RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
BIPOLAR COAGULATION INSTRUMENTS

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical bipolar coagulation instruments. Instruments for electrosurgery may only be used by persons who have been specially trained or instructed in using these instruments.
You have received a high-quality product, the proper handling and use of which is described below.

NON STERILE RUDOLF Medical instruments are supplied 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

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

The instruments are not restricted to a specific population. The instrument should not be used if, in the opinion of the attending physician, the risks exceed the benefits for the patient.

CONTRAINDICATION

The instruments must not be used for tubal coagulation after sterilization or tubal sterilization.

PRODUCT INFORMATION

– **Maximum output voltage of the HF generator Umax:** 500Vp
- Observe the application and safety instructions provided by the manufacturer of the HF generator as well as the information on compatible bipolar HF cables.

INCIDENTS REPORTED IN CONNECTION WITH THE USE OF ELECTROSURGICAL SYSTEMS

- Unintentional activation resulting in tissue damage and/or damage to the equipment
- Fire in connection with cover cloths and other flammable materials
- Alternating electricity paths that lead to burns at spots where the patient or user comes into contact with uninsulated components
- Explosions caused by sparks in the vicinity of flammable gases
- Perforation of organs, sudden severe bleeding

WARNINGS & PRECAUTIONS

- When using the scissors, the coagulation of parenchymal tissue can lead to deflagration.
- Special requirements apply when using electrosurgery on patients with pacemakers or other active implants (e.g. low HF power, patient monitoring). A cardiologist or an appropriate specialist must always be consulted.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, please follow the applicable national regulations regarding the disposal and reprocessing of instruments.
- Non-observance of these instructions for use and safety instructions as well as improper use can lead to injuries, malfunctions, premature wear or risks for patients and users.
- Only activate the HF current when the contact surfaces are fully visible and in good contact with the tissue to be treated. Do not touch any other metal instruments, trocar sleeves, optics or similar objects during the application.
- Instruments that are temporarily not in use must be put aside without any contact to the patient.
- Never use the instruments in the presence of flammable or explosive substances.
- Take care when handling sharp cutting edges as there is a risk of injury.
- Never use damaged instruments.

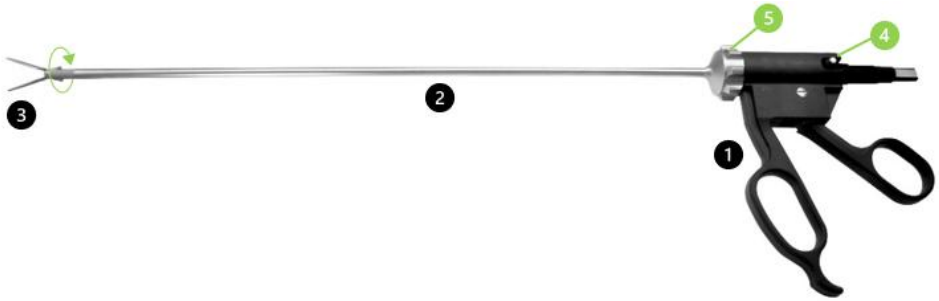
- Do not use metal brushes or abrasive cleaners, as corrosion can occur if the surface is damaged.
- Do not leave the instruments in the disinfectant for too long. Follow the instructions of the disinfectant manufacturer.
- Automated cleaning/disinfection should be preferred to manual cleaning/disinfection, as automated processes can be standardized, reproduced and therefore validated.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for the following:
- Correct function
- Cleaning agent or disinfectant residues
- It is very important to inspect each surgical instrument for visible damage and wear, e.g. cracks, breaks or defects in the insulation before each use.
- Especially areas such as tips, locks and all moving parts and ceramic elements must be checked carefully.

PRODUCT DESCRIPTION

Coagulation instrument with ring handle



1 Handle
2 Guide shaft
3 Instrument insert
4 Push pin for locking/unlocking
5 Push pin for locking/unlocking

ASSEMBLY

1. First insert the instrument insert (3) into the guide shaft (2) and tighten it, ensuring that the jaws are closed.
2. Guide the inserted instrument insert (3) into the opening of the handle (1) and now press the pin lock (4), so that the inserted instrument insert can be attached to the handle (1).

