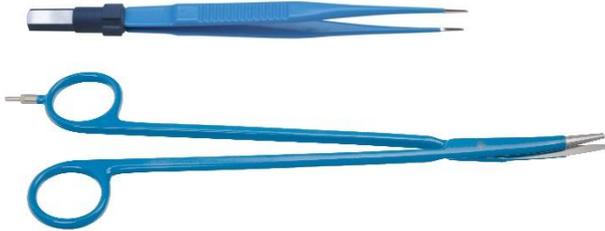


INSTRUCTIONS FOR USE (EN) BIPOLAR FORCEPS AND SCISSORS



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 **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 are receiving a high-quality product, the proper handling and use of which is described below. Instruments for electrosurgery may only be used by persons who have been specially trained or instructed in their use.



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.

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 (U_{max}) of the HF generator 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 cover cloths 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

- 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 be consulted in any case.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of instruments 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 and users.
- 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 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 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:

- 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.
- Pay particular attention to areas such as tips, joints, all moving parts and ceramic elements, which must be checked carefully.

REPROCESSING INSTRUCTIONS

Restrictions on reprocessing

- Due to the product design, the materials used and the intended use, 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 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.
- Do not use fixing agents or hot water (> 40°C).

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. Rinse the instruments extremely thoroughly with demineralized water to remove the disinfectant completely.

Manual drying

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

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 OR	5	55
	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 a 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, joints and other areas that are difficult to access.
- 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.
- In the case of individual packaging, it must be ensured that it is large enough to hold the product without causing tension on the seal seam or tearing the packaging. Tips and sharp blades must not perforate the sterilization packaging.

STERILIZATION

- The scissors must be sterilized when **closed** 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

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 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 or your medical technology department if you have any questions in this regard.
- 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 specialist dealer.
- 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.
- 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