") from Tekno-Medical Optik-Chirurgie GmbH. (See article list in the last paragraph of these instructions for use).

2 INSPECTIONS

Before each use of the electrodes, they must be checked for breaks, cracks, deformation, damage and functionality. Areas such as insulation, connections and working ends must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

3 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 the instruments for specific applications or surgical use, the appropriate training of the staff and the experience in handling the products.

4 PURPOSES

The electrodes are used as accessories for resectoscope working elements in urology and hysteroscopy.
Electrodes (in conjunction with the resectoscope) must not be used if, in the opinion of a qualified physician/surgeon, such use would endanger the patient, e.g., due to the patient's general condition or if the treatment method as such is contraindicated.

Do not use for other purposes!

5 INDICATION

The electrodes are used to ablate, cut, vaporise, cut or coagulate soft tissue in conjunction with a **monopolar** or **bipolar** electrosurgical unit.

6 CONTRAINDICATIONS

The instrument is not intended for use on the central nervous and circulatory system.
Risks from improper use:

- Material fatigue and loss of function due to exceeding the product service life.
- Risk of electric shock due to damage to the insulation, which can occur if the operating conditions and product service life are exceeded and the reprocessing instructions are disregarded.
- Risk of injury due to use of the instrument without HF current.

7 PATIENT POPULATION

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

8 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.

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9 USE AND SAFETY-NOTES

Failure to observe these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents!

9.1 General safety-notes

- Do not touch the distal end.
- Do not touch sharp edges and tips.
- The transport packaging is unsuitable for the high temperatures during autoclaving and must be discarded before the first sterilisation.
- Do not overload the instruments. Overloading due to excessive force can lead to breakage, bending and malfunction of the medical device and to injury to the patient or user. Do not bend bent instruments back into their original position, risk of breakage.
- Do not use a damaged or defective product. Sort out and label damaged product immediately and exclude further use.

9.2 HF-specific safety-notes

- For patients with pacemakers, check their compatibility with HF radiation.
- Do not place the instrument on the patient.
- Avoid carbonisation of the tissue!
- Instruments that are temporarily not in use must always be placed away from the patient to prevent patient injury in the event of accidental activation of the HF current.
- Only activate the HF current if the contact surfaces are within the visual range and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics, cables or similar.
- Only use the instrument if the insulation is undamaged.

For monopolar application:

- Use a suitable neutral electrode.
- Position the neutral electrode so that the patient is in contact with the entire surface of the neutral electrode.
- Risk of burns due to excessive heating of the neutral electrode!

Always check the electrodes and working elements for:

- Poor electrical connection between the working element and the electrode,
- poor fit between the working element and the electrode.

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

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

Exogenous burn hazard: Exogenous burns are burns caused by the heat of flammable liquids or gases. Explosions are also possible. Causes can be:

- Ignition of skin cleansers and disinfectants,
- ignition of anaesthetic gases, etc.

The working end of the electrode may still be hot after switching off the electrical current and cause burns.

10 COMBINATIONS

Incorrect combination of the products can lead to injuries to the patient, user or third parties or to damage to the products!
Our electrodes are intended for use in combination with the following products:

- Resectoscopes
- HF generators (monopolar or bipolar) via specific HF cables
- Neutral electrodes (monopolar electrodes).

It must be ensured that the correct electrode size is selected so that the electrode fits securely in the inner shaft of the resectoscope.
Details on the correct positioning of the neutral electrode can be found in the product-specific instructions for use for the neutral electrode.
In combination with the resectoscope working element, the electrodes are designed for a recurring peak voltage of **max. 2000 Vp** in the usual cutting and coagulation mode. Exceeding the maximum recurring peak voltage of the electrodes or the wrong operating mode can destroy the insulation of the electrode and lead to leakage currents.

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Recommended power levels:

Cutting mode: 120 - 180 watts
Coagulation mode: max. 100 watts

It is recommended to start with a low power setting.
Excessive power settings can lead to significantly higher electrode wear

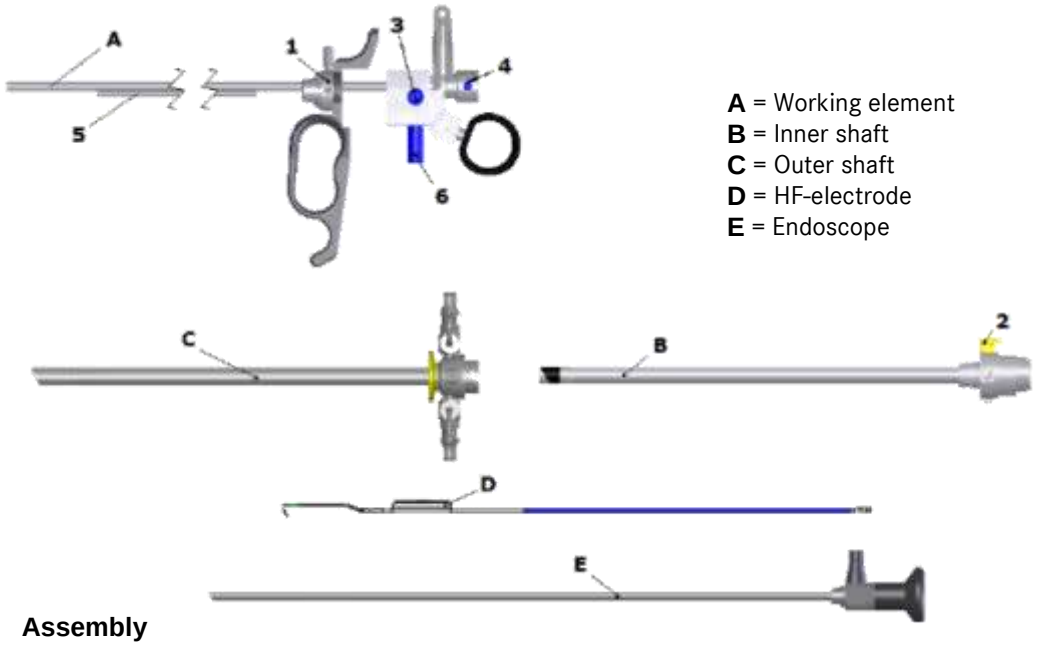
10.1 HF cables

Tekno's HF cables are compatible with all our working elements and electrodes. The type of HF generator determines the design of the connector on the device side.
(HF cables are described in more detail in the instruction manual GebA 40 HF Kabel).

