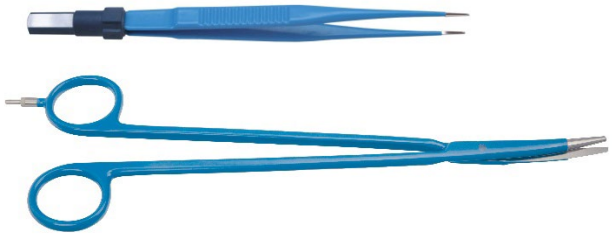
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
BIPOLAR FORCEPS AND SCISSORS



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

D0169 / Rev J / ACR01189 / 2025-07-16

CE 0297

PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical bipolar forceps and bipolar scissors. You receive a high-quality product, the proper handling and use of which is described below. The instruments for electrosurgery are intended for the professional user (surgeon, operating room nurse, reprocessing technician). The professional user must be trained in the application of HF (RF) instruments.

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 forceps are intended to grasp, dissect, and coagulate tissue during open surgical procedures.
Bipolar scissors are intended to cut, dissect, and coagulate tissue during open surgical procedures.

INDICATIONS

The bipolar forceps and scissors are used in open surgery and in various open-surgery disciplines such as the following: general surgery, visceral surgery, neurosurgery, ENT surgery (ear, nose, throat), gynecological surgery, urological surgery, plastic and reconstructive surgery.

CONTRAINDICATIONS

The bipolar forceps and scissors are not intended for use on the central nervous and circulatory systems.

TARGET POPULATION

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

PRODUCT INFORMATION

- The instrument will be connected to the bipolar output of an HF generator using a suitable cable.
- The following maximum output voltages (Umax) for the following RUDOLF Medical instruments (REFs in brackets) must not be exceeded:

  300 Vp (RU 138x-xx)

  300 Vp (HF510-011 - HF511-511)

  500 Vp (HF515-015 - HF533-618)
- Observe the application and safety instructions provided by the manufacturer of the HF generator.

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 drapes and other flammable materials
- Alternating current paths that lead to burns at points 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 AND PRECAUTIONS

- The maximum output voltages mentioned above must not be exceeded.
- The bipolar devices must not be used in a magnetic field (MRI = magnetic resonance imaging).
- It is recommended to use a smoke evacuation system.
- Make sure that the bipolar instruments do not come in contact with drapes or other flammable materials.
- When using electrosurgery on patients with pacemakers or other active implants, due to electromagnetic interference special precautions such as reduced HF power and continuous patient monitoring must be taken. In all cases, a cardiologist or appropriately qualified specialist should be consulted.
- Tip adhesion to tissue: Due to electrosurgery, there is a potential risk of the tips of bipolar instruments adhering to tissue. Remove any adherent tissue during the procedure. If this is no longer possible, replace the bipolar instrument.
- 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.
- Non-observance of these instructions for use and safety instructions as well as misuse of these instruments can lead to injuries, malfunctions, premature wear or risks for patients, users, and third parties.
- Bipolar scissors contain high-quality ceramic parts that must be handled with particular care and protected against breakage.
- The safe combination of instruments with each other or with accessories must be checked by the user before clinical use.
- 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 in a manner that they are not in contact with 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 disinfectant manufacturer's instructions.
- 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:

- External damage (such as dents, burrs, cracks or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Perfect 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 instrument tips (contact surfaces)
- Areas such as tips, all moving parts and ceramic elements must be carefully inspected.
- See also section "Maintenance, control and inspection".
- Defective products: See section "Repairs and returns".

REPROCESSING INSTRUCTIONS

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
- Instruments for electrosurgery are naturally subject to increased wear depending on the type and duration of use.
- The plastic handles must not be treated with hydrogen peroxide (H2O2), as this may damage them.

Initial treatment at the place of use

- Defective instruments must be visibly labeled. They must also be reprocessed before they are disposed of or returned.
- Immediately after use, rinse the instruments under cold tap water until all visible contamination has been removed; a soft plastic brush can be used if necessary.
- For precleaning, do not use fixing agents or hot water (> 40°C) because this can lead to hardening of residues and thus impair the cleaning success.

Transportation

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

Manual pre-cleaning

- Place the instruments in cold tap water for 5 minutes.
- Brush all surfaces of the instruments under cold tap water with a soft brush until all visible contamination has been removed.

Manual cleaning and disinfection

Pre-treatment in an ultrasonic bath

1. Remove heavily encrusted contamination in an ultrasonic bath before automated cleaning. To do this, use a 0.5% enzymatic cleaning agent at 40°C with a sonication time of 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 detergent manufacturer's instructions. Cidezyme from Johnson & Johnson was used for the validation.
2. Rinse the instruments under cold tap water (< 40°C) until all visible contamination has been removed.
3. Remove stubborn contamination with a soft brush.
4. Immerse the instruments completely in the prepared cleaning bath. Observe the exposure time according to the manufacturer's instructions.
5. Clean the immersed instruments manually with a soft brush. Brush all surfaces several times.
6. Rinse the instruments thoroughly with demineralized water to completely remove the cleaning agent.

