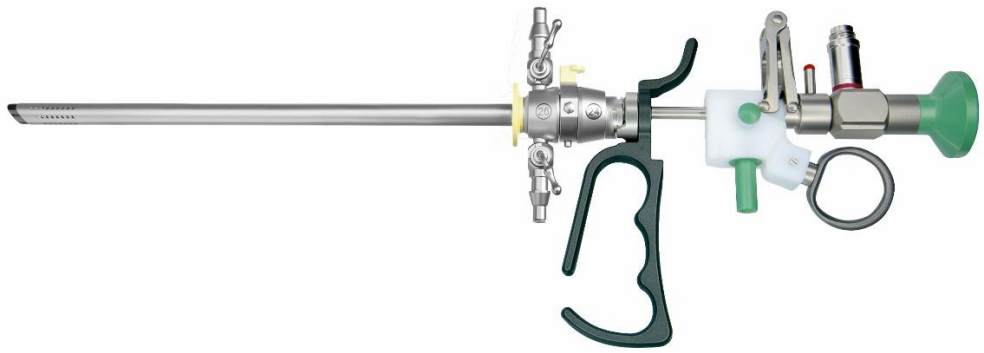
INSTRUCTIONS FOR USE (EN)

RESECTOSCOPY SYSTEMS



RUDOLF Medical GmbH + Co KG
Zollerstrasse 1, 78567 Fridingen an der Donau,
Germany
Phone +49 7463 9956-0
Fax +49 7463 9956-56
sales@RUDOLF-med.com
www.RUDOLF-med.com

D0288 / Rev R / ACR00667 / 2025-03-19

CE 0297

PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

- These instructions for use are valid for the RUDOLF Medical resectoscopy system. A resectoscopy system always consists of a working element, an endoscope, an electrode and, depending on the locking mechanism, an inner and outer sheath.
- The obturator/visual obturator is used for atraumatic insertion of the outer sheath. The obturator is then replaced by the endoscope and the working element with electrode.

You have received a high-quality product, the proper handling and use of which is described below.

The instruments must only be used by persons who have been specially trained and instructed in their use (surgeon, operating room nurse, specialist for reprocessing).

NON STERILE RUDOLF Medical instruments are supplied non-sterile and must be cleaned, disinfected and sterilized before first use and immediately after each use. Ensure that the packaging is undamaged on delivery. Protective caps and transport packaging must be removed beforehand.

INTENDED PURPOSE

Resectoscopy system

Sheaths and guides are intended for endoscopic diagnosis and treatment during urological and gynaecological procedures.
Working elements for resectoscopy in combination with suitable HF electrodes are intended for minimally invasive surgical procedures.

Obturator and stricture scalpel

Obturators are intended for the gentle insertion of sheaths during endoscopic procedures in gynaecology and urology.
Stricture scalpels are intended to perform an incision of the urethra with an optical urethrotome during endoscopic procedures in gynaecology and urology.

Urethrotome

Urethrotomes are used in urology and are intended for an incision of the urethra.

CONTRAINDICATION

The instrument should not be used in the following cases:

- If in the opinion of the attending physician, the risks exceed the benefits for the patient.
- The endoscopic procedure is found to be contraindicated in patients.
- If at least one of the following situations exists:
  - Patients with pacemakers
  - Presence of flammable or explosive substances
  - Coagulation disorder

For gynecological surgery:

- Acute inflammation in the abdomen
- Vaginal infection
- Pregnancy

For urological surgery:

- Urinary tract infection

SIDE EFFECTS AND RESIDUAL RISKS

- Direct current or low-frequency currents generate electrolysis in the human body at the point where the electrode touches the tissue. At higher frequencies, these chemical effects disappear.
- Direct current or low-frequency currents can cause depolarization of the cell membranes and neuromuscular irritation.
- Compared to scalpel incisions, electrotomy causes greater collateral tissue damage and creates histological distortions at the resection margins.
- Damage caused by heat can cause charring at the resection margins, vascular thrombosis and collagen denaturation. Careful consideration of the advantages and suitability for the intended application is therefore recommended.

QUALIFICATION OF THE USER

- The products must only be used in medical facilities by sufficiently qualified medical personnel.

⚠ WARNINGS AND PRECAUTIONS

General:

- **Improper use can lead to dangerous situations.**
- **An incorrect combination of products can lead to injuries to patients and users as well as damage to the products used.** The safe combination of instruments with each other must be checked by the user before clinical use.
- Incorrect use and overstraining due to twisting/levering can lead to fractures and permanent deformation.
- Do not use metal brushes or abrasive cleaners, as corrosion can occur if the surface is damaged.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of instruments must be applied.

