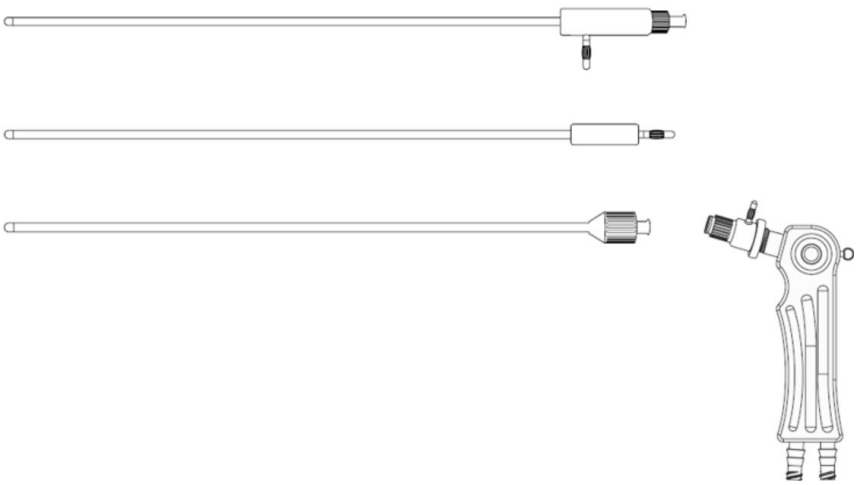
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)

MONOPOLAR MIS ELECTRODES – WITH AND WITHOUT SUCTION AND IRRIGATION



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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. MIS electrodes are connected to corresponding monopolar HF cables to perform endoscopic procedures. This allows for suction and irrigation under optimal pressure and visual conditions during the procedure.

You are receiving a high-quality product whose proper handling and use are described below.

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

Patient population: 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.

RUDOLF Medical instruments are delivered 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

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

INDICATION

MIS electrodes are intended for minimally invasive procedures in the fields of laparoscopy, endoscopic gynecology, and endoscopic urology.

CONTRAINDICATIONS

- The medical devices are not intended for the use on the central nervous and circulatory system.
- Do not use the medical device when at least one of the following situations is given:
  - Patients with a pacemaker or other active implants. Please consult the corresponding expert before using the instrument on the patient.
  - Acute inflammation of the abdominal area
  - Vaginal infection
  - Pregnancy

WARNINGS AND PRECAUTIONS

General:

- Use the instrument only when the insulation is undamaged.
- Coagulate only if you can see the contact surfaces of the instrument. During coagulation, do not touch any metal objects.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use inflammable or explosive substances during surgery.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- 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.

- The safe combination of instruments with each other or with implants must be checked by the user before clinical use.
- Monopolar laparoscopic instruments must not be used in MRI applications and X-ray imaging.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

Handling instructions for HF surgery:

- Use the instrument only with a maximum recovery peak voltage of **2,000 (two thousand) Vp** in combination with the original equipment.
- The output voltage of the HF generator must only be set to the value that is absolutely necessary for the procedure. If the usual coagulation performance is not achieved despite the standard setting of the HF generator, do not increase the output voltage. The maximum permissible peak voltage of the instrument must not exceed in the respective mode.
- The surfaces of the contact points at the working end (jaw) must be free of contamination. In order to achieve optimal coagulation results, it is necessary that the working ends of the instruments are always clean. Dried blood and tissue residues impact the functionality. When the coagulation performance decreases do not increase the voltage, but clean the working ends of the instrument using a moist sterile swab.
- Inadvertent activation or movement of the electrode outside the view of the user can lead to patient injury.
- Only when the electrode is in the view of the user and has contact with the tissue, turn on the HF power. Otherwise, the irrigation fluid can become too hot and injure the patient.

Risk of infection

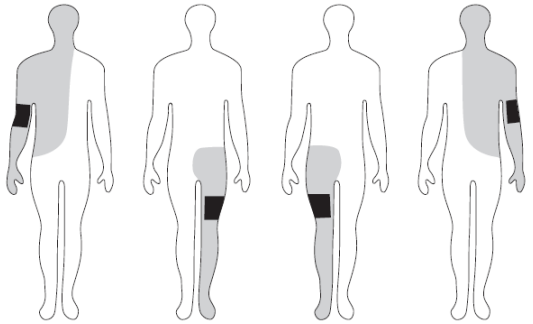
- For patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices must be applied.
- Insufficient cleaning and sterilization can also lead to a risk of infection.

POSITIONING THE PATIENT

– Ensure the correct positioning of the return electrode, otherwise there is a risk of burns.
– Make sure 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 that the patient has skin-to-skin contact (arms, legs). Place dry gauze between the patient's body parts such as 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 must not flow across the thorax.
– There is a risk of burns if body hair in the affected area is not removed and moisture, e.g., disinfectant, is still present at the point of contact.
– The following illustration shows the position of the return electrode (black rectangle) and the permissible areas of use (grey) for the electrically conductive working ends of the instrument (jaws).
– Make sure that you select a monitoring-capable return electrode that is compatible with the contact quality monitoring system.



PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

The functional tests show whether the instrument and its components are functioning properly. Perform the functional test after automated washer-disinfector processing, after assembly, and before sterilization.

Check for the following:

- External damage (e.g., deformed shaft, dents, burrs, cracks or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Clear passage through the working channels
- Note the following in particular:
  - Proper contact of all HF connectors and cables
  - Functioning of the foot switch
  - Damage of the insulation of the HF cable and the instrument
- Cleanliness of the distal end of the instrument (contact surfaces)

Please see also:

- See also section “Maintenance, control and inspection” in these instructions for use.
- Defective products: See the "Repairs and returns" section.

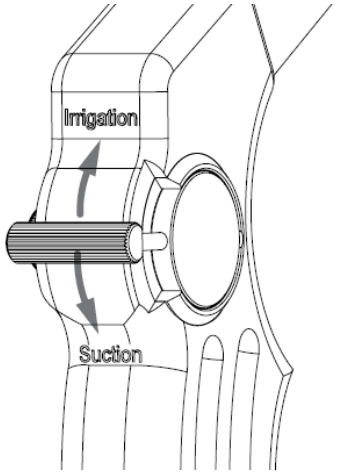
Functional test of the handles and electrodes

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.



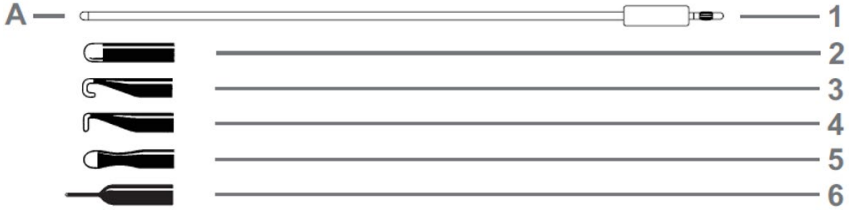
PRODUCT DESCRIPTION

⚠ 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.
- 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.
- Electrodes and handles cannot be disassembled. Only handles with a suction-irrigation function can be disassembled.

Electrodes without a suction-irrigation function

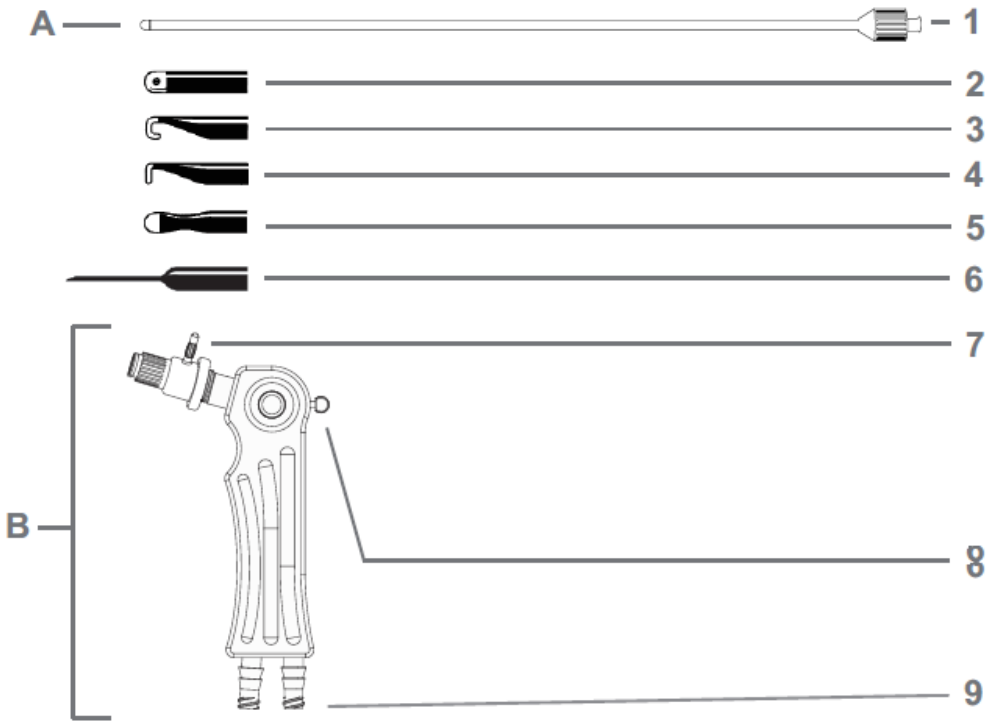
The following electrodes do not have a suction-irrigation opening hole at the distal end. Consequently, suction and irrigation are not possible during surgical procedures. The electrode is inserted into the handle via the HF contact pin.



A Electrode
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 connected to a suction-irrigation handle via an electrode adapter.
- The handle has an HF contact pin.
- A connection at the distal end allows for suction and irrigation.



