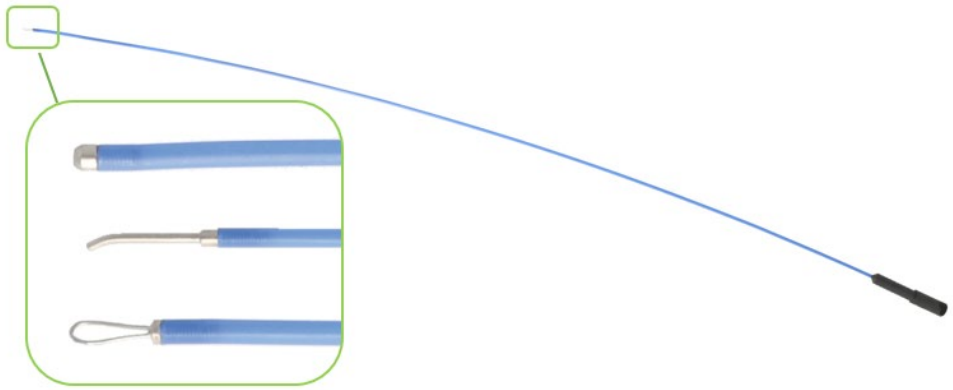
RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
FLEXIBLE HF ELECTRODES, MONOPOLAR



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PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the flexible monopolar HF electrodes from RUDOLF Medical. Flexible HF electrodes are connected to suitable monopolar HF cables to perform endoscopic procedures.

You have received a high-quality product, the proper handling and use of which is described below.

The instruments are intended for use the professional users (surgeon, operating room nurse, medical device reprocessing technicians). The user must be trained in the handling of HF instruments.

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

NON STERILE RUDOLF Medical instruments are supplied non-sterile and must be cleaned, disinfected and sterilized before first use and immediately after each use. Ensure that the packaging is undamaged on delivery. Protective caps and transport packaging must be removed before reprocessing.

INTENDED PURPOSE

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

INDICATION

Flexible HF electrodes are used for minimally invasive procedures in endoscopic gynecology and endoscopic urology.

CONTRAINDICATION

- The instrument is not intended for use on the central nervous and circulatory system.
- Do not use the instrument if at least one of the situations listed below applies:
  - Patients with pacemakers or other active implants. Do not use the instruments without first seeking professional advice.
  - Acute inflammation of the abdominal area
  - Vaginal infection
  - Pregnancy

WARNINGS AND PRECAUTIONS

General:

- The instrument may only be used if the insulation is undamaged.
- Only coagulate when the contact surfaces of the instrument are visible. Do not touch any metal objects during coagulation.
- Incorrect use and overloading due to twisting/levering can lead to cracks and permanent deformation.
- No highly flammable or explosive substances may be in the vicinity.
- Take care when handling sharp tips and cutting edges as there is a risk of injury.
- Do not use abrasive brushes, sponges or abrasive cleaners as they can damage the surface, which in turn can lead to corrosion. The insulation can be damaged, which can lead to uncontrolled combustion.
- The safe combination of instruments with each other or with implants must be checked by the user before clinical use.
- Monopolar laparoscopic instruments cannot be used for MRI applications or X-ray pictures.
- Automated cleaning/disinfection should be preferred to manual cleaning/disinfection, as automated processes are standardized, reproducible and can therefore be validated.

Handling instructions for HF surgery:

- Only use the instrument with a maximum return peak voltage of **2000Vp** in combination with original accessories.
- Make sure that the electrode size corresponds to the size of the instrument channel.
- The output power of the electrosurgical unit may only be set to the value which is absolutely necessary for the procedure. If the usual coagulation power does not occur despite the standard setting of the electrosurgical unit, the output power of the unit must never be increased without prior testing. The maximum permissible peak voltage of the instrument must not be exceeded in the respective mode.
- The surfaces of the contact points must be free of residues at the working end (jaw). To achieve optimum coagulation results, it is essential that the working ends of the instruments are always clean. Dried blood and tissue residues lead to functional impairments. If the coagulation performance decreases, do not increase the performance, but clean the working ends of the instruments with a moist sterile swab.
- Unintentional activation or movement of the electrode outside the field of view may result in injury to the patient.
- Only switch on the HF current when the electrode is in the surgeon's field of view and in contact with the tissue. Otherwise, the irrigation fluid may become too hot and injure the patient.