   Note: Make sure that the opening of the guide shaft (2) and the pin lock (5) fit together.
3. Pressing the thumb-operated ring handle produces an audible click and the instrument is ready for use.

DISASSEMBLY

1. To release the instrument insert (3) including the guide shaft (2) from the handle (1), first press the pin lock (5). The is the first step of unlocking.
2. The instrument insert (3) including the guide shaft (2) can now be completely released from the handle (1) by pressing the second pin lock (4).
3. Finally, unscrew the instrument insert (3) at the jaw out of the thread of the guide shaft and slide the instrument insert (3) out.

REPROCESSING INSTRUCTIONS

Restrictions

- Due to the product design, the materials used and the intended purpose, it is not possible to set a defined limit for the maximum number of reprocessing cycles that can be carried out. The service life of the instruments is determined by their function and careful handling.
- Instruments for electrosurgery are naturally subject to increased wear depending on the type and duration of use.

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.
- Immediately after use, rinse the instruments under cold tap water using a soft plastic brush until the visible contamination has been removed.
- Do not use fixing agents or hot water (> 40°C).

Transportation

- The instruments should be stored and transported safely in a closed container / container system to the reprocessing site to prevent damage to the instruments and contamination of the environment.
- All surgical instruments should always be handled with the utmost care during transport, cleaning, maintenance, sterilization and storage. This applies in particular to cutting edges, fine tips and other sensitive instrument areas.

Preparation before cleaning

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

Manual cleaning and disinfection

Cleaning agents for manual cleaning and disinfection

Process	Cleaning agent	Manufacturer
Cleaning	Cidezyme Enzymatic Detergent Solution; enzymatic	Johnson & Johnson
Disinfection	Cidex OPA Solution	Johnson & Johnson

Pre-treatment in an ultrasonic bath

1. Place the instruments in an ultrasonic bath with a 0.5% enzymatic cleaning agent. Temperature 40°C; sonication time at least 15 minutes.
2. Remove the instruments and rinse them completely with cold water to remove the cleaning agent.

Cleaning

1. Prepare a cleaning bath according to the cleaning agent manufacturer's instructions.
2. Rinse the instruments under cold tap water (< 40°C) until all visible contamination has been removed.
3. Remove stubborn dirt with a soft brush.
4. Place the instruments in the prepared cleaning bath. Observe the exposure time according to the manufacturer's instructions.
5. Clean the inserted instruments manually with a soft brush and brush all surfaces several times.
6. **For inner tube surfaces:**
   a) Run a soft brush in and out of the tube at least six times.
   b) Rinse the tubes with demineralized water.
   c) Repeat these steps.
7. Rinse the instruments thoroughly with demineralized water to completely remove the cleaning agent.

Disinfection

1. Prepare a disinfectant bath according to the disinfectant manufacturer's instructions.
2. Place the instruments in the disinfection bath and observe the exposure time according to the manufacturer's instructions.
3. Rinse the instruments thoroughly with demineralized water to completely remove the disinfectant.

Manual drying

- Use a lint-free cloth.
- Use sterile compressed air to dry cavities and ducts.

Automated cleaning and disinfection

- Clean and disinfect the instruments only in suitable washer/disinfectors (WD) and with a procedure / program validated for the WD and surgical instruments (EN ISO 15883).
- The operating and loading instructions of the WD manufacturer must be observed.
- For cleaning, instruments with joints must be opened by approximately 90 degrees.
- When selecting the cleaning agent, consider the material and properties of the instrument, 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 (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Cleaning agents for automated cleaning in the WD

Process type	Cleaning agents	Manufacturer
Alkaline	neodisher® FA	Dr. Weigert
Enzymatic	Endozime	Ruhof company

Automated cleaning program with thermal disinfection in the WD using an alkaline OR an enzymatic procedure:

Place the instruments in a wire tray on the slide-in trolley or in the inserts of the MIS trolley and start the cleaning program:

Process	Reagents	Time / min	Temp. / °C
Pre-rinsing	Water in drinking water quality	1	Cold
Emptying	-----	-----	-----
Pre-rinsing	Water in drinking water quality	3	Cold
Emptying	-----	-----	-----
Cleaning	Water, 0.5% alkaline cleaning agent	5	55
	OR		
	Water, 0.5% enzymatic cleaning agent		45
Emptying	-----	-----	-----
Neutralization	Water in drinking water quality and neutralizer	3	Warm (> 40)
Emptying	-----	-----	-----
Rinsing	Water in drinking water quality	2	Warm (> 40)
Emptying	-----	-----	-----
Disinfection *	Thermal disinfection with demineralized water	> 5	> 90
Drying **	-----	> 20	max. 93

- * Carry out a mechanical thermal disinfection under consideration of the national requirements regarding the A0 value from ISO 15883-1 (A0 = 3000).
- ** If necessary, the outer surface of the instruments can also be dried with a lint-free cloth. Dry instrument cavities with sterile compressed air.

MAINTENANCE, INSPECTION AND TESTING

- 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.
- If contamination residues/liquids are still visible, cleaning and disinfection must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear and damage (cracks, rust) and, if necessary, replaced.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.
- See also "Prior each use: Visual and functional inspection" in these instructions.

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 causing tension on the seal seam or tearing the packaging. Points and sharp edges must not perforate the sterilization packaging.

STERILIZATION

- Sterilization must be performed in accordance with DIN EN ISO 13060 / ISO 17665 or in accordance with a validated steam sterilization procedure (fractionated vacuum procedure) in a sterilizer in accordance with EN 285 / DIN 58946.
- The manufacturer's instructions for the sterilization device must be observed.
- 3 pre-vacuum phases with at least 60mbar pressure:

Sterilization temperature	Minimum holding time	Drying time
132°C - 137°C	3 - 5 minutes; maximum 18 minutes	At least 10 minutes

STORAGE

- Sterilized instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following agents and machines were used in the validation:

Manual cleaning – Pre-treatment in an ultrasonic bath	• 0.5% enzymatic cleaning agent • Temperature: 40°C • Sonification time of at least 15 minutes
Manual cleaning	Cleaning bath with Cidezyme Enzymatic Detergent Solution; Johnson & Johnson
Manual disinfection	Disinfection bath with cleaning agent Cidex OPA; Johnson & Johnson
Automated cleaning, alkaline	Cleaning agent: neodisher® FA; Dr. Weigert
Automated cleaning, enzymatic	Cleaning agent: Endozime; Ruhof company
Washer / disinfector	• Disinfector G 7735 CD; Miele • Slide-in trolley E 327-06; Miele • MIS trolley E 450; Miele
Disinfection	Thermal
Neutralizer	neodisher® Z; Dr. Weigert
Sterilization	Steam sterilization

For details– see reports:

- SMP GmbH # 01707011901 (Automated cleaning)
- MDS GmbH # 135196-10 (Manual cleaning/disinfection)
- Nelson Labs # 200432706-02 (Sterilization)
- MDS GmbH Test report 084183-10 (Sterilization)

ADDITIONAL NOTES

- If the specified cleaning agents and machines are not available, the user needs to validate their 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 recycling the products/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 must only be carried out by trained and qualified persons. If you have any questions, please 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 / INCIDENTS

- The user should report any problems with 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 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. Should any discrepancies occur, please contact RUDOLF Medical.

APPLIED STANDAARDS AND GUIDELINES FOR REPROCESSING

- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- 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 – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- DIN EN 13060: Small steam sterilizers
- DIN EN ISO 15883: Washers/disinfectors - Part 1: General requirements, terminology and test methods
- DIN EN ISO 17664: Reprocessing of health care products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices

SYMBOLS

	Consult instructions for use
	Caution
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Manufacturer
	Date of manufacture
CE 0297	CE marking according to Regulation (EU) 2017/745 for medical devices (MDR) with the ID of the notified body
MD	Medical Device