

Bipolar Scissors

Item numbers

RU 1381-18	RU 1381-21	RU 1381-23
RU 1381-28		

Caution

Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments.

Intended Use

The bipolar scissors are designed for dissecting, cutting and bipolar coagulation of tissue. They have to be connected by a suitable bipolar cable to the appropriate output of a high frequency electrosurgical generator. The coagulation current is activated by means of a footswitch.

Maximum output voltage of the generator U_{max} : 300 V_p

Maximum output power in Coag mode:

70 Watt

Suitable Cables:

Rudolf Bipolar Cable Art. No:

HF300-XXX; HF310-XXX

Note: Instruments for electrosurgery should only be used by individuals who have been specially trained in their use.



Safety notice

- All instruments have to be completely cleaned, disinfected and sterilized before initial use and any other use.
- It is very important to check each surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular, areas such as blades, tips, notches, locking and blocking devices as well as all mobile parts, insulations and ceramic elements have to be checked carefully.
- Bipolar scissors include high-quality ceramic parts which have to be treated with particular care and protected against breakage.
- Never use damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument may not be laid down on the patient.

- Coagulation should only be performed if the contact surfaces are visible. Do not touch any other metallic instruments during coagulation.

Reprocessing

Due to the product design, the raw materials used and the intended purpose it is not possible to determine a precise limit with regard to the maximum possible number of reprocessing cycles. The serviceable life of the instruments is determined by their function as well as by a careful handling.

Instruments for electrosurgery are by nature subject to increased wear depending on the type and time of use.

Preparation and transport

Remove coarse dirt from the instruments immediately after each use. Do not use fixation agents or hot water (>40°C) as this may result in the fixation of residues and could reduce the cleaning success.

Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container to avoid any damage to the instruments and any contamination of the environment.

Handle with extreme care, do not throw or drop!

Machine reprocessing

Manual precleaning

1. Insert the Instrument for 5 minutes in cold tap water.
2. Clean the Instruments under cold tap water with a soft brush until all visible dirt is removed.

Cleaning

Place the instrument with the scissor blades open in a basket on the insert module or on the inserts of the MIS module and start the cleaning process.

1. Prerinse for 1 min. with cold water
2. Discharging
3. Prerinse for 3 min. with cold water
4. Discharging
5. Wash for 5 min. at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent.
6. Discharging
7. Neutralize for 3 min. with warm tap water (>40°C) and a neutralizing agent.
8. Discharging
9. Rinse for 2 min. with warm tap water (>40°C).
10. Discharging

Disinfection

Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to the A0 value (see ISO 15883).

Drying

Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine. If necessary, manual drying may additionally be carried out using a lint free cloth. Dry cavities of the instruments by blowing with sterile compressed air.

Manual reprocessing

Cleaning

Prepare a cleaning bath according to the manufacturer's instructions.

1. Rinse products with cold tap water (<40°C) until all visible accumulations of dirt have been removed. Remove stuck dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submersed. Observe residence time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. All surfaces must be brushed several times.
4. Rinse the products thoroughly with running tap water to remove the cleaning agents without residue.

Disinfection

Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer.

Place the instruments in the disinfectant bath and observe the specified residence time.

Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

Drying

Manual drying is carried out using a lint free cloth and, in particular, for drying cavities and channels, sterile compressed air.

Functional test and packaging

Perform visual inspection for cleanliness; if required, perform an assembly and functional test according to the operating instructions.

If necessary, repeat the reprocessing process until the instrument is optically clean.

Packaging has to comply with ISO 11607 and EN 868 standards for packaging for sterilized instruments.

Sterilization

The products must be sterilized with the scissor blades closed in order to fully maintain a smooth action of the blades.

Sterilization of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) in consideration of the respective national requirements.

- 3 pre-vacuum phases, pressure at least 60 mbar
- Heating up to a sterilization temperature of min. 132°C and max. 137°C
- Shortest exposure time: 3 min.
- Drying time: at least 10 min.

Storage

Sterilized instruments have to be stored in a dry, clean and dust-free area at moderate temperatures from 5°C to 40°C.

Repairs

Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly. For any question on these matters, please contact either the manufacturer or your medico-technical department.

Attention: Defect products must pass the complete reprocessing process before being returned for repair.

Handling

During transport, cleaning, care, sterilization and storage, all surgical instruments should be handled with maximum care.

This applies particularly to blades, fine tips and other sensitive areas.