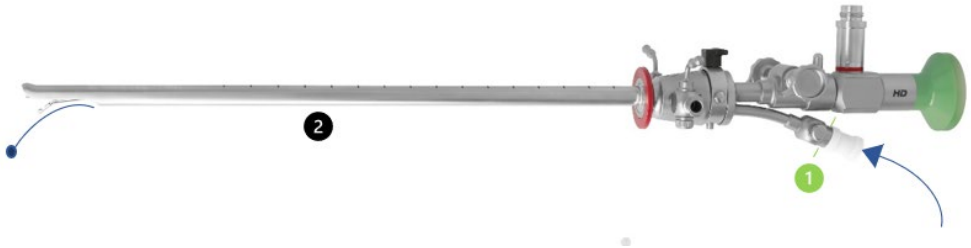
Risk of infection:

- 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.
- Inadequate cleaning and sterilization can also lead to a risk of infection.

COMBINATION PRODUCTS

⚠ An incorrect combination of products can lead to injuries to patients and users as well as damage to the products used.

- The compatibility of the flexible electrode through the instrument channel (blue marking) must always be determined by the length of the instrument and the lumen of the instrument channel (1).
- Combination products from RUDOLF Medical are surgical sheaths with instrument channel (2) and endoscope bridges with instrument channel (3).

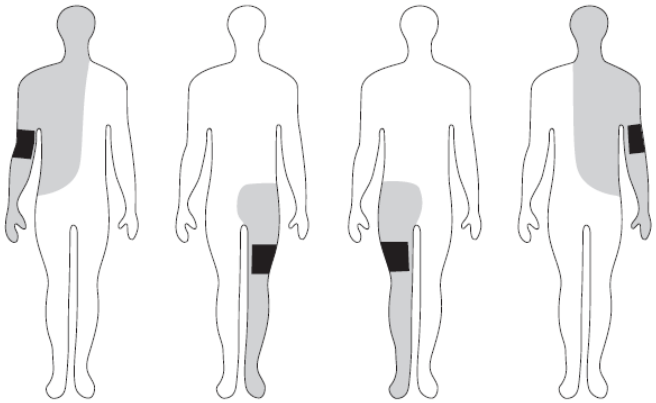


POSITIONING THE PATIENT

- Ensure that the neutral electrode is positioned correctly, otherwise there is a risk of burns.
- The patient must never come into contact with other metal parts (i.e. operating table) and must be insulated from all electrically conductive parts.
- The patient must be placed on a dry, electrically insulated surface.
- Avoid skin-to-skin contact (arms, legs). Place dry gauze between the body, arms and legs to avoid skin-to-skin contact.
- The operating table must be grounded.

CURRENT FLOW IN THE BODY DURING MONOPOLAR HF SURGERY

- The current paths in the patient's body should be short and never run via the thorax.
- There is a risk of burns, if body hair has not been removed from the affected area and moisture, e.g. disinfectant, is still present at the point of contact.
- The following illustration shows the positioning of the neutral electrode (black rectangle) and the permissible application areas (gray) for the electrically conductive working ends of the instruments (jaws).
- When selecting your neutral electrode, make sure that it can be monitored and that it is compatible with the contact quality monitor.



PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:
- External damage (e.g., bent, broken, loose parts, cracks, wear, scratches)
- For cables: insulation, damage to the cable
- Correct functioning
- Residues from cleaning agents or disinfectants

Please also note the following:
- See also section "MAINTENANCE, CONTROL AND INSPECTION" in these instructions.
- Defective products: See section "REPAIRS AND RETURNS".

REPROCESSING INSTRUCTIONS

- Wear personal protective equipment during reprocessing.
- The instruments must be reprocessed within one hour after use to prevent contamination from drying.
- Only use the specified cleaning agents. If you use other cleaning agents, these must be validated by you.
- When choosing another cleaning agent, please 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) respectively the national recommendations.
- Do not use any fixing agents.
- Use a disinfectant with corrosion protection.
- Do not rinse under hot water.
- Do not use abrasive brushes, sponges or abrasive agents as they can damage the surface, which in turn can lead to corrosion. The insulation can be damaged, which can lead to uncontrolled burns.

Restrictions

⚠ Since HF electrodes are made of thin metal parts, paper sterilization packaging should not be used because the electrodes could perforate the paper seal.
- 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
- Do not use fixing agents or hot water (> 40°C) to pre-clean the instruments, as this can lead to hardening of residues and thus impair the cleaning.
- Never leave the instruments in the disinfectant solution for too long. Follow the instructions of the disinfectant solution manufacturer.

Initial treatment at the place of use

- Defective instruments must be clearly labelled as such. They have to be reprocessed before they are disposed of or returned.
- The instruments must be reprocessed within one hour after use to prevent contamination from drying.
- Heavy contamination on the instrument must be removed with a disposable cloth immediately after use.

Transportation

- Safe transport of the instruments to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Manual pre-cleaning

1. Rinse the electrodes under cold water for at least 5 minutes.
2. Brush the electrodes with a soft brush until no more deposits are visible with the naked eye.
3. Rinse the electrodes under cold water.

