RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
LAPARASCOPY INSTRUMENTS

RUDOLF Medical GmbH + Co. KG
Zollerstr. 1, 78567 Fridingen, Germany
Tel. +49 7463 9956-0
Telefax +49 7463 9956-56
sales@RUDOLF-med.com
www.RUDOLF-med.com

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PLEASE READ BEFORE USE AND KEEP IN A SAFE PLACE.

GENERAL
RUDOLF Medical reusable surgical instruments can be used by medical professionals for a surgical procedure and can be reused after proper reprocessing.

The professional user selects the appropriate instruments according to the intended use, the tissue to be manipulated, and the anatomical structures.

INTENDED USE
The RUDOLF Medical three-part dismountable laparoscopic forceps and scissors with a high-frequency (HF) connection are intended for grasping, preparing, cutting, and dissecting tissues in minimally invasive procedures in the fields of laparoscopic surgery, gynecology, and urology. Laparoscopic instruments with a monopolar HF connection can be used with electrosurgical devices and generators, respectively.

The instruments are not limited to any kind of population.

INDICATION
RUDOLF Medical laparoscopic instruments are dismountable instruments for use in minimally invasive surgery. Coagulation and cutting are carried out with electrical power that is generated by HF electrosurgery generators. The instruments are only suitable for short-term coagulation with minor bleeding.

CONTRAINDICATION
Do not use in patients with pacemakers or other active implants without consulting a specialist. The device may interfere with or damage active implants.

The device is not suitable for the use with bipolar currents.

The devices should not be used during single-port laparoscopic procedures, because the proximity to other instruments may result in capacitive or direct coupling which may lead to serious complications like visceral or organ burns.

SIDE EFFECTS
The most common side-effects associated with HF forceps are burns that can be caused by the current at the point of the body where the neutral electrode is applied.

⚠ GENERAL WARNINGS AND PRECAUTIONS
- RUDOLF Medical instruments must be cleaned, disinfected, and sterilized before each use. Protective caps and transport packaging must be removed beforehand.
- A complete functional check must be carried out before each use.
- Do not use defective devices.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use any metal brushes or abrasives, because there is a risk of corrosion due to surface damage.
- Before the clinical use, the safe combination of instruments or of instruments with implants must be checked by the user.
- Be careful when handling sharp tips and cutting edges because they pose a risk of injury.
- In the case of patients with the Creutzfeldt-Jakob disease (CJD), with a suspected CJD or with possible variants of this disease, the applicable national regulations regarding the reprocessing of instruments must be applied.
- Do not leave the instruments in the disinfectant solution for too long. Follow the instructions of the disinfectant solution manufacturer.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.
- Do not use the device near flammable or explosive materials (e.g., endogenous gases, flammable anesthetics, nitrous oxide, oxygen). Materials such as lint, cotton, and any materials soaked with the above-mentioned substances must be placed far from the surgical environment.
- Only cut or coagulate if the contact surfaces are visible, so that there is no contact with any other metal instruments.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION
Check for:
- External damage (deformed shaft, dents, sharp edges, damages in the insulation)
- Correct functioning
- Detergent or disinfectant residues
- Clear passage through the working channels

⚠ SPECIFIC WARNINGS AND PRECAUTIONS
- A deep understanding of the biophysical principles of high-frequency electrical energy is essential.
- If the electrically conductive working end of the instrument comes near the patient's body, current leakage may result in a burn.
- When direct or low-frequency current enters the body, electrolysis occurs at the interface of the electrically conductive working end and the tissue. The chemical effects of electrolysis disappear at higher frequencies.
- Direct or low-frequency current can depolarize cell membranes and cause neuromuscular excitation.
- Thermal damage may cause vessel thrombosis, collagen denaturation, and carbonization at the incision. Therefore, it is recommended to carefully consider the advantages and suitability of the intended application.
- Visceral preparation, especially of the bowel, is important if it is expected that these surrounding organs are at risk.
- Due to a restricted view, chances of direct trauma or injury of surrounding tissues and organs is increased during laparoscopic surgery. Therefore, the power to the instrument must only be then activated when the targeted tissue is within vision.
- Do not use hybrid trocar sleeves. Using metal-only trocar cannulas can reduce the risk of a capacitive coupling.
- Activating the power to the instrument while the instrument is in the air and not in use creates an "open" circuit that can also result in a capacitive current. Avoid this situation by implementing multiple short activation times that allow for normal tissue to remain cool.