Information on the validation of the reconditioning

The following testing instructions, materials and equipment have been used for validation:

Cleaning agents (for machine use):

- Neodisher FA by Dr. Weigert (alkaline)
- Endozime by Ruhof (enzymatic)

Cleaning agents (manual cleaning):

- Enzol Enzym, detergent by Johnson&Johnson

Neutralising agent:

- Neodisher Z by Dr. Weigert

Cleaning and disinfection device:

- Miele G 7736 CD
- Miele insert module E 327-06
- Miele MIS module E 450






For details, see report.

SMP GmbH # 01707011901-2 (machine cleaning)
 Northview Laboratories #P8H066 (manual cleaning, sterilis.)
 MDS GmbH Testbericht 084183-10 (sterilization)
 If the chemicals and machines described above are not available, the user has to validate the used process accordingly.

Warranty

Rudolf Medical GmbH + Co. KG exclusively supplies tested and faultless products to the customers. All our products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which, compared to the original product, have been modified, misused or handled or used in an inexpert way.

Safety information and explanation of symbols

	Follow the instructions for use
REF	Order number
	Attention Non Sterile Product
	Potential danger for persons or material assets
	Manufacturer
	Manufacturing date
LOT	Lot-Number
CE 0297	CE marking with the identification number of the notified body


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account the safety and warning instructions given in these instructions for use.

Incidents that have been reported in connection with the use of electrosurgical systems:

- Unintended activation with resulting tissue injury in the wrong location and/or damage to the equipment.
- Fire in connection with surgical drapes and other inflammable materials.
- Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
- Explosions caused by sparks in the proximity of inflammable gases.
- Perforation of organs. Sudden severe bleedings.

⚠ WARNINGS AND PRECAUTIONS

- The Bipolar Forceps may only be used by surgeons who have been trained in the usage of the products and who have the required knowledge and experience for the specific surgical procedures.
- When using electrosurgery in patients with pacemakers or other active implants, special requirements apply (e.g., low HF current, patient monitoring) In any case, a cardiologist or appropriate medical specialist must be consulted.
- Activate electrosurgical current only if the contact areas are in full view and have good contact with the tissue that needs to be treated. Do not touch any other metallic instruments, trocar sleeves, optics or similar objects during use.
- When temporarily not in use, the instrument must be placed electrically insulated from the patient.
- Never use the instruments in the presence of flammable or explosive substances.
- Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator.
- RUDOLF Medical instruments must be cleaned, disinfected, and sterilized before first use. Protective caps and transport packaging must be removed beforehand.
- A complete functional check must be carried out before each use.
- Check for damage and wear, in particular for insulation defects.
- Never use damaged instruments.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use metal brushes or abrasives, as there is a risk of corrosion due to surface damage.
- The safe combination of instruments with each other or with accessories must be checked by the user before clinical use.
- Be careful when handling sharp tips and cutting edges - risk of injury.
- In the case of patients with Creutzfeldt-Jakob disease (CJK), suspected CJK or possible variants of this disease, the applicable national regulations regarding the preparation of instruments must be applied.

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PLEASE READ BEFORE USE AND KEEP IN A SAFE PLACE

INTENDED USE

The Bipolar Forceps are designed to grasp, dissect and coagulate selected tissue during open surgical procedures. They must be connected to the bipolar output of an electrosurgical generator using a suitable bipolar cable and must only be used with parameters for bipolar coagulation.

Do not exceed a maximum output of

- 300 Vp (HF510-011 – 511-511)**
- 500 Vp (HF515-015 – HF533-722)**

of your generator.

CONTRAINDICATIONS

- Do not use the instrument if, in the opinion of the attending physician, the risks to the patient outweigh the benefits.
- The Bipolar Forceps are not effective for tubal sterilization, coagulation of the fallopian tubes, etc.
- Since the safe and effective use of bipolar forceps strongly depends on factors such as tissue type, pathology and surgical procedure, the above information can only be used as a general guidance. The clinically successful application is dependent upon the knowledge and experience of the surgeon, who is responsible for deciding which structures can be reasonably treated and whether the patient's condition, e.g., the coagulation status, allows a successful treatment while taking into

- Never leave instruments in disinfectant solution too long. Follow the instructions of the respective manufacturer.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced and thus validated.

PRIOR TO EACH USE:

VISUAL AND FUNCTIONAL INSPECTION

Check for:

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

REPROCESSING INSTRUCTIONS

Restrictions

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

Initial treatment at the place of use

- 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.
- Working channels and lumens must be flushed through at least 3 times immediately after use to avoid blockages.
- Do not use any fixing agents or hot water (> 40 ° C), as this leads to the fixing of residues and can affect the success of the cleaning procedure.
- Defective instruments must be identified and clearly marked. They are also to be reprocessed.