HF surgery:

- The electrodes used for standard resectoscopy may only be used in standard cutting and standard coagulation mode with a return peak voltage of max. 2 kVp.
- The electrode tip may still be hot enough to cause burns even after the power has been switched off.
- Unintentional activation or movement of the electrode outside the field of view may result in injury to the patient.
- As soon as the current flow is activated via the foot pedal, no other metallic instrument may touch the resectoscope sheath, otherwise an electric shock may result.
- Endogenous risk of burns can be caused by a critical current density in the patient's tissue. Possible causes: the patient has accidentally come into contact with electrically conductive parts. In the event of direct skin contact with HF cables and electrodes, the capacitive currents can cause burns.
- Exogenous burn hazard can be caused by the ignition of liquids and gases or by explosions. Possible causes include the ignition of skin cleansing agents, disinfectants or anesthetic gases.
- Switch on the HF current only when the electrode is in the surgeon's field of view and in contact with the tissue. Otherwise, the resectoscopy fluid may become too hot and injure the patient.
- Do not bend, deform or modify the electrode or the cutting wire.
- Make sure that the electrode size corresponds to the size of the inner sheath.
- To minimize the health risk associated with the procedure, specially designed smoke evacuation systems should be used, if available, and surgical masks should be worn.
- Before inserting the electrode, make sure that there is no moisture in the insulator (A) of the working element. In addition, the insulator must be kept completely dry during the surgical procedure.
- Using the wrong irrigation fluid may lead to a short circuit and injure the patient. Therefore, make sure you select the correct irrigation fluid depending on whether you use a monopolar or a bipolar resectoscope. For monopolar resection, the irrigation solution is electrolyte-free, e.g. 1.5% glycine or a mixture of sorbitol and mannitol. For bipolar resectoscopy, an isotonic saline solution (NaCl) of 0.9% is prescribed as irrigation fluid.

⚠ When used in combination with the laser resectoscope

- When using laser, comply with the instructions of the laser device manufacturer and the general regulations on laser.
- The prescribed personal protective equipment must be worn.
- For instruments with a corresponding holder, the laser probe must always be inserted as far as it goes. If the laser probe is not inserted as far as it will go or is accidentally retracted, the edge of the sheath or the endoscope may be destroyed when the laser probe is activated.
- The resectoscope must not be used outside the field of view.
- The laser may only be activated when the tip of the laser probe appears fully in the field of view of the endoscope and the intended application area has been contacted. The exit of the pilot beam must be inspected.
- The focused laser beam generates heat.
- The heat generated by the laser beam impairs the stability of the instrument parts.
- Do not point the laser beam at instrument parts, especially plastic parts.
- Maintain sufficient safety distance.
- There is a risk of eye damage when used without a suitable filter attachment on the eyepiece of the endoscope.
- Patient leakage currents can add up if endoscopes with endoscopically usable accessories operated electrically, or other electrically operated products are connected to the instruments.
- A smoke extraction system is recommended when using a laser probe, due to the formation of gases and vapors.

⚠ If the manufacturer of the laser probe makes technical changes to the working length and the diameter, there is a risk that compatibility is no longer guaranteed. It is therefore important to check the compatibility of the laser probe, the fixation and distal position of the probe head before use.

POSITIONING THE PATIENT

– Make sure that the neutral electrode is positioned correctly, otherwise there is a risk of burns.
– The patient must never come into contact with other metal parts (e.g. operating table) and must be insulated from all electrically conductive parts.
– The patient must be placed on a dry, electrically insulated surface.
– Avoid skin-to-skin contact (arms, legs). Place dry gauze between the body, arms and legs to avoid skin-to-skin contact.
– The operating table must be earthed.

CURRENT FLOW IN THE BODY DURING MONOPOLAR HF SURGERY

– The current paths in the patient's body should be short.
– When selecting the neutral electrode, make sure that it can be monitored and that it is compatible with the contact quality monitor.
– The neutral electrode must be installed in such a way that no liquid can accumulate around the electrode.

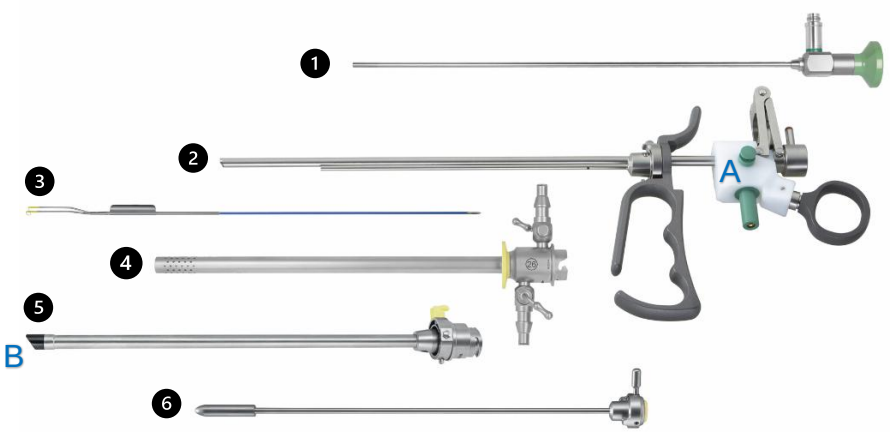
PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for the following:

- External damages including:
  - Deformed sheath, dents, burrs, cracks, sharp edges, breaks, loose parts
  - For cables: insulation, damage to the cable
  - Wear and tear
  - Also look out for damage to plastic and ceramic parts.
  - Stricture knife: the stricture knife must be in perfect condition and should be inspected before each use. It must be replaced, if the plastic parts are damaged.
- Correct function
- Cleaning agent or disinfectant residues
- After cleaning and disinfection or before sterilization, we recommend lubricating moving parts with silicone-free, biocompatible medical white oil approved for steam sterilization.
- Grease especially the taps and threads of the sheaths with instrument grease. See section "Grease taps during assembly".

