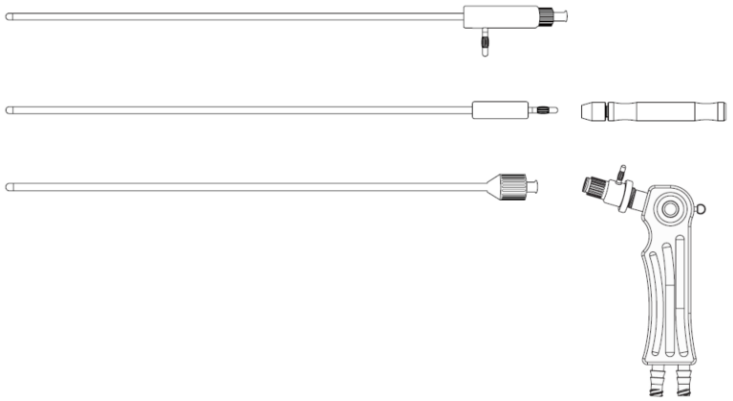
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)

MONOPOLAR MIS ELECTRODES – WITH AND WITHOUT SUCTION



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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the RUDOLF Medical monopolar MIS electrodes. You are receiving a high-quality product whose proper handling and use are described below.

The instruments are intended for use by the professional user (surgeons, operating room nurses, medical device reprocessing technicians).

There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

⚠ Remove the packaging with great care. Do not touch the sharp edges and tips. Do not use damaged instruments or carry out repairs on the instruments.

NON STERILE RUDOLF Medical instruments are delivered non-sterile and must be cleaned, disinfected, and sterilized before first use and immediately after each use. Protective caps and transport packaging must be removed beforehand.

INTENDED PURPOSE

Monopolar instruments are intended to dissect, grasp, cut and coagulate tissue during minimally invasive surgical procedures.

INDICATION

The instruments are intended for minimally invasive surgery, especially the laparoscopy.

The electrode is inserted through a trocar sleeve and is intended for dissecting, coagulating, and cutting of tissue.

CONTRAINDICATION

This instrument is not intended for the use on the central nervous and circulatory system.

⚠ WARNINGS AND PRECAUTIONS

- **Please see also the notes in the “Operation” section**.
- Exceeding the product lifetime leads to material fatigue and loss of functionality.
- Use the instrument only when the insulation is undamaged.
- Do not use explosive substances during surgery.
- Do not place the instrument on the patient.
- Avoid carbonization of tissue.
- Coagulate only if you can see the contact surfaces of the instrument. During coagulation, do not touch any metal objects.
- Do not use the instrument for spray coagulation.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.

Risk of electric shock

- Use only compatible HF generators that meet the technical specifications. Use the instrument only with a maximum recovery peak voltage of 2.000 Vp in combination with original equipment. See the “Technical Specifications” section.
- Exceeding the operating parameters and the product lifetime, and improper processing can lead to a risk of an electric shock.
- Using the instrument without HF current can lead to a risk of injury.
- For patients with pacemakers, check for the compatibility of pacemakers and HF current.

Risk of infection

- For suspected or confirmed CJD patients or CJD variants please observe the applicable national regulations regarding disposal and/or reprocessing.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

The functional tests shows whether instruments and their components work properly. Perform the functional test after assembly and reprocessing.

Check for:

- External damage (e.g., deformed shaft, dents, burrs, cracks or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Free passage through the working channels

Functional test of the handles and electrodes

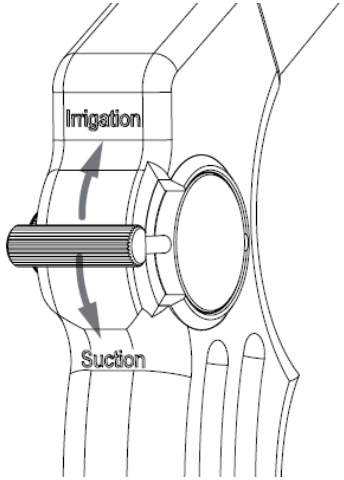
Perform the following functional tests on the handles that have the suction-irrigation function.

Suction-irrigation handle with a sliding valve

Requirement: The instrument is assembled.

Move the sliding valve in the position “Suction” and then in the position “Irrigation.”

The sliding valve should move freely.



PRODUCT DESCRIPTION

⚠ Incorrect handling and worn instruments can lead to a risk of injury.

- The electrode is inserted into the surgical site through a trocar sleeve. Select the trocar sleeve according to the instrument diameter. When a trocar sleeve with a larger dimension is used the tissue will be punched. Therefore, use a reducer for trocar sleeves with a larger diameter.

