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# INSTRUCTIONS FOR USE (EN)
# BIPOLAR FORCEPS

RUDOLF Medical GmbH + Co. KG
Zollerstr. 1, 78567 Fridingen, Germany
Tel. +49 7463 9956-0
Fax +49 7463 9956-56
sales@RUDOLF-med.com
www.RUDOLF-med.com

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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 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.
- 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 * | Demineralized 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<br>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 |
| LOT | Batch code |
| REF | Article no. |
| QTY | No. per package |
|  | Non-sterile |
|  | Lubricate with silicon-free, biocompatible white medical oil approved for steam sterilization. |
|  | Caution |
| CE 0297 | CE marking according to EG-directive 93/42/EWG with the identification number of the notified body |
|  | Manufacturer |
|  | Manufacture date |
| MD | Medical Device |