PRODUCT DESCRIPTION

System components



1 Endoscope
2 Working element
3 Electrode
4 Outer sheath
5 Inner sheath
6 Obturator
A Insulator (insulating Teflon block)
B Ceramic tip

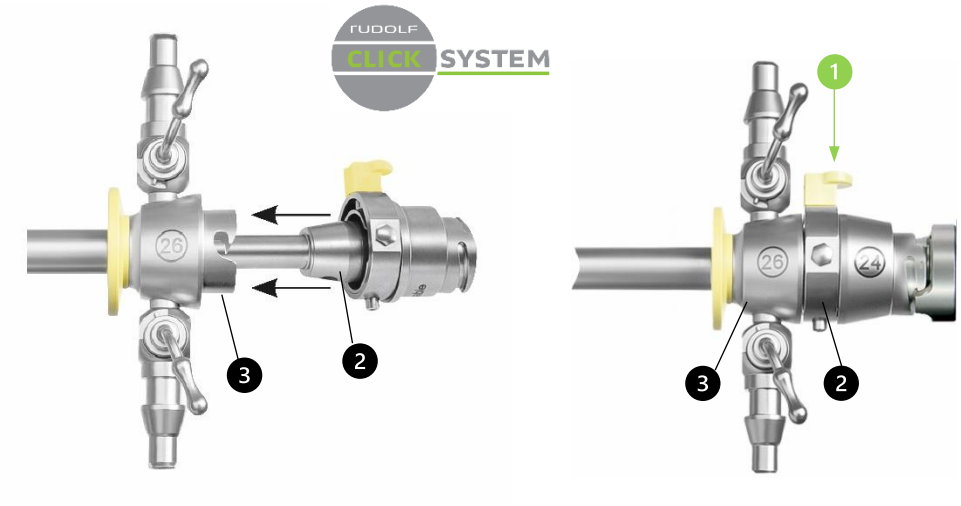
CLICK SYSTEM / BAYONET LOCK

Depending on the version, the sheaths are equipped with a click system and/or a bayonet locking system. The working element and the endoscope generally have a bayonet locking system.

CLICK SYSTEM

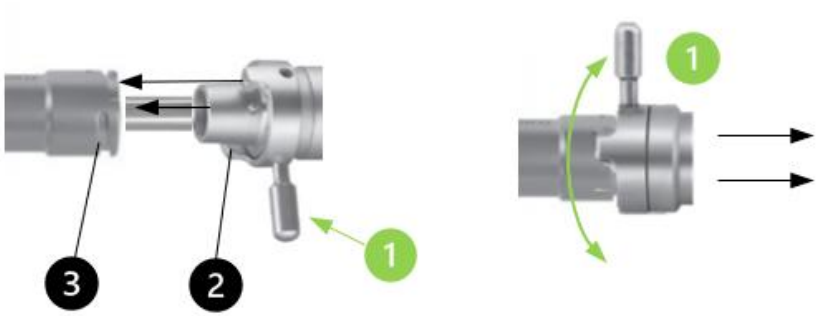
- The Click System is an automatic locking mechanism in which instruments, which can be combined, are locked together by simply pressing the adapter (2) into the holder (3) are locked to each other with a "click".
- Pressing the push button (1) on the adapter (2) releases the connection to the holder (3). The instruments can then be detached from each other.

⚠ Only combine compatible instruments with the same colour coding.
The arrow markings on the instrument lock may also serve you as orientation. If these arrows have the same dimensions or contour, compatibility is guaranteed.

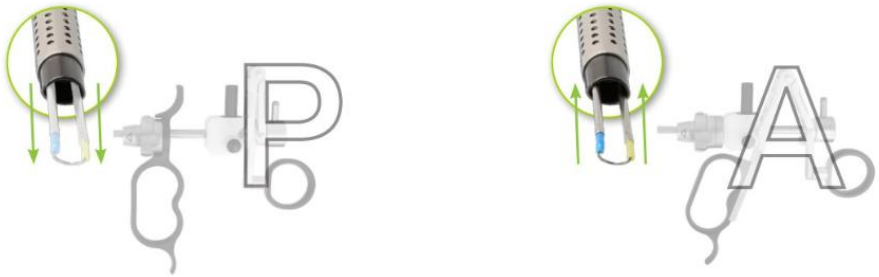


BAYONET LOCK

- With the bayonet locking system, two instruments that can be combined, are locked by means of a lever. The adapter (2) must be positioned by turning the lever (1) so that its claws can be inserted into the threaded groove of the holder (3) and locked using the lever (1).
- The instruments can be separated from each other by releasing the lever (1) from the adapter (2) from the holder (3).



Distinction between passive and active working element

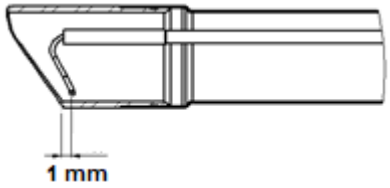


The working element essentially differs in the position of the electrode in the basic position of the instrument:

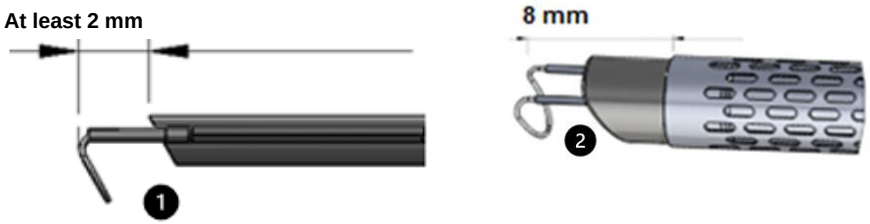
1. With a passive working element (P), the electrode is pushed out of the sheath by moving the handle.
2. With an active working element (A), the electrode is withdrawn into the sheath by moving the handle.