Disinfection

1. Prepare a disinfection bath according to the disinfectant manufacturer's instructions. Cidex OPA from Johnson & Johnson was used for the validation.
2. Place the instruments in the disinfection bath. Observe the exposure time according to the manufacturer's instructions.
3. Do not leave the instruments in the disinfectant for too long. Follow the disinfectant manufacturer's instructions.
4. Rinse the instruments thoroughly with demineralized water to remove the disinfectant completely.

Manual drying

- Use a lint-free cloth.
- If need be, use sterile compressed air.

Automated cleaning and disinfection

- The instruments may only be cleaned and disinfected in suitable washer/disinfectors and with a procedure/program validated for the washer/disinfector and the type of instrument (EN ISO 15883).
- The operating and loading instructions of the washer/disinfector manufacturer must be observed.
- Articulated instruments must be opened by approx. 90 degrees for cleaning.
- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agent recommended by the washer/disinfector manufacturer for the respective application and the recommendations of the Robert Koch Institute (RKI) and the DGHM (German Society for Hygiene and Microbiology).

Cleaning agents for automated cleaning in washer/disinfectors

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

Automated cleaning program with thermal disinfection in the washer/disinfector using an alkaline OR enzymatic process:

Process	Reagents	Time / min	Temp. / °C
Pre-cleaning	Water in drinking water quality	1	Cold
Emptying	-----	-----	-----
Pre-cleaning	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	Tap water in drinking water quality and neutralizer	3	Warm (> 40°C)
Emptying	-----	-----	-----
Rinsing	Tap water in drinking water quality	2	Warm (> 40°C)
Emptying	-----	-----	-----
Disinfection *	Demineralized water	> 5	> 90
Drying **	-----	> 20	max. 93

- * Carry out an automated thermal disinfection taking into account the national requirements regarding the A0 value from ISO 15883-1 (A0 = 3000).
- ** If necessary, the exterior of the instruments can also be dried with a lint-free cloth. Dry instrument cavities with sterile compressed air.

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

PACKAGING

- Standard-compliant packaging of instruments for sterilization is carried out in accordance with DIN EN ISO 11607 and DIN EN 868.
- When using individual packages, it is important to ensure that they are large enough to accommodate the product without stress, without putting strain on the seal or damaging the packaging.

STERILIZATION

- The scissors must be **closed** for the sterilization to ensure that the blades run smoothly.
- Sterilization must be performed in accordance with DIN EN ISO 13060 / ISO 17665 or in accordance with a validated steam sterilization process (fractionated vacuum process) 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 60 mbar 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 ON THE VALIDATION OF THE REPROCESSING

The following tools and machines have been used in the validation:

Manual cleaning – Pre-treatment	• Ultrasonic bath • 0.5% enzymatic cleaning agent • Temperature: 40°C • Sonication time of at least 15 minutes
Manual cleaning	Cleaning bath with cleaning agent Cidezyme (Enzol Enzym. Detergent); Johnson & Johnson
Manual disinfection	Disinfection bath with cleaning agent Cidex OPA; Johnson & Johnson
Machine cleaning, alkaline	Cleaning agent: neodisher® FA; Dr. Weigert
Mechanical cleaning, enzymatic	Cleaning agent: Endozime; Ruhof company
Cleaning device / disinfection device	• Disinfector G 7735 CD; Miele • Slide-in trolley E 327-06; Miele • MIC trolley E 450; Miele
Disinfection	Thermal
Neutralizer	neodisher® Z; Dr. Weigert
Sterilization	Steam sterilization

ADDITIONAL NOTES

- If the means and machines described above are not available, it is the responsibility of the user to validate his process accordingly.

DISPOSAL

- Products may only be disposed of properly after successful cleaning and disinfection.
- When disposing of or recycling the product, its components and its packaging, the national regulations must be observed.
- The product must be disposed of in an environmentally friendly manner in accordance with the applicable hospital guidelines.
- Be careful with sharp tips. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS AND RETURNS

- Never carry out repairs yourself. Service and repairs may only be carried out by trained and qualified persons. Please contact RUDOLF Medical, your distributor or your medical technology department if you have any questions in this regard.
- Due to infection risk, defective products must have undergone the entire reconditioning 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 is established.

GUARANTEE

- The instruments are made of high-quality materials and undergo strict quality control before delivery. Should any discrepancies occur, please contact RUDOLF Medical or your distributor.
- Liability is excluded for products that have been modified compared to the original, that have been misused, improperly handled or used.

ACCESSORIES

Suitable bipolar connection cables:

- For bipolar scissors: HF300-20x
- For bipolar forceps: HF310-xxx

REPROCESSING – APPLICABLE STANDARDS

- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 868 Packaging for terminally sterilized medical devices - Part 8: Reusable sterilization containers for steam sterilizers conforming to EN 285; requirements and test methods
- DIN EN ISO 11607: Packaging for terminally medical devices to be sterilized - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- DIN EN 13060: Small steam sterilizers
- DIN EN ISO 15883: Washer-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 mark in accordance with Regulation (EU) 2017/745 for medical devices (MDR) with the identification number of the notified body
MD	Medical Device