» HYBRID RESECTOSCOPY «

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Content

TEKNO GERMANY
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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 resectoscopes of Tekno-Medical Optik-Chirurgie GmbH.
(Optics, obturators, HF generators and HF cables are not part of this product group and are therefore not described in these instructions for use.)

2 INSPECTIONS

Before each use of the resectoscopes and their accessories, 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. The stainless steels (stainless) and aluminum alloys used for production form specific passive layers as protective layers due to their alloy. These materials are only partially resistant to the attack of 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 professionally and continuously cared for and professionally 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.

Do not use for other purposes!

Resectoscopes basically consist of the following parts:

- Handpieces,
- Inner shafts,
- Outer shafts,
- Electrodes.

Handpieces are used to pick up and fix the optics and the electrode as well as for the controlled insertion of flexible/semi-rigid auxiliary instruments via the instrument inlet channel under optical control.
Inner shafts are used to accommodate and fix the work element and work insert.
Outer shafts are used to pick up and fix the inner shaft and to vacuum out rinsing fluid.
Electrodes are used to ablate, cut, cut or coagulate soft tissue.

4 INTENDED PURPOSE

Endoscopic electrosurgical handles are used to pick up and operate various working parts. These handles are used to establish the connection to HF devices.

5 INDICATION

Resectoscopes are used in endoscopic diagnosis and treatment in the context of urological and gynecological procedures.

6 CONTRAINDICATION

The use of resectoscopes 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.

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Not for use on the central circulatory and nervous system within the meaning of the Medical Device Regulation (EU) 2017/745 (MDR). The doctor in charge must decide on the basis of the patient's general condition whether the intended application can be carried out.

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.
Instruments that are temporarily unused must be placed in isolation from the patient. 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 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 anesthetic gases, etc.

Electrodes in combination with the resectoscope working element are designed for a recurring peak voltage of **max. 2000 V_p** in the usual cutting and coagulation mode.
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 electrode 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.

8 PATIENT POPULATION

There are no fundamental restrictions on 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 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 jewelry of the patient must be removed before HF-use.

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10 COMBINATIONS

10.1 General

Our instruments are designed to be combined with the following products:

- rigid endoscopes (uroscopes, cystoscopes)
- HF generators (monopolar or bipolar) via specific RF cables
- Obturators (allow atraumatic insertion of the resectoscope).

Resectoscopes are intended for use with RF electrodes. Monopolar and bipolar electrodes can be used. It is important to ensure that the correct electrode size is chosen so that the electrode fits securely into the inner shaft.

10.2 Electrodes

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 setting can lead to significantly higher electrode wear.
It is important to ensure that the correct electrode size is chosen so that the electrode fits securely into the inner shaft of the resectoscope.
Details on the proper positioning of the neutral electrode (monopolar application) can be found in the product-specific instructions for use of the neutral electrode

10.3 HF Cable

Tekno's RF cables are compatible with all our working elements and electrodes. The type of RF generator determines the design of the straightener on the side of the device.

10.4 HF generators

Electrical safety tests were carried out in combination with an HF generator ME MB2 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 has been made with an appropriate cable.

Maximum output voltage: 2000 V_p.

⚠ A faulty combination of the products can lead to injury to the patient, user or third parties or to damage to the products! Observe the application and safety instructions of the generator manufacturer!

Potential hazardous situations!

Always check active electrodes and handles for:

⚠
- visibly exposed metal of the shaft of the active electrode at the point of connection 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.

10.5 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 instruments is 200 - 300 mm.

11 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.

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12 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).
- 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.

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.

Make sure that there is no moisture in the sliding part (white part) of the working element before inserting the electrode. In addition, the sliding part must be completely dry during the entire application.

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.

Brand new products must have gone through the complete reprocessing process once before they are used for the first time. Resectoscopes corrode and are impaired in their function if they come into contact with aggressive substances. For this reason, it is imperative to follow the reprocessing and sterilization instructions.

Do not press the release button (button (3)) during use.
Otherwise, if the HF current is switched on, sparking and damage to the instrument may occur.

Risk of injury to patient and / or user!

To plug in and pull out the cable, always touch only the plug, never pull 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.

Damaged HF cables must not be used!

Insertion of resectoscopes only with the obturator (atraumatic) inserted, otherwise unintentional tissue damage could be the result.

Do not insert a resectoscopy shaft without an obturator!

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!