Electrode position

1. In the rest position of the passive working element, the electrode loop is located approx. 1 mm behind the distal end of the sheath.
2. When using an active working element, the rest position is reached by fully closing the instrument handle.



The distance between the non-insulated electrode tip and the endoscope is at least 2 mm in the rest position. The wire loop runs parallel to the sheath and the endoscope (1). During HF applications, a minimum distance of 8 mm is required from the tip of the HF electrode (i.e. wire loop, ball head and blade) to the distal end of the endoscope or sheath (2).



⚠ Never bend or deform the wire loop. This can damage the electrode, resulting in injury to the patient and user.

⚠ Insufficient distance between HF-conductive components and other conductive components can lead to unintentional tissue and/or instrument damage.

Explanation of the combination products in resectoscopy

⚠ Only combine compatible instruments with the same color coding. An incorrect combination of products can injure patients and users as well as damage products from RUDOLF Medical and other manufacturers.

Monopolar color coding (inner/outer sheath and obturator)

- 19Fr white
- 24Fr yellow
- 27Fr black

Bipolar color coding (inner/outer sheath and obturator)

- 17.5Fr green
- 19Fr turquoise
- 24Fr violet

Monopolar HF electrodes

Resectoscopes are to be used together with HF electrodes for resectoscopy. The corresponding sheaths and electrodes are color-coded according to size as follows:

- 19Fr white
- 24Fr yellow
- 27Fr brown

Bipolar HF electrodes

Bipolar HF electrodes are coded at the distal end with a double color code:

- 17.5Fr green/green (can also be used for monopolar application)
- 19Fr white/blue
- 24Fr yellow/blue

HF cable

The HF cables supplied by RUDOLF Medical are compatible with all our working elements and electrodes. It is the HF generator model, which is used, that determines the cable plug at the generator and therefore must be checked by the specialist distributor before ordering.

HF generator

Electrical safety tests were carried out with the ME MB2 HF generator from KLS Martin. Comparable HF generators can be used together with medical products from RUDOLF Medical, if the maximum output power (maximum 2 kVp) is not exceeded and the connection is made with suitable cables.

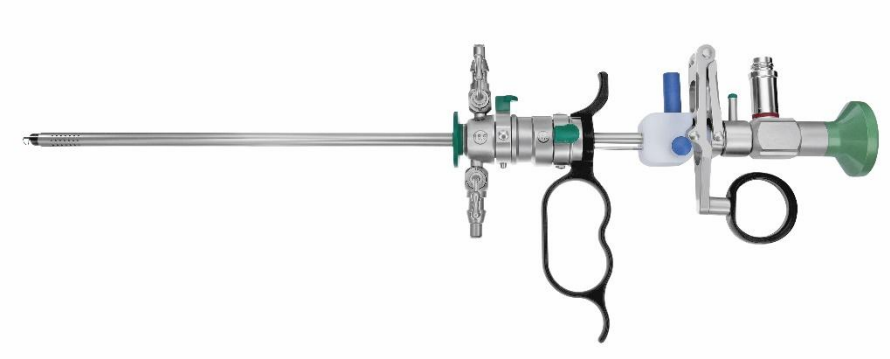
⚠ To ensure optimal resection results, please make sure in advance that the HF generator has an appropriate mode for monopolar / bipolar resection.

Recommended settings on the HF generator

Sudden and excessive electrical power can lead to significantly higher wear of the electrodes. It is therefore recommended to start with a low power and gradually increase it to the desired value:

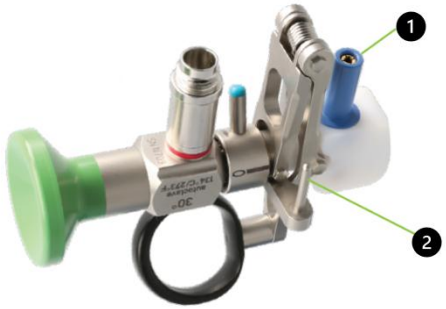
- Cutting: 120-180 watts
- Coagulation: maximum 100 watts

Special features of the hybrid resectoscope



With the hybrid mini-resectoscope (sheath system 18.5 Fr./Charr. together with the green electrode 17.5 Fr./Charr.) you have the choice between monopolar or bipolar application. Pay attention to the following during the surgical setup:

– Correct connection (see illustration below)
– Cable
– Correct flushing liquid

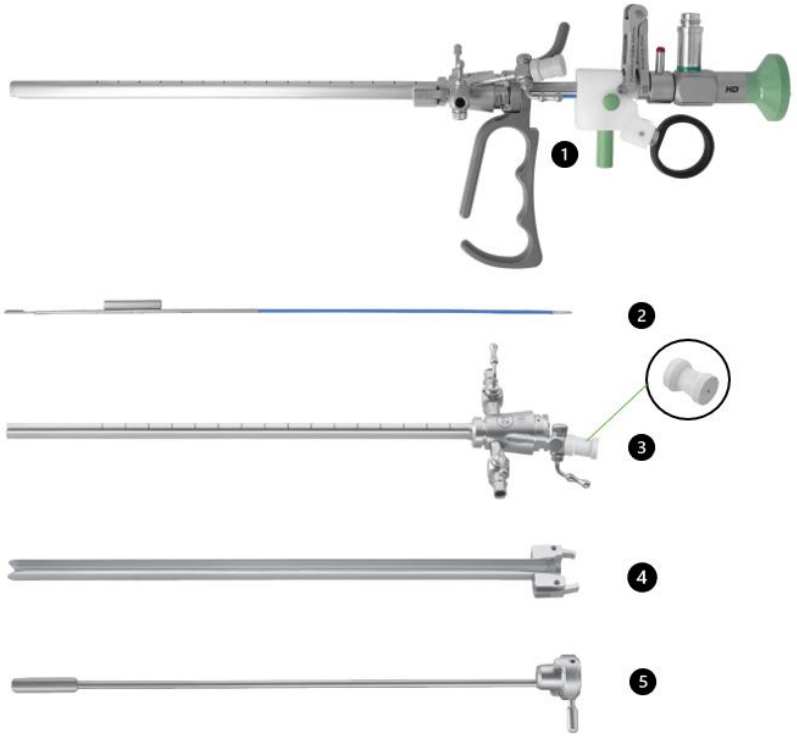


1 Monopolar connection
2 Bipolar connection

The Hybrid Mini Resectoscope also differs from the other resectoscopes in that the handle is not firmly connected to the guide sheath of the electrode. However, the basic principle of the click lock still applies, as shown in the mounted illustration.

Special features of the urethrotome

⚠ **The visual urethrotome is not intended for use with HF current.**



⚠ Be careful when inserting the sheath. If you feel resistance and the sheath does not slide further into the urethra, the distal end of the sheath has reached the stricture to be cut.

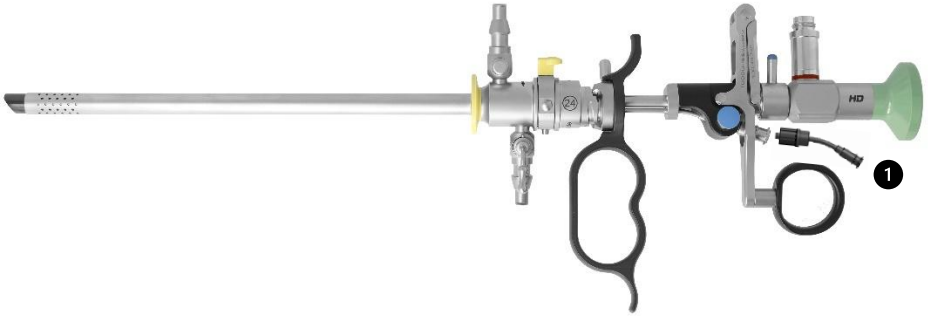
Assembly of the working element with shank, stricture knife and optics

1. Pull the obturator (5) out of the urethrotome sheath (3). Unlock the obturator by turning it counterclockwise.
2. Insert the working element (1) with the stricture knife (2) and the optic into the sheath.
3. Lock the working element on the bayonet catch by turning the working element (1) clockwise.
4. Open the stopcock on the guide probe opening (3) of the sheath.
5. Insert a compatible guide probe (instrument channel 5 Fr./Charr.). Push the guide wire under visual control until it has passed the stricture.
6. Slide the additional sheath (4) onto the urethrotome sheath (3) until it clicks into place.
7. Make sure that the locking mechanism of the additional sheath (4) engages in the urethrotome sheath (3).

⚠

- Always make sure that the working channel of the urethrotome sheath is fitted with the rubber cap (REF number RZ200-000) and that the rubber cap is not visibly damaged.
- Remove the rubber cap from the instrument for reprocessing.
- Do not exert any lateral force on the stricture knives, as this could cause them to break Do not touch the stricture knife with your bare fingers, but only with a cloth, for example.

Special features of the laser resectoscope



Field of application

Laser resectoscopy is intended for endoscopic minimally invasive tissue removal (removal of adenomas and soft tissue tumors) via the natural opening. The instruments are used in conjunction with light sources and flexible light guides, cameras and endoscopic accessories (e.g. laser fibers, ureteral catheters, forceps, bougies).

Application

1. Insert the laser probe into the working element.
2. Press the push button and keep it pressed to insert the laser probe.
3. Insert the laser probe into the adapter RC040-452 fitted for this purpose (1).
4. Insert the nose into the corresponding groove as far as it will go, depending on the desired laser exit point.
5. Release the push button. The laser fiber is fixed in the working element.

⚠ The laser probes have a marking for aligning the distal laser exit point. This marking is used to align the laser probe in the working element.