⚠ DEVICE-RELATED SAFETY MEASURES AND PRECAUTIONS
- Check the insulation thoroughly.
- Use the lowest possible power setting.
- Use a brief intermittent activation.
- Do not activate the device in an open circuit.
- Do not activate the device near or in direct contact with another instrument.
- If needed, use bipolar electrosurgery instruments.
- Choose the proper current waveform mode. In monopolar electro surgery, use either the cutting or the coagulation waveform to achieve a cutting or fulguration effect.
- Whenever possible, use electrosurgical accessory safety equipment, such as systems for active or return electrode monitoring.

⚠ HANDLING
- The surfaces of the contact points in the jaw must be bare.
- After connecting a suitable monopolar cable to the RUDOLF Medical laparoscopic instrument that has a HF connection, the cable can be connected to the output of one of the HF surgical devices made by Erbe, Berchtold, Martin and Valleylab.
- Before switching on the HF surgical device, make sure that the working end of the instrument is not in contact with any conductive accessories or liquids. When activating the surgical device, the working end should be kept in the view of the user.
- Use the instrument only when the specified maximum recurring voltages are greater than or equal to the set maximum output voltage of the HF surgical device.

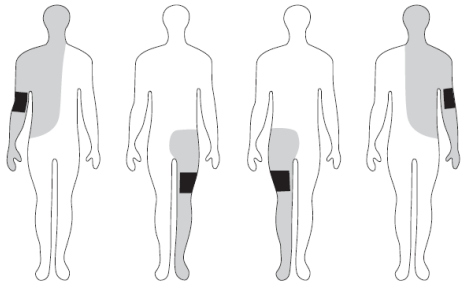
- RUDOLF Medical laparoscopic instrument with a HF connection and its insulation are designed for the following maximum recurring voltages:
  - **1200 VP in cutting mode**
  - **2000 VP in blend mode**
- Set the output power of the HF surgical device only to the value that is absolutely necessary for the procedure. If normal coagulation is not achieved in spite of using the standard setting of the HF surgical device, never increase the output capacity of the device without prior checking the output power.
- Check especially for the following:
  - Proper contact of all HF plugs and cables
  - Proper functioning of the pedal
  - Insulation of the HF cable and the instrument
  - Cleanliness of the distal end of the instrument (contact surfaces)
- The coagulation current is activated using the pedal.
- To achieve optimal coagulation results, it is vital that the metal working ends of the instruments are always clean. Dried blood and residual tissue impair the functionality. When the coagulation decreases, do not increase the output but clean the working ends of the instruments.
- In order not to damage the working part, insert the instrument carefully into the trocar. Avoid bringing these instruments into contact with uninsulated instruments. During surgery, the contact surfaces of the instrument must be kept clean. Dried tissue residue or bodily fluids can be wiped away with a damp sterile swab.
- Avoid large, forceful manual movements. Handle the instrument with great care.

POSITIONING THE PATIENT

- Make sure that the patient never comes into contact with other metal parts (e.g., operating table) and is insulated against all electrically conductive parts.
- Lay the patient on a dry, electrically insulated pad.
- Avoid skin-to-skin contact (arms, legs). Place dry lint between the body, arms, and legs to prevent skin contact.
- The operating table must be earthed.

CURRENT FLOW IN THE BODY DURING MONOPOLAR HF SURGERY

- The path of the current in the patient's body should be short and should not flow across the thorax.
- The following illustration shows the position of the return electrode (black rectangle) and the permissible area of use (grey) for the electrically conductive working ends of the instrument (jaw sections).



⚠ **RISK OF BURNS**

Endogenous burn risk:

This risk is caused by high current density in the patient's tissue. The cause of this can be, among others, accidental contact of the patient with electrically conductive parts. In the event of direct skin contact with the electrodes and HF cables, capacitive currents can lead to burns.

Exogenous burn risk:

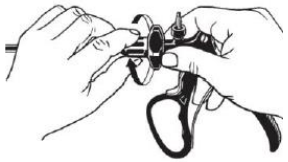
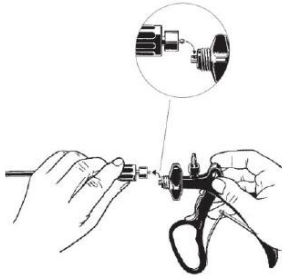
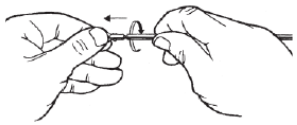
This risk is caused by the heat of ignited fluids or gases. Even explosions are possible. Cause can be, among others, ignition of skin-cleaning and disinfection agents, and the ignition of anesthetic gases.