Automated cleaning and disinfection

1. Place the electrodes in the cleaning device in an inclined position to favor the drainage of the liquid.
2. Set the program with the following parameters and start it:

Process type	Enzymatic
Cleaning agent	neodisher® MediClean by Dr. Weigert
Concentration	0,5%
Washer / disinfector	Miele PG 8535

Automated cleaning process:

Phase	Duration	Temperature	Cleaning agent
Pre-cleaning	At least 2 minutes	Cold tap water of drinking quality (≤ 23°C)	n/a
Cleaning 1	At least 2 minutes	55°C	Enzymatic
Neutralization	At least 3 minutes	Cold deionized water (≤ 23°C)	n/a
Flush 1	At least 2 minutes	Cold deionized water (≤ 23°C)	n/a

Thermal disinfection	Duration: 5 minutes Temperature: at least 93°C ⚠ HF electrodes must not be immersed in chemical disinfectants. Residues of disinfectants can impair their function.

MAINTENANCE, CONTROL AND INSPECTION

- The electrodes must be inspected visually for cleanliness and damage after each cleaning and disinfection. They must be macroscopically clean (free of visible residues). See also section "PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION" in these instructions.
- If dirt residues/liquids are still visible, cleaning and disinfection must be repeated.
- Ensure that the electrode is in good condition before each use.
- The insulation and the HF plug must be intact.
- Plastic parts should be checked before sterilization. The electrode must be replaced if the plastic parts are brittle, cracked or worn.
- Due to the different surgical procedures and the time required for reprocessing, we recommend replacing the electrodes after each use, even if an inspection has been carried out in accordance with these instructions for use.

PACKAGING

- Standardized packaging of instruments for sterilization is carried out in accordance with DIN EN ISO 11607 and DIN EN 868.
- The products are supplied non-sterile in sealed plastic or in a protective box/foam packaging. The transport packaging is not suitable for sterilization.
- The products must be packaged for sterilization in suitable sterilization packaging in accordance with ISO 11607 and/or AAMI/ANSI ST77:2006.
- The "EA 1940" film packaging from E.Line S.r.l. was used for the validation.
- In the case of individual packaging, ensure that the packaging is large enough to hold the product without creating tension on the seal seam or tearing the packaging. Tips and sharp blades must not perforate the sterilization packaging.

STERILIZATION

- Product sterilization using the fractionated pre-vacuum method in accordance with ISO 17665 was validated with the following parameters:

Steam sterilization in a pre-vacuum

Packaging	Film packaging ⚠ HF electrodes: Do not use paper packaging for sterilization, as HF electrodes are made of thin metal components and can therefore perforate the paper packaging.
Temperature	At least 132°C (270°F)
Holding time	At least 3 minutes
Drying time	At least 20 minutes
Notes	Important: • The drying time depends on several variables, including altitude of the location, humidity, type of packaging, preconditioning, size of the chamber, mass of the load, material of the load and placement in the chamber. • It must be ensured that the electrodes also dry with the specified drying time.

STORAGE

- The sterilized electrodes must be stored in a suitable sterilization container in accordance with the standards.
- The storage room must be dust-free, low in germs, dark and free from temperature fluctuations.

INFORMATION ON THE VALIDATION OF THE REPROCESSING PROCEDURE

The following tools and machines were used in the validation:

Automated cleaning: **Enzymatic cleaning agent**	neodisher® MediClean from Dr. Weigert Concentration 0.5%
Washer / disinfector	Miele PG 8535
Disinfection	Thermal disinfection
Sterilization	Steam sterilization
Sterilization device	Lautenschläger ZentraCert

ADDITIONAL NOTES

- If the specified cleaning agents and machines are not available, the user needs to validate their process.

DISPOSAL

- The products should only be disposed of properly after successful cleaning and disinfection.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS AND RETURNS

- Never carry out repairs yourself. Service and repairs must only be carried out by trained and qualified persons. If you have any questions, contact RUDOLF Medical, your distributor or your medical technology department.
- Due to the risk of infection, defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PROBLEMS/EVENTS

- 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 them 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. If there are any discrepancies, please contact your respective distributor or RUDOLF Medical.

REPROCESSING – APPLICABLE STANDARDS

- AAMI/ANSI ST77:2006 Containment Devices for Reusable Medical Device Sterilization
- 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: Washer/disinfectors - Part 1: General requirements, terminology and test methods
- DIN EN ISO 17664: Reprocessing of healthcare products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices
- ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and control of the use of a sterilization process for medical devices

SYMBOLS

	Consult instructions for use
	Caution
LOT	Batch number
REF	Article number
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
	Keep dry
	Keep away from sunlight
MD	Medical device