RINSING SOLUTION - MONOPOLAR / BIPOLAR

⚠ Use the following rinsing solution depending on the application:

MONOPOLAR

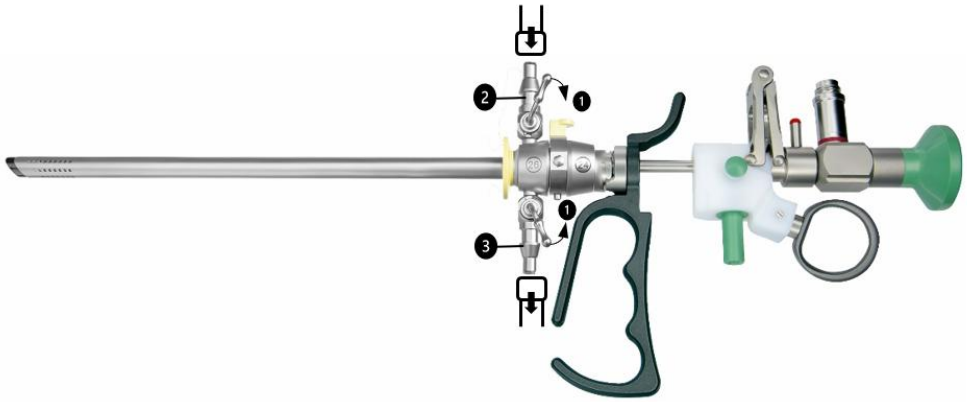
Electrolyte-free rinsing solution, e.g. 1.5% glycine, purisols, mixture of sorbitol and mannitol

BIPOLAR

Isotonic saline solution (NaCl) of 0.9% (saline)

Connecting the irrigation tubes

1. Close the irrigation stopcock (1).
2. Connect the inflow tube (Luer lock connection) to the inflow stopcock (2).
3. Connect the outflow tube (Luer lock connection if necessary) to the outflow stopcock (3).

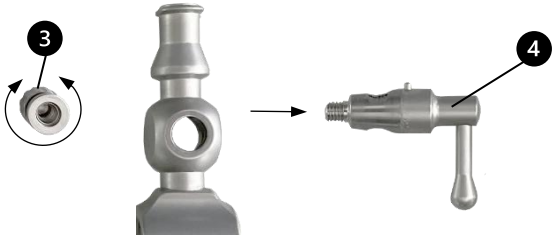


STOPCOCKS FOR INFLOW AND OUTFLOW

⚠ **The stopcocks must be removed from the sheath system for reprocessing. Place all parts in the sterilization tray**

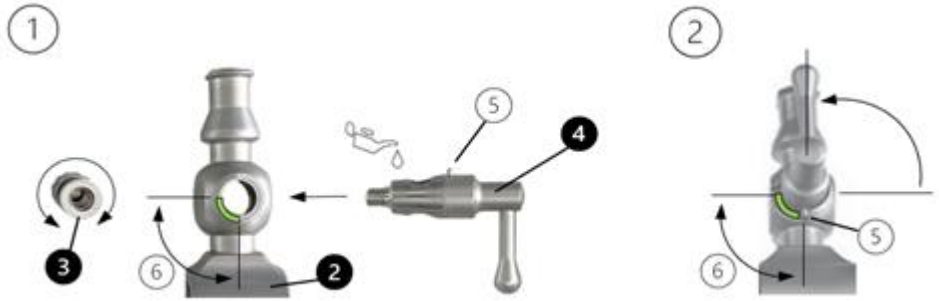
Disassembly

Unscrew the spring caps (3) and remove the stopcock plug (4) from the tap.



Assembly

1. Insert the stopcock plug (4) into the stopcock holder (2). Make sure that the guide pin (5) of the stopcock plug runs in the recess (6) of the holder (2).
2. Then screw the spring cap (3) on the opposite side of the stopcock to the stopcock plug. Check the mobility of the stopcock plug.
3. The stopcock must be open for sterilization. To do this, swivel the lever of the stopcock plug towards the opening of the Luer lock connection.

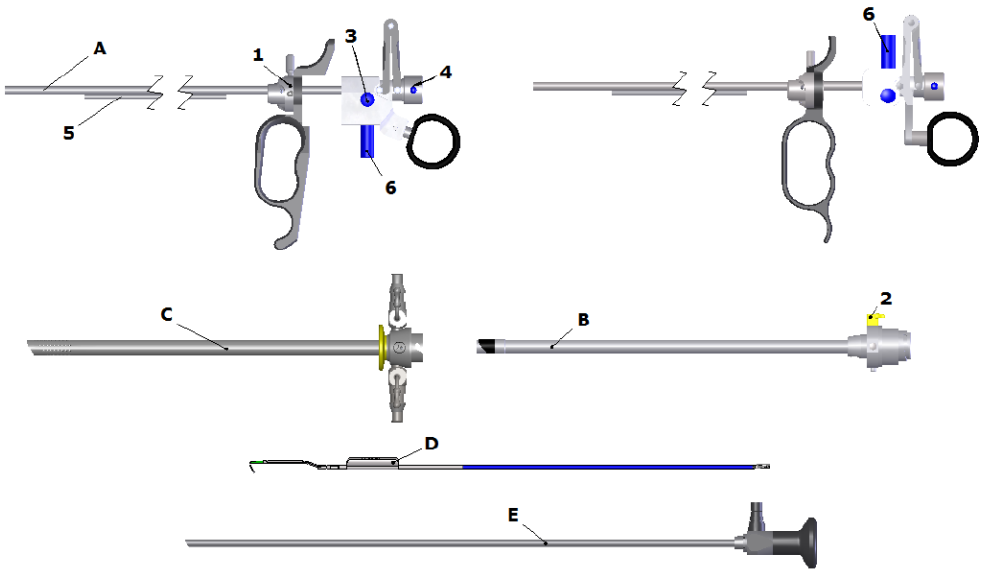


⚠ After cleaning and disinfection or before sterilization, the thread and the sealing rings of the sheath must be lubricated with instrument grease approved for medical devices and steam sterilization.