A Electrode B Handle 1 Luer-Lock connection 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 at 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

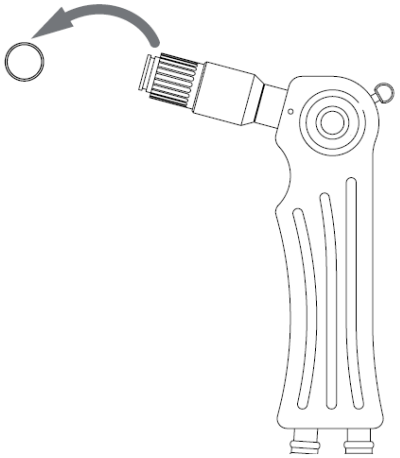
DISASSEMBLY OF THE INSTRUMENT

Note:

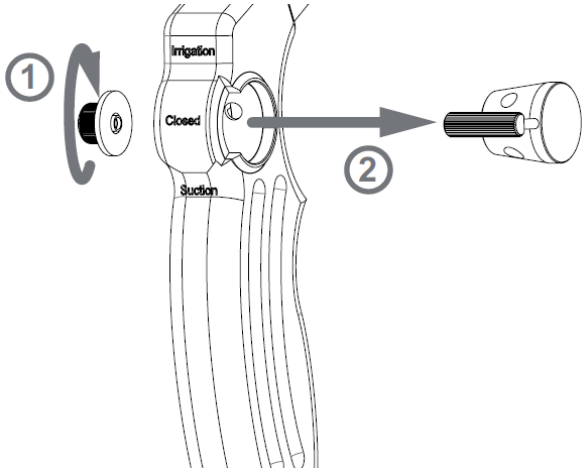
The electrodes and handles cannot be disassembled. Only the handles with a suction-irrigation function can be disassembled.

Suction-irrigation handle with a sliding valve

Remove the O-ring:



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

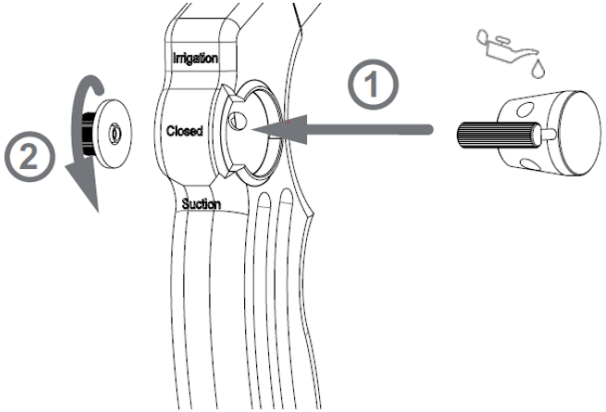


ASSEMBLY OF THE INSTRUMENT

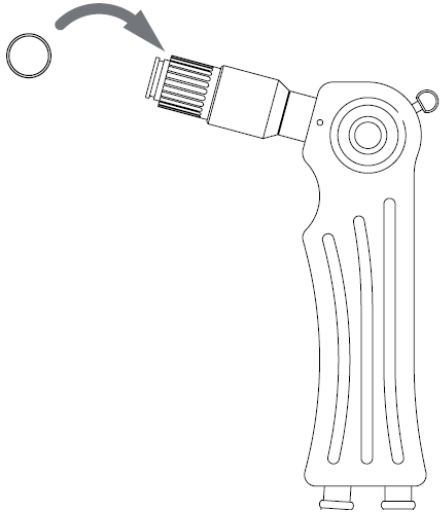
⚠ There is a risk of infection from improperly reprocessed instruments. Instruments must be cleaned and disinfected in a washer-disinfector before assembly.

Suction-irrigation handle with a sliding valve

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



Insert the O-ring:



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.
- Ensure the return electrode is placed with full-surface contact on the patient's skin.
- 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:
   Insert the electrode into the clamping shaft or insert the electrode directly into a handle that has 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

- The instruments must be reprocessed within an hour after use to prevent contamination from drying 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. A damaged surface can lead to an uncontrolled burn injury.

Restrictions on reprocessing

- The lifespan of the product is influenced by several factors, including:
  - The number of uses and the frequency of reprocessing cycles
  - The quality of care, handling, and maintenance
  - The continued legibility of any direct product markings
- For the precleaning 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.
- Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.

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.
2. To avoid contamination of the surrounding area, rinse the instrument in the water bath and brush it 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. Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.

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 in the ultrasonic bath during cleaning.

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

When necessary, use medical compressed air to dry the instrument. Only use filtered compressed air (free of oil, germs and particles).

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. Please see also “Prior to each use: visual and functional inspection” in these instructions.
- 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.

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 the RUDOLF Medical 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 strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical or your distributor.

REPROCESSING – APPLIED STANDARDS

- AAMI/ANSI ST77: Containment devices for reusable medical device sterilization
- DIN EN 285: Sterilization – Steam sterilizers – Large sterilizers
- DIN EN 868: Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
- DIN EN ISO 11607: Packaging for terminally sterilized medical devices
- DIN EN 13060: Sterilizers for medical purposes – Small steam sterilizers – Requirements and testing
- DIN EN ISO 15883-1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
- DIN EN ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- DIN EN ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- DIN EN ISO 17665: Sterilization of health care products – Moist heat – Requirements for the development, validation and routine control of a sterilization process for 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 marking according to the Medical Device Regulation (EU) 2017/745 (MDR) with the ID of the notified body
	Keep dry
	Keep away from sunlight
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
MD	Medical Device