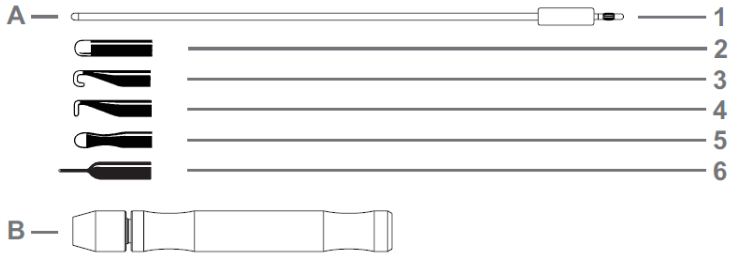
  Trocar sleeve:

Electrode	Compatible trocar sleeve
Ø 5mm	Ø 5mm Ø 5.5mm

- The electrodes are available with various electrode tips and thus can be used for different areas of application. See the “Areas of application” section below.
- Depending on the model, the electrodes have a suction-irrigation opening hole at the distal end and must be mounted with a suitable handle. The exception are the electrodes that are described in the “Electrodes with a suction-irrigation function and with integrated handle” section. For these electrodes, an additional handle is not required.
- The handles come in various designs. Depending on the model, it is possible to switch between the suction and irrigation functions on the handle.
- Coagulation is achieved by means of electric current that is generated by a compatible HF generator and that flows to the electrode via a contact pin.
- Electrodes and handles cannot be disassembled. Only handles with a suction-irrigation function can be disassembled.

Electrodes and handles without a suction-irrigation function

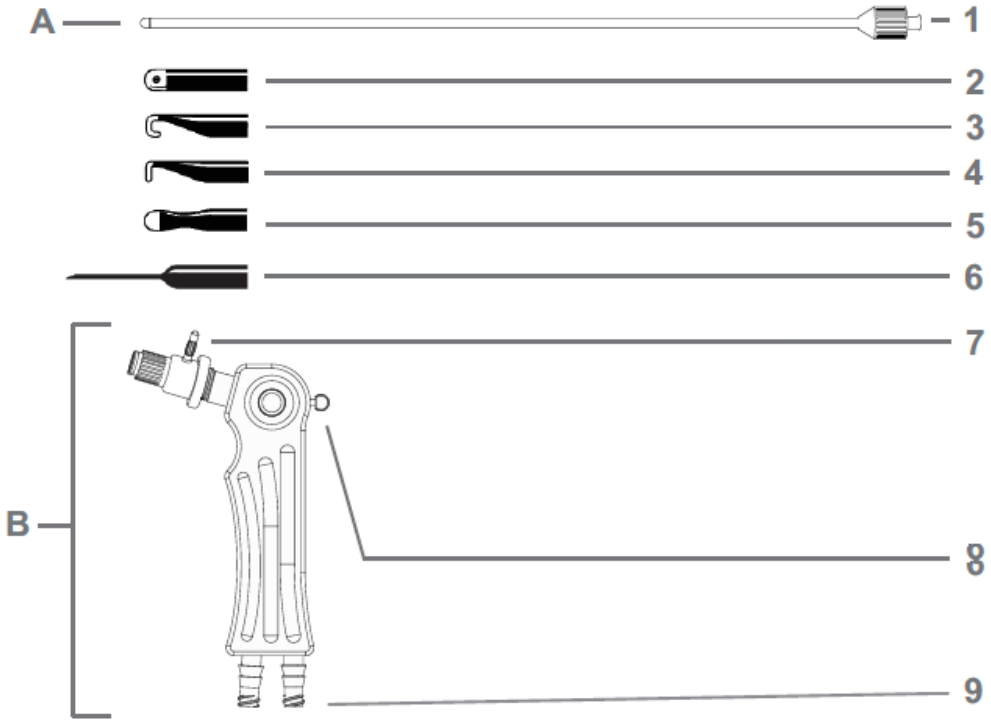
The following electrodes are used with the handle shown in the figure and do not have a suction-irrigation opening hole on the distal end. Consequently, suction and irrigation are not possible during the surgical procedure. The electrode is inserted into the handle via the HF contact pin.



A - Electrode
B - Handle
1 - HF contact pin (connection for handle)
2 - Ballpoint electrode
3 - Round hook electrode
4 - Hook electrode 90°
5 - Spatula electrode
6 - Needle electrode

Electrodes and handles with a suction-irrigation function

- The following electrodes are either connected to a suction-irrigation handle via an electrode adapter or are directly inserted into a handle with an integrated electrode adapter.
- Handle and electrode adapter have a HF contact pin.
- A connection at the distal end allows for suction and irrigation.