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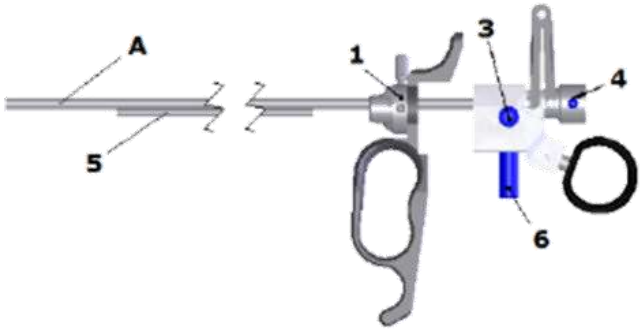
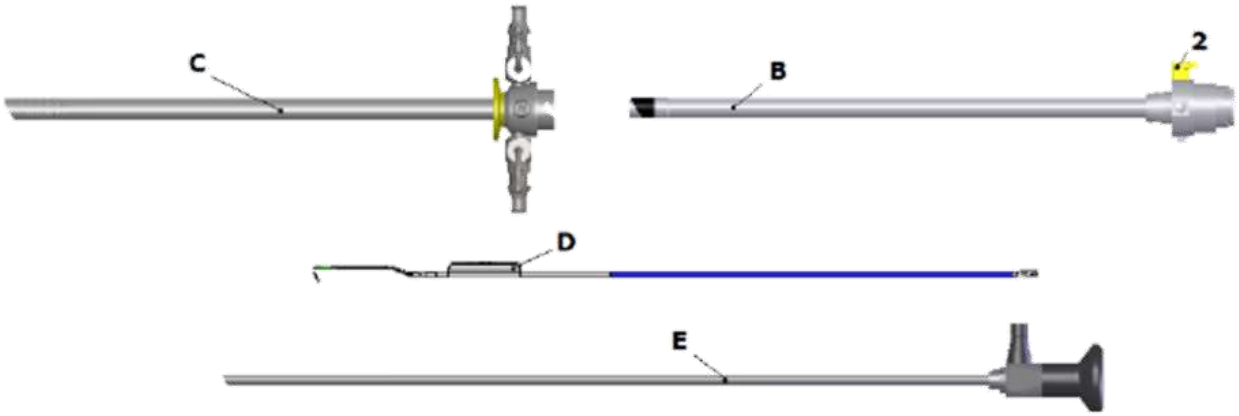
13 ASSEMBLY & DISASSEMBLY



A = Work Item
B = Inner shaft
C = outer shaft
D = HF electrode
E = endoscope



13.1 Assembly

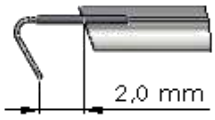
- Push the HF electrode (**D**) through the small tube (**5**) of the working element (**A**) until it stops and snaps into place.
- Slide the inner shaft (**B**) onto the working element (**A**) and lock it with a lock (**1**).
- Slide the outer shaft (**C**) onto the inner shaft (**B**) and lock by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

Insert resection electrode:

- Insert the proximal end of the electrode into the distal opening of the electrode guide tube.
- Advance the electrode into the carriage of the working element until it clicks into place
- Grasp the electrode on the stabilizing cuff, pull in the distal direction. The electrode must be firmly fixed

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

Check the position of the electrode



Check that the distance between the insulated distal end of the electrode and the optics is at least 2 mm.

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

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

Correct form

Incorrect form

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13.2 Dismounting

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

13.3 Shafts with connections (taps)

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 variants (stainless steel or plastic).

1 Port
2 Feather cap
3 Lever (Steel Variant)
4 Lever (plastic variant)

The connections (taps) must be maintained after each use of the instrument as follows:

- loosen the spring cap,
- take out the lever,
- thoroughly clean all parts and coat them thinly with special tap grease,
- reinstall levers,
- tighten the spring cap,
- Testing.

14 PREPARATION

14.1 Introduce optics

Insert compatible optics through the optics channel of the work item and make sure that the optics are locked correctly.

14.2 Replacing the electrode

Remove the HF cable from the working item before each insertion or replacement of the HF electrode. Only after inserting the electrode reconnect the HF cable.

14.3 Introduce work item / transporter

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

14.4 Connecting the HF cable

Plug a compatible HF cable into the HF connector on the working element and make sure that the HF cable is securely seated in the port to ensure proper electrical contact.

14.5 Visual and functional inspection

The optics must be easily inserted into the working element and locked using the bayonet lock.

Check the locking mechanism of the shaft lock.

15 REPROCESSINGINSTRUCTIONS

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.
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 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.)

Instruments made of aluminum must only be treated with non-alkaline, neutral disinfectants and cleaning agents and fully desalinated water, otherwise damage to the anodized surface may occur. Alkaline cleaning processes lead to color fading and stains on color anodized surfaces after a few cycles.

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15.1 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% 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.

15.2 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.

15.3 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.

15.4 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.

15.5 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

15.6 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. Dry cavities and channels of instruments with sterile compressed air. Allow products to cool down to room temperature.	

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15.7 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.

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.)

15.8 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.

15.9 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.

15.10 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.

15.11 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)	

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.

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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/

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	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		

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21 PRODUCT LISTING

REF

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21.1 Working elements

797-300	797-308	797-570
797-305	707-309	797-571

21.2 Shafts

The current product list of resectoscopy shafts can be found in the **GebA 31-II-004_01**.

21.3 Electrodes

The current product list of resectoscopy electrodes can be found in the **GebA 510-II-007_01**.

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