Transportation

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

Preparation for decontamination

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

Manual pre-cleaning

- Before automated cleaning in case of heavily encrusted soiling, cleaning must be carried out in the ultrasonic cleaning bath with 0,5 % enzymatic cleaning detergent (cleaning solution < 40 ° C, sonication time min. 15 min.).
- Remove the instrument and rinse them completely with cold water to remove the cleaning detergent.
- Observe the manufacturer's instructions for the cleaning agent (concentration, temperature, and sonication time).

Automated cleaning

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with a procedure / program validated for the WD and this type of instrument (EN ISO 15883).
- The operating and loading instructions of the WD manufacturers must be observed.
- When choosing the cleaning agent, please 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 Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM, German society for hygiene and microbiology).

Detergent for automated cleaning in washers and disinfectors (WD)

Process Type	Detergent	pH value	Manufacturer
Alkaline	Neodisher® FA	12.2	Dr. Weigert
Enzymatic	Endozime	7	Ruhof

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

Process	Reagents	Time / min	T / °C
Pre-cleaning	Water	1	cold
Drain			
Pre-cleaning	Water	3	cold
Drain			
Cleaning	Water, 0.5 % alkaline detergent	5	55
	OR Water, 0.5 % enzymatic detergent		45
Drain			
Neutralization	Water	3	Warm tap water (>40°C)
Drain			
Rinsing	Water	2	Warm tap water (>40°C)
Drain			
Disinfection *	DeminerIALIZED water	> 5	> 90
Drying **		> 20	max. 93

* Carry out mechanical thermal disinfection by considering the national requirements regarding the A0 value from 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, lumen, 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 function, wear, and damage (cracks, rust) and replaced, if necessary.
- Defective products must have gone through the entire reprocessing process before being returned for repair or complaint.

Non-Stick Bipolar Forceps

- The polished precious metal forceps tips may tarnish, similar to silver.
- This does not impair function.

Bipolar forceps with Irrigation

The enclosed wire insert should always be inserted in the respective irrigation channel, except during use and cleaning, in order to prevent clogging. The irrigation channel must be rinsed very thoroughly during cleaning. The passage has to be checked after cleaning.

PACKAGING

- Packaging of the instruments for sterilization according to standards ISO 11607 and 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

- Sterilization has to be carried out according to DIN EN ISO 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 60 mbar pressure.
- Heat up to a sterilization temperature of 132°C - 137°C.
- Minimum holding time: 3 - 5 min.
- Drying time: minimum 10 min.
- Please observe the manufacturers' instructions of the sterilizer.

STORAGE

Sterilised 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 materials & machines have been used during the validation procedure:

Table 1: Materials and machines

Alkaline detergent	Neodisher® FA Dr. Weigert
Enzymatic detergent	Endozime by Ruhol
Washer / Disinfector	G 7735 CD (Miele)
Slide-in cart	Slide-in cart E 327 – 06 MIS–Slide-in cart E 450

ADDITIONAL NOTES

If the described chemical agents and machines are not available, it is the duty of the user to validate his process.

DISPOSAL

- Products may be disposed of correctly, only after they have been cleaned and disinfected properly.
- Adhere to national regulations when disposing of or recycling the product, its components and its packaging.
- Dispose of the product in an environmentally friendly manner in accordance with the applicable hospital guidelines.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

RETURNS

- If an instrument is damaged, it should go through the complete reprocessing process before it is sent back to the manufacturer for repair. No own repairs may be carried out on the instrument.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

PROBLEMS / EVENTS

- The user should report any problems with our products to the respective specialist dealer.
- In the event of serious incidents with the products, he must report this to RUDOLF Medical as the manufacturer and the competent authority of the member state in which the user is established.

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.












ACCESSORIES

Suitable cables:

RUDOLF Medical Bipolar Cables
with flat-plug:
HF310-104 – HF310-135

RUDOLF Medical Bipolar Cables
with 2-pin-plug:
HF310-3031 – HF310-333

SYMBOLS

	Consult instructions for use
	Batch code
	Article no.
	No. per package
	Non-sterile
	Lubricate with silicon-free, biocompatible white medical oil approved for steam sterilization.
	Caution
	CE marking according to EG-directive 93/42/EWG with the identification number of the notified body
	Manufacturer
	Manufacture date
	Medical Device