A - Electrode
B - Handle
1 - Luer-Lock connection (for handle or electrode adapter)
2 - Ballpoint electrode
3 - Round hook electrode
4 - Hook electrode 90°
5 - Spatula electrode
6 - Needle electrode
7 - HF contact pin
8 - Sliding valve for the suction-irrigation function
9 - Luer-Lock connection

Electrodes with a suction-irrigation function and integrated handle

For the following electrodes, an additional handle is not required. Suction and irrigation occur via the Luer-Lock connection on the proximal end of the electrode.

A - Electrode with Luer-Lock connection on the handle
1 - Luer-Lock connection
2 - HF contact pin
3 - Ballpoint electrode
4 - Round hook electrode
5 - Hook electrode 90°
6 - Spatula electrode
7 - Needle electrode

Areas of application of the electrodes

Application	Ballpoint electrode	Spatula electrode, hook electrode 90°, round hook electrode, needle electrode
+ compatible - not compatible		
Coagulation	+	+
Cutting	-	+
Vaporization	+	+

TECHNICAL SPECIFICATIONS

Operating conditions

Designation	Value
Peak voltage	2.000 Vp
Ambient temperature	≤ 137°C
Duty cycle	≤ 30s; not suitable for continuous operation

Product lifetime of the electrodes

Designation	Value
Reprocessing	≤ 50 cycles
Time	≤ 2 years

Product lifetime of the handles and electrode adapters

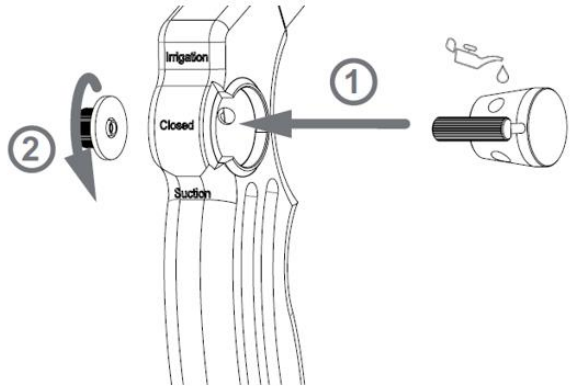
Designation	Value
Reprocessing	≤ 400 cycles
Time	≤ 5 years

ASSEMBLY OF THE INSTRUMENT

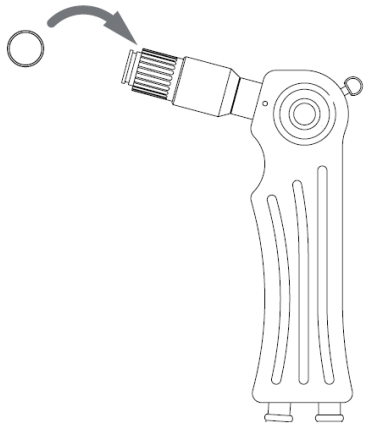
⚠ **There is risk of infection from unsterile instruments. The instruments must be reprocessed before assembly**.

Suction-irrigation handle with a sliding valve

Insert the stopcock (1) and screw it on using the spring cap (2):



Insert the O-ring:



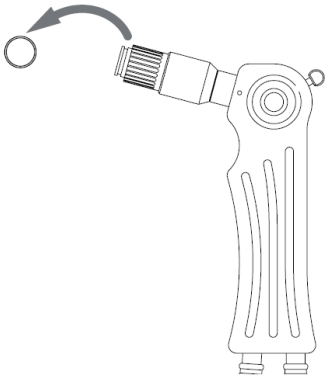
DISASSEMBLY OF THE INSTRUMENT

Note:

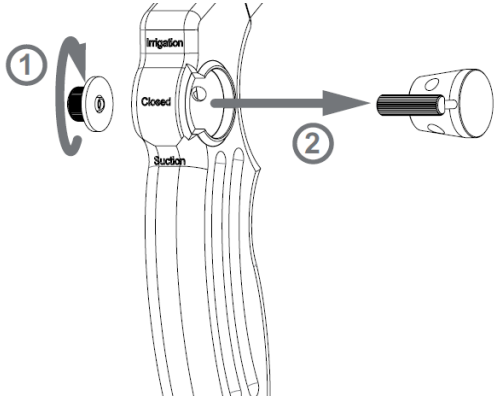
The electrodes and handles cannot be disassembled. Only the handles with a suction-irrigation function can be disassembled.

