RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
HANDLES AND ELECTRODE INSERTS FOR ELECTROSURGERY

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE.

PRODUCT

These instructions for use are valid for RUDOLF Medical handles and electrode inserts for electrosurgery.
You have received a high-quality product, the proper handling and use of which is described below.

For professional use only: Instruments for electrosurgery must only be used by persons who have been specially trained or instructed in their use.

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

Monopolar electrode handles are intended to hold suitable electrodes and to activate the HF current from the HF generator.

Monopolar electrodes are intended to cut and coagulate tissue during open surgical procedures.

Patient population: There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

Contraindications

- The medical devices should not be used if, in the opinion of the responsible physician, the risks for the patient exceed the benefits.
- The medical devices are not intended for the use on the central nervous and circulatory system.

Maximum output voltage of the generator Umax

- Maximum output voltage of the generator (Umax) for monopolar electrodes: 4kVp
- The cutting or coagulation current is set on the HF generator.
- Activation of the current by using the buttons on the handle:
  - Yellow button (1) = Activation of the cutting current
  - Blue button (2) = Activation of the coagulation current
- The current can also be activated via the foot switch connected to 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 AND INSTRUCTIONS FOR USE

- ⚠ Ensure that the neutral electrode is applied correctly to the patient, otherwise there is a risk of burns.
- Failure to observe these instructions can lead to injuries, malfunctions or other unexpected incidents.
- Incorrect use and overloading due to twisting/levering can lead to fractures and permanent deformation.
- Special requirements apply when using electrosurgery on patients with pacemakers or other active implants (e.g. low HF current and patient monitoring). A cardiologist or appropriate specialist must always be consulted.
- Never use damaged instruments.
- Do not use the instruments in the presence of flammable or explosive substances.
- Place instruments that are temporarily not in use away from the patient.
- Only activate the HF current if the contact surfaces are within the visual range and have good contact with the tissue to be treated. The contact surfaces must not touch any other metallic instruments, trocar sleeves, optics or similar.
- Do not use metal brushes or abrasive cleaners, as corrosion can occur if the surface is damaged.
- 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.
- 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 CHECK

Check for:

- Correct function
- Cleaning agent or disinfectant residues
- Visible damage and wear, e.g. cracks, breaks or defects in the insulation. Areas such as cutting edges, tips, joints, ratchets and locks in particular, but also all moving parts, insulation and ceramic elements must be checked carefully.

REPROCESSING INSTRUCTIONS

Restrictions

- 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.
- Do not use any fixing agents or hot water (>40°C), because this causes a hardening of residues which can impair the cleaning of the instruments.

Initial treatment at the place of use

- Defective instruments must be clearly marked as such. They must also be reprocessed before they are disposed of or returned.
- The instruments must be reprocessed within 1 hour after use to prevent contamination from drying.
- Heavy contamination on instruments must be removed immediately after use. To do this, 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

- The instruments should be transported safely to the reprocessing site in a closed receptacle / container system to prevent damage to the instruments and contamination of the environment.

Preparation before cleaning

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

Manual pre-cleaning

- In case of heavy contamination, pre-cleaning must be carried out in an ultrasonic bath with a 0.5% enzymatic cleaning agent. (The temperature of the cleaning agent must be below 40°C; the sonication time must be at least 15 minutes.)
- Remove the instruments from the ultrasonic bath and rinse them thoroughly to remove the cleaning agent.
- Observe the cleaning agent manufacturer's instructions (concentration, temperature and sonication time).

Automated cleaning and disinfection

- Clean and disinfect the instruments only in suitable washer-disinfectors (WD) and with a procedure / program validated for the WD and surgical instruments (EN ISO 15883).
- The operating and loading instructions of the WD manufacturer must be observed.
- For cleaning, instruments with joints must be opened by approximately 90 degrees.

- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Cleaning agents for automated cleaning in the washer and disinfector (WD)

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

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

Process	Reagents	Time / min	T / °C
Pre-cleaning (pre-rinse)	Water	1	Cold
Drain (emptying)	---	---	---
Pre-cleaning (pre-rinse)	Water	3	Cold
Drain (emptying)	---	---	---
Cleaning	Water, 0.5 % alkaline cleaning agent	5	55
	-- OR --		
	Water, 0.5 % enzymatic cleaning agent		45
Drain (emptying)	---	---	---
Neutralization	Water and neutralizer	3	Warm tap water (> 40°C)
Drain (emptying)	---	---	---
Rinsing	Water	2	Warm tap water (> 40°C)
Drain (emptying)	---	---	---
Disinfection *	Demineralized water	> 5	> 90
Drying **	---	> 20	Max. 93

- * For mechanical thermal disinfection, observe the national requirements for the A_0 value from ISO 15883-1 (A_0 = 3000).
- ** If necessary, manual drying with a lint-free cloth can also be carried out. Dry the instrument cavities with sterile compressed air.

MAINTENANCE, CONTROL AND INSPECTION

- After cleaning and disinfection, the instruments must undergo a visual and functional check. The instruments must be macroscopically clean (free of visible residues).
- If residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before sterilization, the instrument must be checked for function, wear & tear, and damage (cracks, rust) and, if necessary, replaced.
- Defective products must be reprocessed before being returned for repair or complaint.
- See also the chapter "PRIOR TO EACH USE: VISUAL AND FUNCTIONAL CHECK" in these instructions.

PACKAGING

- Standardized 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, ensure that the packaging is large enough to hold the product without causing tension on the seal seam or tearing the packaging. Tips and sharp edges must not perforate the sterilization packaging.

STERILIZATION

- The sterilizers are validated in accordance with DIN EN 13060 and DIN EN 285.
- The steam sterilization process (fractionated vacuum process) is validated in accordance with DIN EN ISO 17665-1.
- 3 Pre-vacuum phases with at least 60 mbar pressure.

Sterilization temperature	Minimum holding time	Drying time
132°C - 137°C	3 minutes - max. 18 minutes	At least 10 minutes

or

Sterilization according to ANSI AAMI ST77

Sterilization temperature	Minimum holding time	Drying time
132°C - 135°C	4 minutes	20 minutes

The manufacturer's instructions for the sterilization device must be observed.

STORAGE

- Store the sterilized instruments in a dry, clean and dust-free environment. Observe the nationally applicable guidelines.

INFORMATION ON THE VALIDATION OF THE REPROCESSING PROCEDURE

The following tools and machines were used in the validation:

Alkaline cleaning agent	neodisher® FA; Dr. Weigert
Enzymatic cleaning agent	Endozime; Ruhof company
Neutralizer	neodisher® Z; Dr. Weigert
Washer / disinfector	Miele G 7735 CD
Slide-in cart	Miele E 327-06 Miele MIS trolley E 450

Reprocessing reports

- SMP GmbH # 01707011901 (Automated cleaning)
- Nelson Labs # 200432706-02 (Sterilization)
- MDS GmbH Test report 084183-10 (Sterilization)

ADDITIONAL NOTES

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

DISPOSAL

- The products should be disposed of accordingly only after they have been cleaned and disinfected properly.
- 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 receptacles to protect third parties from injury.

REPAIRS / RETURNS

- Never carry out repairs yourself. Service and repairs must 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 reprocessing process before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report all problems in connection with RUDOLF Medical products to the respective distributor.
- In the event of serious incidents involving 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 RUDOLF Medical.

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 marking according to the Medical Device Regulation (EU) 2017/745 (MDR) with the ID of the notified body
MD	Medical Device