RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
MONOPOLAR AND BIPOLAR HF CABLES

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D1223 / Rev A / ACR00333 / 2022-04-20

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PLEASE READ BEFORE PROCESSING AND KEEP IN A SAFE PLACE

INTENDED PURPOSE

HF surgery cables are intended to transmit electrical current from the output of a HF generator to the instrument or to the connector of a neutral electrode at the generator.

The cables must be used only with compatible HF generators and instruments.

The combination possibilities depend on the corresponding connection types at the generator and instruments.

WARNINGS AND PRECAUTIONS

Improper use can lead to hazardous situations.

An incorrect combination of products can lead to injury of patients, users, or third parties as well as to product damage.

- Instruments and cables for HF surgery must only be used by trained or qualified personnel.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of this disease, the applicable national regulations regarding the preparation of instruments must be applied.

Connection and Activation

- Before using monopolar instruments, ensure that a designated HF neutral electrode is correctly attached to the patient and properly connected to the designated HF generator. This does not apply to bipolar applications.
- When connecting the cable make sure that the HF generator is switched off or in standby mode (where applicable).
- When combining with other HF accessories, make sure to avoid output settings on the HF generator where the maximum output voltage may exceed the rated accessory voltage listed below.
- Failure to observe these warnings and precautions may result in injury, malfunction, or other unexpected occurrences.
- Improper use will result in immediate loss of warranty. No liability will be accepted for any damage caused by improper handling.
- Prior to each use, the cables must undergo a visual and functional inspection.
- Make sure that the correct connection at the generator or instrument is selected and that the cable is completely plugged in.
- Never use damaged cables.
- Do not kink the cables or wind them too tightly to avoid cable breakage.
- Always unplug the HF cables by the plug and never by the cable to avoid damage.
- Do not use the cables in the presence of flammable or explosive substances.

Combinability / Compatibility

- Before use, make sure that the product is compatible with the HF accessories and the HF generator intended for the procedure.
- The HF cables must never be connected to different or unknown power sources.

The instructions, safety, and warning notes in the operating instructions of the accessories and HF generator used must be followed.

Other Important Notes:

Maximal Rated Accessory Voltage (Umax)

Product	Umax
Monopolar HF cables	4.3 kVp
Bipolar HF cables	0.8 kVp
Neutral electrode cable	4.3 kVp

- When combined with other HF accessories, the maximum rated accessory voltage of the system is equal to the lowest rated accessory voltage of the individual products.
- The maximum rated accessory voltage of the product can be found in these instructions for use, on the label or in the current product catalogue.
- If you have any questions, please contact RUDOLF Medical.
- Before use, the entire instructions for use of this product and any accessories used, as well as of the HF generator and HF neutral electrode (monopolar application) must be observed.
- The specifications, safety instructions and warnings in the respective instructions for use must be observed and followed.

REPROCESSING INSTRUCTIONS

NON STERILE

Products are delivered in a non-sterile state and must be cleaned, disinfected, and sterilized before the first and any other subsequent use.

Restrictions

- Due to the product design, the materials used and the intended purpose, it is not possible to provide a maximum number of possible reprocessing cycles.
- The service life of the products is determined by their function and the careful handling of them.

Initial Treatment at the Place of Use

- The products must be reprocessed within 1 hour after use, to prevent dirt from drying on the products.
- Heavy soiling on the instrument must be removed with a disposable rag, cloth, or tissue immediately after use.
- 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.

Transportation

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

Automated Cleaning and Disinfection

- Clean and disinfect the cable only in suitable washers and disinfectors (WD) and with a procedure / program validated for the WD and this type of cable (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 German Society for Hygiene and Microbiology (DGHM, Deutsche Gesellschaft für Hygiene und Mikrobiologie).

Detergents for the automated cleaning in a WD

Process	Detergent	pH value	Manufac-turer
Alkaline	neodisher® FA	12.2	Dr. Weigert
Enzyma-tic	deconex® 23 Neutrazym	9.7	Borer

Automated cleaning with thermal disinfection in a washer/disinfector with an alkaline or enzymatic detergent

Process	Reagents	Time / Min.	T / °C
Pre-wash	Water	1	Cold
Draining			
Pre-wash	Water	3	Cold
Draining			
Cleaning	Water, 0.5% alkaline detergent	5	55
	OR		
	Water, 0.5% enzymatic detergent		45
Draining			
Neutrali-zation	Water	3	Cold
Draining			
Rising	Water	2	Cold
Draining			

Process	Reagents	Time / Min.	T / °C
Disinfection*	Demineralized water	> 5	> 90
Drying**		> 20	max. 93

* Carry out an automated thermal disinfection taking into account the national requirements for the A0 value according to ISO 15883-1 (A0 = 3000).
** If necessary, manual drying with a lint-free cloth can also be carried out.

MAINTENANCE, CONTROL, AND INSPECTION

- After cleaning and disinfection, the cables must be subjected to a visual and functional inspection. The cables must be macroscopically clean (free of visible residues). Particular attention should be paid to connections and other difficult areas to access.
- If dirt residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before each sterilization, the correct function / current transmissibility of the cable must be checked.
- The insulation in particular must not be damaged.
- Plugs and connections must be tight.
- The cable must not be kinked.
- Defective products must have gone through the entire reprocessing process before being returned for repair or complaint.

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 ISO 13060 / ISO 17665 using the fractionated vacuum method. Observe the national requirements.

- 3 pre-vacuum phases with at least 60 mbar pressure
- Heat up to a minimum sterilization temperature of 132°C; maximum 137°C
- Holding time: minimum 3 minutes; maximum 18 minutes
- Drying time: minimum 10 minutes

STORAGE

- Store the cable in a clean, cool, and dry place
- The cables should always be handled with the utmost care during transport, cleaning, maintenance, sterilization, and storage.
- The cables should only be rolled loosely and neither kinked nor folded.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials and machines have been used during the validation procedures:

Materials and Machines

Automated cleaning: alkaline detergent	neodisher FA, Dr. Weigert
Automated cleaning: enzymatic detergent	Endozime, Ruhof
Manual cleaning: enzymatic detergent	Enzol Enzym Detergent, Johnson & Johnson
Neutralizer	neodisher Z, Dr. Weigert
Washers / disinfector	Miele G 7736 CD
Instrument rack	Miele E 327-06
Key Hole Surgery Rack	Miele E 450

The details can be found in the respective reports:

- SMP GmbH # 01707011901 (Automated cleaning)
- MDS GmbH # 135196-10 (Manual cleaning / disinfection)
- Nelson Labs # 200432706-02 (Sterilization)
- MDS GmbH Testbericht 084183-10 (Sterilization)

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 must be disposed of correctly, only after they have been cleaned and disinfected properly.
- Comply with national regulations when disposing of or recycling the product or its components.
- 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.

REPAIR

- Never attempt to perform repairs yourself. Service and repair work must be carried out by personnel qualified and trained accordingly. If you have any questions, please contact RUDOLF Medical or your medical device service.
- Defective instruments must go through the entire reprocessing procedure before they can be returned.

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 resides.

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.

SYMBOLS

	Consult instructions for use.
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
CE	CE marking according to Medical Device Regulation (EU) 2017/745 (MDR)
	Manufacturer
	Date of manufacture
MD	Medical Device
UDI	Unique Device Identification