10.2 HF-Generators

Electrical safety tests were carried out in combination with an ME MB2 HF generator from KLS Martin. Comparable HF generators can be used in combination with our products if it is ensured that the maximum output voltage is not exceeded and the connection is made with an appropriate cable.
Observe the generator manufacturer's application and safety instructions!

11 ASSEMBLY AND DISSASEMBLY



A = Working element
B = Inner shaft
C = Outer shaft
D = HF-electrode
E = Endoscope

11.1 Assembly

- Push the HF electrode (D) through the small tube (5) of the working element (A) until it stops and clicks into place.
- Push the inner shaft (B) onto the working element (A) and lock with the lock (1).
- Slide the outer shaft (C) onto the inner shaft (B) and lock by confirming the print head (2).
- Push the endoscope (E) through the working element (A) and lock with the lock (4).

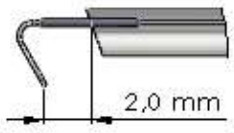
11.1.1 Insert electrode

- Insert the proximal end of the electrode into the distal opening of the electrode guide tube.
- Push the electrode into the slide of the working element until it engages
- Hold the electrode by the stabilisation sleeve and pull in a distal direction. The electrode must be firmly fixed in place.

11.1.2 Check the position of the electrode

In this position, the loop must be approx. 1.0 mm behind the distal end of the shaft.

In this position, the distance between the insulated distal end of the electrode and the optics must be at least 2 mm.



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During the administration of HF current, there must be a minimum distance of 8 mm between the working end of the electrode and the distal end of the endoscope or shaft.

Never bend the working end of the electrode. Tampering with the electrode can lead to damage.

Korrekte Form Nicht korrekte Form

Danger to patient and user!

11.2 Disassembly

- Unlock (4) the endoscope (E) and pull it out of the working element (A).
- Unlock and pull out the outer shaft (C) by pressing the push button (2)
- Unlock (1) inner shaft (B) and pull it out
- Unlock and pull out the HF electrode (D) by pressing the pushbutton (3).

11.3 Replacing the electrode

Always disconnect the HF cable from the working element before inserting or replacing the HF electrode. Only reconnect the HF cable after inserting the electrode.

11.4 Connecting the HF cable

Plug a compatible HF cable into the HF connection on the working element and ensure that the HF cable is securely seated in the holder to guarantee perfect electrical contact. When plugging in and unplugging the cable, always hold the plug, never pull on the cable.

The use of damaged cables can lead to dangers that should not be underestimated.

Check the cable for visible damage before each use.

12 REPROCESSING

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the reprocessing of surgical 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 publications of processing expert committees.
Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is 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 has been verified over 200 preparations.

12.1 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.

12.2 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.

12.3 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 dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

12.4 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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12.5 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

12.6 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 the instruments with sterile compressed air. 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.

12.7 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.
All moving parts must be checked with particular attention.
If errors or damage occur, the products must be sorted out immediately.
Functional testing and maintenance of the instruments must be carried out extremely thoroughly. A suitable maintenance procedure increases the service life of the instruments.

12.8 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.

12.9 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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12.10 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.

12.11 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/h)
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)	

13 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 and anodized coatings. 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.

14 REPORTABLE EVENTS

In accordance with the requirements of the Regulation (EU) on Medical Devices 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO

If you cannot reach us directly for reportable events, please send an email to:
safety@tekno-medical.com
Serious incidents must also be reported to the responsible local authority.

15 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno accepts no liability for any incidental or consequential damages. Tekno 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 declines any responsibility for reuse.

16 SERVICE AND REPAIR

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this.

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

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17 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 mark with the number of the notified body: **mdc – medical device certification GmbH,** Kriegerstrasse 6, D – 70191 Stuttgart		

18 PRODUCT LISTING

REF

Printed on 28.08.2024

Monopolar electrodes						
790-350*	791-350	791-358	791-451	791-467	793-252	793-354
790-350-XL*	791-351	791-363	791-452	793-240	793-253	793-355
790-352*	791-352	791-365	791-453	793-242	793-254	
790-352-W*	791-353	791-367	791-457	793-243	793-255	
790-352-XL*	791-354	791-421	791-458	793-244	793-350	
790-354-XL*	791-355	791-422	791-463	793-245	793-352	
790-363*	791-357	791-450	791-465	793-250	793-353	
Bipolar electrodes						
799-350	799-353	799-355-001*	799-360	799-367	799-373	799-576
799-350-001*	799-354	799-356	799-361	799-371	799-373-001*	799-578
799-351	799-354-001*	799-357	799-362	799-372	799-374	799-579
799-352	799-355	799-358	799-365	799-372-001*	799-378	799-580
799-577						

Monopolar electrodes have the following colour coding:

- 11 Charr, green
- 13 Charr, red
- 19 Charr, white
- 24 Charr., yellow
- 27 Charr., brown / black

Bipolar electrodes have double colour coding at the working ends:

- 19 Charr, white / blue
- 24 Charr., yellow / blue
- 27 Charr., brown / blue

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