1. Lubricate the running surface of the stopcocks with a thin layer of instrument grease.
2. After you have fitted and tightened the stopcock, remove any excess instrument grease.

DISASSEMBLY OF THE RESECTOSCOPY SYSTEM

1. Turn the locking lever (4) counterclockwise and pull the endoscope out of the working element (A).
2. Unlock the outer sheath with the unlocking button (2) and remove the outer sheath from the inner sheath (B).
3. Depending on the variant, turn the locking lever or press the unlocking button on the working element to unlock the inner sheath (1) and remove the inner sheath from the working element (A).
4. Unlock the HF electrode (D) with the unlocking button (3) and pull it out of the working element (A).



ASSEMBLY OF THE RESECTOSCOPY SYSTEM

1. Push the HF electrode (D) through the tube (5) of the working element (A) until the electrode engages in the working element (3). Before inserting the electrode, make sure that there is no moisture in the insulator (white Teflon block) of the working element. The insulator must also be kept completely dry during the surgical procedure.
2. Insert the working element (A) into the inner sheath (B) and lock it by turning the locking lever (1). With the RUDOLF Medical Click System version, the instrument is locked by pushing the inner sheath (B) with the arrow onto the arrow mark (1) of the working element (A); the instrument is locked with a click.
3. Slide the system assembly consisting of inner sheath, working element and electrode (A + B + D) into the outer sheath (C) and lock it with the unlocking lever or click system, depending on the variant.
4. Insert the endoscope (E) into the working element (A) and lock it by turning the locking lever (4) clockwise.

REPROCESSING INSTRUCTIONS

Restrictions

- The product service life depends on the following:
  - Number of applications and the associated reprocessing cycles
  - Care and maintenance
- Do not use fixing agents or hot water (> 40 C), as this can lead to hardening of residues and thus impair the cleaning success.

Initial treatment at the place of use

- Defective instruments must be visibly labelled. They must also be reprocessed before they are disposed of or returned.
- The instruments must be reprocessed within one hour after use to prevent the drying of contamination on the instrument.
- Heavy contamination on the instrument must be removed immediately after use with a disposable cloth.
- The working channels and lumen must be rinsed at least three times immediately after use to prevent blockages.

Transportation

- The instruments should be transported safely to the reprocessing site in a closed receptacle/container system to prevent damage to the instruments and contamination of the environment.

Preparation before cleaning

- For reprocessing, the instruments must be disassembled or opened as far as possible without using tools.

Manual pre-cleaning

1. Manual pre-cleaning of the instruments

a) Rinsing and brushing:

1. Rinse the instruments thoroughly under cold tap water (≤ 23°C).
2. Use a soft brush and a correspondingly large soft brush for the hollow parts to remove visible deposits.
3. While rinsing and brushing, operate all moving parts to reach all surfaces.

b) Ultrasonic bath:

1. Prepare an ultrasonic bath with an enzymatic cleaning agent according to the manufacturer's instructions. Validated with the cleaning agent neodisher MediClean of Dr. Weigert and the ultrasonic cleaner Branson 8800.
2. Immerse the instruments in the prepared cleaning agent.
3. Rinse all hollow parts with the cleaning agent. Operate all moving parts such as the stopcock lever, locking lever, push buttons, handle of the optical forceps and the rotating wheels of the Albarran deflector.
4. Leave the instruments in the ultrasonic bath for 10 minutes and then remove them.

c) Rinsing and brushing:

1. Rinse the instruments thoroughly under cold tap water (≤ 23°C, 60 ml per lumen).
2. Use a soft brush and a correspondingly large soft brush for the hollow parts to additionally support the rinsing.
3. While rinsing, operate all moving parts such as the stopcock lever, locking lever, push buttons, handle of the optical forceps and the rotating wheels of the Albarran deflector.
4. Rinse all hollow parts with a syringe filled with tap water (120 ml per part or 60 ml per lumen).

2. Manual pre-cleaning of the stricture knives and HF electrodes

1. Rinse the stricture knives / HF electrodes for at least 5 minutes under cold tap water (≤ 23°C).
2. Brush off the visible deposits with a soft brush.
3. Rinse the stricture knives / HF electrodes under cold tap water (≤ 23°C).

Notes:

- Instruments with hard-to-reach areas such as lumens, cavities, bores, threads and slots must be immersed in cold water (≤ 23°C) for at least 5 minutes and rinsed under water with a water jet gun for at least 10 seconds (pulsed procedure).
- In case of heavy incrustation, pre-cleaning must be carried out in an ultrasonic bath with a 0.5% enzymatic cleaning agent (temperature of the cleaning agent is below 40°C; the sonication time is at least 15 minutes).
- Remove the instruments from the ultrasonic bath and rinse them thoroughly to rinse off the cleaning agent.

- Observe the cleaning agent manufacturer's instructions (concentration, temperature and sonication time).
- Dry the instruments completely with a lint-free cloth and medical compressed air (20 psi / 1400 hPa) before sterilization.