Safety precautions during use

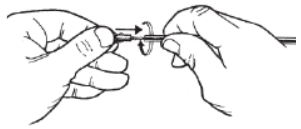
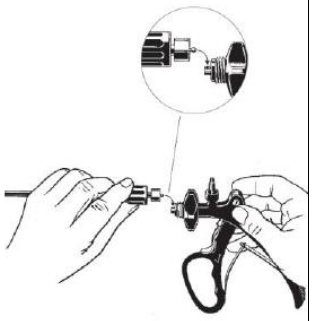
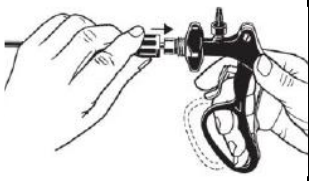
- The maximum acceptable operating temperature of 40°C must not be exceeded.
- Place monitoring electrodes from surgical electrodes as far as possible when HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
- During surgical HF application, do not use needle monitoring electrodes.
- It is recommended to use monitoring systems that have devices for limiting the HF current.

DISASSEMBLY / ASSEMBLY

Disassembly

	Open the handle.
	Hold the rotating adapter firmly and loosen the fastening screw in the opposite direction.
	Remove the tube shaft, and then detach the ball end.
	Unscrew the jaw part from the tube shaft, and then pull it out.

Assembly

	Insert the jaw part into the tube shaft, and screw it securely.
	Attach the tube shaft with the jaw part screwed into the handle, and attach the ball end.
	Close the handle.
	Screw together the tube shaft and handle with the fastening screw.

REPROCESSING INSTRUCTIONS

Restrictions

- Repeated / frequent reprocessing according to these instructions has only little effect on the life of the instruments.
- The life cycle of a reusable instrument is essentially determined by wear and damage caused by the application.

Initial treatment at the place of use

Step 1: Conserve moisture
Immediately after use, the instrument must be placed in a sieve/container and covered with a cloth moistened with sterile, distilled water. Do not use any fixing agents or hot water (>40°C) because this causes residues to stick which can negatively affect successful cleaning.

Step 2: Enzymatic soaking
Immerse the instruments in a permitted enzymatic solution in accordance with the recommendations of the solution manufacturer. Turn and tilt the instrument to ensure that all bubbles are removed from cavities.

Step 3: Rinsing
Remove the enzymatic solution after the manufacturer's recommended time and rinse the instruments with tap water.

Step 4: Clean the instruments
Use a small, soft, clean brush to clean the instruments while they are immersed in the cleaning solution.

Step 5: Rinsing
Rinse the instrument by immersing it in demineralized water and wipe it with a clean, soft cloth.

Step 6: Visual inspection
Visually inspect the instrument for cleanliness.

Step 7: Drying
Instruments must be thoroughly dried. Any residual moisture can cause corrosion.

- The instruments must be reprocessed within 1 hour after use to prevent dirt from drying on the instruments.
- Heavy soiling on the instrument must be removed with a disposable rag, cloth, or tissue immediately after use.
- To avoid blockages, working channels and lumens must be flushed at least 3 times immediately after use.
- Do not use any fixing agents or hot water (>40°C), as this leads to the build-up of residues. That in turn can impede proper cleaning.
- Defective instruments must be identified and clearly marked. They are also to be reprocessed.

Transportation

- Ensure safe storage and transportation of the instruments to the reprocessing site in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Preparation for decontamination

- The instruments must be disassembled or opened for reprocessing without using tools as far as possible.

⚠ ***Do not treat the plastic handles with hydrogen peroxide (H_2O_2) because the handles could be damaged.***

Manual pre-cleaning

- Instruments with difficult-to-access areas such as lumens, cavities, bores, threads, and slots must be soaked in cold water for at least 5 minutes and rinsed under water with a water jet pistol for at least 10 seconds (pulsed procedure).
- Brush the inside of the tube shafts with a brush.
- Rinse again the tube shafts with a water jet pistol for 10 seconds (1.8 bar).
- In case of heavily encrusted soiling, cleaning must be carried out in an ultrasonic cleaning device (cleaning solution <40°C, sonication time minimum of 10 minutes) to support manual cleaning and before automated cleaning.
- Observe the manufacturer's instructions of the cleaning agent (concentration, temperature, and sonication time).
- Vibration can loosen small parts such as screws and nuts. After the ultrasound treatment, ensure that the instruments are complete and check out for loosened small parts.