Suction-irrigation handle with a sliding valve

Remove the O-ring:



Unscrew the spring cap (1) and remove the stopcock (2).



OPERATION

⚠ **Notes:**

- **Please see also the notes in the "Warnings and Precautions" section.**
- Incorrect handling and worn / defective instruments can lead to a risk of injury.
- During operation and application, wear two pairs of gloves on top of each other.
- When coagulating with the electrode, use only the suction function.
- Remove disinfectant residues from the patient's body.
- Use a suitable neutral electrode. For more information, please see the user manual of the HF generator.
- Place the neutral electrode in such a way that the patient lies on the entire surface of the neutral electrode.
- Only activate the HF current when you can see the instrument.
- You may only touch the insulated areas with your fingers, not the contact pin.
- Do not touch or bend the distal end.
- Use only original accessories because there is a risk of injury due to the use of incompatible instruments.
- Adjust the voltage of the HF generator to the cutting speed to support primary hemostasis.

Using the instrument

⚠ **Requirement**: The instrument is reprocessed, and the HF generator is turned off.

1. Put on two pairs of gloves.
2. Attach the neutral electrode to the patient and connect it to the HF generator.
3. When using electrodes that need to be mounted with a handle:
   a. Screw the electrode adapter into a suction-irrigation pistol handle.
   b. Insert the electrode into the electrode adapter or insert the electrode directly into a handle with an integrated electrode adapter.
4. If present, remove the protective cap from the electrode tip.
5. Remove the protective cap from the contact pin.
6. Connect the HF cable with the contact pin. Make sure that the contact pin is completely covered.
7. Connect the other end of the HF cable to the monopolar output of the HF generator.
8. Insert the instrument via a trocar sleeve.
9. Activate the HF generator using the pedal.
10. Perform the surgical procedure.
11. After the surgical procedure, turn off the HF generator.
12. Reprocess the electrode.

REPROCESSING INSTRUCTIONS

- Wear personal protective equipment during reprocessing.
- The instruments must be reprocessed within an hour after use to prevent that contamination dries on the instruments.
- Use only the specified agents. If other agents are used, those agents must be validated.
- When choosing another cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the washer/disinfector manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM), or the respective national recommendations.
- Do not use any fixing agents.
- Use disinfectants with corrosion protection.
- Do not rinse with hot water.
- Plastic components must not come into contact with hydrogen peroxide (H_2O_2).
- Do not use scratchy brushes, sponges, or abrasives because they can damage the surface which can also lead to corrosion. The insulation can be damaged resulting in a risk of uncontrolled burn injury.
- Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.

Restrictions

- Information on the product lifetime is provided in the “Technical Specifications” section above.
- Do not use any fixing agents or hot water (>40°C), because this causes a hardening of residues which can impede the cleaning of the instruments.

Initial treatment at the place of use

- Defective instruments must be clearly marked as such. They have to be reprocessed before being disposed of or returned.
- Rinse the instrument with cold water.
- Remove coarse soiling with cold water. A plastic brush is recommended for heavily encrusted tissue residues.
- Flush lumen with cold water.

Note: If it is not possible to rinse the instrument with cold water, wrap the instrument in a moist cloth to prevent any residues from drying.

Transportation

- Safe storage and transport of the instruments to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Manual pre-cleaning

A manual pre-cleaning is necessary before the automated cleaning and disinfection to prevent surgery residues from drying.

Cleaning	Detergent	Dosage	pH value
Enzymatic	Cidezyme of Johnson & Johnson	0.8%	7.8 – 8.8 (diluted)

1. Immerse the instrument into a cold-water bath with a 0.8% cleaning solution and let the instrument soak for 5 minutes. To avoid contamination of the surrounding area, rinse the instrument in the water.
2. Brush the instrument under cold water until all visible soiling is removed.
3. Disassemble the instrument as far as possible. See the “Disassembly of the instrument” section.
4. While the instrument is in the water bath, brush the instrument using a soft round brush until all visible soiling has been removed.
5. Where applicable, rinse lumen, drillings, and threads using a spray gun: >10 seconds with 3 - 5 bar.
6. Remove the instrument from the water bath and rinse it with cold water.
7. Immerse the instrument into a combined cleaning-disinfectant solution to prevent any residue from drying.

Automated cleaning and disinfection

- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.
- Clean the instrument when disassembled. If present, remove protective caps.
- Instruments with a lumen (tubes, sheaths, hoses) need to be connected to a suitable irrigation system to ensure that the lumina are flushed.

