connection cable monopolar / bipolar

unsterile

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A. BASICS

It is imperative that all requirements and special information described in these instructions are met or taken into account. Otherwise, the products may not be used for clinical use. The specific instructions for use that may be attached to the products must also be observed.
If you are unsure or have any questions, please contact us before using the products.
These instructions for use cannot replace training, care and the state of the art at the user. We therefore assume that the relevant legal provisions, standards and recommendations (e.g. of the RKI or AKI) are known (see under "Standards / References") and therefore limit ourselves to the instructions and information to be followed by the user for each product which are important for our products. The reasons for these instructions and the dangers arising from non-compliance are listed in the legal provisions and recommendations.
Repairs and maintenance may only be carried out by authorized specialists.
The product may only be operated with the accessories and spare parts specified in the operating instructions and in the combinations specified there. Accessories and wearing parts as well as other combinations may only be used if they do not affect performance features or safety requirements and they are expressly intended for the intended application.
Before each use and return, the product must be processed in accordance with the instructions for use to protect patients, users and third parties.
Technical changes reserved!
Due to further developments, the illustrations and technical data may differ slightly

It should only be used by trained, surgically trained medical specialists who have been instructed in the relevant procedures in the context of generally recognized training courses and only taking into account the relevant literature.

READ ALL APPLICABLE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE USING A PRODUCT FOR THE FIRST TIME!

B. INFORMATION AND SYMBOLS ON LABELS

REF	Article or order number	CE 0297	CE-Mark and registration number of the Notified Body DQS Medizinprodukte GmbH August-Schanz-Straße 2, 60433 Frankfurt, Germany
	ATTENTION! Important instructions!		Follow the instructions You can also find useful information on the website www.a-k-i.org "Instrument reprocessing done right"
LOT	Batch number		Symbol for manufacturer Date of manufacture year-month
NON STERILE	Information for NON sterile product	LATEX	Not made with natural rubber latex

1. INTENDED USE

Cables for electrosurgery are designed either to conduct electrical power from the output of a high-frequency generator to the instrument or to connect a neutral electrode with the generator.
When combining with other electrosurgical devices, ensure that the output parameters of the electrosurgical generator do not exceed the rated voltage of the cable.
Use only with compatible electrosurgical generators and instruments. The connectivity depends on the specific types of connectors, both on the generator side and the instrument side.

Instruments and cables for electrosurgery may only be used by persons who have been specially trained or instructed for them. It should only be used by trained, surgically trained medical specialists who have been instructed in the relevant procedures in the context of generally recognized training courses and only taking into account the relevant literature.

All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

Read these instructions carefully before using your new device for the first time. You protect yourself, the patient and any third parties from damage that can result from incorrect connection, damage or improper operation!

2. USE AND SAFETY INSTRUCTIONS

Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

- All cables have to be completely cleaned, disinfected and sterilised before initial use and any other use.
- The cables have to be submitted to a visual inspection and a functional test before each use.
- Ensure that the correct connector both on the generator side and the instrument side has been chosen and that the connector has been fully inserted.
- Never use damaged cables.
- Do not kink to avoid cable break.
- To avoid damages, grasp plug to remove cable, do not pull cord.
- Never use the instruments in the presence of flammable or explosive substances.

3. REPROCESSING

Due to the product design, the materials used and the intended purpose, it is not possible to define a limit with regard to the maximum possible number of reprocessing cycles. The serviceable life of the instruments is determined by their function as well as by a careful handling.

Preparation and transport

Remove coarse dirt from the cables immediately after each use. Do not use fixing agents or hot water (> 40 ° C).

Machine reconditioning

Cleaning

Place the instruments in a mesh tray on the slide-in trolley or on the inserts of the MIS module and start the cleaning process.

1. Prerinse. with cold water for 1 min
2. Discharge
3. Prerinse with cold water for 3 min.
4. Discharge
5. Wash at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent for 5 min.
6. Discharge
7. Neutralise with warm tap water (>40°C) and a neutralising agent for 3 min.
8. Discharge
9. Rinse with warm
10. Discharge

Disinfection

Machine-operated thermal disinfection must be carried out under observation of the national requirements regarding the A0 value (see ISO 15883).

Drying

Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine. If necessary, manual drying may additionally be carried out using a lint-free cloth. Dry cavities by blowing with sterile compressed air.