Automated cleaning

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) with a procedure / program validated for the WD and this type of instrument (EN ISO 15883).
- Instruments with cavities (tubes, shafts, hoses) must be connected to appropriate flushing devices to ensure that these cavities are flushed.
- Observe the operating and loading instructions of the WD manufacturers.
- Open instruments with joints for cleaning by approximately 90 degrees.
- When choosing the cleaning agent, observe the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application, and the relevant lists and recommendations of the Robert Koch Institute (RKI) and of the German society for hygiene and microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Detergent for automated cleaning in washers and disinfectors (WD)

Process type	Cleaning agent	pH value	Manu-facturer
Alkaline	Deconex 28 Alka One	12.2	Borer - Zuchwil

Automated cleaning program with thermal disinfection in the WD using an alkaline process

Process	Reagents	Time / Min	Temp / °C
Pre-cleaning	Water	4	Cold
Draining			
Cleaning	Water, 0.5%, alkaline cleaning agent	6	55
Draining			
Neutralization	Water	3	>40
Draining			
Rinsing	Wasser	2	>40
Draining			
Disinfection *	Demineralized water	10	93
Drying **		>20	max. 93

* Carry out mechanical thermal disinfection by considering the national requirements regarding the A0 value according to ISO 15883-1 (A0 = 3000).
** If necessary, manual drying with a lint-free cloth can also be carried out. Dry instrument cavities with sterile compressed air.

MAINTENANCE, CONTROL AND INSPECTION

- After cleaning and disinfection, the instruments must be subjected to a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, ratchets, locks, and other areas that are difficult to access.
- If dirt residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before each sterilization, the instrument must be assembled and checked for functioning, wear, and damage (cracks, rust) and replaced, if necessary.
- Before sterilization, close instruments with a ratchet only in the first notch of the ratchet or keep them open.
- After each cleaning and before sterilization, the moving parts must be oiled and maintained with a physiologically harmless oil (paraffin oil according to DAB or Ph. Eur. or USP), especially locks, joints, and ratchets.
- Before being returned for repair or complaint, defective products must have gone through the entire reprocessing process.

PACKAGING

- The packaging of the instruments for sterilization must be according to standards ISO 11607 and EN 868.
- Pointed and sharp cutting edges must not perforate the sterilization packaging.
- In case of individual packaging, ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or without tearing the packaging.

STERILIZATION

- Sterilization has to be carried out according to EN 13060 / ISO 17665 or a validated steam sterilization method (fractionated vacuum method) in a sterilizer according EN 285 / DIN 58946.
- 3 pre-vacuum phases with at least a pressure of 60 mbar
- Heat up to a sterilization temperature of a minimum of 134°C according EN 285, point 8.3.1.
- Minimum holding time: 5 minutes
- Drying time: minimum 10 minutes
- Observe the manufacturers' instructions of the sterilizer.

STORAGE

RUDOLF Medical HF forceps should be stored in a suitable sterilization container according to DIN 58952, and until use, according to DIN 58953. The sterilization container should be designed in a way that the instrument is secured firmly in place and protected from damage:

- Temperature: -20°C to 50°C
- Relative humidity: 20-75%, non-condensing
- Suitable sterilization container
- Storage of the sterilized instruments in a low-germ, dry, clean and dust-free environment at 5-40°C.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials & machines have been used for the validation procedure:

Table 1: Materials and Machines

Alkaline cleaning agent	neodisher® FA
Enzymatic cleaning agent	deconex® 23 Neutrazym
Washer / Disinfector	G 7735 CD (Miele)
Slide-in cart	Slide-in cart E 327 – 06 MIS slice in cart E 450

ADDITIONAL NOTES

- If the described chemical agents and machines are not available, it is the duty of the users to validate their process.

DISPOSAL

- Dispose of the products only after the products have been cleaned and disinfected properly.
- Comply with national regulations when disposing of or recycling the products or their components.
- Dispose of the product in an environmentally friendly manner according to the applicable hospital guidelines.
- Be careful with sharp tips and cutting edges.
- Use suitable protective caps or containers to prevent injuries.

RETURNS

- If an instrument is damaged, it should go through the complete reprocessing process before it is returned to the manufacturer for repair. Do not carry out any repairs on the instrument.
- Be careful with sharp tips and cutting edges.
- Use suitable protective caps or containers to prevent injuries.

PROBLEMS / EVENTS

- The user should report any problems with our RUDOLF medical products to the respective dealer.
- In the event of serious incidents with the products, the user must report this 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 are subjected to a strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical.

SYMBOLS

	Consult instructions for use.
LOT	Batch code
REF	Article no.
Qty	Number per package
	Non-sterile
	Lubricate with silicon-free, biocompatible white medical oil approved for steam sterilization.
	Caution
CE	CE marking according to EG directive 93/42/EWG
CE 0297	CE marking according to EG directive 93/42/EWG with the ID of the notified body
	Manufacturer
	Date of manufacture
MD	Medical Device