Cleaning in the ultrasonic bath

Clean the components in the ultrasonic bath before or in combination with the automated cleaning:

Temperature	Frequency	Duration
40 - 45°C	35 - 45 kHz	10 - 15 minutes

Turn and move the components during cleaning in the ultrasonic bath.

Detergent for the automated alkaline cleaning in the washer

Cleaning	Detergent	Dosage	pH value
Alkaline	neodisher® FA of Dr. Weigert	0.5%	12.2 - 14 (diluted)

Washer: Miele G 7735 CD

Preparation:

1. Place the instruments in a sieve tray of the MIS slide-in cart of the washer/disinfector in such a way that the inner and outer surfaces can be properly cleaned.
2. If applicable, close the irrigation connection of the MIS slide-in cart.
3. Start the cleaning program.

Program	Detergent	Duration	Temp. °C
1. Pre-rinsing	Cold tap water	1 minute	Cold
2. Draining	----	----	----
3. Pre-rinsing repeated	Cold tap water	3 minutes	Cold
4. Draining	----	----	----
5. Cleaning	0.5% alkaline detergent	5 minutes	55°C
6. Draining	----	----	----
7. Neutralization	Deionized water	3 minutes	----
8. Draining	----	----	----
9. Rinsing	Deionized water	2 minutes	----
10. Draining	----	----	----
11. Drying (drying program in the washer/ disinfector)	----	15 – 25 minutes	90 – 110°C
12. At the end of the cycle, immediately remove the instrument, if it is not too hot.	----	----	----
13. If necessary, dry the instrument using sterile compressed air.	----	----	----

Disinfection

Device	Disinfectant	Temp. °C	Holding time
Getinge 88 Series	Deionized water	90 + 3°C	≥5 minutes

MAINTENANCE, CONTROL, AND INSPECTION

- After cleaning and disinfection, the instruments must be inspected visually and for functionality. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, lumen, locks, and other areas that are difficult to access. Particular attention should be paid to slots, lumen, locks, and other areas that are difficult to access.
- If residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear & tear, and damage (cracks, rust) and replaced, if necessary.
- After each cleaning and before sterilization, the moving parts of the handle must be lubricated with a silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.
- Please see also “Prior to each use: visual and functional inspection” in these instructions.

PACKAGING

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

STERILIZATION

- Before sterilization, the instrument must be assembled. See the “Assembly of the instrument” section.
- The sterilization was validated using the sterilizers Selectomat S 3000 of the MMM Group and Varioclav 400 E of Fisher Scientific.
- Observe the manufacturer’s instructions of the sterilizer.
- The sterilizers are validated according to DIN EN 13060 and DIN EN 285, respectively.
- Place the instruments in the sterilizer so that the instruments do not touch each other, and steam can circulate freely.

Triple fractionated pre-vacuum:

Sterilization temperature	Minimum holding time (exposure time)	Pressure	Drying time
134°C – 137°C	3 - 5 minutes	3 bar 44 psi	Minimum of 10 minutes

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean, and dust-free area, preferably in sterilization containers.
- Store the sterilization container in a clean and dry area at room temperature and with controlled humidity.
- Do not store the sterilization containers near aggressive substances such as alcohol, acids, bases, solvents, and disinfectants.
- Keep the sterile instruments away from sunlight.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials and machines have been used during the validation procedure:

Pre-cleaning	Cidezyme of Johnson & Johnson
Alkaline detergent for the automated cleaning	neodisher® FA of Dr. Weigert
Washer	Miele G 7735 CD
Disinfector	Getinge 88 Series
Sterilizers	– Selectomat S 3000 of MMM Group – Varioclaov 400 E of Fisher Scientific
Sterilization	Steam sterilization (moist heat)

ADDITIONAL NOTES

- If the specified chemical agents and machines are not available, the user needs to validate their process.

DISPOSAL

- Only after the products have been cleaned and disinfected properly, they should be disposed of accordingly.
- 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 containers to prevent third parties from being injured.

REPAIRS & RETURNS

- Never carry out repairs yourself. Service and repairs should only be carried out by appropriately instructed and qualified persons. If you have any questions, contact RUDOLF Medical or your medical technology department.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report any problems with our products to the respective distributor.
- In the event of serious incidents with the products, the user must report this to RUDOLF Medical as the manufacturer and 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	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
CE 0297	CE marking according to EC directive 93/42/EWG with the ID of the notified body
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
MD	Medical Device