Automated cleaning and disinfection

1. Place the instruments in an inclined position in the WD to facilitate the drainage of the liquid.
2. Set the program and start it:

Process type	Enzymatic
Cleaning agent	neodisher® MediClean of Dr. Weigert
Concentration	0,5%
Washer / disinfector	Miele PG 8535 / STERIS Reliance Genfore

Automated cleaning process:

Phase	Duration	Temperature	Cleaning agent
Pre-cleaning	At least 2 minutes	Cold tap water of drinking quality (≤ 23)	n/a
Cleaning 1	At least 2 minutes	55°C	Enzymatic
Neutralization	At least 3 minutes	Cold deionized water (≤ 23)	n/a
Rinsing 1	At least 2 minutes	Cold deionized water (≤ 23)	n/a

Disinfection	Duration: 5 minutes Temperature: at least 93°C ⚠ Stricture knives and HF electrodes must not be immersed in chemical disinfectants. Residues of disinfectants can impair the function.

- Clean and disinfect the instruments only in a suitable washer/disinfector and with a procedure/program validated for the WD and surgical instruments (EN ISO 15883).
- Observe the operating and loading instructions of the WD manufacturer.
- Articulated instruments must be opened for cleaning by approx. 90 degrees.
- Instruments with cavities (tubes, sheaths, hoses) must be connected to an appropriate rinsing device to ensure that these cavities are rinsed.
- To ensure sterility, disassemble the stopcocks of the sheaths and the Albarran deflector before autoclaving.
- When selecting the cleaning agent, consider the material and properties of the instrument, of the cleaning agents recommended by the WD manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (DGHM).

MAINTENANCE, CONTROL AND INSPECTION

- After cleaning and disinfection, the instruments must undergo a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, latches, locks and other areas that are difficult to access.
- See also "Prior to each use: Visual and functional inspection" in these instructions.
- If residues/liquids are still visible, cleaning and disinfection must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear & tear, and damages (rust, cracks) and, if necessary, replaced.
- After each cleaning and before sterilization, the moving parts must be lubricated and maintained with a silicone-free, biocompatible, medical white oil. See section "Lubricating stopcocks during assembly".
- Insulation and HF plug must be intact.
- Plastic parts should be checked before sterilization.
- The ceramic tip must be checked for cracks and breaks.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PACKAGING

- Standardized packaging of instruments for sterilization is carried out in accordance with DIN EN ISO 11607 and DIN EN 868.
- Tips and sharp cutting edges must not perforate the sterilization packaging.
- In the case of individual packaging, ensure that the packaging is large enough to hold the product without causing tension on the sealing seam or tearing the packaging.

STERILIZATION

The manufacturer's instructions for the sterilization device must be observed.

Steam sterilization in a pre-vacuum

Packaging	Film packaging Standardized packaging of instruments for sterilization is carried out in accordance with DIN EN ISO 11607 and DIN EN 868. In the case of individual packaging, ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or tearing the packaging. ⚠ HF electrodes: **Do not** use paper packaging for sterilization, as HF electrodes consist of thin metal components and can therefore perforate the paper packaging.
Temperature	At least 132°C (270°F)
Holding time	At least 3 minutes (18 minutes is the maximum for a pre-vacuum cycle).
Drying time	At least 50 minutes
Notes	Rapid cooling of the instruments after sterilization will damage the instruments. After sterilization, install the taps under sterile conditions as described in the section "Taps for inflow and outflow".

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean and dust-free environment at 5 - 40°C.

INFORMATION ON THE VALIDATION OF THE REPROCESSING

The following tools and machines were used in the validation:

Manual pre-cleaning in an ultrasonic bath, enzymatic	Cleaning agent: neodisher MediClean of Dr. Weigert; Ultrasonic device Branson 8800
Washer / disinfector	Miele PG 8535; STERIS Reliance Genfore
Automated cleaning: enzymatic cleaning agent	neodisher® MediClean of Dr. Weigert; 0.5 %
Sterilization	Steam sterilization

ADDITIONAL NOTES

- If the specified chemical agents and machines are not available, it is the responsibility of the user to validate the process.

DISPOSAL

- The products should be disposed of accordingly only after they have been cleaned and disinfected properly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or receptacles to prevent third parties from being injured.

REPAIRS AND RETURNS

- Never carry out repairs yourself. Service and repairs must only be carried out by trained and qualified persons. Please contact RUDOLF Medical, your specialist distributor or your medical technology department if you have any questions in this regard.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report all problems with RUDOLF Medical products to the respective distributor.
- In the event of serious incidents with the products, the user must report them to RUDOLF Medical as the manufacturer and to the competent authority of the member state in which the user resides.

WARRANTY

- The instruments are made of high-quality materials and undergo strict quality control before delivery. If there are any discrepancies, please contact your respective dealer or RUDOLF Medical.

REPROCESSING – APPLICABLE STANDARDS

- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 13060 Small steam sterilizers
- DIN EN ISO 15883-1-3 Washer/disinfectors
- DIN EN 868 Packaging materials and systems for medical devices to be sterilized - Part 8: Reusable sterilization containers for steam sterilizers according to EN 285; requirements and test methods
- DIN EN ISO 11607 Packaging for medical devices to be sterilized in the final packaging
- DIN EN ISO 17664 Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices

SYMBOLS

	Consult instructions for use
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
CE 0297	CE mark in accordance with Regulation (EU) 2017/745 for medical devices (MDR) with the identification number of the notified body
	Lubricate taps, threads and sealing rings with instrument grease approved for medical devices and steam sterilization.
	Keep dry
	Keep away from sunlight
	Eye protection during lasering
MD	Medical Device