Manual reprocessing

Cleaning

Prepare a cleaning bath according to the manufacturer's instructions.

1. Rinse products with cold tap water (<40°C) until all visible contamination has been removed. Remove adhering dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submersed. Observe residence time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. Brush all surfaces several times.
4. Rinse the products thoroughly with DI water to

Disinfection

Prepare a disinfectant bath according to the instructions from the disinfectant manufacturer. Place the instruments in the disinfection bath and observe the prescribed exposure time. Rinse the products extremely thoroughly with fully demineralized water to completely remove the disinfectant.

Drying

Manual drying is carried out using a lint-free cloth and sterile compressed air, in particular for drying cavities and channels.

Functional testing and packaging

Perform visual inspection for cleanliness and integrity. If necessary, repeat reprocessing until the instrument is visually clean. Packaging must comply with the ISO 11607 and EN 868 standards for packaging for sterilised instruments.

4. STERILIZATION

Sterilisation of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) under observation of the respective national requirements.

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

NON STERILE

If contamination with prions (CJD) is suspected, differing national guidelines are to be followed and longer holding times (i.e. 15min.) may apply.

5. REPAIRS

- Even when used as intended, medical products are subject to greater or lesser wear and tear depending on the intensity of use. Wear is due to technical reasons and is inevitable.
- Do not carry out repairs yourself. Service and repairs may only be carried out by us as the manufacturer or by persons authorized by us.
- Medical devices that are sent in for repair must be cleaned, disinfected and sterilized beforehand

NON STERILE

Defective products must complete the entire reprocessing process before being returned for repair.

6. REPROCESSING VALIDATION INFORMATION

The following testing instructions, materials and equipment have been used for validation:

Cleaning agent (machine):	Neodisher FA; Dr. Weigert (alkaline) Endozime Fa. Ruhof (Enzymatically)
Cleaning agent (manual):	Enzol Enzym, Detergent, Johnson&Johnson
Disinfectants (manual):	Cidex OPA, Johnson&Johnson
Neutralizer:	Neodisher Z; Dr. Weigert
Washer-disinfector:	Miele G 7736 CD Miele Slide-in cart E 327-06 Miele MIC-Cart E450
For details see reports:	SMP GmbH #01707011901 (mach. cleaning)

MDS GmbH #135196-10 (man. Cleaning / disinfection)
Nelson Labs #200432706-02 (Sterilization)
MDS GmbH Review 084183-10 (Sterilization)

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly.

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly. All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

7. REUSABILITY

The instruments can be reprocessed and reused with due care and provided that they are undamaged and fully functional. The service life is limited by damage and normal wear and tear; these products are to be sorted out after processing. The service life depends on many factors including the type and duration of use, as well as handling, storage and transport of the instruments. Careful checks and function tests before the next use are the best way to identify and sort out an instrument that is no longer functional.

Handling
Store the cables in a clean, cool and dry place. During transport, cleaning, care, sterilisation and storage, all cables should be handled with maximum care. Coil cables loosely, do not kink or fold them.

Note!
To avoid damage during transport of the product, we recommend using the original packaging for shipping.
The applicable country-specific regulations / laws must be observed when disposing of the product, packaging material and accessories. Further information can be obtained from the manufacturer.

8. DISPOSAL

Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

9. NORMS - REFERENCES

- DIN EN 285 large steam sterilizers
- DIN EN 13060 small steam sterilizers
- DIN EN ISO 11135 Sterilization of Healthcare Products - Ethylene Oxide
- DIN EN ISO 15883-1-3 washer-disinfectors
- DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10 packaging materials
- DIN EN ISO 17664 / ANSI AAMI ST81 sterilization - information from the manufacturer
- DIN EN ISO 17665-1 sterilization process - moist heat
- AKI1 - Guide "Instrument reprocessing done right"
- RKI2 - recommendation: "Hygiene requirements for the reprocessing of medical products"

1 AKI: Working group for instrument reprocessing
2 RKI: Robert Koch Institute

10. WARRANTY

The operator / product user is responsible for the proper cleaning, disinfection and sterilization of products. National re-gulations, including restrictions, must be observed.

REDA Instrumente GmbH only delivers tested and error-free products to its customers.
All of our products are designed and manufactured in such a way that they meet the highest quality standards. Liability for products that have been modified, misappropriated or improperly treated or used compared to the original is excluded.

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